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Leaders | Trans treatments

What America has got wrong about gender medicine

Too many doctors have suspended their professional judgment

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Apr 5th 2023

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FOR MANY Americans, the great tragedy of trans rights is the story of how Republican governors and state legislatures are stigmatising some of society's most put-upon people—all too often in a cynical search for votes. This newspaper shares their dismay at these vicious tactics. In a free society it is not the government's place to tell adults how to live and dress, which pronouns to use, or what to do with their bodies.

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However, nestled within that first tragedy appears to be a second—this time a tragedy of good intentions. On different sides of the Atlantic, medical experts have weighed the evidence for the treatment of gender-dysphoric children and teenagers, those who feel intense discomfort with their biological sex. This treatment is life-changing and can lead to infertility. Broadly speaking, the consensus in America is that medical intervention and gender affirmation are beneficial and should be more accessible. Across Europe several countries now believe that the evidence is lacking and such interventions should be used sparingly and need further study. The Europeans are right.

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The number of children and teenagers diagnosed with gender dysphoria in America has soared. One estimate found that there were over 42,000 new diagnoses in 2021, three times the count in 2017. Gender-affirming care, as America understands it, stipulates counselling, which can lead to puberty-blocking drugs and subsequently cross-sex hormones (testosterone for girls and oestrogen for boys—used, by one estimate, in 10% of cases). Occasionally, there may be mastectomies and, very rarely in the under 18s, the construction of ersatz genitals from flaps of skin or pieces of bowel. The goal is to align the patient's body with the way that they think about themselves.

Proponents say that the care is vital to the well-being of dysphoric children. Failure to provide it, they say, is transphobic, and risks patients killing themselves. The affirmative approach is supported by the American Academy of Paediatrics, and by most of the country's main medical bodies.

Arrayed against those supporters are the medical systems of Britain, Finland, France, Norway and Sweden, all of which have raised the alarm, describing treatments as "experimental" and urging doctors to proceed with "great medical caution". There is growing concern that, if teenagers are offered this care too widely, the harms will outweigh the benefits.

As we report in this week's briefing, one concern is that doctors have changed the safeguards built into the original treatment design, devised in the Netherlands in the 1980s and 1990s. Twenty years ago, the typical patient was male, with a long history of dysphoria. Children and teenagers with psychological problems besides dysphoria were disqualified from treatment. These days most patients are adolescent girls. Their dysphoria may be relatively recent. Some are depressed, anxious or autistic, but mental illness is no longer a hard barrier to treatment. Do these patients respond to drugs and surgery in the same way?

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It is unclear. And that is because the clinical evidence for intervention in broader categories of adolescents is vague. A formal British review of the clinical evidence, prepared in 2020, found that almost all the studies in this area were of poor quality; one in Sweden came to similar conclusions. When researchers find benefits, the effects tend to be small. It is often impossible to conclude whether they are lasting, or how much the credit is down to drugs or counselling or both. Some older studies suggest that, left alone, most children will naturally grow out of their dysphoric feelings. The long-term effects of puberty-blockers remain unknown, though there are worries about brain development and decreasing bone density.

Medical bodies build safeguards into their treatment protocols, but they vary. And in any case practitioners may ignore them. Whistle-blowers say that some children and teenagers are being put on puberty-blockers after only a cursory assessment. A growing number of "detransitioners", who regret their treatment, say that they have been left scarred, infertile, with irreversibly altered appearances and were unhappy with how their dysphoria was treated.

America's professional bodies acknowledge the science is low quality, but say they have a duty to alleviate patients' mental anguish. Some patients suffer regret in all medical procedures, from knee surgery to liposuction. And they observe that the most shocking allegations about poor treatment are only anecdotes. Speaking on American radio last year, Rachel Levine, assistant secretary for health and a paediatrician, was very clear: "There is no argument among medical professionals…about the value and the importance of gender-affirming care."

Except that there is. And when medical staff raise concerns—that teenage girls may be caught up in a social contagion, say, or that some parents see transition as a way to have a straight daughter rather than a gay son—they have been vilified as transphobic and, in some cases, suffered personal and professional opprobrium.

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Medical science is not supposed to work this way. Treatments are supposed to be backed by a growing body of well-researched evidence that weighs the risks and benefits of intervention. The responsibility is all the heavier when treatments are irreversible and the decisions about whether to go ahead are being taken by vulnerable adolescents and their anxious parents.

What to do? To some, the uncertainties that surround medical interventions are grounds for an outright ban. In fact, the lack of evidence cuts both ways. Perhaps, when proper trials are complete, their proponents will be proved correct. The right policy is therefore the one Britain's NHS and the Karolinska Institute in Sweden seem to be working towards. This would promote psychotherapy and reserve puberty-blockers and cross-sex hormones for a system in which patients would almost always be enrolled in a well-run clinical trial.

Ideally, American regulators would insist on trials, too. If the culture wars put that compromise out of reach, professional bodies should uphold their own protocols by welcoming whistle-blowers and advance science by calling on patients to be in trials. Sometimes, they will need to protest against illiberal laws. Above all, they should not add to the tragedy. ■

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This article appeared in the Leaders section of the print edition under the headline "The dangers of gender medicine"

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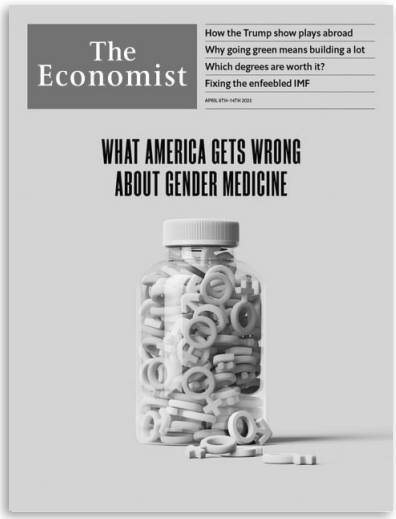

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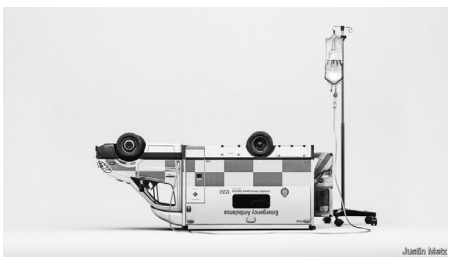

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ACTA PÆDIATRICA NURTURING THE CHILD WILEY

REVIEW ARTICLE

A systematic review of hormone treatment for children with gender dysphoria and recommendations for research

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Abstract

Aim: The aim of this systematic review was to assess the effects on psychosocial and mental health, cognition, body composition, and metabolic markers of hormone treatment in children with gender dysphoria.

Methods: Systematic review essentially follows PRISMA. We searched PubMed, EMBASE and thirteen other databases until 9 November 2021 for English-language studies of hormone therapy in children with gender dysphoria. Of 9934 potential studies identified with abstracts reviewed, 195 were assessed in full text, and 24 were relevant.

Results: In 21 studies, adolescents were given gonadotropin-releasing hormone analogues (GnRHa) treatment. In three studies, cross-sex hormone treatment (CSHT) was given without previous GnRHa treatment. No randomised controlled trials were identified. The few longitudinal observational studies were hampered by small numbers and high attrition rates. Hence, the long-term effects of hormone therapy on psychosocial health could not be evaluated. Concerning bone health, GnRHa treatment delays bone maturation and bone mineral density gain, which, however, was found to partially recover during CSHT when studied at age 22 years.

Abbreviations: BMD, bone mineral density; CSHT, cross-sex hormone treatment; DXA, dual-energy X-ray absorptiometry; GnRHa, gonadotropin-releasing hormone agonist (analogues); GRADE, grades of recommendation, assessment, development and evaluation; ICD, International Classification of Diseases; MRI, magnetic resonance imaging; SBU, Swedish Agency for Health Technology Assessment and Assessment of Social Services.

Berit Kriström and Mikael Landén have equal contrbution.

[†]Part of the original study group but deceased in December 2021.

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Conclusion: Evidence to assess the effects of hormone treatment on the above fields in children with gender dysphoria is insufficient. To improve future research, we present the GENDHOR checklist, a checklist for studies in gender dysphoria.

KEYWORDS
adolescent, bone density, gender dysphoria, gonadotropin-releasing hormone agonist, psychosocial functioning

1 | INTRODUCTION

Gender incongruence refers to a mismatch between the biological sex and perceived gender identity. When gender incongruence causes significant discomfort, it is called gender dysphoria. When gender dysphoria causes clinically significant distress, the condition might meet the diagnostic criteria for transsexualism according to the (international classification of disease) ICD-10 guidelines,[1] or gender dysphoria according to the DSM-5.[2] Gender identity-affirming health care is provided to ease gender dysphoria.[3] The treatment aims to align bodily characteristics with the individual's gender identity, and usually includes cross-sex hormone treatment (CSHT), as well as chest and genital surgery.

In youth with gender dysphoria, gonadotropin-releasing hormone analogues (GnRHa) have been used to inhibit spontaneous puberty development. The rationale is to prevent irreversible bodily changes and give young individuals time to explore their gender identity. Following the first case report in which a GnRHa was used to suppress puberty in a female-to-male transsexual individual,[4] the '"Dutch protocol" was developed.[5] According to this protocol, young pubertal people presenting with gender dysphoria should first undergo a thorough psychological evaluation. If the diagnosis gender dysphoria is confirmed, GnRHa treatment is recommended to start during the early stages of puberty (Tanner stages 2–3). If gender dysphoria subsides, the individual may discontinue GnRHa treatment, at which point spontaneous puberty will restart. If gender dysphoria persists, CSHT might start at age 16 years and sex-reassignment surgery at 18 years. Gender dysphoria in youth was a rare phenomenon when the Dutch multidisciplinary protocol for the treatment of gender dysphoria was introduced. Seeking care for gender dysphoria has since become increasingly common in younger people in many parts of the western world,[6,7] with an exponential rise among children born female.[8] Although not all children with gender dysphoria receive gender identity affirming treatment, there has been an ensuing increase in hormones to treat children with gender dysphoria, of which data on the effects and side effects are limited. There is no previous systematic review or meta-analysis of hormone treatment for children with gender dysphoria.

This systematic review aimed at assessing (a) psychosocial effects, (b) effects on bone health, (c) effects on body composition and metabolism, and (d) satisfaction and therapy persistence in children aged <18 years with gender dysphoria undergoing hormone therapy.

Key Notes

- This systematic review assessed psychosocial effects, bone health, body composition and metabolism, and therapy persistence in children (<18 years of age) with gender dysphoria undergoing treatment with gonadotropin-releasing hormone analogues (GnRHa).
- Long-term effects of hormone therapy on psychosocial health are unknown. GnRHa treatment delays bone maturation and gain in bone mineral density.
- GnRHa treatment in children with gender dysphoria should be considered experimental treatment of individual cases rather than standard procedure.

In this review, trans women are referred to as male-to-female and trans men as female-to-male.

2 | METHODS

2.1 | Preregistration

This systematic review originated from a 2-year commissioned work from the governmental body the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). Ongoing SBU reviews are registered on the SBU website (https://www.sbu.se/en/ongoing-projects/) but not recorded in external databases.

2.2 | Selection criteria

The search was restricted to children aged <18 years with reported gender dysphoria. We included observational studies, randomised controlled trials, and systematic reviews according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[9] Case reports, editorials, and non-human studies were excluded from further review. The search was limited to English-language publications.

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2.3 | Search strategy

Two professional information specialists at the Swedish Agency for Health Technology Assessment and Assessment for Social Services (SBU) performed a comprehensive search of the following medical databases up until 9 November 2021: CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE (Embase.com), PsycINFO (EBSCO), PubMed (NLM), Scopus (Elsevier), and SocINDEX (EBSCO). They also searched the Campbell Library, Epistemonikos, Evidence Search, International HTA database, as well as three NIHR Centre for Reviews and Dissemination (CRD) databases: Database of Abstracts of Reviews of Effects (DARE), Health, and Technology Assessment (HTA), and NHS Economic Evaluation Database (EED). Finally, we searched PROSPERO, an international prospective register for systematic reviews, to identify any relevant ongoing systematic reviews but found none. The search, selection, and assessment were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[9] The search and selection processes are outlined in Figure 1. Only studies of low or moderate bias were eligible for this review. Full literature search strategy is provided at the SBU web page (https://www.sbu.se/contentassets/4062b596a35c4e1383405766b7365076/bilaga-1-litteratursokning.pdf).

2.4 | Relevance, risk of bias, and quality of evidence

Two independent experts checked all hits for relevance. Relevant studies (based on a pre-defined PICO) were then evaluated for risk of bias, also by two independent experts, according to ROBINS-I (Risk of bias in non-randomised studies of interventions).[10,11] Robins-I assesses possible bias in seven domains: confounding; bias due to selection, measurement classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result.

If the two reviewers did not agree on content or quality, the paper was discussed in the larger research team of four experts (JFL, PR, BK, ML). Randomised controlled trials were planned to be assessed by RoB–2.[10,11] To rate the quality of evidence for specific outcomes, we used the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system.[12] GRADE has four levels of evidence (very low, low, moderate, high) and considers five domains that can decrease the level of certainty one or two levels (risk of bias, imprecision, inconsistency, indirectness (similar to 'external validity'), and publication bias).

2.5 | Data extraction

Two reviewers (MH, JA) retrieved data from the included studies. The data extracted included the outcomes mental and psychosocial health including suicidality, anthropometric measures and metabolism, bone health, adverse events, and the characteristics of each study including age at referral or intake, age at start of GnRHa treatment, age at start of CSHT, number of participants enrolled in study, number of transgender participants, number of hormone treated transgender participants, number of non-transgender participants, number of participants evaluated, treatment type (drugs, dosages, type of administration, treatment frequency), total treatment duration, and total follow-up time. The full data extraction of included studies is provided at the SBU web page (https://www.sbu.se/contentassets/4062b596a35c4e1383405766b7365076/bilaga-3-tabellverk-over-inkluderade-studier.pdf).

2.6 | Statistics

No statistical analyses were performed.

2.7 | Ethics

Ethical approval is not applicable for this systematic review.

3 | RESULTS

3.1 | Identified studies

After duplicate removal, the search yielded 9934 potential studies (Figure 1). Of these, 195 were selected for thorough reading. Of these, 36 were relevant and assessed for risk of bias. Twelve studies were excluded because of high risk for bias, leaving 24 studies with low to moderate, moderate, or moderate to high risk of bias reviewed in this paper. A list of excluded studies is provided at the SBU web page (https://www.sbu.se/contentassets/4062b596a35c4e1383405766b7365076/bilaga-2-exkluderade-studier-med-hog-risk-for-bias.pdf).

3.2 | Characteristics of the 24 studies

All 24 relevant studies had been published since 2014 (Table 1). Study participant age at the start of GnRHa therapy was typically between 11 and 15 years (range 9–18.6 years), with CSHT rarely being introduced before age 15. Except for the Hisle-Gorman et al.[6] ($n=3754$ participants) and Mullins et al.[13] ($n=611$) papers, few studies included >200 individuals. GnRHa treatment often continued for around 2 years, sometimes up to 4 years, and similar treatment durations were observed or reported for CSHT as observations were usually not reported after age 18 years. Full details of included studies are given at the SBU web page. Overall, there were eight studies on GnRH alone, 13 studies on GnRH + CSHT, and three studies on CSHT alone.

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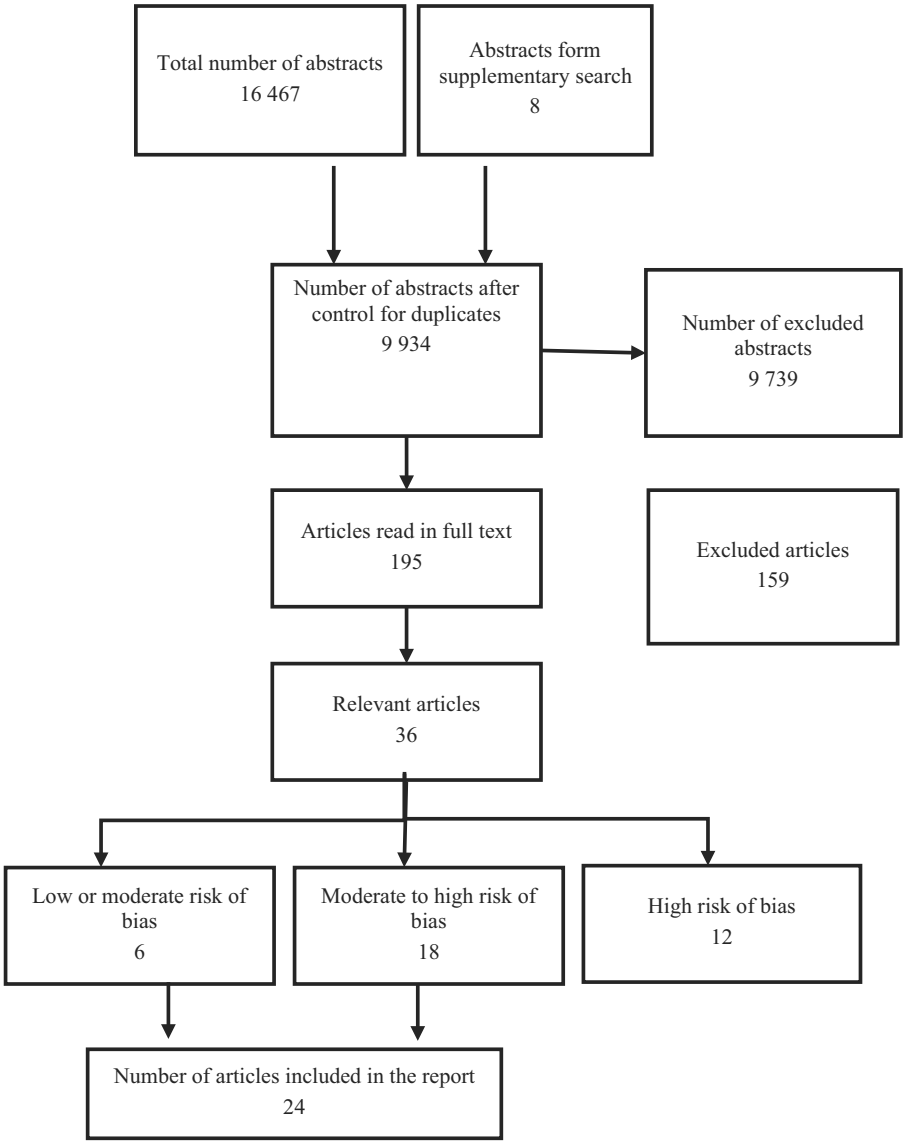

FIGURE 1 PRISMA flow diagram.

3.3 | Psychosocial and mental health

Table 2 outlines the six studies that examined psychosocial outcomes and cognitive effects.[14–19] Three of these studies found significantly improved overall psychosocial function after GnRHa treatment as measured by the Children's Global Assessment Scale (CGAS).[14–16] Two of these studies observed no statistically significant change in gender dysphoria.[15,16] Two of these studies reported significantly improved self-rated quality of life after treatment measured through Kidscreen-27, Short Form-8 (SF-8), Child Behaviour Checklist (CBCL) (parent report), and Youth Self Report (YSR),[16,17] while another study reported no statistically significant differences in anxiety and depression between those who started and not started hormone therapy.[18]

Because these studies were hampered by small number of participants and substantial risk of selection bias, the long-term effects of hormone treatment on psychosocial health could not be evaluated. Of note, the above studies do not allow separation of potential effects of psychological intervention independent of hormonal effects.

3.4 | Cognitive outcomes

We could only identify one study of low-moderate bias on cognitive outcomes in children with gender dysphoria receiving GnRHa therapy.[19] This cross-sectional study from the USA comprised 20 treated (8 male-to-female and 12 female-to-male) and 20 untreated (10 male-to-female and 10 female-to-male) young transgender persons and a control group ($n=45$). Controls were identified from age-matched family members and friends. The Tower of London task was administered to assess executive functioning. The study neither found differences in cognitive function between treated and untreated transgender persons, nor between treated transgender persons and controls. However, because no before-after GnRHa therapy analyses were performed, the study

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TABLE 1 Overview of 24 included studies.

Reference	Ages of patients (years)			Numbers of patients						Interventions			Time: duration and follow-up			Outcomes extracted
	Age at intake range (mean)	Age at start of GnRH range (mean)	Age at start of CSHT range (mean)	*n* referred	*n* TG enrolled	*n* TG HT	*n* TG non-HT	*n* non-TG	*n* TG HT at last FU	GnRH	CSHT	Surgery[b]	GnRH duration range (mean)	CSHT duration range (mean)	Follow-Up time range (mean)	Mental health Bone health Anthropometrics Metabolism
Mental health																
de Vries 2014[14]	11–17 (13.6)	11.5–18.5 (14.8)	13.9–19 (16.7)	196	111	55			32	x	x	x	1 year[a]	4 years[a]		UGDS, global functioning (CGAS), depression (BDI), anxiety (STAI), anger (TPI)
Costa 2015[15]	12–17 (15.5)	13–17 (16.5)		436	201	101	100		35	x			1 year		1.5 years	UGDS, psychosocial functioning (CGAS)
Becker-Hebly 2020[17]		11–17 (15.5)	13–17 (15.5)	434	75	54	21		54	x	x	x	0.5–4 years[a]	0.5–4 years[a]	7–49 months	Global functioning (CGAS), psychosocial functioning (YSR/ASR)
Cantu 2020[18]		11–xx (15)	xx–18 (15)		80	42	38		28	x	x		NR	NR	1–11 months (5 months)	Psychosocial functioning (PHQ-9, GAD-7), acute distress, suicidality
Carmichael 2021[16]		12.0–15.3 (13.6)			44	44			14	x			12–59 months (31 months)		12–36 months	UGDS, CGAS, psychological functioning (CBCL, YSR), Self-harm, BIS, HRQoL (Kidscreen52)
Hisle-Gorman 2021[6]	8–13 (10)		16.6–19.8 (18.2)		3754	963		6603	963	x	x		0.7–2.7 years (1.5)	0.7–2.7 years (1.5)	8.5 years	Mental health diagnosis, psychotropic medication use, medication days, service use
Staphorsius 2015[19]		min 12			41	20	20	45		x			0.6–2.6 years (1.6)			Psychological functioning (CBCL), cognitive function (executive function task)

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	Ages of patients (years)			Numbers of patients						Interventions			Time: duration and follow-up			Outcomes extracted
Reference	Age at intake range (mean)	Age at start of GnRH range (mean)	Age at start of CSHT range (mean)	*n* referred	*n* TG enrolled	*n* TG HT	*n* TG non-HT	*n* non-TG	*n* TG HT at last FU	GnRH	CSHT	Surgery[b]	GnRH duration range (mean)	CSHT duration range (mean)	Follow-Up time range (mean)	Mental health Bone health Anthropometrics Metabolism
Bone health																
Joseph 2019[23]		12–14 (13)				70			70	x			1–xx years		up to 2.8 years	Height, weight, BMI BMD, BMAD, Z-score (hip, spine)
Klink 2015[21]		11.4–18.3 (15)	15.6–19 (16)			34			34	x	x	x	0.25–8 years	xx–8 years	up to age 22	Height, BMD, aBMD, Z-score, T-score (femoral neck, lumbar spine)
Vlot 2017[22]		11.5–18.6 (14)	14.0–19.5 (16)		215	70			57	x	x		1–xx years		up to 2 years	Height, BMAD, Z-score (hip, lumbar spine), bone markers (P1NP, OC, ICTP)
Schagen 2020[20]		12.2–16.5 (14)	15.0–17.9 (16)			127			121	x	x		1.5–4 years	3 years		aBMD, Z-score (hip)
Stoffers 2019[24]		11.8–18.0 (16)	14.9–18.4 (17.2)		64	62			15	x	x		3 months–3 years	5 months–3 years	2 years	Height, BP, BMD, Z-score (femoral neck, lumbar spine)
Navabi 2021[25]		13.4–17.4 (15)			198	172			116	x			6 months–2 years		1.5 years	BMD, aBMAD, Z-score (hip, lumbar spine)
van der Loos 2021[26]		11–17	15–17			322			322	x	x	x	1–3 years	2–6 years	up to 4 years	Subperiostal width, endocortical diameter
Lee 2020[27]		9.6–13.4 (11.5)			95	63			63	x			2 months			BMD, aBMAD, Z-score (hip, lumbar spine)
Anthropometrics and metabolism																
Schagen 2016[28]		11.1–18.6 (14)			138	116			77	x			3–12 months		1 year	Height, weight, BMI, lean body mass, liver enzymes, creatinine
Klaver 2018[31]		12.7–17.3[a] (15)	15.3–17.8[a] (16)	489	192	192			192	x	x	x	0.5–2.9 years (1.5[a])	1.6–3.4 years (2.9[a])	age 22	Weight, BMI, total body %, WHR

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Reference	Ages of patients (years)			Numbers of patients						Interventions			Time: duration and follow-up			Outcomes extracted
	Age at intake range (mean)	Age at start of GnRH range (mean)	Age at start of CSHT range (mean)	*n* referred	*n* TG enrolled	*n* TG HT	*n* TG non-HT	*n* non-TG	*n* TG HT at last FU	GnRH	CSHT	Surgery[b]	GnRH duration range (mean)	CSHT duration range (mean)	Follow-Up time range (mean)	Mental health Bone health Anthropometrics Metabolism
Klaver 2020[32]		12.8–17.2[a] (14.9)	15.3–17.8[a] (16.6)		192	192			192	x	x	x	0.5–2.9 years (1.5)[a]	1.1–3.4 years (2.5[a])	age 22	BMI, SBP, DBP, glucose, insulin, HOMA-IR, cholesterol, triglycerides
Perl 2020[33]		13.4–15.4 (14)	14.2–16.0 (15)		48	15			15	x	x		2–4 months	2–6 months		BMI, BP
Schulmeister 2021[29]		9.0–14.5 (11.5)			92	55	226		55	x			10–14 months		1 year	Height velocity, BMI, z-score
Nokoff 2021[30]		10.2–14.1 (12)			17	17	31		17	x			0.5–5.8 years			Insulin, glucose HbA1c, HOMA-IR, body fat, % lean mass
Tack 2016[34]			NR (15–17)		45	43			43		x			6–18 months (12)	1.5 years	Height, weight, BMI, triglycerides, cholesterol, suicide, side effects
Jarin 2017[35]		103–xx	xx–25 (16–18)		116	116			116	(x)	x				2 years	BMI, BP, haematocrit, Hb, cholesterol
Mullins 2021[13]			13–24 (17)	1406	611	611			611		x			0.8–2.8 years (1.5 years)	3 years	Haematology, thrombosis, BMI

Note: Number of patients:*n* referred = number of patients referred to gender clinic for evaluation of gender dysphoria (not same at number of patients receiving GD diagnosis)*n* TG enrolled = number of patients enrolled in the study at start*n* TG = number of patients with gender dysphori*an* TG HT = number of patients with gender dysphoria treated with hormones (GnRH alone, GnRH + CSHT, or CSHT only)*n* TG non-HT = number of patients with gender dysphoria treated NOT with hormones*n* TG HT at last FU = number of patients with gender dysphoria treated with hormones (GnRH alone, GnRH + CSHT, or CSHT only) evaluated at last follow-up time*n* non-TG = number of subjects in study without gender dysphoria (reference population).

Abbreviations: BDI, Beck Depression Inventory; BIS, Body Image Scale; BMAD, Bone Mineral Apparent Density; BMD, Bone Mineral Density; BMI, Body Mass Index; BP, Blood pressure; CBCL, Child Behaviour Checklist; CGAS, Global functioning Children's Global Assessment Scale, [higher scores (>80) indicating better global functioning]; CSHT, Cross-Sex Hormone Treatment/ gender-affirming treatment, testosterone, oestradiol, cyproterone acetate (CA), spironolactone, lynestrenol; GAD-7, Generalised Anxiety Disorder-7; GnRH, Gonadotropin Releasing Hormone analogue: triptorelin; HRQoL, Health Related Quality of Life; HT Hormone treatment, either GnRH, CSHT, or both; PHQ-9, Patient Health Questionnaire-9; SF-8, Short Form-8: (<18 years); STAI, Spielberger's Trait Anxiety; TG, Transgender; TPI, Anger Spielberger's Trait Anger; UGDS, Utrecht Gender Dysphoria Scale, score range 12–60 points [high score = high level of GD]; WHR, Waist-hip ratio; YSR, Youth Self Report: YSR (ages 11–18 years); Adult version (ASR, >18 years), [higher scores reflect higher degree of problems]; NR, not reported.

[a]Calculated by SBU.

[b]Surgery = any kind of gender reassignment surgery (gonadectomy, mastectomy, hysterectomy, laryngeal surgery, hair removal, phalloplasty, vaginoplasty).

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TABLE 2 Summary of findings on psychosocial outcomes of puberty-blocking treatment (GnRHa) treatment in children with gender dysphoria.[14–19]

Outcome measures	Number of study participants, description of studies	Main result	"Certainty of evidence"	Deduction in GRADE[a]
Global function	*n* on hormones = 254 *n* evaluated = 113 Four observational cohort studies: one prospective and three retrospective studies[14–17]	Improved global function as assessed with the CGAS	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Suicide ideation	*n* on hormones = 42 *n* evaluated = 28 One prospective observational cohort study with mixed treatment (38 subjects with no pharmacological treatment)[18]	No change in suicide ideation	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Gender dysphoria	*n* on hormones = 145 *n* evaluated = 49 Two prospective observational cohort studies[15,16]	No change in gender dysphoria	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Depression	*n* on hormones = 97 *n* evaluated = 60 Two prospective observational cohort studies of which one included mixed treatment[14,18]	No change in depression	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Anxiety	n on hormones = 97 n evaluated = 60 Two prospective observational cohort studies[14,18]	No change in anxiety	Cannot be assessed	−2 risk of overall bias[a] −2 precision[b]
Cognition	*n* on hormones = 20 *n* evaluated = 20 One study[19]	No change in cognition compared with matched controls	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Quality of life	*n* on hormones = 98 *n* evaluated = 46 Two observational cohort studies, whereof one retrospective[16,17]	1. Improvement in quality of life most pronounced in subjects receiving puberty-blocking hormones, followed by gender-affirming hormone treatment[17] 2. Some improvement[16]	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]

Abbreviation: CGAS, Children's Global Assessment Scale.

[a]Starting at 4 for optimal studies in each study type.

[b]Selection of study participants is difficult to assess, analysis not based on stage in puberty development.

[c]Few study subjects in each study, heterogeneity in outcome and analyses.

could not investigate potential cognitive effects of hormone therapy.

3.5 | Bone health outcomes

Six longitudinal studies used dual-energy X-ray absorptiometry (DXA) scan technology to explore bone health before and again after some time with GnRHa treatment (Table 3). The second DXA scan usually coincided with CSHT initiation leading to different follow-up durations. The third DXA scan was performed after variable time with CSHT, performed with variable dosing and administration. The lumbar spine and hip were most often examined. One study investigated bone geometry.[20] Six studies were retrospective[21–26] and one study was prospective.[20] An additional study was cross-sectional where study participants in early puberty (Tanner stages 2–3) were examined only once, before the start of GnRHa therapy.[27]

Three studies reported a lower bone mineral density (BMD) in patients before or at start of GnRHa treatment compared with the general population of the same biological sex and age.[21,23,27] During GnRHa treatment, BMD estimated through area or volume, and expressed in z-scores increased less compared with general population reference values. However, the mean absolute BMD remained unchanged up to 2–3 years of GnRHa treatment.[20,23] The initiation of CSHT stimulated bone maturation and mineral accrual, increasing BMD.[21,22] After a median CSHT duration of 5.4 years in in female-to-male and 5.8 years in male-to-female, the lumbar spine mean areal BMD z-score was still significantly lower than at the start of GnRH therapy, while the other volume BMD and femoral neck estimates had normalised.[21] In another study, female-to-male receiving testosterone replacement therapy for 1–2 years had not regained their group mean BMD z-score registered at the start of GnRHa therapy.[24]

Bone geometry, estimated as subperiosteal width and endocortical diameter, was studied on DXA scans before start of GnRHa

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TABLE 3 Summary of effects on bone development by puberty-blocking treatment (GnRHa) followed by CSHT in children with gender dysphoria.[20–25]

Outcome measures	Number of study participants, description of studies	Main Result	"Certainty of Evidence"	Deduction in GRADE[a]
Bone density during puberty-blocking hormonal treatment (g/cm^2, g/cm^3)	*n* on hormones = 363 *n* evaluated = 297 Five observational cohort studies (four retrospective and one prospective)[20–24]	Unchanged bone density (DXA measurement)	⨁⨁◯◯ Low certainty	−1 risk of overall bias[b] −1 precision
Bone density during puberty blocking hormonal treatment in relation to reference data in the literature (*z*-score)	*n* on hormones = 408 *n* evaluated = 292 Five observational cohort studies (four retrospective, and one prospective)[21–25]	Decreased increase in bone density over time	⨁⨁◯◯ Low certainty	−1 risk of overall bias[b] −1 precision
Bone density after 1–3 years (up to 22 years of age) of CSHT, which had been preceded by puberty-blocking hormonal treatment in relation to reference data in the literature	*n* on hormones = 268 *n* evaluated = 165 Three observational cohort studies (two retrospective and one prospective)[21,24,25]	After group median five years with CSHT, bone density recovered in hip but not in lumbar spine compared to data at start of treatment (*z*-score)	⨁⨁◯◯ Low certainty	−1 risk of overall bias[b] −1 precision

Abbreviations: CSHT, Cross-sex hormone treatment; DXA, Dual-Energy X-ray Absorptiometry.

[a]Starting at 4 for optimal studies in each study type.

[b]Analysis not based on stage in puberty development.

treatment and after at least two years on CSHT and compared with reference values of the general population: the bone geometry resembled the reference curve for the experienced sex only when GnRHa was started during early puberty. Bone geometry estimates in those who started GnRHa treatment during mid and late puberty remained within the reference curve of the biological sex.[26]

3.6 | Body composition and metabolic markers

GnRHa treatment effectively reduced endogenous sex hormone serum levels (Table 4). DXA scans after 1 year of GnRHa treatment revealed increased fat mass and reduced lean body mass.[28] Longitudinal growth depends on bone maturity (bone age) of those in the study group. Ongoing pubertal growth spurt will be arrested when GnRHa therapy is started, reducing the growth velocity to the prepubertal rate.[29]

Nokoff et al studied body composition and insulin sensitivity during 1 year of GnRHa therapy.[30] In addition to body composition, metabolic effects as insulin sensitivity during CSHT, and changes in blood pressure during testosterone therapy were examined.[31–33] Of these studies, three originated from Amsterdam.[29,32,33] The Amsterdam studies included observations during GnRHa therapy,[28] 1 year after starting CSHT,[32] as well as after a group median >5 years with CSHT in a cohort of 22-year-old adolescents.[31,33] The studies from Amsterdam were generally larger than the other studies. CSHT changed body composition towards the affirmed sex.[31,32] Obesity (defined as BMI >30 at age 22 years) was more prevalent in the transgender population[33] (Table 4).

3.7 | CSHT in children without prior GnRHa treatment

We were able to identify three studies of low-to-moderate bias examining CSHT in children without prior GnRHa treatment.[13,34,35] All were retrospective longitudinal studies. Because the number of study participants was small, studies were deemed to have low external validity, and because the studies examined different outcomes (e.g., lipid serum levels, Hb, blood pressure, metrorrhagia), it was not possible to draw any overall conclusions from these studies. Although the Mullins et al. paper[13] included several individuals at elevated risk of arterial or venous thrombosis, no cases of thrombosis were reported.

4 | DISCUSSION

We performed an extensive literature search to examine psychosocial and cognitive outcomes as well as metabolic and bone health in children with gender dysphoria taking hormone therapy. No randomised controlled trials were found, but we could identify 24 relevant observational studies. However, these were limited by

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TABLE 4 Summary of findings of puberty-blocking (GnRHa) hormone treatment on anthropometric measures, body composition, and metabolism in children with gender dysphoria.[28–33]

Outcome measures	Number of study participants, description of studies	Main result	"Certainty of Evidence"	Deduction in GRADE[a]
Anthropometric measures	*n* on hormones = 192 *n* evaluated = 192 One retrospective observational cohort study[31]	Increased weight and body mass index	Cannot be assessed	−2 risk for overall bias[b] −1 precision[c] −1 indirectness[d]
Body composition	*n* on hormones = 325 *n* evaluated = 286 Two prospective observational cohort studies and one controlled cross-sectional study[28,30,31]	Decreased lean body mass	Cannot be assessed	−2 risk for overall bias[b] −1 precision[c] −1 indirectness[d]
Metabolic measures	*n* on hormones = 209 *n* evaluated = 209 One retrospective observational cohort study and one controlled cross-sectional study[30,32]	No change in serum lipids or blood pressure Increased insulin level in MtF Decreased insulin sensitivity	Cannot be assessed	−2 risk for overall bias[b] −1 precision[c] −1 indirectness[d]
Blood pressure	*n* on hormones = 15 *n* evaluated =15 One retrospective observational cohort study[33]	Change in blood pressure	Cannot be assessed	−2 risk for overall bias[b] −1 precision[c] −1 indirectness[d]
Growth (cm/year)	*n* on hormones = 55 *n* evaluated = 55 One prospective multicentre observational GnRHa treatment cohort study[29]	Reduced growth velocity	Cannot be assessed	−2 risk for overall bias[b] −1 precision[c] −1 indirectness[d]

[a]Starting at 4 for optimal studies in each study type.

[b]Selection of study participants is difficult to assess. Analysis not based on stage in puberty development.

[c]Few study subjects in each study, hence there is heterogeneity in outcome and analyses.

[d]Single study. In this context, 'indirectness' is similar to 'external validity'.

methodological weaknesses, for instance lack of or inappropriate control group, lack of intra-individual analyses, high attrition rates that precluded conclusion to be drawn. The exception being that children with gender dysphoria often had lower group mean values for BMD already prior to GnRHa treatment, and that GnRHa treatment delays the physiologically occurring BMD gain during pubertal sex hormone stimulation. However, this GnRHa-induced delay in BMD gain is almost fully compensated for by later ensuing CSHT. Although study participants were followed up to 22 years of age, the observed remaining deficit may depend on the limited study group size or on too short observation time.[21]

Our review highlights several specific knowledge gaps in gender dysphoria that are important to bridge not least given the recent increased incidence in many countries.[6,7] First, randomised controlled trials are lacking in gender dysphoria research. We call for such studies, which may be the only way to address biases that we have noted in the field. Given the current lack of evidence for hormonal therapy improving gender dysphoria, another ethically feasible option would be to randomise individuals to hormone therapy with all study participants, independent of intervention status, receiving psychological and psychosocial support. However, controlled trials do not necessarily require placebo treatment, but could for example build on the date or time of starting hormonal therapy to generate comparison groups. However, it should also be noted that this is a highly vulnerable population.

A second limitation concerns the statistical management of data. In the reviewed studies, observational data have frequently been analysed at a group level where intra-individual changes would have been more appropriate. Intra-individual analyses would allow for a better understanding of how subgroups of individuals respond (both positively and negatively) to hormone therapy. Group-level analyses are sensitive to selection bias because of high drop-out rates: The group studied at the end of the study is a selection of the group studied at baseline, which increases indirectness (reduces external validity). Moreover, it is important to analyse the distribution of individual data to be able to identify outliers who may be at risk for severe consequences of treatment.

Third, many studies only present data on chronological age but fail to account for puberty stage and biological age. This is a concern because the main purpose of GnRHa treatment is to suppress puberty and, with that, biological ageing.

Fourth, long-term studies are lacking. The duration of GnRHa treatment and CSHT was rarely >4 years. The absence of long-term studies is worrying because many individuals start treatment as minors (<18 years) and CSHT is lifelong. Fifth, individuals who stop GnRHa treatment before the start of CSHT need to be described and followed up. Sixth, some of the findings underlying this review are old, and studies reflecting the changing demographics of individuals seeking care for gender dysphoria are warranted.

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TABLE 5 The GEnder Dysphoria HORmone treatment (GENDHOR) checklist.

	Recommendations
Aim	Describe the aim of the study
Study participants:	
Cases/exposed	Define gender dysphoria in your study, including the assessment tools used. Define eligibility criteria for your study (including chronological age, bone age or puberty stage, according to Tanner or Prader (when study concerns adolescents), biological sex, perceived gender identity, psychiatric and somatic comorbidities, medications at baseline). List exclusion criteria (diagnoses). List ages of participants at the start of each treatment (including absolute age ranges).
Comparators/ unexposed	Clarify how controls were selected (were controls recruited from the general population?) or whether national/ regional reference data (for instance, Z-scores) were used instead of individual controls.
Study design	Describe the study design: Cross-sectional, retrospective, prospective; case–control (and if nested), cohort study, randomised clinical trial.
Setting	Describe the setting of the study. Were study participants included at a tertiary centre or from the general population? Describe the catchment area/population of participating centres.
Intervention	Hormone treatment Describe whether GnRHa, anti-androgens, CSHT, or a combination was used. List generic names, mode of administration, and dosages of all treatments. Specify the treatment duration of each treatment. If hormone serum concentrations are studied, include the standard procedure for the timing of blood samples to hormone intake. If patients undergo surgery, clarify the type of surgery and number of participants undergoing each surgical procedure (gonadectomy, mastectomy, laryngeal surgery, vaginoplasty/phalloplasty, etc.). Clarify if any participant received psychiatric counselling before, or during the study, including total duration and frequency of counselling.
Variables	Define each variable (including co-variates) and its source. If possible, mention any effort to validate the variables.
Data measurement	Clarify who collected the data on study participants. Present time between first and second measurements if your study is longitudinal and includes “before-after” measurements in relation to the intervention. Mention if study participants had previously been included in other studies with a different aim or examining other outcomes.
Blinding	Describe if the data collectors were blinded to participant status/treatment or not.
Loss to follow-up	Indicate the number of participants discontinuing GnRHa/ CSHT and the reason(s) for discontinuation, including no longer wish to pursue gender reassignment treatment. Describe loss to follow-up/missing data
Statistical methods	Describe statistics according to a relevant checklist. Consider when applicable: Intra-individual changes (mean, SD, median, range) vs. between-group differences.
Descriptive data	In addition to usual demographic, clinical, social/socioeconomic information, report body mass index (BMI), smoking, use of oral contraceptives (type) or other hormonal treatment, puberty stage. Report any psychiatric illness at baseline, as well as the use of psychotropic medication. Describe other comorbidities, including disorders that could be considered contraindications for either hormone treatment or surgery. Specify follow-up time (median, mean) since the start of the intervention and since start of hormone treatment (define intervention start).
Outcome data	Specify main outcome of the study. Indicate all secondary outcomes, including adverse events.
Adverse events/ complications	Describe all adverse events.
Main results	Present absolute numbers. Calculate absolute and relative risks/Intraindividual effects/change and group mean/ median. Present incidence data. Describe any adjustment for potential confounders.
Limitations	Discuss limitations of your study, including limitations of the measurements used (e.g., DXA) and sources of potential bias or imprecision.
Generalisability/ external validity	Can data be generalised to individuals with gender dysphoria outside your study centre and the study country?
Conflict of interest	Report any conflict of interest.

Note: Based on our literature review, we created a *GEnder Dysphoria HORmone treatment checklist* (GENDHOR).

This list consists of recommendations that researchers may consider when planning a study of gender dysphoria, whether observational or interventional.

Abbreviations: CSHT, Cross-sex hormone treatment; DXA, Dual-Energy X-ray Absorptiometry; GnRHa, Gonadotropin-releasing hormone agonist (analogues).

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Finally, we could not evaluate the frequency of individuals who drop out from GnRHa treatment and no longer wish to continue with gender transition. However, a follow up study was published after our literature search.[36] Of 720 children (31% born male and 69% born female) who started GnRHa treatment in adolescence, 98% continued to use hormone treatment into adulthood, which suggests that children generally continue with gender transition once they have started GnRHa treatment. We know from internet-based surveys that detransitioning exists,[37] but such studies cannot provide reliable estimates of detransitioning frequency because of selection bias. Studies that closely follow individuals who start GnRHa therapy and/or CSHT until at least age 30 are urgently needed. We also acknowledge there are other potential side effects from GnRHa therapy or CSHT that were not included in our review such as alopecia and abscesses from injections.[38]

Due to limitations in reporting of data, previous published studies in this field repeatedly contain insufficient details on drug administration and dosages, treatment duration, and the type of surgery performed. Some of these limitations will be partly remedied by the introduction of the new ICD version 11, and the Utrecht criteria,[39] but the field also urgently needs high quality longitudinal studies that not only assess medical outcomes but also those outcomes that matter most for affected individuals. Building on the identified limitations in previous research, we compiled a checklist to improve gender dysphoria research ("GENDHOR", Table 5). The aim of this checklist is not to replace existing research guidelines, but using it together with existing guidelines might support researchers and peer reviewers, and ultimately benefit patients and their families.

Last, there have been studies in this field published after the date of our literature search (9 November 2021). These have not been added to this study in order to not depart from the systematic approach. We nevertheless wish to comment on some of the publications. First, the National Institute for Health and Care Excellence in England (NICE) conducted evidence reviews of GnRHa[40] as well as CSHT[41] for children with gender dysphoria, which were independent from our work. The conclusions generally align with our findings. Second, Chien et al.[42] recently published a prospective study of psychosocial functioning during 2 years after initiation of CSHT in youths (12–20 years of age) with gender dysphoria. Of 315 participants, 162 completed that study. Life satisfaction increased, and depression and anxiety scores decreased, among biological females but not biological males. The strongest finding was a moderately improved appearance congruence. No information on concomitant psychological or psychopharmacological therapy was provided.

5 | CONCLUSION

This systematic review of almost 10 000 screened abstracts suggests that long-term effects of hormone therapy on psychosocial and somatic health are unknown, except that GnRHa treatment seems to delay bone maturation and gain in bone mineral density.

AUTHOR CONTRIBUTIONS

Study concept and design: All authors. Acquisition of data: Malin Höistad, Jan Adolfsson. Drafting of the manuscript: All authors. Interpretation of data and critical revision of the manuscript for important intellectual content: All authors. Administrative, technical, or material support: Jan Adolfsson, Malin Höistad. Funding acquisition: the Swedish agency for technology assessment and assessment for social services.

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Information specialists Klas Moberg and Hanna Olofsson designed and performed the literature search.

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CONFLICT OF INTEREST STATEMENT

JFL coordinated an unrelated study on behalf of the Swedish inflammatory bowel disease quality register (SWIBREG) that received funding from the Janssen Corporation. JFL has also received financial support from Merck Sharp & Dohme developing a paper reviewing national healthcare registers in China. JFL is currently discussing potential research collaboration with Takeda. ML has received lecture honoraria for Lundbeck pharmaceuticals and served as consultant for AstraZeneca. The other authors report no conflict of interest.

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BMJ INVESTIGATION

Gender dysphoria in young people is rising—and so is professional disagreement

More children and adolescents are identifying as transgender and are being offered medical treatment, especially in the US—but some providers and European authorities are urging caution because of a lack of strong evidence. Jennifer Block reports

Jennifer Block *investigations reporter*

Last October the American Academy of Pediatrics (AAP) gathered inside the Anaheim Convention Center in California for its annual conference. Outside, several dozen people rallied to hear speakers including Abigail Martinez, a mother whose child began hormone treatment at age 16 and died by suicide at age 19. Supporters chanted the teen's given name, Yaeli; counter protesters chanted, "Protect trans youth!" For viewers on a livestream, the feed was interrupted as the two groups fought for the camera.

The AAP conference is one of many flashpoints in the contentious debate in the United States over if, when, and how children and adolescents with gender dysphoria should be medically or surgically treated. US medical professional groups are aligned in support of "gender affirming care" for gender dysphoria, which may include gonadotrophin releasing hormone analogues (GnRHa) to suppress puberty; oestrogen or testosterone to promote secondary sex characteristics; and surgical removal or augmentation of breasts, genitals, or other physical features. At the same time, however, several European countries have issued guidance to limit medical intervention in minors, prioritising psychological care.

The discourse is polarised in the US. Conservative politicians, pundits, and social media influencers accuse providers of pushing "gender ideology" and even "child abuse," lobbying for laws banning medical transition for minors. Progressives argue that denying access to care is a transphobic violation of human rights. There's little dispute within the medical community that children in distress need care, but concerns about the rapid widespread adoption of interventions and calls for rigorous scientific review are coming from across the ideological spectrum.[1]

The surge in treatment of minors

More adolescents with no history of gender dysphoria—predominantly birth registered females[2]—are presenting at gender clinics. A recent analysis of insurance claims by Komodo Health found that nearly 18 000 US minors began taking puberty blockers or hormones from 2017 to 2021, the number rising each year.[3 4] Surveys aiming to measure prevalence have found that about 2% of high school aged teens identify as "transgender."[5] These young people are also more likely than their cisgender peers to have concurrent mental health and neurodiverse conditions including depression, anxiety, attention deficit disorders, and autism.[6] In the US, although Medicaid coverage varies by state and by treatment, the Biden administration has warned states that not covering care is in violation of federal law prohibiting discrimination.[7] Meanwhile, the number of private clinics that focus on providing hormones and surgeries has grown from just a few a decade ago to more than 100 today.[4]

As the number of young people receiving medical transition treatments rises, so have the voices of those who call themselves "detransitioners" or "retransitioners," some of whom claim that early treatment caused preventable harm.[8] Large scale, long term research is lacking,[9] and researchers disagree about how to measure the phenomenon, but two recent studies suggest that as many as 20-30% of patients may discontinue hormone treatment within a few years.[10 11] The World Professional Association for Transgender Health (WPATH) asserts that detransition is "rare."[12]

Chloe Cole, now aged 18, had a double mastectomy at age 15 and spoke at the AAP rally. "Many of us were young teenagers when we decided, on the direction of medical experts, to pursue irreversible hormone treatments and surgeries," she read from her tablet at the rally, which had by this time moved indoors to avoid confrontation. "This is not informed consent but a decision forced under extreme duress."

Scott Hadland, chief of adolescent medicine at Massachusetts General Hospital and Harvard Medical School, dismissed the "handful of cruel protesters" outside the AAP meeting in a tweet that morning. He wrote, "Inside 10 000 pediatricians stand in solidarity for trans & gender diverse kids & their families to receive evidence-based, lifesaving, individualized care."[13]

Same evidence, divergent recommendations

Three organisations have had a major role in shaping the US's approach to gender dysphoria care: WPATH, the AAP, and the Endocrine Society (see box). On 15 September 2022 WPATH published the eighth edition of its Standards of Care for the Health of Transgender and Gender Diverse People, with new chapters on children and adolescents and no minimum age requirements for hormonal and surgical treatments.[2 12] GnRHa treatment, says WPATH, can

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be initiated to arrest puberty at its earliest stage, known as Tanner stage 2.

The Endocrine Society also supports hormonal and surgical intervention in adolescents who meet criteria in clinical practice guidelines published in 2009 and updated in 2017.[14] And the AAP's 2018 policy statement, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, says that "various interventions may be considered to better align" a young person's "gender expression with their underlying identity."[15] Among the components of "gender affirmation" the AAP names social transition, puberty blockers, sex hormones, and surgeries. Other prominent professional organisations, such as the American Medical Association, have issued policy statements in opposition to legislation that would curtail access to medical treatment for minors.[16-19]

These documents are often cited to suggest that medical treatment is both uncontroversial and backed by rigorous science. "All of those medical societies find such care to be evidence-based and medically necessary," stated a recent article on transgender healthcare for children published in *Scientific American*.[20] "Transition related healthcare is not controversial in the medical field," wrote Gillian Branstetter, a frequent spokesperson on transgender issues currently with the American Civil Liberties Union, in a 2019 guide for reporters.[21] Two physicians and an attorney from Yale recently opined in the *Los Angeles Times* that "gender-affirming care is standard medical care, supported by major medical organizations . . . Years of study and scientific scrutiny have established safe, evidence-based guidelines for delivery of lifesaving, gender-affirming care."[22] Rachel Levine, the US assistant secretary for health, told National Public Radio last year regarding such treatment, "There is no argument among medical professionals."[23]

Internationally, however, governing bodies have come to different conclusions regarding the safety and efficacy of medically treating gender dysphoria. Sweden's National Board of Health and Welfare, which sets guidelines for care, determined last year that the risks of puberty blockers and treatment with hormones "currently outweigh the possible benefits" for minors.[24] Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued similar guidelines, calling for psychosocial support as the first line treatment.[25] (Both countries restrict surgery to adults.)

Medical societies in France, Australia, and New Zealand have also leant away from early medicalisation.[26,27] And NHS England, which is in the midst of an independent review of gender identity services, recently said that there was "scarce and inconclusive evidence to support clinical decision making"[28] for minors with gender dysphoria[29] and that for most who present before puberty it will be a "transient phase," requiring clinicians to focus on psychological support and to be "mindful" even of the risks of social transition.[30]

Box: The origins of paediatric gender medicine in the United States

The World Professional Association for Transgender Health (WPATH) began as a US based advocacy group and issued the first edition of the Standards of Care in 1979, when it was serving a small population of mostly adult male-to-female transsexuals. "WPATH became the standard because there was nobody else doing it," says Erica Anderson, a California based clinical psychologist and former WPATH board member. The professional US organisations that lined up in support "looked heavily to WPATH and the Endocrine Society for their guidance," she told *The BMJ*.

The Endocrine Society's guidance for adolescents grew out of clinicians' research in the Netherlands in the late 1990s and early 2000s. Peggy Cohen-Kettenis, a Utrecht gender clinic psychologist, collaborated with endocrinologists in Amsterdam, one of whom had experience of prescribing gonadotrophin releasing hormone analogues, relatively new at the time. Back then, gender dysphoric teens had to wait until the age of majority for sex hormones, but the team proposed that earlier intervention could benefit carefully selected minors.[40]

The clinic treated one natal female patient with triptorelin, published a case study and feasibility proposal, and began treating a small number of children at the turn of the millennium. The Dutch Protocol was published in 2006, referring to 54 children whose puberty was being suppressed and reporting preliminary results on the first 21.[41] The researchers received funding from Ferring Pharmaceuticals, the manufacturer of triptorelin.

In 2007 the endocrinologist Norman Spack began using the protocol at Boston Children's Hospital and joined Cohen-Kettenis and her Dutch colleagues in writing the Endocrine Society's first clinical practice guideline.[42] When that was published in 2009, puberty had been suppressed in just over 100 gender dysphoric young people.[40]

American Academy of Pediatrics (AAP) committee members began discussing the need for a statement in 2014, four years before publication, says Jason Rafferty, assistant professor of paediatrics and psychiatry at Brown University, Rhode Island, and the statement's lead author. "The AAP recognised that it had a responsibility to provide some clinical guidance, but more importantly to come out with a statement that said we need research, we need to integrate the principles of gender affirmative care into medical education and into child health," he says. "What our policy statement is not meant to be is a protocol or guidelines in and of themselves."

"Don't call them evidence based"

"The brief history of guidelines is that, going back more than 30 years ago, experts would write articles and so on about what people should do. But formal guidelines as we think of them now were seldom or non-existent," says Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University, Ontario.

That led to the movement towards developing criteria for what makes a "trustworthy guideline," of which Guyatt was a part.[31] One pillar of this, he told *The BMJ*, is that they "are based on systematic review of the relevant evidence," for which there are also now standards, as opposed to a traditional narrative literature review in which "a bunch of experts write whatever they felt like using no particular standards and no particular structure."

Mark Helfand, professor of medical informatics and clinical epidemiology at Oregon Health and Science University, says, "An evidence based recommendation requires two steps." First, "an unbiased, thorough, critical systematic review of all the relevant evidence." Second, "some commitment to link the strength of the recommendations to the quality of the evidence."

The Endocrine Society commissioned two systematic reviews for its clinical practice guideline, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*: one on the effects of sex steroids on lipids and cardiovascular outcomes, the other on their effects on bone health.[32,33] To indicate the quality of evidence underpinning its various guidelines, the Endocrine Society employed the GRADE system (grading of recommendations assessment, development, and evaluation) and judged the quality of evidence for all recommendations on adolescents as "low" or "very low."

Guyatt, who co-developed GRADE, found "serious problems" with the Endocrine Society guidelines, noting that the systematic reviews

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didn't look at the effect of the interventions on gender dysphoria itself, arguably "the most important outcome." He also noted that the Endocrine Society had at times paired strong recommendations—phrased as "we recommend"—with weak evidence. In the adolescent section, the weaker phrasing "we suggest" is used for pubertal hormone suppression when children "first exhibit physical changes of puberty"; however, the stronger phrasing is used to "recommend" GnRHa treatment.

"GRADE discourages strong recommendations with low or very low quality evidence except under very specific circumstances," Guyatt told *The BMJ*. Those exceptions are "very few and far between," and when used in guidance, their rationale should be made explicit, Guyatt said. In an emailed response, the Endocrine Society referenced the GRADE system's five exceptions, but did not specify which it was applying.

Helfand examined the recently updated WPATH Standards of Care and noted that it "incorporated elements of an evidence based guideline." For one, WPATH commissioned a team at Johns Hopkins University in Maryland to conduct systematic reviews.[34 35] However, WPATH's recommendations lack a grading system to indicate the quality of the evidence—one of several deficiencies. Both Guyatt and Helfand noted that a trustworthy guideline would be transparent about all commissioned systematic reviews: how many were done and what the results were. But Helfand remarked that neither was made clear in the WPATH guidelines and also noted several instances in which the strength of evidence presented to justify a recommendation was "at odds with what their own systematic reviewers found."

For example, one of the commissioned systematic reviews found that the strength of evidence for the conclusions that hormonal treatment "may improve" quality of life, depression, and anxiety among transgender people was "low," and it emphasised the need for more research, "especially among adolescents."[35] The reviewers also concluded that "it was impossible to draw conclusions about the effects of hormone therapy" on death by suicide.

Despite this, WPATH recommends that young people have access to treatments after comprehensive assessment, stating that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents."[12] And more globally, WPATH asserts, "There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures," procedures that "are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria."[12]

Those two statements are each followed by more than 20 references, among them the commissioned systematic review. This stood out to Helfand as obscuring which conclusions were based on evidence versus opinion. He says, "It's a very strange thing to feel that they had to cite some of the studies that would have been in the systematic review or purposefully weren't included in the review, because that's what the review is for."

For minors, WPATH contends that the evidence is so limited that "a systematic review regarding outcomes of treatment in adolescents is not possible." But Guyatt counters that "systematic reviews are always possible," even if few or no studies meet the eligibility criteria. If an entity has made a recommendation without one, he says, "they'd be violating standards of trustworthy guidelines." Jason Rafferty, assistant professor of paediatrics and psychiatry at Brown University, Rhode Island, and lead author of the AAP statement, remarks that the AAP's process "doesn't quite fit the definition of systematic review, but it is very comprehensive."

Sweden conducted systematic reviews in 2015 and 2022 and found the evidence on hormonal treatment in adolescents "insufficient and inconclusive."[24] Its new guidelines note the importance of factoring the possibility that young people will detransition, in which case "gender confirming treatment thus may lead to a deteriorating of health and quality of life (i.e., harm)."

Cochrane, an international organisation that has built its reputation on delivering independent evidence reviews, has yet to publish a systematic review of gender treatments in minors. But *The BMJ* has learnt that in 2020 Cochrane accepted a proposal to review puberty blockers and that it worked with a team of researchers through 2021 in developing a protocol, but it ultimately rejected it after peer review. A spokesperson for Cochrane told *The BMJ* that its editors have to consider whether a review "would add value to the existing evidence base," highlighting the work of the UK's National Institute for Health and Care Excellence, which looked at puberty blockers and hormones for adolescents in 2021. "That review found the evidence to be inconclusive, and there have been no significant primary studies published since."

In 2022 the state of Florida's Agency for Health Care Administration commissioned an overview of systematic reviews looking at outcomes "important to patients" with gender dysphoria, including mental health, quality of life, and complications. Two health research methodologists at McMaster University carried out the work, analysing 61 systematic reviews and concluding that "there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people." The body of evidence, they said, was "not sufficient" to support treatment decisions.

Calling a treatment recommendation "evidence based" should mean that a treatment has not just been systematically studied, says Helfand, but that there was also a finding of high quality evidence supporting its use. Weak evidence "doesn't just mean something esoteric about study design, it means there's uncertainty about whether the long term benefits outweigh the harms," Helfand adds.

"Evidence itself never tells you what to do," says Guyatt. That's why guidelines must make explicit the values and preferences that underlie the recommendation.

The Endocrine Society acknowledges in its recommendations on early puberty suppression that it is placing "a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm."[14]

WPATH acknowledges that while its latest guidelines are "based upon a more rigorous and methodological evidence-based approach than previous versions," the evidence "is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion." In the absence of high quality evidence and the presence of a patient population in need—who are willing to take on more personal risk—consensus based guidelines are not unwarranted, says Helfand. "But don't call them evidence based."

An evidence base under construction

In 2015 the US National Institutes of Health awarded a $5.7m (£4.7m; €5.3m) grant to study "the impact of early medical treatment in transgender youth."[36] The abstract submitted by applicants said that the study was "the first in the US to evaluate longitudinal

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outcomes of medical treatment for transgender youth and will provide essential evidence-based data on the physiological and psychosocial effects and safety" of current treatments. Researchers are following two groups, one of participants who began receiving GnRHa in early puberty and another group who began cross sex hormone treatment in adolescence. The study doesn't include a concurrent no-treatment control group.

Robert Garofalo, chief of adolescent medicine at the Lurie Children's Hospital in Chicago and one of four principal investigators, told a podcast interviewer in May 2022 that the evidence base remained "a challenge . . . it is a discipline where the evidence base is now being assembled" and that "it's truly lagging behind [clinical practice], I think, in some ways." That care, he explained, was "being done safely. But only now, I think, are we really beginning to do the type of research where we're looking at short, medium, and long term outcomes of the care that we are providing in a way that I think hopefully will be either reassuring to institutions and families and patients or also will shed a light on things that we can be doing better."[37]

While Garofalo was doing the research he served as "contributor" on the AAP's widely cited 2018 policy statement, which recommends that children and adolescents "have access to comprehensive, gender-affirming, and developmentally appropriate health care," including puberty blockers, sex hormones, and, on a case-by-case basis, surgeries.[15]

Garofalo said in the May interview, "There is universal support for gender affirming care from every mainstream US based medical society that I can think of: the AMA, the APA, the AAP. I mean, these organisations never agree with one another." Garofalo declined an interview and did not respond to *The BMJ*'s requests for comment.

The rush to affirm

Sarah Palmer, a paediatrician in private practice in Indiana, is one of five coauthors of a 2022 resolution submitted to the AAP's leadership conference asking that it revisit the policy after "a rigorous systematic review of available evidence regarding the safety, efficacy, and risks of childhood social transition, puberty blockers, cross sex hormones and surgery." In practice, Palmer told *The BMJ*, clinicians define "gender affirming" care so broadly that "it's been taken by many people to mean go ahead and do anything that affirms. One of the main things I've seen it used for is masculinising chest surgery, also known as mastectomy in teenage patients." The AAP has told *The BMJ* that all policy statements are reviewed after five years and so a "revision is under way," based on its experts' own "robust evidence review."

Palmer says, "I've seen a quick evolution, from kids with a very rare case of gender dysphoria who were treated with a long course of counselling and exploration before hormones were started," to treatment progressing "very quickly—even at the first visit to gender clinic—and there's no psychologist involved anymore."

Laura Edwards-Leeper, a clinical psychologist who worked with the endocrinologist Norman Spack in Boston and coauthored the WPATH guidelines for adolescents, has observed a similar trend. "More providers do not value the mental health component," she says, so in some clinics families come in and their child is "pretty much fast tracked to medical intervention." In a study of teens at Seattle Children's Hospital's gender clinic, two thirds were taking hormones within 12 months of the initial visit.[38]

The British paediatrician Hilary Cass, in her interim report of a UK review into services for young people with gender identity issues, noted that some NHS staff reported feeling "under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and diagnosis that they have been trained to undertake in all other clinical encounters."

Eli Coleman, lead author of WPATH's Standards of Care and former director of the Institute for Sexual and Gender Health at the University of Minnesota, told *The BMJ* that the new guidelines emphasised "careful assessment prior to any of these interventions" by clinicians who have appropriate training and competence to assure that minors have "the emotional and cognitive maturity to understand the risks and benefits." He adds, "What we know and what we don't know has to be explained to youth and their parents or caregivers in a balanced way which really details that this is the evidence that we have, that we obviously would like to have more evidence, and that this is a risk-benefit scenario that you have to consider."

Joshua Safer, director of the Center for Transgender Medicine and Surgery at Mount Sinai Hospital in New York and coauthor of the Endocrine Society guidelines, told *The BMJ* that assessment is standard practice at the programme he leads. "We start with a mental health evaluation for anybody under the age of 18," he says. "There's a lot of talking going on—that's a substantial element of things." Safer has heard stories of adolescents leaving a first or second appointment with a prescription in hand but says that these are overblown. "We really do screen these kids pretty well, and the overwhelming majority of kids who get into these programmes do go on to other interventions," he says.

Without an objective diagnostic test, however, others remain concerned. The demand for services has led to a "perfunctory informed consent process," wrote two clinicians and a researcher in a recent issue of the *Journal of Sex and Marital Therapy*,[39] in spite of two key uncertainties: the long term impacts of treatment and whether a young person will persist in their gender identity. And the widespread impression of medical consensus doesn't help. "Unfortunately, gender specialists are frequently unfamiliar with, or discount the significance of, the research in support of these two concepts," they wrote. "As a result, the informed consent process rarely adequately discloses this information to patients and their families."

For Guyatt, claims of certainty represent both the success and failure of the evidence based medicine movement. "Everybody now has to claim to be evidence based" in order to be taken seriously, he says—that's the success. But people "don't particularly adhere to the standard of what is evidence based medicine—that's the failure." When there's been a rigorous systematic review of the evidence and the bottom line is that "we don't know,'" he says, then "anybody who then claims they do know is not being evidence based."

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Topic Brief: Treatments for Gender Dysphoria in Transgender Youth

Date: 1/8/2021
Nomination Number: 0928

Purpose: This document summarizes the information addressing a nomination submitted on July 17, 2020 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Youth who identify as transgender experience high rates of depression, anxiety, eating disorders, substance use disorders, and suicide ideation or attempts. There is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation.

Program Decision:

The EPC Program will not develop a new systematic review because we found protocols for two systematic reviews that addresses portions of the nomination, and an insufficient number of primary studies exist to address the remainder of the nomination.

Key Findings

- We found a protocol for a systematic review that included key questions (KQs) that met the nominator's needs for KQ1 regarding pubertal suppression in transgender youth.
- For KQ 2 and 3, we found two protocols (one is the same as that for KQ1) for systematic reviews that partially address each of the two KQs, respectively. We did not find any studies addressing the parts of the KQs not addressed by these protocols.

Background

The term transgender refers to individuals whose gender identity persistently and consistently does not match their assigned sex.[1] An estimated 0.6 percent of adults[2] and 0.7 percent of youth ages 13 to 17 in the U.S. identify as transgender or "gender nonconforming." [3] Many transgender youth experience gender dysphoria, characterized as an impairment in peer and/or family relationships, school performance, and other aspects of life as a consequence of the discordance between their gender identity and assigned sex.[1] Transgender youth also experience high rates of depression, anxiety, eating disorders, and suicide.[4-6]

Gender affirmation is a complex interpersonal process of reflection, acceptance, social and legal recognition and medical interventions. Gender-affirming behavioral, social and medical interventions may improve psychological functioning in children and adolescents.[6] Available interventions include the following: 1) social affirmation (e.g., expressing one's asserted gender

through hairstyle, clothing, pronouns, name, etc.); 2) legal affirmation (e.g., name and gender officially reflected on legal documents); 3) medical affirmation (e.g., using cross-sex hormones in adolescents who have initiated puberty to facilitate the development of secondary sex characteristics of the sex the individual identifies with); and/or 4) surgical affirmation (e.g., surgical interventions to masculinize or feminize features).[1]

Gender-affirming health care is part of comprehensive primary care for many gender-diverse patients. There is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation. While there are some existing guidelines and standards of care,[1, 7, 8] most are derived from expert opinion or have not been updated recently. A comprehensive evidence review is currently not available.

Scope

1. For children and adolescents who identify as transgender and have not initiated puberty, what are the benefits and harms of pubertal suppression?
2. For adolescents who identify as transgender and have initiated puberty, what are the benefits and harms of medical affirmation with hormone therapy?
3. For adolescents who identify as transgender and have initiated puberty, what are the benefits and harms of surgical affirmation?

Table 1. Questions and PICOs

Questions	1. Pubertal suppression	2. Hormone therapy	3. Surgical affirmation
Population	Children and adolescents who identify as transgender and have not initiated puberty	Adolescents who identify as transgender and have initiated puberty	Adolescents who identify as transgender and have initiated puberty
Interventions	Pubertal suppression	Medical affirmation with hormone therapy	Surgical affirmation
Comparators	No pubertal suppression	No intervention; Social affirmation only	No intervention; social affirmation with other medical affirmation (e.g., hormone therapy); social affirmation without medical affirmation

Questions	1. Pubertal suppression	2. Hormone therapy	3. Surgical affirmation
Outcomes	• Depression/anxiety, suicidality, distress/dysphoria, social interaction, quality of life • Medication effects (e.g., weight gain, height, decreased secondary sex characteristics, hot flashes, headache, bone density, fertility)	• Depression/anxiety, suicidality, distress/dysphoria, social interaction, quality of life • Estrogen effects (feminization, weight gain, mood swings, hot flashes, VTE, migraine, fertility, cancer risks), antiandrogen effects (feminization, hypotension, electrolyte abnormality, VTE), androgen effects (masculinization, cancer risks, hypertension, hyperlipidemia, vascular disease)	• Depression/anxiety, suicidality, distress/dysphoria, social interaction, quality of life • Surgical risks (e.g., infection, bleeding, poor healing of incisions, hematoma, seroma, necrosis, nerve injury, stenosis of the vagina, injury of the urinary tract, painful intercourse)

Abbreviations: PICOS=population, intervention, comparator, outcome; VTE=venous thromboembolism.

Assessment Methods

See Appendix A.

Summary of Literature Findings

We identified a protocol for a systematic review that covered KQ1,[9] protocols that partially covered KQ 1 and 2, and no primary literature to cover the portions of KQs 2-3 not covered by the protocols.

For KQ1, we identified a protocol for a systematic review[9] that included the following key questions that meet the nominator's needs:

- "For transgender adolescents, what are the long term effect of GnRH agonists compared to no treatment, in terms of surrogate outcomes, clinical outcomes, and harms?"
- "For transgender people, what are the effect of progesterones (cyproterone) compared to Medroxyprogesterone and other progesterones in terms of breast growth (adults), delay of puberty (children), and side effects?"
- "For transgender adolescents, what are the effects of suppressing puberty with GnRH agonists on quality of life?"

For KQ2, we found a protocol for a systematic review[9] that partially covered KQ2:

- "For transgender people, what are the psychological effects (including quality of life) associated with hormone therapy."
- "For transgender people, what are the effects of hormone therapy on metabolic syndrome?"
- "For transgender people, what are the effects of hormone therapy on fertility?"

We did not find any systematic reviews or protocols for systematic reviews for hormone effects such as cancer risks, hot flashes, or migraine, nor did we find any primary studies addressing

these remaining portions of KQ2. We did find 11 non-randomized controlled trial studies that either did not include a comparator group[10-17] or that included a comparator group that did not match the PICOs.[18-21] These studies were not included in our assessment of the feasibility of a systematic review, but are mentioned here as they are related and may be of interest.

For KQ3, we found a protocol for a systematic review that partially covered KQ3.[22] Specifically, it covered top, but not bottom surgery:

- "How does age affect the benefits and risks of top surgery for transmasculine individuals and gender nonconforming individuals assigned female at birth, particularly for those under age 18?"

- "How does age affect the benefits and risks of top surgery, particularly for those under age 18 for
transfeminine individuals and gender-nonconforming individuals assigned male at birth?"

We did not find any studies addressing the remainder of KQ3, namely, bottom, or genital, surgery.

Table 2. Literature identified for each KQ

Question	Systematic reviews (1/2018-1/2021)	Primary studies (1/2016-1/2021)
Question 1: Pubertal suppression	Total: 1 • PROSPERO protocol: 1	N/A
Question 2: Hormone therapy	Total: 1 • PROSPERO protocol: 1	Total: 0
Question 3: Surgical affirmation	Total: 1 • PROSERO protocol: 1	Total: 0

Abbreviations: KQ=key question; NA=not applicable; RCT=randomized controlled trial.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

There is a lack of current evidence-based guidance for care of children and adolescents who identify as transgender regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation. A systematic review is currently underway that addresses KQ1, and parts of KQs 2 and 3. There is insufficient evidence at this time to create a new systematic review that would inform the development of evidence-based guidance for the remainder of the nomination.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years, January 7, 2018 - January 7, 2021, on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
  - EHC Program https://effectivehealthcare.ahrq.gov/
  - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
  - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- PubMed https://www.ncbi.nlm.nih.gov/pubmed/

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed from the last five years 1/7/2016 - 1/7/2021. We reviewed all identified titles and abstracts for inclusion and classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

Search strategy
Ovid MEDLINE ALL 1946 to January 07, 2021
Date searched: January 8, 2021
1 Gender Dysphoria/ or Transgender Persons/ or Transsexualism/ or (F2M or M2F or "assigned female" or "assigned male" or "female-to-male" or (gender adj3 (dysphor* or minorit* or nonbinary or non-binary or nonconforming or non-conforming)) or "male-to-female" or transboy* or transfemale or trans-female or transfeminine or trans-feminine or transgender* or

trans-gender* or transgirl* or transmale or trans-male or transmasculine or trans-masculine or transsexual* or trans-sexual*).ti,kf. (20784)
2 Adolescent/ or Child/ or (adolescence or adolescent* or boy or boys or child* or girl or girls or juvenile* or paediatr* or pediatr* or prepubertal or pre-pubertal or prepubesc* or pre-pubesc* or pubesc* or pubertal or puberty or school or teen* or tween* or youth*).ti,ab,kf. or (adolescen* or child* or paediat* or pediat*).jw. (3984645)
3 Androgens/ or exp Estrogens/ or exp Gonadal Steroid Hormones/ or Hormone Replacement Therapy/ or Testosterone/ or ((gender adj3 (affirm* or confirm* or reassign*)) or androgen* or antiandrogen* or anti-androgen* or estradiol or oestradiol or estrogen* or oestrogen* or feminising or feminizing or "gonadotropin-releasing hormone" or GnRH or GnRHa or inhibit* or HRT or (hormon* adj3 (replac* or suppress* or therap* or treat*)) or progestin* or suppress* or testosteron*).ti,ab,kf. (3230286)
4 Sex Reassignment Procedures/ or Sex Reassignment Surgery/ or (((bottom or gender or genital) adj3 surger*) or clitoroplast* or genitoplast* or hysterectom* or labiaplast* or metoidioplast* or oophorectom* or orchiectom* or phalloplast* or (sex* adj3 reassign*) or vaginectom* or vaginoplast*).ti,ab,kf. (54867)
5 or/3-4 (3275183)
6 and/1-2,5 (1189)
7 6 not ((exp animals/ not humans/) or (animal* or canine* or crustacean* or dog or dogs or mice or monkey* or mouse or murine or primate* or rat or rats or rattus).ti. or comment/ or editorial/ or exp review/ or meta analysis/ or consensus/ or exp guideline/) (847)
8 limit 7 to english language (791)
9 (systematic review or meta-analysis).pt. or (metaanal* or meta-anal*).ti,ab,kf. or ((systematic or evidence or integrat* or "mixed methods") adj3 (review or synthesis)).ti,ab,kf. (361026)
10 and/8-9 (6)
11 limit 10 to yr="2018 -Current" (6) <u>Systematic Review and Meta-analysis Results</u>
12 randomized controlled trials as topic/ or Clinical Trials, Phase III as Topic/ or Clinical Trials, Phase IV as Topic/ or Controlled Clinical Trials as Topic/ or ("randomized controlled trial" or "controlled clinical trial").pt. or (blind* or placebo* or random* or trial*).ti,ab,kf. (2138071)
13 and/8,12 (37)
14 limit 13 to yr="2016 -Current" (23) <u>Trial Results</u>
15 exp cohort studies/ or exp epidemiologic studies/ or (clinical study or observational study).pt. or (before-after or "case control" or "case series" or (control and (group* or study)) or cohort or cohorts or ((comparative or evaluation) adj (study or studies)) or observational).ti,ab,kf. (4289515)
16 and/8,15 (286)
17 limit 16 to yr="2016-Current" (181) <u>Observational Studies Results</u>
18 Focus Groups/ or Grounded Theory/ or "Interviews as Topic"/ or Qualitative Research/ or "Surveys and Questionnaires"/ (585616)
19 ("critical interpretive" or "critical race" or "critical realism" or "critical realist" or ethnograph* or "grounded theory" or phenomenolog*).ti,ab,kf,kw. (51085)
20 ("case study" or "content analysis" or descriptive or "focus group" or "focus groups" or interview* or "mixed design" or "mixed methods" or qualitative or questionnaire* or survey*).ti,ab,kf,kw. (1669770)
21 (attitudes or barriers or facilitators or experiences or perceptions or perspectives or preferences or values or viewpoints or views).ti,ab,kf,kw. (1845932)
22 or/18-21 (3290543)
23 and/8,22 (335)
24 limit 23 to yr="2016-Current" (226) <u>(Qualitative Studies Results)</u>

Ovid EBM Reviews - Cochrane Central Register of Controlled Trials November 2020
Date searched: January 8, 2021
1 Gender Dysphoria/ or Transgender Persons/ or Transsexualism/ or (F2M or M2F or "assigned female" or "assigned male" or "female-to-male" or (gender adj3 (dysphor* or minorit* or nonbinary or non-binary or nonconforming or non-conforming)) or "male-to-female" or transboy* or transfemale or trans-female or transfeminine or trans-feminine or transgender* or trans-gender* or transgirl* or transmale or trans-male or transmasculine or trans-masculine or transsexual* or trans-sexual*).ti. (897)
2 Adolescent/ or Child/ or (adolescence or adolescent* or boy or boys or child* or girl or girls or juvenile* or paediatr* or pediatr* or prepubertal or pre-pubertal or prepubesc* or pre-pubesc* or pubesc* or pubertal or puberty or school or teen* or tween* or youth*).ti,ab. or (adolescen* or child* or paediat* or pediat*).jw. (271417)
3 Androgens/ or exp Estrogens/ or exp Gonadal Steroid Hormones/ or Hormone Replacement Therapy/ or Testosterone/ or ((gender adj3 (affirm* or confirm* or reassign*)) or androgen* or antiandrogen* or anti-androgen* or estradiol or oestradiol or estrogen* or oestrogen* or feminising or feminizing or "gonadotropin-releasing hormone" or GnRH or GnRHa or inhibit* or HRT or (hormon* adj3 (replac* or suppress* or therap* or treat*)) or progestin* or suppress* or testosteron*).ti,ab. (164326)
4 Sex Reassignment Procedures/ or Sex Reassignment Surgery/ or (((bottom or gender or genital) adj3 surger*) or clitoroplast* or genitoplast* or hysterectom* or labiaplast* or metoidioplast* or oophorectom* or orchiectom* or phalloplast* or (sex* adj3 reassign*) or vaginectom* or vaginoplast*).ti,ab. (8156)
5 or/3-4 (170755)
6 and/1-2,5 (16)
7 6 not ((exp animals/ not humans/) or (animal* or canine* or crustacean* or dog or dogs or mice or monkey* or mouse or murine or primate* or rat or rats or rattus).ti.) (16)
8 limit 7 to yr="2016 -Current" (6)

Ovid PsycInfo 1806 to January Week 1 2021
Date searched: January 8, 2021
1 Gender Dysphoria/ or Transgender/ or Transsexualism/ or (F2M or M2F or "assigned female" or "assigned male" or "female-to-male" or (gender adj3 (dysphor* or minorit* or nonbinary or non-binary or nonconforming or non-conforming)) or "male-to-female" or transboy* or transfemale or trans-female or transfeminine or trans-feminine or transgender* or trans-gender* or transgirl* or transmale or trans-male or transmasculine or trans-masculine or transsexual* or trans-sexual*).ti. (15710)
2 (adolescence or adolescent* or boy or boys or child* or girl or girls or juvenile* or paediatr* or pediatr* or prepubertal or pre-pubertal or prepubesc* or pre-pubesc* or pubesc* or pubertal or puberty or school or teen* or tween* or youth*).ti,ab. or (adolescen* or child* or paediat* or pediat* or youth*).jw. (1123314)
3 ((gender adj3 (affirm* or confirm* or reassign*)) or androgen* or antiandrogen* or anti-androgen* or estradiol or oestradiol or estrogen* or oestrogen* or feminising or feminizing or "gonadotropin-releasing hormone" or GnRH or GnRHa or inhibit* or HRT or (hormon* adj3 (replac* or suppress* or therap* or treat*)) or progestin* or suppress* or testosteron*).ti,ab. (213738)
4 (((bottom or gender or genital) adj3 surger*) or clitoroplast* or genitoplast* or hysterectom* or labiaplast* or metoidioplast* or oophorectom* or orchiectom* or phalloplast* or (sex* adj3 reassign*) or vaginectom* or vaginoplast*).ti,ab. (1929)
5 or/3-4 (215040)
6 and/1-2,5 (494)

7 6 not (animal* or canine* or crustacean* or dog or dogs or mice or monkey* or mouse or murine or primate* or rat or rats or rattus).ti. (451)
8 limit 7 to english language (393)
9 limit 8 to ("0830systematic review" or 1200 meta analysis or 1300 metasynthesis) (3)
10 limit 9 to yr="2018 -Current" (3) Systematic Review and Meta-analysis Results
11 limit 8 to "0300 clinical trial" (0)
12 limit 11 to yr="2016 -Current" (0) Trial Results
13 limit 8 to ("0400 empirical study" or "0430 followup study" or "0450 longitudinal study" or "0451 prospective study" or "0453 retrospective study" or 1800 quantitative study or 2100 treatment outcome) (201)
14 limit 13 to yr="2016 -Current" (109) Observational Study Results
15 limit 8 to 1600 qualitative study (39)
16 limit 15 to yr="2016 -Current" (32) Qualitative Study Results

ClinicalTrials.gov
Date searched: January 8, 2021
EXPERT SEARCH MODE: (F2M OR M2F OR F-2-M OR M-2-F OR EXPAND[Concept] "assigned female" OR EXPAND[Concept] "assigned male" OR EXPAND[Concept] "female-to-male" OR gender dysphoria OR gender minority OR nonbinary OR non-binary OR nonconforming OR non-conforming OR EXPAND[Concept] "male-to-female" OR transboy OR transfemale OR trans-female OR transfeminine OR trans-feminine OR transgender OR trans-gender OR transgirl OR transmale OR trans-male OR transmasculine OR trans-masculine OR transsexual OR trans-sexual) AND (adolescence OR adolescent OR boy OR boys OR child OR girl OR girls OR juvenile OR paediatric OR pediatric OR prepubertal OR pre-pubertal OR prepubescent OR pre-pubescent OR pubescent OR pubertal OR puberty OR school OR teen OR tween OR youth) AND (gender affirming OR gender confirming OR gender reassignment OR androgen OR antiandrogen* OR anti-androgen OR estradiol OR oestradiol OR estrogen OR oestrogen OR feminising OR feminizing OR EXPAND[Concept] "gonadotropin-releasing hormone" OR GnRH OR GnRHa OR inhibit OR HRT OR hormone replacement OR suppression OR hormone therapy OR hormone treatment OR progestin OR testosterone OR bottom surgery OR gender surgery OR genital surgery OR clitoroplasty or genitoplasty OR hysterectomy OR labiaplast OR metoidioplasty OR oophorectomy OR orchiectomy OR phalloplast8 OR sex reassignment OR vaginectomy OR vaginoplasty) | Child | First posted from 01/01/2016 to 01/08/2020 (26)

clinicaltrials.gov link

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the United States?	Yes
1b. Is the nomination a request for an evidence report?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	An estimated 0.6% of adults[2] and 0.7% of youth ages 13 to 17[3] in the United States identify as transgender or "gender nonconforming". While this may not be a large proportion of the population, it affects a vulnerable population.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes, transgender individuals represent a vulnerable population. Transgender youth experience high rates of depression, anxiety, eating disorders, and suicide.[4-6]
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes, the cost to transition genders costs about $20,000 over two years.[24]
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	No. We found one protocol for a systematic review that addresses KQ1. We found protocols that partially cover KQ 2 and 3.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes. There is a lack of current evidence-based guidance for care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation. While there are some existing guidelines and standards of care, [1, 7, 8]most are derived from expert opinion or have not been updated recently.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes. There is a lack of current evidence-based guidance for care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation. While there are some existing guidelines and standards of care, [1, 7, 8]most are derived from expert opinion or have not been updated recently.

Selection Criteria	Assessment
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We did not find any studies addressing the remaining portions of KQ2 and 3 that were not covered by existing protocols.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=key question.

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2023-08-21 8:30AM in 11B

STK-CV-UMM-2023-0001612

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN JOAQUIN – STOCKTON BRANCH

CHLOE E. BROCKMAN a/k/a CHLOE COLE, an individual

Plaintiff,

v.

KAISER FOUNDATION HOSPITALS, INC., a California Corporation, THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual, and DOES 1 through 50, inclusive,

Defendants.

Case No.:

COMPLAINT FOR:

1. **MEDICAL NEGLIGENCE**
2. **MEDICAL NEGLIGENCE – HOSPITAL/MEDICAL GROUP**

JURY TRIAL DEMANDED

Plaintiff CHLOE E. BROCKMAN aka CHLOE COLE, an individual ("Plaintiff" or "Chloe"), brings this Complaint against Defendants LISA KRISTINE TAYLOR, M.D., an individual, HOP NGUYEN LE, M.D., an individual, SUSANNE E. WATSON, PHD., an individual ("collectively, the "Defendant Providers"), THE PERMANENTE MEDICAL GROUP, INC., a California Corporation, KAISER FOUNDATION HOSPITALS, INC., a California Corporation (collectively, the "Institutional Defendants") (the Defendant Providers and the Institutional Defendants are collectively referred to as the "Defendants"), and DOES 1 through 50, alleging as follows:

INTRODUCTION

1. This case is about a team of doctors (i.e., the Defendants) who decided to perform a mutilating, mimicry sex change experiment on Chloe, then a thirteen-year-old vulnerable girl struggling with complex mental health co-morbidities, who needed love, care, attention, and regular weekly psychotherapy, not cross-sex hormones and mutilating surgery.

2. Chloe is a biological female who suffered from a complex, multi-faceted array of mental health symptoms as a child and adolescent. Her presentation of symptoms and concerns included, among other things, the following: social anxiety; general anxiety; speech difficulties; depression; pubertal struggles associated with significantly increased negative emotions; body dysmorphia and serious self-image concerns; disruptive behavior; learning disabilities; autism spectrum symptoms; symptoms of an eating disorder; concerns about being sexually abused or raped, that eventually materialized into a sexual assault; exposure to only negative aspects about being female, without any discussion of the positive aspects of being female; and ongoing confusion regarding her gender. She needed regular weekly psychotherapy for an extended period of time to evaluate, assess, and treat her complex co-morbid mental health symptoms.

3. After being exposed for hours at a time to online transgender influencers, Chloe developed the erroneous idea that she was a boy. When Chloe informed her parents that she thought she was a boy, her parents didn't know what to do and promptly sought guidance from the Defendants. Defendants immediately affirmed Chloe in her self-diagnosed gender dysphoria. They did not question, elicit, or attempt to understand the psychological events that led her to this belief, nor did they seek to evaluate or appreciate her multi-faceted presentation of co-morbid symptoms.

Defendants should have performed an extended period of assessment and treatment comprising at least twelve weekly, one-hour sessions that should have included numerous informed consent discussions about the potential harms and hoped-for benefits. Instead, Defendants assumed that Chloe, a thirteen-year-old emotionally troubled girl, knew best what she needed to improve her mental health and handed her the prescription pad. They quickly put her on the puberty blockers and hormones "conveyer belt" of mimicry sex change. There is no other area of medicine where doctors will surgically remove a perfectly healthy body part and intentionally induce a diseased state of pituitary gland function based simply on the patient's wishes. Thus, they abetted her erroneous notion that she could change her sex.

4. Under Defendants' "care," between ages 13–17 years, Chloe underwent harmful transgender transition, specifically, off-label puberty blockers and cross-sex hormone "treatment," and a radical double mastectomy of her healthy breasts. There is at least one high quality, large scale, 30-year, population-based study that demonstrated that transgender individuals who chemically/surgically "transition" have poor mental health outcomes. This includes increased psychological morbidity, increased suicidal ideation and attempt, and a *19-fold increased rate of suicide as compared with the general population.* The studies that purportedly support positive outcomes for this "gender affirmation" treatment are "low to very low-quality studies", meaning they present a significant risk of containing erroneous conclusions and present a significant risk that patients will not attain the purported desired outcomes of treatment. In contrast, multiple reliable studies consistently indicate that *between 80% and 90% of minors that present with gender dysphoria accept their biological sex by late adolescence.* These risks all materialized in Chloe's case. She did not experience any long-term relief from her gender dysphoria treatment. Rather, her mental health condition declined as she proceeded through this treatment, and she eventually developed suicidal ideation after her radical double mastectomy, which symptoms she never experienced prior to this so-called "gender affirmation treatment."

5. Defendants blindly ramrodded Chloe through this transition "treatment," ignoring her extensive co-morbidities, her declining mental health condition, and the failure of her social and academic functionality to improve after each predetermined sequence of social, hormonal and

surgical "gender affirmation treatment." Put another way, Chloe was not responding to treatment and Defendants ignored this fact.

6. Defendants also failed to provide Chloe and her parents with proper informed consent. Informed consent is a process that takes time for this type of "treatment". It requires regular therapy sessions over an extended period of time and assessment of the complete mental health condition of the patient. Defendants did provide regular in-depth therapy, which entirely prevented the possibility of informed consent in Chloe's case. They provided crisis-oriented psychotherapy, typically lasting 30 minutes or less, which was widely spaced until the next request from the parents. There were no in-depth meetings with the parents to discuss the short and long-term harms and hoped-for benefits well before the next medical or surgical step was undertaken. Defendants obscured and concealed important information such as the following: the conflicting studies in this area; the high quality evidence demonstrating poor mental health outcomes; the existence of only low to very low-quality studies purportedly supporting this treatment; the significant likelihood that desired outcomes would not be attained; the significant possibility of desistence, detransition and regret; and the lack of accurate models for predicting desistence and detransition. They also did not disclose the significant health risks associated with a biological female taking high doses of harmful male hormone drugs and off-label puberty blockers. They did not discuss with Chloe or her parents the worrisome patterns that adult transgendered persons have demonstrated. Furthermore, Defendants falsely represented certain opposite facts, including that Chloe's dysphoria would never resolve unless she chemically/surgically transitioned, and that she represented a high-risk of suicide unless she transitioned. These were materially false representations. Chloe's parents were also asked: "would you rather have a dead daughter, or a live son?" This unethical form of coercion reflects a lack of understanding of suicide risk, or a deliberate decision to misrepresent suicide risk. Defendants' coercion, concealment, misrepresentations, and manipulation are appalling and represent an egregious breach of the standard of care. This misconduct also constitutes fraud, malice, and oppression.

7. As occurs in most gender dysphoria cases, Chloe's dysphoria was not persistent and resolved when she was close to reaching adulthood. Consequently, she detransitioned and no longer

identifies as a male. Unfortunately, as a result of the so-called transgender "treatment" that Defendants performed on Chloe, she now has deep physical and emotional wounds, severe regrets, and distrust of the medical system. Chloe has suffered physically, socially, neurologically, and psychologically. Among other harms, she has suffered mutilation to her body and lost social and physical development along with her peers, and at key developmental milestones that can never be regained.

8. Chloe was the victim of Defendants who did not have any interest in taking the time necessary to sit with her and perform the regular, weekly psychotherapy that Chloe needed. Defendants grossly breached the standard of care by pushing Chloe into this harmful experimental treatment regimen without a proper period of psychological evaluation, without evaluating and treating her serious co-morbidities, without providing informed consent, and while actively utilizing emotionally super-charged and false information to derail the rational decision-making process of Chloe and her parents. Defendants were not "caring" for Chloe, they were experimenting on her, and doing so all to their own great financial benefit.

PARTIES

9. At all times relevant herein, Plaintiff Chloe E. Brockman, an individual, was a resident of the County of San Joaquin, State of California.

10. Plaintiff is informed and believes and thereon alleges that at all relevant times alleged herein, Defendant Lisa Kristine Taylor, M.D. ("Dr. Taylor"), is a physician duly licensed by the State of California to practice medicine in California. On information and belief, Dr. Taylor practices medicine primarily in Oakland, California, but accepted the Plaintiff as a patient and assisted with providing a course of experimental transgender medical treatment on Plaintiff that occurred at least in part in Manteca, California, and caused substantial injury to Plaintiff in Manteca, California.

11. Plaintiff is informed and believes and thereon alleges that at all relevant times alleged herein, Defendant Hop Nguyen Le, M.D. ("Dr. Le"), is a physician duly licensed by the State of California to practice medicine in California. On information and belief, Dr. Le practices primarily in San Rafael, California, but accepted the Plaintiff as a patient and assisted with providing a course of experimental transgender medical "treatment" to Plaintiff that occurred at least in part in Manteca,

California and caused substantial injury to Plaintiff in Manteca, California.

12. Plaintiff is informed and believes and thereon alleges that at all relevant times alleged herein, Defendant Susanne E. Watson, PhD ("Dr. Watson"), is a psychologist duly licensed by the State of California to practice medicine in California. On information and belief, Dr. Watson practices primarily in Oakland, California, but accepted the Plaintiff as a patient and assisted with providing a course of experimental transgender medical "treatment" to Plaintiff that occurred at least in part in Manteca, California and caused substantial injury to Plaintiff in Manteca, California.

13. Collectively, Doctors Taylor, Le, and Watson are referred to as the "Defendant Providers."

14. Plaintiff is informed and believes and thereon alleges that at all relevant times alleged herein, Defendant The Permanente Medical Group, Inc. ("Medical Group"), is, and at all times mentioned in this complaint was, a California professional medical corporation with its executive offices located in Oakland, California. On information and belief, The Permanente Medical Group, Inc., is the medical group through which Drs. Watson, Taylor, and Le collaborated to provide a course of experimental transgender medical "treatment" to Plaintiff that occurred and caused substantial injury to Plaintiff at least in substantial part in Manteca, California.

15. Plaintiff is informed and believes and thereon alleges that at all relevant times alleged herein, Defendant Kaiser Foundation Hospitals ("Kaiser Hospitals") is, and at all times mentioned in this complaint was, a California corporation operating in Northern California, with executive offices located in Oakland, California. On information and belief, Kaiser Hospitals is the hospital network through which experimental transgender medical treatment was provided by Drs. Watson, Taylor, and Le to Plaintiff, causing substantial injury to Plaintiff in Manteca, California.

16. The Medical Group and Kaiser Hospitals are collectively referred to as the Institutional Defendants.

17. Plaintiff is ignorant of the true names and capacities of defendants sued herein as DOES 1 through 50, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will amend her Complaint to allege their true names and capacities and causes of action against said fictitiously named defendants when the same have been ascertained. Plaintiff is informed and

believes and thereon alleges that each of the defendants designated herein as a "DOE" is responsible in some manner and liable herein to Plaintiff for her injuries.

18. Plaintiff is informed and believes and thereon alleges that at all times herein mentioned all of the DOES were the agents, servants and employees of their co-defendants and in doing the things hereinafter alleged were acting within the course and scope of their authority as such agents, servants and employees with the authorization, permission and consent of their co-defendants, except where stated otherwise below. Each of these acts and failures to act is alleged against each Defendant whether acting individually, jointly, or severally. Each of the Defendants or their alter egos agreed and conspired with the others in the commission of these acts or failures to act and fully ratified those acts.

19. At all times mentioned herein, each Defendant was the agent and employee of each and all of the other defendants and, in performing the acts herein alleged, was acting within the course and scope of such agency and employment. Plaintiffs are informed and believe that all of the wrongful acts alleged herein were authorized and/or ratified by officers, directors or other managerial agents of Defendants.

20. On November 9, 2022, Chloe sent a notice of intent to sue letter to the Defendant. The statutorily prescribed 90-day hold period for litigation has expired.[1]

JURISDICTION AND VENUE

21. This Court has jurisdiction over this matter, and venue is proper, because a substantial portion of the injury and experimental medical treatment upon which this action is based occurred in San Joaquin County, State of California, in the city of Manteca.

22. The amount in controversy exceeds the jurisdictional minimum of this Court.

GENERAL ALLEGATIONS

23. Chloe is a biological female who suffered from social anxiety, generalized anxiety, depression, disruptive behavior disorder, social troubles, body dysmorphia, autism spectrum symptoms, a cleft palate for which surgery had been performed, a likely eating disorder, learning

[1] https://libertycenter.org/wp-content/uploads/2022/11/Notice-of-Intent-to-Sue-Ltr-11-09-22-Redacted.pdf

disabilities, and gender confusion. She had suffered from various of these issues for multiple years. Chloe began to go through puberty earlier than most of her peers and experienced bullying and teasing by her pears as result. She also had difficulty at school and trouble with social interaction and learning. On September 12, 2012, at eight years old, she was diagnosed with Disruptive Behavior Disorder. On November 26, 2013, at nine years old, she had a diagnosis indicating an "encounter for school problem." On October 9, 2015, she had a diagnosis of ADHD. She received no mental health counseling related to her social and behavioral problems at school and was never diagnosed or treated for autism spectrum disorder, though she had multiple indications of being on the autism spectrum.

24. When Chloe was a child, as young as age six, she liked to wear boy clothes, but on the other hand, she also liked to play with dolls. When she was nine years old, she began struggling more with her female identity. Chloe had an idea in her mind that to be an ideal, attractive female she needed to have voluptuous bodily attributes. But Chloe did not perceive her own appearance as being voluptuous. She was critical of her broad shoulders and thinner, more muscular body. Therefore, she naively thought she was not and could not ever be an attractive female. This was a serious, albeit common, struggle for Chloe and many young girls while entering adolescence.

25. During this time, Chloe was also exposed to many negative ideas both online and in her social sphere about being female. This included negative discussions of menstrual cycles, pregnancy, childbirth, male domination, and similar distorting ideas. She also was exposed to concerns over sexual abuse and rape. In her social sphere, she had heard about women being sexually assaulted and raped. Chloe had a constant underlying fear of the possibility of sexual abuse.

26. In Chloe's social sphere, there was never any discussion of the positive experiences of being female, such as the joy and intimacy that can be shared with a loving, caring spouse, and the joy and intimacy that can be shared between a mother and child.

27. In sum, Chloe erroneously thought that becoming a woman was undesirable and thought that she could not be the type of woman that she naively perceived as ideal. She also continued to struggle socially with having friends. She especially struggled with having female friends as she often felt more comfortable around less judgmental boys. But, as she and her peers began to develop, the divide between her and her male friends grew as well. Her female physical

features developed more, but not as much as she had hoped. Her male friends' physical abilities surpassed her own. She experienced bullying and teasing in this regard. These changes were all discouraging to her.

28. Defendants never meaningfully discussed nor attempted to treat with psychotherapy Chloe's struggles and these underlying conflicts. They never told Chloe that puberty changes are a struggle for most people, particularly females, and that negative emotions tend to increase during puberty, and further that it takes time to settle into these changes to one's evolving body. These are very basic components of psychotherapy for young adolescent girls that should have been evaluated and discussed with Chloe but were not discussed.

29. Chloe also began researching her feelings online, sometimes for hours at a time in a single day. During this process, she was exposed to various LGBT activist groups and transgender influencers that praised and promoted individuals who identified as transgender. These groups also praised and promoted individuals who underwent the process of transitioning to appear like the opposite biological sex. Chloe craved the social approval that these individuals received and that she was not otherwise receiving from her peers.

30. Although Chloe was still attracted to males and had no significant interest in romantic relationships with a female, these transgender influencers first put the false idea into Chloe's head that perhaps she was actually a boy. Chloe began to abandon her ideal of being a voluptuous female. She perceived that she could never meet this voluptuous female standard, and she was strongly influenced by all the imagined negative connotations of being female. Consequently, this idea that she was a boy became very attractive to her.

31. Eventually she "came out" to some of her peers that she was a boy and engaged with these various online activist LGBT groups, receiving the support and praise for her decision that she craved. By May 2017, when Chloe was twelve years old, she wrote a letter to her parents telling them that she wanted to be referred to as "Ky" or "Chi," and that she wanted to be treated as a boy. Chloe's parents were hesitant and concerned that this was not the best thing for Chloe, but they were unsure how to respond and sought the guidance of medical professionals. They contacted Chloe's pediatric care provider on June 2, 2017, expressing an interest in counseling for Chloe.

32. About two weeks later, on June 13, 2017, Chloe and her parents had a preliminary consultation with a psychologist who immediately affirmed Chloe in her misguided beliefs without evaluating or attempting to understand the motivation for Chloe's self-proclaimed diagnosis that she was a "boy." After this occurred, Chloe had various visits with mental health providers, wherein she reported at various times anxiety, depression, social anxiety, shyness, limited friends, and feeling disgusted with her hips, chest, and thin arms. She also later expressed a desire to bind her breasts that were growing larger. Chloe's providers opined that binding could be helpful but failed to disclose its health risks. Therefore, Chloe began socially transitioning, i.e., presenting as a male in social settings. Her serious co-morbid symptoms were not discussed or addressed, if they were even perceived. Her symptoms persisted and intensified. It was as though her providers believed that once the criteria for gender dysphoria were met, there was nothing to do but put her on the chemical/surgical path. Thus, they failed to afford her the opportunity that any other child with psychiatric symptoms would be given: thorough evaluation, appreciation of her developmental history, and an opportunity to treat the symptoms through understanding within a trusted extensive relationship with one qualified psychotherapist.

33. At age thirteen, on November 30, 2017, Chloe had her first consultation with an endocrinologist, who advised against beginning hormone therapy due to Chloe's young age. Chloe was disappointed, so she and her parents sought a second opinion from Defendant Taylor. Remarkably, Dr. Taylor was willing to begin puberty blockers and testosterone treatment immediately, and with no proper evaluation or treatment of Choe's constellation of other symptoms.

34. Dr. Taylor prescribed Lupron Depot, a puberty blocker, and testosterone to Chloe. These chemicals stopped Chloe's natural progression of puberty, and medically induced various endocrine disorders, including among others, hypogonadotropic hypogonadism.[2] This condition is a pituitary gland dysfunction, wherein the female ovaries or male testes produce little or no sex hormones. This dysfunction requires chemical treatment to correct and can be otherwise caused by

[2] https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/hypogonadotropichypogonadism#:~:text=Definition,the%20pituitary%20gland%20or%20hypothalamus.

damage to the pituitary gland from surgery, injury, tumor, radiation, genetic defects, heroin use, abuse of opiate medicines, iron overload, and other causes. Chloe's pituitary gland was not malfunctioning. To the contrary, it was functioning normally and was producing proper hormones to further her normal biological development. Dr. Taylor introduced these chemical interventions to disrupt the proper functioning of Chloe's pituitary gland, intentionally inducing various endocrine disorders in the process. In prescribing testosterone, Dr. Taylor also caused Chloe to develop more masculine characteristics, to suffer severe atrophy and damage to her reproductive organs, and other harms discussed in more detail below.

35. The use of Lupron Depot and testosterone to treat "gender dysphoria" is not approved by the FDA and is an off-label use. Additionally, this "treatment" had been previously and repeatedly tried without success both in the U.S. and in other countries.[3] Among others, the negative results caused the U.S. transgender clinic at Johns Hopkins Hospital to shut down decades ago, and also caused the Tavistock Transgender Clinic in England to shut down recently.[4] Finland, Sweden, England, France, Belgium, and more recently Florida's Boards of Medicine, have all conducted systematic reviews of the relevant literature and concluded that the risks far outweigh any supposed benefits.[5] Among others, one key study in this area is a high quality, 30-year, large scale, population-based study, out of Sweden.[6] This prior study found increased psychiatric morbidity, increased suicidality, and a 19-fold increased rate of completed suicide as compared with the general population for transgender individuals "treated" with transition chemicals and surgery. When this data set was

[3] *Independent Review of Gender Identity Service for Children and Young People: Interim Report,* THE CASS REVIEW (February 2022) (https://cass.independent-review.uk/publications/interim-report/ (accessed Feb. 10, 2023); Chapman, M., *Johns Hopkins Psychiatrist: Transgender is 'mental disorder;' Sex Change 'biologically impossible'*, CNSNEWS.COM (June 21, 2015) https://www.cnsnews.com/article/national/michael-w-chapman/johns-hopkins-psychiatrist-transgender-mental-disorder-sex (last accessed February 7, 2023).

[4] Ibid.

[5] Buttons, C., *Finland's Leading Gender Dysphoria Expert Says 4 Out Of 5 Children Grow Out Of Gender Confusion*, THE DAILY WIRE (Feb. 2023).

[6] Dhejne, C., et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, PLOS ONE (Feb. 2011) (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885)

analyzed by biological sex, the suicide rate for females who were presenting themselves as men was 40-fold higher than controls. These data have been available since 2011. Thus, strong evidence had established that transition treatment does not improve long-term mental health for transgender individuals and, therefore, is never clinically indicated for naïve, confused, and vulnerable minors like Chloe.

36. Meanwhile, many U.S.-based medical groups like the Institutional Defendants are ignoring the strong evidence against the use of chemical and surgical transition and are instead relying upon low to very-low quality studies to support their "guidelines" for gender affirming care and transition.[7] This low quality means the studies present a high possibility of containing erroneous conclusions regarding efficacy for "treatment" and present a significant risk that patients undergoing

[7] See e.g., Hembree, W., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline*, THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM (Sept. 2017); (The endocrine society guidelines in "Section 2.0 Treatment of Adolescents" recommend the use of puberty blockers and cross-sex hormones for adolescents who meet the diagnostic criteria for gender incongruence. Each of the recommendations is designated with the symbols "⨁⨁○○" or "⨁○○○." The section titled "Method of Development of Evidence-Based Clinical Practice Guidelines" explains that the recommendations/suggestions designated by the symbol "⨁⨁○○" means that the recommendation is based on **low quality evidence** and the recommendations designated with the symbol ""⨁○○○" are based on **very low-quality evidence**. So, the endocrine society acknowledges that the supporting studies for these guidelines are low to very low quality studies).See also Buttons, C., *Finland's Leading Gender Dysphoria Expert Says 4 Out Of 5 Children Grow Out Of Gender Confusion*, THE DAILY WIRE (Feb 2023); Abbruzzese, E., *The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies—and research that has followed* JOURNAL OF SEX & MARITAL THERAPY (2022) (https://doi.org/10.1080/0092623X.2022.2150346).

It is worth noting that the 2009 version of the endocrine society guidelines did not recommend treatment with cross-sex hormones until at least the age of 16 and did not recommend a breast mastectomy until at least age 18. See e.g. Hembree, W., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM (Sept. 2009). This change in the clinical guidelines did not reflect a change in scientific knowledge, but instead reflected a downgrade in the quality of the supporting evidence. The 2009 guidelines are identified as being based on low to moderate quality evidence, whereas the 2017 guidelines are identified as being based on low to very low-quality evidence. In order to suggest this "treatment" for lower age groups, the endocrine society shifted away from higher quality evidence relying instead on lower quality evidence.

In Chloe's case, had she not undergone any of this "treatment" until she was 16-18, the serious and permanent harm that she suffered would never have occurred. Chloe's case is a prime example demonstrating the higher quality of the prior clinical guidelines.

this treatment will not experience the purported/intended effects.[8] Defendants advised transition allegedly relying upon risky low-quality studies, while ignoring high-quality evidence contraindicating this "treatment." This advice was reckless, willful, malicious, oppressive, and fraudulent, and intended to benefit Defendants financially.

37. Furthermore, eleven studies of childhood gender dysphoria have been conducted, including three large-scale follow-up studies and eight smaller studies.[9] Collectively, these studies establish a desistence rate somewhere between 62% to 97.5% of cases averaging to around an 80-90% desistence rate.[10] The largest study found a desistence rate of approximately 92%. In sum, a well-established body of research demonstrates that gender dysphoria in children will desist by adulthood in approximately 62%-97.5% of cases, with the person's mental state shifting to align with the person's biological sex.[11] The American Psychiatric Association DSM-5 identifies these same desistence rates.[12] Cases of gender dysphoria that first present in later adolescence are not well studied. Nevertheless, medically significant desistence/detransition rates have been identified, and in recent years, the rate of desistence/detransition for later adolescent onset gender dysphoria is accelerating.[13] Furthermore, and of great importance, there are no diagnostic criteria and no models

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[8] Levine, S., et al., *Reconsidering informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, JOURNAL OF SEX & MARITAL THERAPY (March 2022) (DOI: 10.1080/0092623X.2022.2046221).

[9] Buttons, C., *Finland's Leading Gender Dysphoria Expert Says 4 Out Of 5 Children Grow Out Of Gender Confusion*, THE DAILY WIRE (Feb 2023); Korte, A., et al., *Gender Identity Disorders in Childhood and Adolescence*, DTSCH ARZTEBL INT. (Nov. 2008) (DOI: 10.3238/arztebl.2008.0834); Cantor, J., *Do Trans-Kids Stay Trans- When They Grow Up?* SEXOLOGY TODAY (http://www.sexologytoday.org/2016/01/do-trans-kids-stay-trans-when-they-grow_99.html (accessed Feb. 7, 2023)) (summarizing the eleven studies of desistence including three large scale follow-up studies and eight smaller scall studies).

[10] *Ibid*.

[11] *Ibid*.

[12] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition Text Revision DSM-5-TR™*, AMERICAN PSYCHIATRIC ASSOCIATOIN PUBLISHING, page 517 (https://ebooks.appi.org/epubreader/diagnostic-statistical-manual-mental-disorders-fifth-edition-text-revision-dsm5tr).

[13] Levine, S., et al., Reconsidering informed Consent for Trans-Identified Children, Adolescents, and Young Adults, JOURNAL OF SEX & MARITAL THERAPY (March 2022) (DOI: 10.1080/0092623X.2022.2046221).

for predicting which cases of gender dysphoria will desist and which cases will persist.[14] Indeed, one parent of a transgender patient of Dr. Watson asked Dr. Watson how she determines who will benefit from hormone treatment. In response, Defendant Watson laughed and replied, ***"there's no criteria, but you kind of get a sense of it."*** Thus, Defendant Watson is not practicing evidence-based medicine; she is experimenting on children and following fashion-based medicine.

38. In addition to the high desistence rates, lack of predictive models for desistence, and lack of mental health improvement, there are many other known and significant risks of administering puberty blockers and cross-sex hormones. These include, among others: sterility, painful intercourse, impairment of orgasm, reduced bone development and inability to obtain peak or maximum bone density, stopped or stunted growth of the pelvic bones for reproductive purposes, increased risk of osteoporosis and debilitating spine and hip fractures as an adult, increased morbidity and death in older age due to increased risk of hip fracture, negative and unknown effects on brain development, emotional lability such as crying, irritability, impatience, anger, aggression, and reports of suicidal ideation and attempt. A recent study by Chen et al (2023) affirmed the previous indicators of a significant increase in mortality among trans adults.

39. Additional risks associated with testosterone include, among others: serious cardiovascular and psychiatric adverse reactions, significant weight gain, increased or decreased libido, headache, anxiety, depression, and generalized paresthesia, premature closure of boney epiphyses with termination of growth causing inability to reach full height for adolescents, and pulmonary embolism (i.e., blood clots in the lungs). There is a study of transgender men in which all of the individuals who reported adverse drug reactions suffered cardiovascular events, and of those reports, 50% of cases involved pulmonary embolism. The labeling also notes risk of liver disfunction, stating that prolonged use of high doses of androgens has been associated with development of hepatic adenomas (benign tumors), hepatocellular carcinoma (cancer), and peliosis hepatis

[14] Korte, A., et al., *Gender Identity Disorders in Childhood and Adolescence*, DTSCH ARZTEBL INT. (Nov. 2008) (DOI: 10.3238/arztebl.2008.0834); Levine, S., et al., Reconsidering informed Consent for Trans-Identified Children, Adolescents, and Young Adults, JOURNAL OF SEX & MARITAL THERAPY (March 2022) (DOI: 10.1080/0092623X.2022.2046221).

(generation of blood-filled cavities in the liver that may rupture)—all potentially life-threatening complications.

40. Specifically for females, studies of transitioned females (i.e., transgender males) taking testosterone have shown a nearly 5-fold increased risk of myocardial infarction. Females can also develop unhealthy, high levels of red blood cells which create an increased risk for cardiovascular disease, coronary heart disease, and death due to both. Other affects include irreversible changes to the vocal cords and Adam's apple, deepening of the voice, abnormal hair growth, and male pattern balding of the scalp. Additional risks include polycystic ovaries, atrophy of the lining of the uterus, and increased risks of ovarian and breast cancer.

41. Chloe was rushed into this experimental transition treatment after only a few months of self-diagnosed gender dysphoria and without any adequate evaluation of her psychological history, her reasons for wanting to be a boy, and her numerous co-morbidities. Defendants should have discussed Chloe's underlying feelings and thoughts leading up to her naive, self-proclaimed diagnosis. Defendants should have performed psychotherapy to treat Chloe for her normal puberty struggles and for her body dysmorphia, social struggles, depression, anxiety, learning disabilities, autism symptoms, eating struggles, (continuing underweight status) and other related co-morbidities. The handful of erratic visits that she had with different mental health professionals lacked adequate follow-up evaluation and continuity of care and were woefully inadequate to properly evaluate and treat Chloe's varied mental health symptoms. Chloe's "gender dysphoria" symptoms were immediately and improperly treated as the top priority symptoms with no meaningful consideration or treatment of her other serious symptoms, which predated her gender dysphoria.

42. Defendants fatally undermined the informed consent process by grossly overemphasizing Chloe's gender dysphoria symptoms and by failing to adequately evaluate and treat her co-morbidities. Proper informed consent in Chloe's case could not occur without Defendants performing at least twelve, one-hour psychotherapy sessions, on a weekly basis. These sessions should have fully explored and considered all of Chloe's co-morbidities and underlying psychological struggles. All relevant diagnoses should have been considered. All potential courses of treatment and the incumbent risks and benefits should have been evaluated and discussed at length with Chloe

and her parents. Even without co-morbidities, the non-permanent, non-invasive option of longer-term psychotherapy, evaluation and treatment should have been discussed as a legitimate option, which it was not. The failed evaluation and assessment resulted in grossly incomplete informed consent for Chloe and her parents.

43. Regarding formalities, Dr. Taylor did not obtain any informed consent form for the puberty blockers, and the informed consent form for the testosterone treatment failed to identify any of the aforementioned risks. The limited informed consent discussions that occurred fell grossly short of properly advising Chloe and her parents of the relevant serious risks and perceived benefits. Indeed, Chloe has expressed that even if the long list of risks noted above had been discussed, it would have been absolutely impossible for her to understand what it would mean to go through menopause symptoms and have atrophy of her reproductive organs as a teenager. She has also expressed that she did not understand, and there was no way she could possibly have understood, the impact of fertility and sexual function loss at age thirteen. She had never had sex. She did not even begin to imagine that she may want to have a romantic relationship with a man and have children until she was a junior in high school. As a child herself, she had never thought about rearing children and/or whether she might want to breast feed them. Defendants made no attempt to convey and impress upon Chloe the gravity of the life-long and devastating decision that she was making. They falsely represented to Chloe that her symptoms would never resolve unless she transitioned and that she was at a high risk of suicide. Chloe's parents were even given the ultimatum: "would you rather have a live son, or a dead daughter?"

44. Therefore, at age thirteen, without proper informed consent and based on fraudulent misrepresentations, Chloe proceeded to receive puberty blocker injections and testosterone injections under Dr. Taylor's "care." This experimental treatment began around January 10, 2018.

45. After several months on cross-sex chemical treatment, Chloe's mental health declined, and she began to experience increasing anxiety, depression, and related issues. She was also sexually assaulted by a boy at school who had frequently teased and harassed her. He groped her breast in public before class. This was an earth-shattering experience, wherein Chloe felt like she was the only person in the room and no one else seemed to care or notice. She was concerned about reporting the

incident to school officials, fearing that the boy would be suspended for a couple days and then return to harass her more and perhaps do her worse harm. It traumatized her to the core. Her earlier childhood fears of sexual abuse were realized. It took Chloe a couple of years to emotionally process, unpack, and come to grips with this assault. At first, she didn't fully recognize the trauma. She was already transitioning at this point. So, she thought that she was already a "boy" and that she just needed to "man up." But the truth is she was not a boy, and this was a deeply traumatic event that constituted a sexual assault. This exacerbated her fears, and further propelled her into the belief that she did not want to be female and that she needed to get rid of her breasts to protect herself from further such abuse.

46. She began binding her breasts daily at this point. Daily binding and weekly testosterone injections caused her breasts to become deformed. Chloe realized that her breasts were losing their form. She felt that they were disgusting and that no one would ever be attracted to her as long as they remained on her body. She resolved that she needed a double mastectomy at this point.

47. Defendants never inquired or treated any of these important underlying psychological traumas, never elicited information related to the assault, and never elicited or evaluated Chloe's complex, conflicting, and confused feelings regarding her thinking that she would be safer being a boy. Any competent provider should have easily discovered this information and recognized the need for an extended period of psychotherapy and further evaluation. A competent provider would also have discovered this decline in her mental health condition and recognized it as a failure to respond to the "treatment." Therefore, Defendants should have immediately stopped the treatment. As it stands, Defendants proceeded with blinders on and let Chloe's complex case slip through the cracks without adequate monitoring and evaluation to the great detriment and suffering of Chloe, but to the financial benefit of Defendants.

48. Due to the failure of proper care, Chloe expressed an interest to Dr. Taylor in continuing with transition and receiving a double mastectomy, naively thinking that it would solve all her problems. Dr. Taylor did not evaluate this interest, did not ask about her underlying feelings, did not ask about or discover the assault that occurred, did not ask about or discover any of the underlying reasons why Chloe wanted to proceed with surgery, and instead blithely affirmed this

tragic decision. Hence, Dr. Taylor simply provided Chloe with a referral for a plastic surgeon.

49. Several months later, at age fourteen, Chloe consulted with Dr. Le regarding the double mastectomy, and he too merely affirmed her in this decision, also without evaluating whether this was the right decision for Chloe. Dr. Le similarly failed to inquire about the assault and as to any of the psychological, emotional, and historical feelings as to why she wanted the surgery. Dr. Le should have inquired and evaluated these issues before performing this radical, permanent, life-altering surgery. Instead, he perfunctorily affirmed that a double mastectomy was an effective way to treat her gender dysphoria and proceeded with the consultation and with scheduling the surgery.

50. It is important to note that the American Society of Plastic Surgeon's Policy Statement for aesthetic breast surgery in teenagers[15] states as follows:

> "Recommendations: Adolescent candidates for (purely) aesthetic breast augmentation should be at least 18 years of age. Breast augmentation that is done for aesthetic reasons is best delayed until the patient has sufficient emotional and physical maturity to make an informed decision based on an understanding of the factors involved in this procedure. This includes being realistic about the surgery, expected outcome and possible additional surgeries. In considering emotional maturity for breast augmentation, the patients should request the procedure for themselves, not to satisfy another's perception of the patient. In addition, they should demonstrate sufficient emotional maturity to understand all aspects of this surgery. This would include having realistic expectations of the procedure itself, the outcome and the potential for future surgeries. Adolescent patients need to understand that, while implants can be surgically removed, the procedure may leave permanent changes on the body, including scarring and tissue changes."

Although Chloe was not seeking augmentation, the need for emotional and physical maturity to make a decision to totally remove one's breasts applies even more dramatically to Chloe's situation.

51. Thereafter, Dr. Susanne E. Watson, Ph.D., performed a pre-operation psychological evaluation and recommended Chloe for the double mastectomy. This evaluation was conducted in a single, two-hour visit. There was no long-term, regular evaluation or assessment, and no follow-up evaluation of Chloe's psychological condition. This perfunctory sign-off on Chloe's mental health condition is grossly deficient from a standard of care perspective. There was no treatment of Chloe's

[15] American Society of Plastic Surgeons, *Policy Statement Breast Augmentation in Teenagers* (approved 2004, reaffirmed 2015) (https://www.plasticsurgery.org/documents/Health-Policy/Positions/policy-statement_breast-augmentation-in-teenagers.pdf).

underlying anxiety and depression that worsened several months after Chloe began the process of chemical transition. Dr. Watson affirmed Chloe in this decision to transition and did not evaluate in any way whether Chloe was making the right decision. Moreover, she failed to elicit the important information discussed above regarding Chloe's traumatic experiences, negative emotions, and related struggles. Like Drs. Taylor and Le, Dr. Watson engaged in a very limited and perfunctory informed consent discussion that occurred in this single visit, as a part of the more general evaluation, and which glossed over the significant health and psychological risks of permanent breast removal surgery and continuing hormone treatment. Dr. Watson's informed consent discussion was fatally flawed by the failure to evaluate properly the full scope of Chloe's psychological condition and underlying trauma, negative emotions, and mental suffering. Dr. Watson neglected to discuss and evaluate her co-morbidities, related diagnoses, treatment options for these varying co-morbidities and for gender dysphoria itself, and entirely failed to present a truthful and complete risk/benefit analysis for Chloe and her parents.

52. Additionally, Dr. Watson entirely failed to mention or discuss the following: (1) the existence of only low to very low quality studies of treating gender dysphoric children with transition chemicals and surgery; (2) the probability of desistence and the significant desistence rates for individuals diagnosed with gender dysphoria; (3) the significant probability that Chloe's dysphoria would resolve on its own without cross-sex hormones and surgery; (4) the significant probability that Chloe may later come to regret these decisions in the event that her gender dysphoria did not persist; (5) the significant possibility that treatment of this type would not attain the desired results of resolving her internal conflict; (6) the lack of accurate models for predicting which cases of gender dysphoria will desist and which will persist into adulthood; (7) the fact that transgender individuals who undergo transition hormones and surgery have a significantly increased suicide risk after transitioning, and (8) the fact that she previously had two significant surgical cleft palate repairs that may have influenced her sense of defectiveness as a girl. Instead, Chloe and her parents were given the opposite information, including that Chloe's condition would never resolve on its own and that Chloe would likely commit suicide if she did not receive this treatment. This was coercive and absolutely false based on Chloe's presentation of symptoms. She had a complex and multi-faceted

presentation of mental health symptoms, but she was never evaluated to be at a significant risk of suicide. Representing that Chloe's suicide risk would increase without transition was unwarranted, false, and manipulative. Presented concurrently, this emotionally supercharged suicide threat and this false decision-making dichotomy backed Chloe and her parents into a corner. They felt they had no option but to continue moving forward with transition and surgery. Thus, Dr. Watson failed to provide important relevant information, obscured true information, provided false information, and manipulated Chloe and her parents into a false decision-making matrix of surgery or death. This represents an egregious breach of the standard of care as well as fraud, malice, and oppression.

53. Sophisticated, thoughtful experienced mental health professionals, particularly those with terminal degrees. are expected to understand that ambivalence is present in every major life decision, including elective body changes with hormones and mastectomy. Throughout her years of care at Kaiser, the professionals who treated her demonstrated no understanding of this fact.

54. In the months following Dr. Watson's evaluation, Chloe had increased mental health issues, including depression, anxiety, fears, and passive suicidal ideation. Neither Dr. Watson nor Dr. Le conducted any further review of Chloe's mental health condition and did not discover these issues. Therefore, they failed to assess and consider these negative mental health developments in evaluating and assessing whether Chloe should in fact proceed with permanent, irreversible, and mutilating surgery. Chloe believed that these feelings would go away when she completed the surgery and continued with transition. No one informed or advised her that a decline in her mental health condition is an indication that she was not responding to the experimental treatment and that resolving these underlying mental health concerns should occur before performing permanent and irreversible and mutilating surgery. In this time frame, Chloe's mother had to request a "VOT [verification of treatment] for intermittent leave" from the pediatric care provider so that Chloe could be excused from school, as needed, because of Chloe's increased mental health issues. Despite this worsening psychological condition, Defendants elected to press forward with permanent, irreversible, and disfiguring transition surgery.

55. Chloe had a few more visits with Dr. Le, who obtained a so-called "informed consent" document that addressed normal risks of surgery that might apply to a breast cancer patient, but that

failed to address informed consent issues relating specifically to "gender dysphoria." Similar to Drs. Taylor and Watson, Dr. Le entirely failed to discuss the lack of adequate studies in this area and the fact that there were only low-quality studies of surgical breast removal as a means of treating gender dysphoria, especially in a minor. Dr. Le also entirely failed to mention the studies demonstrating high rates of desistence for children with gender dysphoria and the lack of accurate models for predicting desistence. He never cautioned Chloe or her parents of the significant probability that her dysphoria would resolve later in life without any surgical intervention and that Chloe may then regret undergoing this permanent, irreversible, and disfiguring surgery.

56. Additionally, even as to the surgery itself, the informed consent discussions were woefully inadequate. Dr. Le never showed Chloe any pictures of poor results of the surgery and never showed her any pictures of what the surgery looks post-op prior to healing. Dr. Le only showed her pictures of "successful" results. A critical part of any informed consent discussion for an elective breast removal surgery includes showing unsuccessful results and showing pictures of the healing process. This discussion and presentation did not occur for Chloe. Complications of mastectomies for adolescent trans-identified patients are well known to plastic surgeons

57. At age fifteen, on June 3, 2020, Dr. Le performed a radical double mastectomy, removing both of Chloe's healthy breasts.

58. Chloe was initially satisfied, believing that she would now be able to socialize with the boys without a shirt, that she would no longer need to wear uncomfortable and cumbersome bindings, and that she would now be happy. But reality set in a few weeks later when she needed to have her stiches removed. The experience was strange and unsettling, both from a sensation perspective and a mental perspective. She was shocked and unprepared for how cut-up her chest looked after the surgery. Her grafts were black because they had been separated from the tissue and reattached and so the outside layer of tissue died. The sensation was very strange and uncomfortable. She had to look at herself daily and was appalled at how she looked. She felt like she had been turned into a monster. She was also led to believe that she would be fully healed within a few months and certainly within a year after surgery. However, she is now more than two years post-op and still has significant complications and problems from the surgery. These problems were never discussed or

disclosed as possible complications.

59. Drs. Taylor, Watson, and Le affirmed Chloe in her desire to have her breasts removed and never evaluated her internal reasoning for this surgery. The Defendants in this case never discovered, assessed, evaluated, or treated the sexual assault that she experienced. They never diagnosed or treated her for her body dysmorphia, the disgust that she had for her breasts, the feelings that she would never be attractive with them on her body, and the other conflicted feelings about her perceived inability to be an attractive woman. They never evaluated or explored treatment options for potential autism spectrum or for her social/behavioral troubles. They never evaluated or treated her apparent eating disorder. They did not provide her with psychological support and treatment for her learning disability and never evaluated the impact of that disability on her social life and her personal confidence.

60. After the surgery, Chloe's internal feelings of conflict with her gender returned more vigorously than before. Her mental health issues declined further. Her depression and anxiety got worse, and she developed suicidal ideation. Her gender dysphoria did not resolve with this additional stage of transition; instead, her mental state got worse. She began to feel that it was all a huge mistake. She also took a psychology class, wherein she learned about the Harlow monkey experiment and the importance of a bond between a mother and a child. This class made her think for the first time about her natural desire to be a mother. At the same time, this caused her serious distress because she thought for the first time about caring for a child and about how she might want to breast feed that child. Consequently, she researched for the first time about the benefits of breast feeding a child. She is heartbroken at the thought that she can never have the option to nourish and nurture a child through breast feeding. She is heart-broken that she can never experience the physical touch, bonding, and intimacy that a mother and child can share through breastfeeding. The cross-sex chemicals she received also caused her severe distress as she suddenly realized the tragic impact of her potential loss of fertility and a host of other related issues. She could not have possibly comprehended these tragic consequences as a child, especially while taking such powerful drugs.

61. Throughout and during her cross-sex hormone treatment, Chloe experienced a host of other significant and severe physical and mental sufferings. She experienced hot flashes,

accompanied by severe itching in random areas of her body, to the point that she could not wear sweaters or long pants during the colder seasons. She would also hear loud cracks in her neck and back while breathing. She has permanent changes to her bone structure, including wider shoulders, a stronger jaw, forehead, and nose; a larger ribcage; underdeveloped hips; an Adam's apple; and a masculine voice. She suffered loss of sensation and severe atrophy of her reproductive organs. She suffered frequent urinary tract infections, discomfort, and related issues.

62. After Chloe stopped the hormones, she continued to have increased loss of sensation and increased dysfunction of her reproductive organs, masculine voice, weakening of her voice that now has a greater tendency to crack and lose power. Chloe has continuing issues with more frequent UTI-like symptoms. In the first few months after stopping hormones, she had clotting issues, incontinence issues, and digestive track issues. She developed and continues to have joint pain in her knees and she continues to be prone to itching and rashes on her limbs, especially her legs. Her joint paint continues to increase to her back area, and she has sporadic and unpredictable shooting pains across her back.

63. Chloe has ongoing complications with her grafts for the mastectomy, which require regular care to address and that make showering and swimming problematic. The damaged area of her skin on her right nipple graft has also spread off the graft and is moving downwards. She has lost erogenous sensation in her chest area. The nerves are not connected properly, and she will feel sensations in her arm pit instead of her chest. She has lost social development with her peers including with regard to dating and romantic development. She also is at a significant increased risk of having fertility problems. She may be unable to have children, and if she is able to have children, she may be unable to deliver them naturally due to inadequate development of her pelvic bones.

64. She has likely lost at least a couple of inches of her potential adult height. She has increased facial and other body hair. She is at higher risk of having bone density problems and is at an increased risk of bone fractures. At an elderly age, bone fractures can cause serious injury and death. She may have stunted neurological development and has concerns that she should have been treated for autism spectrum disorder. She has now lost the ability to receive that treatment and related neurocognitive development that could have benefited her adult life. She suffered from a sudden

massive increase in libido from taking testosterone, which was extremely difficult for her to navigate as a young female, and she suffered from and developed a pornography addiction. Her dating pool was severely limited during this time. Girls her age started to express an interest in her after transition, but Chloe was still only interested in men. When Chloe stopped the hormones, she became intensely suicidal for the first time and prone to emotional outbursts. She was severely depressed, and it was incredibly difficult for her to focus on anything including school. As a result, she ended up failing out of high school her senior year and had to get a California High School Proficiency Exam Certificate. She struggled with adjusting socially and presenting as a female again. She missed out on important and irreplaceable female socialization due to ill-conceived social transitioning during critical years in her development. After detransitioning, she was bullied because of her masculine physical features and voice.

65. Chloe has suffered severe anxiety, depression, and suicidal ideation as a result of this so-called treatment. She now has deep emotional wounds, severe regrets, and a deep distrust for the medical system. She continues to struggle with depression. It is very difficult for her to cope with the possibility of being unable to have biological children, and her inability to breastfeed them if she is able to have children. She also struggles considerably with her body image, which she describes as having "taken a major hit from all of this."

66. The full extent of Chloe's damages are being investigated and are not fully known at the time of filing this complaint. The allegations herein are intended to be only a partial summary of the relevant facts and medical records, and Chloe's medical issues and damages resulting from the gross negligence, coercion, and fraud Defendants committed in this case.

67. Defendants have also deliberately ignored and failed to meaningfully discuss with Chloe that sex-reassignment is not physically possible even with surgery. There is no way to surgically replace functioning biological female organs with functioning biological male organs. A trans-male (i.e., a woman who transitions to look more like a man) can never produce biological children with a female and vice versa. At best, surgery and chemical treatment can modify a female body to mimic and appear more like a male body and vice versa. Also, the female/male chromosome composition of XX/XY cannot be modified. A female will have XX chromosomes even if she is

surgically and hormonally modified to appear more like a male. But, as noted above, the potential long-term outcomes of this mimicry are devastating for patients who undergo this treatment. Defendants knew that this treatment was not a viable option and does not produce good mental health outcomes, yet they sent Chloe down this terrible path of mutilation and regret without advising her of any other options. These acts and omissions represent a gross breach of the standard of care, and support a finding of fraud, malice, and oppression.

68. In addition, from a financial perspective, patients such as Chloe who "transition" to appear more like the opposite sex represent a lucrative business opportunity for Defendants. Chloe underwent tens of thousands of dollars of so-called medical treatment, which inured to the benefit of Defendants and to the harm of Chloe. Had Chloe continued in her transition path, she would have represented a monetary benefit to the Defendants of tens of thousands of additional dollars in terms of follow-up lifelong treatment and in terms of further risky surgeries to construct fake genitalia. Thus, Defendants have a high monetary incentive to send patients who appear to present with some symptoms of gender dysphoria down the path to transition as soon as possible. Patients like Chloe, who would have naturally desisted from their gender dysphoria by adulthood, represent a significant lost monetary potential if they are not medically treated when symptoms first present. It is well known that the vast majority of patients who start transition through puberty blockers go on to further transition through life altering cross-sex hormones and surgery.

69. It appears that the lucrative nature of transition treatment, rather than sound medical evidence and Chloe's wellbeing, represented a substantial factor motivating Defendants' ill-formed advice to start Chloe on the transition path.

70. Additionally, it appears that surgical/hormone treatment represented an easier more available treatment option to Defendants over regular interval psychotherapy. For over a decade, since 2013, the California Department of Managed Healthcare has conducted an ongoing investigation of Kaiser's inability to adequately staff mental health professionals, and this has been reported in the news.[16] The American Psychological Association has even sent a letter to the Kaiser

[16] See Exhibits 1-6, 8-12.

Foundation Health discussing how Kaiser's lack of availability of follow-up mental health care falls below professional standards of care in this area.[17] Remarkably, there have been multiple protests wherein thousands of mental health professionals affiliated with Kaiser went on strike at various times, including in Oakland, California.[18] Also, hundreds of practitioners have left for private practice apparently due to Kaiser's unethical practice of intentionally understaffing the mental health division.[19] Yet, Kaiser turned a record $8.1 billion profit in 2021 alone.[20]

71. Chloe's case occurred during this time when Kaiser was inadequately staffed with mental health care providers. It appears that this purposeful inadequate staffing, to make more profits, was a contributing factor to Defendants' inadequate mental health evaluation and psychotherapy treatment of Chloe. It also appears that this inadequate staffing contributed to the apparent favoritism for easy chemical/surgical treatment, rather than the critically needed psychotherapy in Chloe's case.

72. In addition to the foregoing, the Institutional Defendants are separately liable for allowing such radical, inadequately studied, off-label, and essentially experimental treatment to occur on minors, including Chloe, at their facilities. They are also liable for failing to have adequate policies and procedures prohibiting and preventing the acts, omissions, failures of informed consent, fraudulent concealment, fraudulent misrepresentations, below the standard of care treatment, and other derelictions that occurred in Chloe's case and as described above. Indeed, not only are the Institutional Defendants' policies and procedures inadequate to prevent such negligent and intentional malpractice, but they actively promote, encourage, and advertise on their website that their facilities and providers offer proper transgender treatment, including for minors.[21] Thus, the Institutional Defendants are jointly and severally liable with the providers for the grossly negligent and fraudulent, malicious, and oppressive acts described in this complaint. The Institutional Defendants are also

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[17] See Exhibit 7

[18] See Exhibit 5,6, 10-12

[19] See Exhibit 10.

[20] Ibid.

[21] https://thrive.kaiserpermanente.org/care-near-you/northern-california/eastbay/departments/gender-affirming-care/pediatric-services-in-the-mst-department/ (accessed February 13, 2023).

separately and independently liable on the grounds described in this paragraph and the paragraphs above, pertaining to the failure to maintain an adequate staff of mental health care providers, all leading to inadequate patient care and follow-up, and the failure to maintain proper facilities, policies, and procedures.

FIRST CAUSE OF ACTION

MEDICAL NEGLIGENCE

(By Plaintiff Against All Defendants)

73. Plaintiff hereby incorporates each and every allegation previously set forth above as though fully set forth herein.

74. During all relevant times, Plaintiff was a patient of Defendants who undertook to supervise, treat, and provide medical care and medical facilities to Plaintiff as described herein. Defendants collaborated to perform a course of experimental chemical and surgical mimicry change "treatment" on Plaintiff as described in detail above. In summary, Defendants intentionally induced in Plaintiff an endocrine disorder through the administration of puberty blockers, placed Plaintiff on cross-sex testosterone hormones, and eventually collaborated to recommend and perform on Plaintiff a radical double mastectomy.

75. By virtue of this doctor-patient relationship, Defendants owed Plaintiff a duty to exercise the level of skill, knowledge, and care in the evaluation, diagnosis, and treatment of Plaintiff that other reasonably careful providers in the same respective fields/specialties would use in similar circumstances. Defendants breached the standard of care as described in more detail above by, among other things: (1) failing to properly evaluate, assess, diagnose, discover, and treat Plaintiff's medical and mental health conditions, including, but not limited to, Plaintiffs' medical and mental health co-morbidities and symptoms that presented prior to and concurrent with her gender dysphoria symptoms; (2) failing to recognize and provide or refer Chloe to a provider who could evaluate and treat her on a regular weekly basis over an extended period of time; (3) grossly overemphasizing Plaintiff's gender dysphoria symptoms to the point of excluding and ignoring her co-morbidities, related symptoms, and their relevant treatment options; (4) failing to provide Plaintiff with competent informed consent regarding the treatment options available and the relevant risks and benefits of

treatment; and (5) manipulating Plaintiff and her parents into a false decision making matrix by deliberately obscuring relevant information, by presenting false and misleading information, and by thwarting their rational decision making process through inserting an emotionally supercharged ultimatum of a grossly exaggerated suicide risk when no such risk existed for Chloe.

76. Regarding informed consent, among other things, Defendants obscured and did not disclose the important potential results, risks of, and alternatives to this transition course of "treatment," as discussed and elaborated in detail above. In addition, Defendants intentionally obscured and failed to disclose relevant information regarding the existence of only low-quality studies purportedly supporting such treatment, and the existence of high-quality studies establishing poor mental health outcomes for this treatment. They also affirmatively misrepresented that Plaintiff's symptoms would never resolve without this chemical/surgical transition, and failed to disclose and discuss desistence rates. Defendants also manipulated and derailed Plaintiff and her parent's rational decision-making process, boxing them into a false decision-making matrix by inserting an emotionally supercharged ultimatum of grossly exaggerated suicide risk when no such risk existed for Chloe. Defendants falsely represented that Chloe presented a high risk of suicide unless she transitioned. Chloe's parents were also coercively asked if they "would rather have a dead daughter or a live son." Defendants failed to adequately assess, evaluate, and diagnose Plaintiff's widely varied presentation of symptoms and co-morbidities, which fatally undermined and obstructed the possibility of Defendants providing Plaintiff with informed consent. The process of assessing, evaluating, diagnosing, and recommending treatment options, risks, and benefits, could not possibly have met the standard of care in the limited therapy sessions that occurred in Plaintiffs case. The same provider should have met with Chloe for 1-hour sessions, weekly, for at least 12 weeks, in order to meet the requisite standard of care. Defendants did not discuss, evaluate, or inform Chloe as to alternate treatment options, and the related risks and benefits. Defendants failed to disclose to Chloe that the decline in her mental health symptoms was an indicator that she was not responding to "treatment" and that she should not continue with "treatment." These, among other issues, represent a gross breach of the standard of care and an egregious failure of informed consent. A reasonable person in Plaintiff's position would not have agreed to the transition treatment if properly and

adequately informed of the risks. Plaintiff suffered harm and damage relating to numerous serious risks that should have been disclosed, discussed, and explained to Chloe and her parents but were not disclosed.

77. As a direct and proximate cause of Defendants' breaches of the standard of care, Plaintiff sustained serious and permanent personal injuries, causing her general and special damages to be determined according to proof at trial.

78. The acts and omissions described in this complaint also constituted fraud, oppression, and malice. Defendants deliberately conveyed false information and obscured and concealed true information. Defendants failed to inform Plaintiff about the issue of high likelihood of desistence and significant risk of regret. Defendants failed to spend sufficient time with Plaintiff over an adequate period of time to evaluate her condition, and failed to inform her of her need for regular psychotherapy and the need for her to seek a therapist who could spend adequate time with her. Defendants did not tell Chloe about the increased risk of suicide for transgender individuals receiving chemical/surgical transition treatment. Defendants did not tell her about the existence of high-quality evidence demonstrating poor mental health outcomes for this treatment and the existence of only low to very low-quality evidence purportedly supporting this treatment. Defendants did not tell her about all of the extensive health risks. Defendants experienced significant financial gain as their intended result. The Institutional Defendants knowingly authorized and ratified this substandard and fraudulent treatment of Plaintiff for their own financial benefit and the detriment of Chloe. These among other despicable acts and omissions support a finding of intentional fraud, malice, and oppression.

79. The harm that Plaintiff experienced in this case as a result of being improperly treated with chemical/surgical interventions rather than psychotherapy for her varied presentation of co-morbid symptoms, would not have occurred unless the Defendants were negligent. The fact that Plaintiff detransitioned after the so-called treatment establishes *res ipsa loquitor* that Plaintiff was not transgender and that Defendants were guilty of medical malpractice in their evaluation, assessment and treatment of Plaintiff. Defendants' diagnoses, evaluation, and "treatment" of Chloe were *de facto* incorrect. Proper evaluation, diagnosis, informed consent, and treatment of Plaintiff

that met the standard of care would never have started Plaintiff down this harmful path of physical transition that ultimately turned out to be a horrible experiment causing irreversible and serious injuries to Plaintiff.

80. The harm occurred while Plaintiff was under the care and control of Defendants, and Plaintiff's own voluntary actions were not a cause contributing to the events that harmed Plaintiff. Plaintiff was a minor incapable of understanding and evaluating the decisions she was making, yet her providers treated her as if she could understand the implications of the decisions that she was making as described in greater detail above.

SECOND CAUSE OF ACTION

MEDICAL NEGLIGENCE – HOSPITAL/MEDICAL GROUP

(By Plaintiff Against Kaiser Hospitals and Medical Group)

81. Plaintiff hereby incorporates each and every allegation previously set forth as though fully set forth herein.

82. The Institutional Defendants were a medical provider for Plaintiff and had a duty of reasonable care to Plaintiff. The Institutional Defendants had the obligation to select, maintain, and ensure the competence of the Defendant Providers. The Institutional Defendants also had the obligation to provide procedures, policies, facilities, supplies, and qualified personnel reasonably necessary for the treatment of Chloe. The Institutional Defendants breached these duties by failing to provide the requisite procedures, policies, facilities, supplies, and qualified personnel, and by failing to adequately select, maintain, and ensure the competence of the Defendant Providers. Among other things, the Institutional Defendants allowed the Defendant Providers to treat Plaintiff with radical, inadequately studied, off-label, and essentially experimental transition "treatment." The Institutional Defendants failed to have adequate policies and procedures in place to prevent the acts, omissions, failures of informed consent, fraudulent concealment, fraudulent misrepresentations, negligent treatment, and other breaches of the standard of care that occurred in regard to Plaintiff as described above. Furthermore, the Institutional Defendants not only have inadequate policies and procedures to prevent such harmful treatment of patients like Chloe, but they actively promote, encourage, and advertise on their website that their facilities and providers offer proper transgender

treatment, including for minors.

83. The Institutional Defendants also failed to employ adequate mental health professionals. This inadequate staffing of mental health providers contributed to preventing Plaintiff from receiving regular psychotherapy evaluation, assessment, and treatment with the same provider, which was necessary in Plaintiff's case to meet the standard of care.

84. Among other acts and omissions, these breaches of the standard of care caused Plaintiff to suffer personal injury and resulting special and general damages according to proof at trial.

85. The acts and omissions described in this complaint also constituted fraud, oppression, and malice. Defendants deliberately conveyed false information and obscured and concealed true information. Defendants failed to inform Plaintiff about the issue of the high likelihood of desistence and the significant risk of regret. Defendants failed to spend sufficient time with Plaintiff over an adequate period of time evaluating her condition and/or failed to inform her of her need for regular psychotherapy and the need for her to seek a therapist who could spend adequate time with her. Defendants did not tell her about the increased risk of suicide for transgender individuals receiving chemical/surgical transition treatment. Defendants did not tell her about the existence of high-quality evidence demonstrating poor mental health outcomes for this treatment and the existence of only low to very low-quality evidence purportedly supporting this treatment. Defendants did not tell her about all of the extensive health risks. Defendants experienced significant financial gain as the intended result. The Institutional Defendants knowingly authorized and ratified this substandard and fraudulent treatment of Plaintiff. The Institutional Defendants knowingly failed to employ adequate mental health professionals to treat complex cases like Chloe. These deficiencies, among other acts and omissions, support a finding of intentional fraud, malice, and oppression.

86. The harm that Plaintiff experienced in this case as a result of being improperly treated with chemical/surgical interventions rather than psychotherapy for her varied presentation of co-morbid symptoms, would not have occurred unless the Defendants were negligent. The fact that Plaintiff detransitioned after the so-called treatment establishes *res ipsa loquitor* that Plaintiff was not transgender and that Defendants were intentional or negligent in their evaluation, assessment and

treatment of Plaintiff. Defendants' diagnoses, evaluation, and "treatment" of Chloe were *de facto* incorrect. Proper evaluation, diagnosis, informed consent, and treatment of Plaintiff that met the standard of care would never have started Plaintiff down this harmful path of physical transition that ultimately turned out to be a horrible experiment causing irreversible and serious injuries to Plaintiff.

87. The harm occurred while Plaintiff was under the care and control of Defendants, and Plaintiff's own voluntary actions were not a cause contributing to the events that harmed Plaintiff. Plaintiff was a minor incapable of understanding and evaluating the decisions she was making, yet her providers treated her as if she could understand the implications of the decisions that she was making as described in greater detail above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants according to law and according to proof, for the following:

1. General damages, in an amount according to proof at the time of trial;
2. Special damages for medical and related expenses, in an amount according to proof at the time of trial;
4. Pain and suffering, past and future, and mental anguish, past and future;
5. Pre-judgment interest on damages;
6. Costs of suit;
7. Such other and further relief as the court deems just and proper.

Respectfully Submitted,

LiMANDRI & JONNA, LLP

DHILLON LAW GROUP INC.

CENTER FOR AMERICAN LIBERTY

Dated: February 22, 2023

By: _____

Charles S. LiMandri
Paul M. Jonna
Robert E. Weisenburger
Harmeet K. Dhillon
John-Paul S. Deol
Jesse D, Franklin-Murdock

Mark E. Trammell*

Attorneys for Plaintiff
Chloe E. Brockman

*Pro Hac Vice motion forthcoming

DHILLON LAW GROUP INC.

DEMAND FOR JURY TRIAL

Plaintiff CHLOE E. BROCKMAN demands a trial by jury on all claims.

Respectfully Submitted,

LiMANDRI & JONNA, LLP

DHILLON LAW GROUP INC.

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Mark E. Trammell*

Attorneys for Plaintiff
Chloe E. Brockman

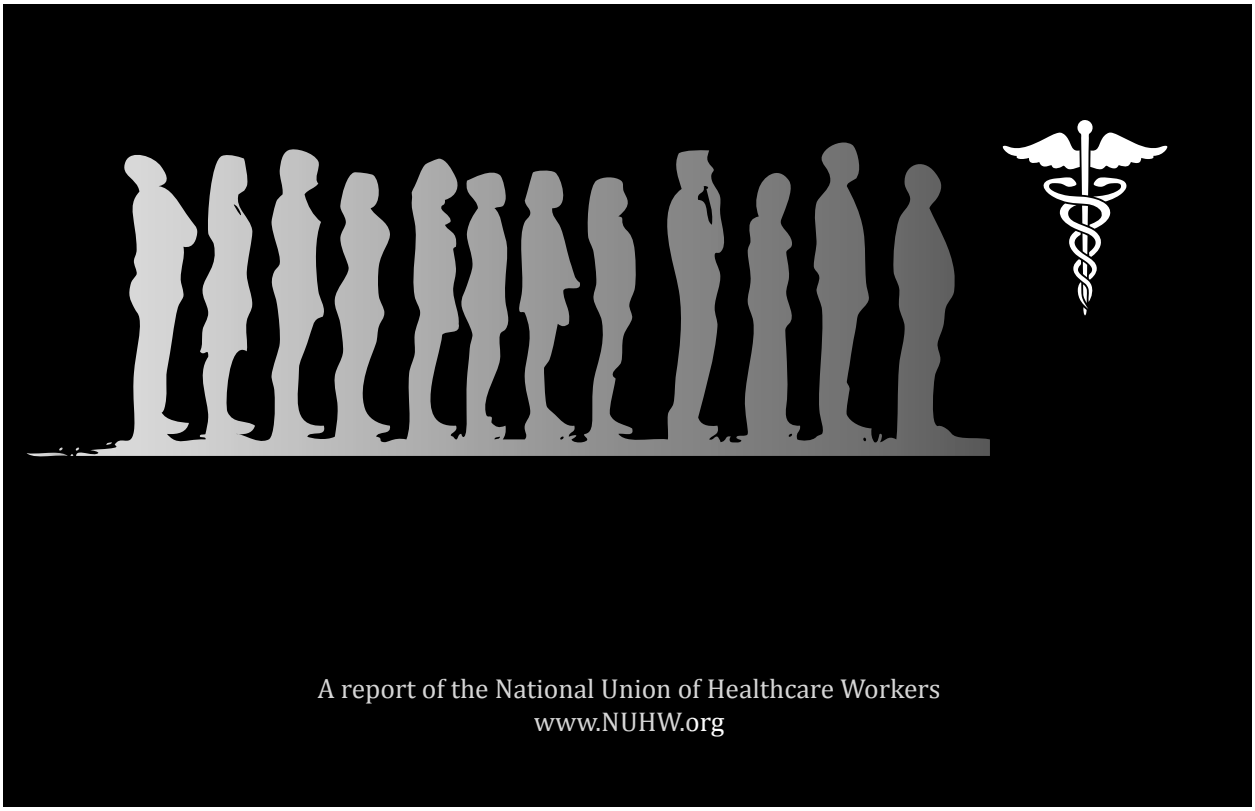
*Pro Hac Vice motion forthcoming

DHILLON LAW GROUP INC.

EXHIBIT 1

CARE DELAYED, CARE DENIED:

Kaiser Permanente's Failure to Provide Timely and Appropriate Mental Health Services



A report of the National Union of Healthcare Workers
www.NUHW.org

November 2011

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Executive Summary

With more than 6.6 million members, Kaiser Permanente is California's largest HMO and plays a massive role in the state's healthcare delivery system by operating more than 35 hospitals and several hundred clinics across the state. Less well known, however, is Kaiser's role in providing mental health services to Californians. Ranking perhaps second only to the State of California, Kaiser is one of the state's largest providers of mental health services. The Oakland-based company guarantees its members a full array of inpatient, outpatient and emergency mental health services provided by several thousand mental health professionals. Each year, thousands of Kaiser's members seek treatment for conditions ranging from autism, anxiety and bi-polar disorder to depression, schizophrenia and suicidal ideation.

Despite Kaiser's pledge to provide comprehensive mental health services to its members, an in-depth analysis suggests that the HMO's mental health services are sorely understaffed and frequently fail to provide timely and appropriate care. Patients often experience lengthy delays in obtaining services, an overreliance on "group therapies," and frustrating obstacles that push many patients to forgo care or seek treatment elsewhere at their own cost.

Drawing on a survey of hundreds of Kaiser's mental health clinicians as well as documentation from regulatory agencies, court filings, patients and frontline caregivers, this study finds that Kaiser frequently fails to comply with California laws aimed at protecting patients' timely access to appropriate services.[1] Furthermore, it finds that Kaiser's failures are systematic and often purposeful. Indeed, the scope and specifics of these failures are sufficiently grave as to merit investigation by state and federal authorities as well as actions for recovery of funds by public and private payers, including individual Kaiser members. For example, despite receiving more than $10 billion annually from Medicare to provide a full range of services, including mental health care, Kaiser appears to be miscoding patient evaluation procedures, which may result in fraudulent claims to the Medicare program.

> *"Treatment is "one size fits all" with overemphasis on medications, groups and educational classes in place of effective levels of scientifically-based, best practices care. [Patient] care treatment is too little in frequency, amount and/or duration…"*
>
> *-Kaiser Psychologist*

The study's key findings are the following:

- **Kaiser often violates California laws requiring HMOs to provide patients with "timely access" to appropriate mental health services.** Clinicians report that patients frequently endure waits of four weeks or longer for return appointments even though California law mandates a maximum wait time of 10 business days for both initial and return visits unless a licensed health professional has documented that a longer waiting time "will not have a detrimental impact on the health of the enrollee."[2] Furthermore, many clinicians report that patients' first appointments are often nothing more than group orientation sessions in which initial evaluations do not take place. When such evaluations finally do take place, clinicians report they are often

cursory and insufficient, but nonetheless are coded as if they were thorough and complete. In a survey of 305 Kaiser clinicians, nearly 90 percent of the respondents reported there is insufficient staffing at their clinic to provide patients with timely return visits. More than 75 percent reported that they are either frequently or very frequently "forced to schedule return visits further into the future than you believe is appropriate."

- **Kaiser reportedly falsifies patient scheduling records in an effort to avoid being cited by state regulators for lengthy appointment delays.** Clinicians report that Kaiser often uses "shadow" scheduling records, deliberately miscategorized appointments, and false appointment cancellations to avoid detection of delays that exceed California's "timely access" requirements.

- **Kaiser often funnels patients into group therapy even when individual therapy would be more effective.** Kaiser often pressures its clinicians to assign patients to group therapy even when clinicians conclude that individual therapy may be more beneficial. More than 50 percent of Kaiser clinicians report that patients are either frequently or very frequently "assigned to group therapy even though individual therapy may be more appropriate."

- **Kaiser reportedly performs initial patient evaluations and other mental health services that not only fall short of recommended clinical standards, but are coded incorrectly in possible violation of Kaiser's contracts with both private and governmental purchasers.** In San Diego, Kaiser has reportedly directed clinicians to spend only half as much time as the clinically recommended minimum for interviewing, assessing and diagnosing patients. This reported "speed-up" of Kaiser's assessment procedures can have serious implications. For example, short-cut evaluations lasting only 20 to 30 minutes may result in the misdiagnosis of patients' conditions. Furthermore, Kaiser appears to be miscoding these procedures in a manner that may result in fraudulent claims to Medicare and other governmental and private purchasers. Interviews with clinicians indicate that Kaiser may be replicating this practice at many sites in California.

- **Kaiser's current mental health care deficiencies are part of an ongoing pattern of substandard care.** During recent years, government inspectors have cited Kaiser multiple times for failing to provide patients with timely access to mental health services. For example, in 2005 the California Department of Managed Health Care (DMHC) cited Kaiser for failing to provide its patients with timely access to mental health care. In 2010, Kaiser was fined $75,000 for unreasonably delaying a child's autism diagnosis for almost 11 months.

In short, Kaiser's systemic failures recall many of the well-documented abuses of HMOs from an earlier era – one that California believed its revised and expanded regulatory structure had long ago overcome. Kaiser is delivering this substandard care at the same time that the HMO is reporting record profits of $5.7 billion since 2009.[3]

The breadth and depth of Kaiser's failures call for state and federal authorities, as well as private payers, to act with deliberate speed to protect the interests of Kaiser enrollees and ensure they receive the mental health care to which they are entitled, and which they need.

As a first step, the California Department of Managed Health Care (DMHC), which regulates Kaiser's HMO plans, and the California

Department of Insurance (CDI), which regulates Kaiser's fee-for-service offerings, should initiate investigations to determine the full extent of Kaiser's regulatory violations and seek remedies as may be justified for Kaiser's violation of timely access standards, its failure to provide patients with clinically appropriate care, the insufficiency of its mental health provider network, and its non-compliance with mental health parity requirements, among other potential violations of state statutes and regulations.

As these investigations proceed, other public and private actions that merit consideration include:

- The State Attorney General initiating an investigation to determine whether any of Kaiser's failures to serve the mental health needs of its patients constitute "unfair business practices" under California Business and Professions Code §17200 or "false advertising" under §17500, and seeking appropriate remedies for any such violations. Additionally, state officials could initiate an investigation by the California Department of Justice's Medi-Cal Fraud Unit of Kaiser's potential false claims to Medi-Cal and Healthy Families and the potential breach of its specific contractual obligations or these programs' general conditions of participation.

- The Office of the Inspector General of the U.S. Department of Health and Human Services initiating an investigation of Kaiser's apparently false claims to the Medicare program for mental heath services provided under the Medicare Advantage program, and its possible violations of its specific contractual obligations or the programs' general conditions of participation.

- Other public and private payers who purchase health care coverage from Kaiser, most notably large public plans like the Federal Employee Health Benefits Program (FEHB) and the California Public Employees' Retirement System (CalPERS), pursuing audits of the treatment provided to plan members and seeking appropriate restitution for Kaiser's failures.

- The California Assembly's and Senate's Health Committees scheduling joint subject matter hearings to review the findings raised in this study and deliberate on what additional safeguards might help prevent the development of schemes to violate mental health patients' rights.

Finally, and most important, Kaiser should:

- Adopt the recommendations of its own mental health providers to increase staffing levels at mental health facilities, limit weekly initial intakes per clinician, and establish a binding system of dispute resolution for staffing problems that is managed by a neutral third party in order to ensure enough capacity to meet state requirements for timely access to appropriate care;

- Cease and desist from the inappropriate management of records, misuse of group therapy, and misrepresentation of orientation sessions and other triage mechanisms to evade its responsibilities to patients with mental health needs; and

- End the practice of 30-minute "intake" evaluations of mental health patients and ensure that patients receive appropriate assessments, properly documented, that conform to the clinical standards set forth by the American Psychological Association (APA) and the American Medical Association (AMA).

EXHIBIT 2

DEPARTMENT OF
Managed
Health Care

OFFICE OF PLAN MONITORING
DIVISION OF PLAN SURVEYS

FINAL REPORT

ROUTINE SURVEY

OF

KAISER FOUNDATION HEALTH PLAN, INC.

BEHAVIORAL HEALTH SERVICES

DATE ISSUED TO PLAN: MARCH 6, 2013
DATE ISSUED TO PUBLIC FILE: MARCH 18, 2013

Final Report of a Routine Medical Survey
Kaiser Foundation Health Plan, Inc.
Behavioral Health Services
March 6, 2013

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EXECUTIVE SUMMARY

On January 6, 2012, the California Department of Managed Health Care (the "Department") notified Kaiser Foundation Health Plan, Inc. (the "Plan") that its Routine Medical Survey had commenced, and requested the Plan to submit information regarding its health care delivery system.

The survey team conducted the onsite portion of the survey from March 12, 2012, through March 15, 2012, and from March 19, 2012, through March 22, 2012. The Department completed its investigatory phase and closed the survey on July 25, 2012.

The Department assessed the following areas:

Quality Management
Grievances and Appeals
Access and Availability of Services
Utilization Management
Continuity of Care

The Department identified **four** deficiencies during the current Routine Medical Survey. The 2012 Survey Deficiencies table below notes the status of each deficiency.

2012 SURVEY DEFICIENCIES

#	DEFICIENCY STATEMENT
	ACCESS AND AVAILABILITY OF SERVICES
1	**The Plan does not ensure that its quality assurance systems accurately track, measure, and monitor the accessibility and availability of contracted providers pursuant to the timely access standards.** (Rules 1300.67.2.2(c)(1) and (5); Rule 1300.67.2.2(d).)
2	**The Plan does not sufficiently monitor the capacity and availability of its provider network in order to ensure that enrollee appointments are offered within the regulatory timeframes.** (Rules 1300.67.2.2(c)(1) and (5); and Rule 1300.67.2.2(d).)
	QUALITY MANAGEMENT/ ACCESS AND AVAILABILITY OF SERVICES
3	**The Plan's Quality Assurance Program does not ensure that effective action is taken to improve care where deficiencies are identified in service elements, including accessibility, availability, and continuity of care.** (Rules 1300.70(a)(1) and (3); Rule 1300.70(b)(1)(D); Rule 1300.70(b)(2)(G)(3); and Rules 1300.67.2.2(c)(1) and (5); and Rule 1300.67.2.2(d)(3).)

	HEALTH EDUCATION SERVICES: MENTAL HEALTH PARITY
4	**The Plan does not provide accurate and understandable effective behavioral health education services, including information regarding the availability and optimal use of mental health care services provided by the Plan or health care organizations affiliated with the Plan.** (Section 1374.72; Rule 1300.67(f)(8); and Rule 1300.80(b)(6)(B).)

EXHIBIT 3

DEPARTMENT OF
Managed
Health Care

OFFICE OF PLAN MONITORING
DIVISION OF PLAN SURVEYS

FOLLOW-UP REPORT

ROUTINE SURVEY

OF

KAISER FOUNDATION HEALTH PLAN, INC.

BEHAVIORAL HEALTH SERVICES

DATE ISSUED TO PLAN: FEBRUARY 13, 2015
DATE ISSUED TO PUBLIC FILE: FEBRUARY 24, 2015

Routine Survey Follow-Up Report
Kaiser Foundation Health Plan, Inc.
Behavioral Health Services
February 13, 2015

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EXECUTIVE SUMMARY

Background

On March 6, 2013, the Department of Managed Health Care ("Department") issued its Final Report concerning the routine medical survey of behavioral health services for Kaiser Foundation Health Plan, Inc. ("Kaiser" or "Plan".) In the Final Report, the Department identified four uncorrected deficiencies related to the Plan's delivery of mental health services to its enrollees and informed the Plan that a Follow-Up Survey would commence within six months.

Because of the serious nature of the deficiencies identified in the Final Report, the Division of Plan Surveys prepared an immediate referral to the Department's Office of Enforcement. The Office of Enforcement investigated the matter further, and then the Department issued a Cease and Desist Order commanding the Plan to cease from engaging in the conduct identified in the violations, and filed an Accusation imposing an administrative penalty in the amount of four million dollars ($4,000,000.00). Although the Plan requested a hearing concerning the administrative penalty, the Plan decided to pay the penalty shortly after the hearing commenced.

The Follow-Up Survey, to determine whether the Plan had fully corrected the outstanding deficiencies, commenced in July 2013. The onsite portion of the survey was conducted during October 2013, March 2014, and April 2014. Throughout the remainder of 2013 and 2014, the Division of Plan Surveys continued work on the Follow-Up Survey and held several meetings with representatives from the Plan to gather additional information concerning corrective actions the Plan had taken to address the deficiencies identified in the Final Report.

Summary of Deficiencies

The Department has determined that Deficiencies #1 and #2 have been corrected by the Plan. However, Deficiencies #3 and #4 have not been corrected.

In *Deficiency #1,* the Department found that the Plan failed to track and capture data necessary to determine whether mental health services are delivered within the timeframes specified in the Timely Access to Non-Emergency Health Care Services regulation, (Title 28, C.C.R., section 1300.67.2.2.). The Final Report identified four specific actions that prevented the Plan from capturing and tracking information needed to determine timely access compliance. In this Follow-Up Survey, the Department concludes that the Plan has taken steps to correct the problems identified in the Final Report.

However, during the Follow-Up Survey process, the Department identified an additional issue related to the Plan's tracking of timely access to services when enrollees receive services from externally-contracted providers. In late 2014, the Plan changed its processes so that it now tracks timely access for its largest and most frequently used external provider network in the Northern Region. The Department has informed the Plan that it needs to ensure that timely access is tracked for all externally-contracted providers to whom patients are referred for services. Additional review of the Plan's

	FOLLOW-UP SURVEY STATUS OF OUTSTANDING DEFICIENCIES FROM FINAL REPORT ISSUED ON MARCH 6, 2013	
#	DEFICIENCY STATEMENT	FOLLOW-UP SURVEY STATUS
	ACCESS AND AVAILABILITY OF SERVICES	
1	**The Plan does not ensure that its quality assurance systems accurately track, measure, and monitor the accessibility and availability of contracted providers pursuant to the timely access standards.** Rules 1300.67.2.2(c)(1) and (5); Rule 1300.67.2.2(d)	**Corrected**
2	**The Plan does not sufficiently monitor the capacity and availability of its provider network in order to ensure that enrollee appointments are offered within the regulatory timeframes.** Rules 1300.67.2.2(c)(1) and (5); and Rule 1300.67.2.2(d)	**Corrected**
	QUALITY MANAGEMENT/ACCESS AND AVAILABILITY OF SERVICES	
3	**The Plan's Quality Assurance Program does not ensure that effective action is taken to improve care where deficiencies are identified in service elements, including accessibility, availability, and continuity of care.** Rules 1300.70(a)(1) and (3); Rule 1300.70(b)(1)(D); Rule 1300.70(b)(2)(G)(3); and Rules 1300.67.2.2(c)(1) and (5); and Rule 1300.67.2.2(d)(3)	**Not Corrected**
	HEALTH EDUCATION SERVICES: MENTAL HEALTH PARITY	
4	**The Plan does not provide accurate and understandable effective behavioral health education services, including information regarding the availability and optimal use of mental health care services provided by the Plan or health care organizations affiliated with the Plan.** Section 1374.72; Rule 1300.67(f)(8); and Rule 1300.80(b)(6)(B)	**Not Corrected**

SECTION III: SURVEY CONCLUSION

Based on all of the information provided and reviewed in connection with the Routine and Follow-Up Survey, the Department concludes that Deficiency #3 and Deficiency #4 remain uncorrected. The available information suggests that, although the Plan has taken steps in good faith to try to correct issues related to timely access to behavioral health services, significant and serious concerns remain.

The volatility in the Plan's monthly timely access reports reveal that the measures taken by the Plan to date are inadequate to provide consistent timely access to behavioral health care services for its enrollees. While the Department understands the unique hurdles the Plan continues to face in recruiting adequate staff and in using externally-contracted providers, these challenges do not relieve the Plan of its statutory obligation to take effective action to correct access and availability problems. The Plan's actions to date have not been adequate to ensure that its enrollees *consistently* have ready access to all mandated behavioral health services consistent with good professional standards of practice and established timely access standards.

Additionally, the Plan must take additional steps to ensure its providers immediately cease disseminating inaccurate information to enrollees concerning behavioral health benefits and coverage. That misleading health education information is disseminated verbally, and in writing, to patients by providers is of great concern to the Department.

The ongoing issues of Plan non-compliance have been referred to the Department's Office of Enforcement for further investigation and possible disciplinary action, based on the Plan's failure to correct Deficiencies #3 and #4.

In the event the Plan wishes to append a brief statement to the Follow-Up Report as set forth in Section 1380(i)(3), please submit the response via the Department's Web portal, eFiling application. Click on the Department's Web Portal, **DMHC Web Portal**

Once logged in, follow the steps shown below to submit the Plan's response to the Follow-Up Report:

- Click the "eFiling" link.
- Click the "Online Forms" link
- Under Existing Online Forms, click the "Details" link for the **DPS Routine Survey Document Request** titled**, 2012 Routine Behavioral Health Survey - Document Request.**
- Submit the response to the Follow-Up Report via the "DMHC Communication" tab.

Plan Response to the Follow-Up Report

EXHIBIT 4

DEPARTMENT OF
Managed
Health Care

OFFICE OF PLAN MONITORING
DIVISION OF PLAN SURVEYS

FINAL REPORT

ROUTINE SURVEY

OF

KAISER FOUNDATION HEALTH PLAN, INC.

A FULL SERVICE HEALTH PLAN

DATE OF FINAL REPORT: JUNE 12, 2017

Final Report of a Routine Survey
Kaiser Foundation Health Plan, Inc.
A Full Service Health Plan
June 12, 2017

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EXECUTIVE SUMMARY

On December 15, 2015, the California Department of Managed Health Care (Department) notified Kaiser Foundation Health Plan, Inc. (Kaiser Permanente or the Plan) that its Routine Survey had commenced and requested the Plan submit information regarding its health care delivery system for both full service and behavioral health services. The survey team conducted the Southern California onsite survey from May 16, 2016 through May 20, 2016 and on March 30, 2017. The Department conducted the Northern California onsite survey from June 20, 2016 through June 24, 2016.

While onsite the Department reviewed plan documents and files for both full service and behavioral health services. For the Full Service survey, the Department's review period for files was from March 1, 2014 through January 15, 2016. For the Behavioral Health survey, the Department's review period for files was from December 1, 2014 through January 1, 2015.

The Department assessed the following areas:

Quality Assurance
Grievances and Appeals
Access and Availability of Services
Utilization Management
Continuity of Care
Access to Emergency Services and Payment
Prescription (RX) Drug Coverage
Language Assistance

The Department identified **six** (**6**) deficiencies during the current Routine Survey. The 2016 Survey Deficiencies table below notes the status of each deficiency.

2016 SURVEY DEFICIENCIES TABLE

#	DEFICIENCY STATEMENT	STATUS
	QUALITY ASSURANCE (QA) Southern California – Behavioral Health	
1	**The Plan does not consistently take effective action to improve care where deficiencies are identified, Plan follow-up where indicated, or monitor whether the provision and utilization of services meets professionally recognized standards of practice.** Section 1370; Rule 1300.70(a)(1); Rule 1300.70(a)(3).	**Not Corrected**

	QUALITY ASSURANCE (QA)/ACCESS AND AVAILABILITY OF SERVICES Southern and Northern California – Behavioral Health	
2	**The Plan's Quality Assurance Program does not ensure that effective action is taken to improve care where deficiencies are identified in service elements, including accessibility, availability, and continuity of care.** Section 1370; Rules 1300.70(a)(1) and (3); Rule 1300.70(b)(1)(D); Rule 1300.70(b)(2)(G)(3); and Rules 1300.67.2.2(c)(1) and (5); and Rule 1300.67.2.2(d)(3).	**Not Corrected**
	GRIEVANCES AND APPEALS Southern and Northern California – Full Service and Behavioral Health	
3	**The Plan does not immediately notify enrollees filing expedited grievances of their right to notify the Department of their grievance.** Section 1368.01(b); Rule 1300.68.01(a).	**Not Corrected**
4	**For expedited grievance decisions to deny, delay, or modify health care service requests by providers based in whole or in part on medical necessity, the Plan does not consistently include in its written response a description of the criteria or guideline used by the Plan and the clinical reasons for the decision.** Section 1368(a)(5); Rule 1300.68(d)(4).	**Not Corrected**
	UTILIZATION MANAGEMENT Southern and Northern California – Full Service and Behavioral Health	
5	**The Plan does not consistently consider the "reasonable person" standard when evaluating the medical necessity of emergency services.** Section 1371.4(a)-(c); Rule 1300.67.2(c).	**Not Corrected**
6	**For decisions to deny emergency services based in whole or in part on medical necessity, the Plan does not consistently include in its written response a description of the criteria or guidelines used, and the clinical reasons for the decision.** Section 1367.01(h)(4).	**Not Corrected**

#3). The Plan submitted a corrective action plan in response to the Preliminary Report. The Department determined this deficiency was uncorrected at the time of the Final Report issued on March 18, 2013, and subsequently determined the deficiency remained uncorrected at the time of the Follow-Up Review conducted in the Fall of 2013 through Spring, 2014 as discussed in the Follow-Up Report issued to the Plan on February 13, 2015. As part of the Department's Follow-Up Review for deficiency #3, it reviewed the ability of enrollees to obtain follow-up appointments. The Department concluded enrollees faced barriers when obtaining appointments for behavioral health services including follow-up appointments. With respect to deficiency #3, the Department concluded in the Follow-Up Report that the Plan must implement a process for regularly tracking availability and timeliness of initial and follow-up appointments and take effective and timely action when problems are identified.

Assessment:

1. The Plan does not take effective and timely action when problems are identified for initial behavioral health appointment availability.

In order to address concerns regarding enrollee access to initial appointments raised in the 2012 Routine Survey, the Plan began tracking initial appointment access under an "Appointments within Standard" methodology. This measure reports, by Plan department and Plan medical center area, the percentage of initial appointments with wait times falling within the timeframe applicable to each appointment type set forth in Rule 1300.67.2.2(c)(5). The Plan set its threshold for corrective action for any medical center that falls below 80% of initial appointments occurring within the standards set forth in Rule 1300.67.2.2(c)(5). If a substantial drop occurs from one month to the next, the Plan takes action prior to any medical center falling below 80%.

Based on the data in Table 2 (below),[6] the Department determined that for the survey period, the Plan did not provide enrollees with timely access to initial appointments for behavioral health services or take effective action regarding these access problems when they were identified. While the Department acknowledges the Plan has significantly improved its compliance with regulatory timeframes,[7] Table 2 demonstrates that several medical centers (identified as A-E in Table 2) had rates for initial behavioral health appointments well below the Plan's internal 80% compliance standard for

[6] Table 2 represents data from a Plan document that tracks enrollee access to initial behavioral health appointments for physician and non-physician providers. The Department reviewed appointment information from four categories: 1) physician urgent 2) physician non-urgent 3) non-physician urgent 4) non-physician non-urgent. In addition, for those months where the table is blank, the Plan met its 80% threshold for access compliance.

[7] The Plan has enhanced its tracking reports to include the new measure on *Percentage Initiated to Seen*, regularly produces and disseminates these reports, improved the timeliness of its implementation of corrective actions, systematized the monitoring of corrective actions to ensure effectiveness, and implemented committee structures to conduct ongoing review of appointment availability. The Plan has also implemented a variety of corrective actions as it deems appropriate for various medical centers including hiring of additional staff, use of contracted providers, adding hours/appointments to individual therapists' schedules and temporarily sending staff from one Plan medical center to another to assist with resolving backlogs.

EXHIBIT 5

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Kaiser Permanente mental health clinicians strike for better patient care

December 14, 2018 | 9:44 AM CST | BY MARILYN BECHTEL

Marilyn Bechtel/PW

OAKLAND, Calif. – As dawn broke over Kaiser Permanente's flagship Oakland Medical Center on Dec. 11, pickets with bright signs saying, "Don't deny my patients mental health care" were already marching and chanting in front of the facility, drawing honks of solidarity from passing cars.

The marchers were mental health clinicians, members of the National Union of Healthcare Workers (NUHW), protesting the long waits their patients must suffer between appointments, in sharp contrast to the prompt scheduling generally experienced by patients with physical illnesses.

Oakland's picketers were among some 4,000 psychologists, therapists, social workers, psychiatric nurses and addiction medicine specialists throughout California, striking the state's largest health care provider for five days, Dec. 10-14, and affecting over 100 Kaiser clinics and hospitals. Their demands included stepping up levels of mental health care staffing, as well as compensation matching that of other unionized Kaiser staff.

The NUHW workers have been without a contract since the end of September.

At noon, over 500 clinicians, union and community supporters – including members of the California Nurses Association and Stationary Engineers Local 39 who struck in sympathy with NUHW – joined in a spirited rally in front of the hospital.

Keynote speaker and leading mental health care advocate Patrick Kennedy told the strikers, "I don't know of another union in this country that represents and works on behalf of those with mental illness and addiction, as you do."

Calling mental illness "a public health epidemic," he told the strikers that while they are supporting their patients in seeking timely care, they are also raising an issue that's largely being ignored around the country, and that suffers from the shame and stigma which often affects patients seeking treatment.

Kennedy, a former U.S. Representative from Rhode Island, called equal treatment for those with mental illness a civil rights issue. H recalled his role while in Congress as a principal sponsor of the 2008 Mental Health Parity Act "that said the brain was part of the body – a radical notion." That legislation requires equal access to care and bans higher premiums and copays, and other forms of discrimination in care.

Sanmit Singh, a psychologist at Oakland's Child and Family Clinic, told the crowd: "I've been here for eight years, and I've always been booked out for four to six weeks." Mental health care shouldn't be a privilege, he said: "We have to compel Kaiser to do what's morally right and what they say they're supposed to do."

Marilyn Bechtel/PW

Jessica Dominguez, a licensed marriage and family therapist at Kaiser's Richmond facility, called attention to the disparities faced by Latinx patients, with services in Spanish even scarcer than those available in English.

California Nurses Association Co-President Zenia Cortez pointed to the "direct effect" the mental health staff shortage has for RNs and nurse practitioners "who see these same patients in Emergency Rooms, hospital units, and overwhelmingly through the call centers."

Oakland City Councilmember-elect Nikki Fortunato Bas told the crowd, "Oakland is a union town. We know Kaiser makes billions in net profits … It is time for Kaiser to step up and be a leader in the mental health sector."

NUHW says Kaiser has a history of forcing patients to endure long waits for therapy appointments. In 2013 California's Department of Managed Health Care fined the system $4 million for violating the state's Mental Health Parity Act, and after finding further violations in the following years, the agency required Kaiser to accept outside monitoring of its mental health services.

The union points out that Kaiser has one fulltime clinician for every 3,000 patients – a ratio unchanged over the last three years.

Marilyn Bechtel/PW

In a conversation after the rally, licensed social worker and NUHW Executive Board member Clement Papazian said the problem of limited and poor access to care creates "all kinds of chaos" as patients' conditions deteriorate.

"What happens when people can't get in for their routine appointments on a regular, frequent basis is that they start to become more acute," he said. "We see them come into our crisis service, our Emergency Room, and they start to overwhelm the intensive outpatient services aimed at some of our sicker people."

Over time, Papazian said, the whole system starts to break down, with people failing to improve, or dropping out of care and therapists trying to see their patients with the time they have but lengthening the intervals further and further.

"Now let's magnify this over decades – and that is why people are out on the street in such numbers, because they are fed up with Kaiser's hollow promises."

Papazian said he hopes Kaiser's executives will start paying real attention to patients' stories. After years of struggle and after workers finally went to state authorities over the crisis, Kaiser said it wanted to work with the clinicians to make the giant health provider a service leade

"But," he said, "our general perception is that their rhetoric just doesn't match their actions. That's why the clinicians are out on the streets."

The day's action concluded with a town hall meeting featuring patients' family members, clinicians and area political leaders who discussed California legislation to assure care is equal for both mental and physical health. That story will follow.

TAGS: health strikes workers

CONTRIBUTOR

Marilyn Bechtel

Marilyn Bechtel writes for *People's World* from the San Francisco Bay Area. She joined the PW staff in 1986 and currently participates as a volunteer. Marilyn Bechtel escribe para People's World desde el Área de la Bahía de San Francisco. Se unió al personal de PW en 1986 y actualmente participa como voluntaria.

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EXHIBIT 6

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HEALTH CARE

California Kaiser Mental Health Workers Launch Strike; Problems 'Keep Getting Worse'

December 16, 2019 · 6:12 PM ET

VANESSA ROMO

More than 4,000 Kaiser Permanente mental health professionals in California launched a five-day strike on Monday at Kaiser facilities across the state.

Psychologists, social workers, psychiatric nurses, addiction specialists and others represented by the National Union of Healthcare Workers say that Kaiser mental health clinics are severely understaffed, forcing some to work after hours to serve more patients. Meanwhile, they say, patients are forced to wait as long as two months for follow-up appointments because of inadequate staffing.

"We're striking because the problems that plague Kaiser's mental health system keep getting worse," said Kenneth Rogers, a Kaiser psychologist, in a statement.

"We don't have enough time to provide proper patient care which includes the preparation and follow up work that goes into every appointment. And patients are being forced to endure even longer wait times for appointments, while Kaiser sits on billions of dollars refusing to fix the problem," Rogers added.

Standing outside the San Leandro child outpatient clinic, clinical psychologist Michael Torres explained that he had joined the picket line to improve services for teenagers struggling with depression, anxiety or serious emotional trauma.

In an online video, Torres said, "I'm thinking of a teenager in my practice, who was tragically gang-raped. And that person had to wait three to five weeks in between sessions to see me for this trauma."

Sponsor Message

National Union of Healthcare Workers
@NUHW · **Follow**

Michael is a psychologist at @kpthrive. He spoke to us about the trauma of his patients and how urgently Kaiser needs to up its game with mental health care.

Watch on Twitter

12:22 PM · Dec 16, 2019

15 Reply Share this Tweet

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He said the long delays prolong symptoms and exacerbate a patient's condition. "There is no nationally recognized standard practice that suggests three to five weeks in between sessions is OK."

Kaiser released a statement critical of employees for walking off the job while reassuring patients that all hospitals and medical offices will remain open throughout the strike.

"We apologize for any inconvenience caused by this unnecessary strike. We believe that NUHW's repeated call for short strikes is disruptive to patient access, operational care and service and is frankly irresponsible," Arlene Peasnall, senior vice president and interim chief human resources officer wrote in an emailed statement.

Peasnall added that Kaiser has been working with an external, neutral mediator to reach a collective bargaining agreement with the health care workers' union. According to Peasnall, the mediator recently delivered a proposed compromise to both sides. While she said it was being seriously considered by Kaiser, "the union has rejected it and announced plans to strike instead of working through the mediated process."

Monday's start of the strike marks a little over a year since the last time Kaiser mental health employees took to the streets. That strike also lasted five days. Union officials say clinicians have been working without a contract for more than a year.

Sponsor Message

As member station KPBS reported, last year Kaiser officials said therapist staffing was up by 30% from 2015. "That's more than 500 new therapists in California — even though there's a national shortage," the company said.

Projections from the American Psychological Association show that the existing psychologist supply is insufficient to meet needs for mental health services in the United States. The organization estimates that there are about 98,000 licensed psychologists.

In 2015, Kaiser agreed to pay a $4 million fine levied by state regulators because of inadequate access to its mental health services, KPBS reported.

This year's strike was meant to begin in November, but it was postponed after the sudden death of Kaiser CEO Bernard Tyson.

health care workers strike kaiser permanente california health care mental health

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EXHIBIT 7

January 27, 2020

VIA EMAIL

Ms. Shelley Rouillard
Director, California Department of Managed Health Care
980 9th Street, Suite 500
Sacramento, CA 95814-2725

Re: Kaiser Access to Mental Health Care

Dear Director Rouillard:

The American Psychological Association (APA), American Psychological Association Services, Inc. (APA Services), and the California Psychological Association (CPA)[1] would like to offer evidence and expertise in connection with very serious allegations from our members about extreme wait times for follow-up psychotherapy appointments for Kaiser Permanente of California (Kaiser) subscribers. Our concern is not only that Kaiser's practices violate California law, but also that Kaiser patients risk being harmed by Kaiser falling far below professional standards of care.

We ask you to consider these serious allegations and to take action to correct the disturbing deficiencies in care, which we have been unable to remedy through informal talks with Kaiser. We plan to participate in the January 31st meeting scheduled by the Department of Managed Health Care (DMHC) and hope to have additional opportunities to contribute to your consideration of this matter.

[1] APA is the leading scientific and professional organization representing psychology in the United States, with more than 121,000 researchers, educators, clinicians, consultants and students as its members. APA Services is a legally separate companion organization to APA and supports advocacy and psychologists' economic and marketplace interests in ways that APA cannot. CPA is a 501(c)(6) non-profit professional association for licensed psychologists and others affiliated with the delivery of psychological services. CPA supports its members' professional interests, promotes and protects the science and practice of psychology, and advocates for the health and welfare of all Californians CPA represents the interests of approximately 17,000 psychologists licensed in California.

Summary of Core Allegation

In a letter to APA dated June 3, 2019 (attached) many members who work for Kaiser reported:

> Due to chronic understaffing at Kaiser's behavioral health services, our adult and child/adolescent patients—even those with complex and acute conditions such as Major Depressive Disorder-Chronic, Bipolar Disorder, Complex Post-Traumatic Stress Disorder, Eating Disorders—routinely wait 4-8 weeks between individual outpatient psychotherapy appointments with their non-physician licensed mental health clinician. At some Kaiser clinics, patients must wait as many as three to four months between appointments.

Our members believe that the company is so focused on meeting the specific time frames required under California law for *initial* appointments, e.g., 10 business days for non-urgent appointments with mental health care providers,[2] that it minimizes the importance of follow-up access. The latter is subject to less specific and non-quantitative regulatory standards – i.e. access to follow-up care must be provided consistent with "professionally recognized standards of practice" and "good professional practice."[3]

Our members also claim that Kaiser manipulates records and data on initial and follow-up care so that the company appears more compliant with applicable laws and regulations than it actually is. More disturbing are the allegations that the company intimidates or retaliates against psychologists who won't cooperate with its data manipulations, or who have raised follow-up access concerns internally and to outside entities like DMHC (including a psychologist who planned to be DMHC's witness in an administrative hearing against Kaiser).

Below is a brief overview of our relevant expertise that we would like to share with DMHC:

A. Clinical Expertise:

Follow-up Appointments: APA is the leading national authority on psychological care. In case DMHC would benefit from our input regarding "professionally recognized standards of practice" and "good professional practice" with respect to access to care, APA's position is that follow-up therapy appointments at 4-8 week or longer intervals, as alleged by our members, fall far below what is appropriate care for most patients. Psychotherapy efficacy and comparative effectiveness studies are typically based on once a week therapy (see, e.g., APA's Clinical Practice Guidelines for the Treatment of Depression and for the Treatment of Posttraumatic Stress Disorder).[4]

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[2] 28 CCR §1300.67.2.2(c)(5)(E)
[3] Health & Safety Code §1367(d); 28 CCR § 1300.70(b)(1)(A); 28 CCR §1300.67.2.2(c)(1)
[4] https://www.apa.org/depression-guideline/index,; https://www.apa.org/ptsd-guideline/index

Initial Assessments: While we have focused on our members' core allegation about access to follow-up care, we have also reviewed the National Union of Healthcare Workers' (NUHW) complaint to DMHC dated May 14, 2019 (attached) alleging that Kaiser "games" the requirement for initial assessments under 28 CCR §1300.67.2.2(c)(5)(E) by giving patients "short-cut" half-hour (or briefer) initial phone assessments.

Our position is that these short-cut assessments are inconsistent with professionally recognized standards of care for mental health evaluations. In practice, assessment interviews are generally done in person, last a minimum of 45 to 60 minutes, cover a wide range of psychosocial and health issues, and determine an initial diagnosis and treatment plan. According to the Centers for Medicare and Medicaid Services, a psychiatric diagnostic evaluation (CPT codes 90791-90792) includes the following: a complete medical and psychiatric history; a mental status examination; establishment of an initial diagnosis; evaluation of the patient's capacity to respond to treatment; and an initial treatment plan.[5] For a comprehensive guideline, please see the American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults.[6] For a guideline on standards of care in the delivery of telepsychology services, please see the American Psychological Association Guidelines for the Practice of Telepsychology.[7]

B. Legal and Insurance Expertise:

APA Services staff have been involved in access to psychological care issues for two decades. We have never seen such an egregious case of delayed access for follow-up appointments.

We also have years of experience evaluating disparities in access to care under mental health parity laws. Kaiser's access to *medical* care seems to be very adequate, leaving the company with a dramatic disparity between good access to medical care and terrible access to mental health care. We can't see any good reason for this disparity that would save the company from a parity law violation. The only explanation that Kaiser offered us was to cite a State of California study indicating an 11% shortage of psychologists and other (non-psychiatrist) mental health providers, but the study actually referred to a projected shortage *a decade from now*.[8] We believe that Kaiser could hire more therapists readily if it admitted that this problem exists and chose to commit some of its ample resources to fixing it.[9]

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[5] https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/31887_33/Outpatient_Psych_Fact_Sheet09.18.14.pdf
[6] https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426760
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[9] See, e.g., https://californiahealthline.org/news/bruising-labor-battles-put-kaiser-permanentes-reputation-on-the-line/

Conclusion

Kaiser's lack of timely access to mental health care has been in the news lately, but APA Services has been investigating and evaluating our members' concerns, and consulting with CPA, for the past 6 months. APA Services initially approached Kaiser with our core concerns about access to follow-up care in an effort to resolve the issue informally and collaboratively. The company's adamant denial that it has a follow-up access problem (combined with the data manipulation and intimidation/retaliation concerns) made an informal resolution unworkable; hence we are reaching out to you.

We would like to discuss these serious allegations with DMHC (and the monitor that DMHC has assigned to Kaiser's compliance if appropriate), to share more detailed information and expertise, and to urge DMHC to take action to resolve these problems and ensure appropriate access to mental health care for Kaiser patients. We look forward to participating in the January 31st meeting and to further communication on this matter.

Thank you for your attention to our concerns.

Jared Skillings, Ph.D.
Chief of Professional Practice
American Psychological Association
American Psychological Association Services, Inc.

Alan Nessman
Senior Special Counsel
Legal and Regulatory Affairs/Practice Directorate
American Psychological Association
American Psychological Association Services, Inc.

Jo Linder-Crow, PhD
Chief Executive Officer l California Psychological Association

Attachments:

June 3, 2019 letter from Kaiser psychologists to APA (psychologists' names removed)

May 14, 2019 letter from NUHW to DMHC

EXHIBIT 8

DEPARTMENT OF
Managed
Health Care

OFFICE OF PLAN MONITORING
DIVISION OF PLAN SURVEYS

FINAL REPORT

ROUTINE SURVEY

OF

KAISER FOUNDATION HEALTH PLAN, INC.

DBA KAISER PERMANENTE

A FULL SERVICE HEALTH PLAN

FEBRUARY 11, 2021

Routine Survey Final Report
Kaiser Foundation Health Plan, Inc.
DBA Kaiser Permanente
A Full Service Health Plan

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EXECUTIVE SUMMARY

On November 16, 2018, the California Department of Managed Health Care (Department) notified Kaiser Foundation Health Plan, Inc. dba Kaiser Permanente (Plan) that it would conduct its scheduled Routine Survey pursuant to Health and Safety Code section 1380. The Department requested the Plan submit information regarding its health care delivery system in connection with the Routine Survey. The survey team conducted the onsite survey from April 15, 2019 through April 20, 2019 in the Northern California region, and May 6, 2019 through May 10, 2019 in the Southern California region.

The Department assessed the following areas:

Quality Assurance
Grievances and Appeals
Access and Availability of Services
Utilization Management
Continuity of Care
Access to Emergency Services and Payment
Prescription (Rx) Drug Coverage
Language Assistance

BEHAVIORAL HEALTH STATUS SUMMARY

The Department identified deficiencies in the Plan's Behavioral Health Quality Assurance (QA) Program in both the 2012 and 2016 Routine Medical Surveys. On July 18, 2017, the Plan entered into a three year Settlement Agreement with the Department, which included corrective action plan deliverables. By entering into the Settlement Agreement, the Plan agreed to improve its Behavioral Health QA program and to ensure effective action was taken to improve care where deficiencies are identified, including in areas of accessibility, availability, and continuity of care. The Settlement Agreement required the Plan to engage the services of a consultant to assist and monitor the Plan's Behavioral Health QA program. The Plan and the consultant were required to work together in order to achieve the goals of the Settlement Agreement. The Plan and consultant were required to focus on six specific "Corrective Action Areas," which are described in the Settlement Agreement and summarized below:

- Improved documentation of the Plan's quality improvement efforts for access compliance;
- Improved transparency in behavioral health appointment access compliance measurement;
- Improved monitoring of member impact as a result of insufficient access and associated real time member remediation;
- Fully implemented systematic process to monitor follow-up appointment access and adherence to the enrollee's treatment plan;
- Improved internal corrective action plan development; and
- Improved integration of external provider access data and oversight.

During the 2016 Routine Follow-Up Survey, the Department determined that the Plan had undertaken appropriate efforts under the terms of the Settlement Agreement to begin correcting these deficiencies. The Department noted these deficiencies as pended in the Follow-Up Survey Report, which was issued to the Plan on January 30, 2019. The Plan's corrective actions noted during the Follow-Up Survey included:

- Development of yearly work plans with the designated expert consultant for the first two years of the consultation period.
- Improved timely access compliance measurement mechanism that delineates when appointments that do not meet timely access standards result from member choice or lack of availability.
- Implementation of improved/revised internal corrective action plan process.
- Implementation of improved monitoring and remediation activities related to impact of when enrollees are not offered a timely appointment.
- Implementation of follow-up appointment monitoring process regarding adherence to an enrollee's treatment plan.
- Implementation of improved data monitoring of external (contracted) network access.
- Updated QA documents, policies and procedures.

For this 2019 Routine Survey, the Department reviewed the Plan's statewide behavioral health QA processes. Although the Department identified one QA deficiency in this 2019 Routine Survey, it is different from the behavioral health QA deficiencies noted in the 2016 Final and Follow-Up Survey Reports.

The Department's assessment included areas related to the Plan's Behavioral Health QA and its Access and Availability of Services for both Northern and Southern California. To assess Behavioral Health QA, the Department reviewed relevant Plan documents including behavioral health files involving potential quality issues (BH PQI files). Based on the BH PQI file review, the Department did not find a deficiency regarding the Plan's failure to follow-up on its corrective action plans (CAPs) intended to improve access to behavioral health appointments as noted in Deficiency #1 of the 2016 Routine Final Report.

To assess Access and Availability of Services, the Department reviewed the following documents:

- Plan policies and procedures related to Appointment Access and the Plan's Monitoring for Access and Availability of Appointments
- The Plan's Access Committee guidelines
- Internal monthly Plan tracking reports on the timeliness of initial appointments with physician and non-physician behavioral health providers for 2017-2018

Based on a review of the Plan's internal monthly initial appointments with physician and non-physician behavioral health providers tracking reports, the Department did not find a basis to cite the Plan for an access deficiency in the 2019 Routine Survey. In Deficiency #2 of the 2016 Routine Final Report, the Plan failed to provide enrollees with timely access to initial appointments for behavioral health services and failed to take

effective action when access problems were identified. In the 2019 Routine Survey, the Department found while some rates for initial behavioral health appointments with non-physician providers fell below the Plan's internal compliance standard for multiple months, the Plan has a process for regularly tracking availability and timeliness of behavioral health initial appointments. In addition, when a particular facility fell below the Plan's threshold for two consecutive months, the Plan took effective and timely action, as described in the Plan's Quality Assurance Program.

Accordingly, in the 2019 Routine Survey, the Department determined the Plan has undertaken appropriate efforts to address Deficiencies #1 and #2 in the 2016 Routine Final and Follow-Up Survey Reports.

2019 Routine Survey Deficiencies

The Department identified **seven** deficiencies during the Routine Survey. The 2019 Survey Deficiencies Table below notes the status of each deficiency.

2019 SURVEY DEFICIENCIES TABLE

#	DEFICIENCY STATEMENT	
	QUALITY ASSURANCE (Statewide)	
1	**The Plan fails to ensure that the quality of care provided is reviewed, problems are identified and effective action is taken to improve care where deficiencies are identified.** Rule 1300.70(a)(1); Rule 1300.70(b)(1)(B).	**Not Corrected**
	GRIEVANCES AND APPEALS (Statewide)	
2	**The Plan's grievance system does not consistently monitor whether grievances are resolved in favor of the enrollee or the Plan.** Section 1368(a)(1); Rule 1300.68(e)(1).	**Not Corrected**
3	**The Plan does not ensure all oral expressions of dissatisfaction are considered grievances, and therefore does not ensure adequate consideration of enrollee grievances and rectification when appropriate.** Section 1368(a)(1); Rule 1300.68(a)(1).	**Not Corrected**
4	**For grievances involving delay, denial or modification of health care services, the Plan's response does not describe the criteria used and clinical reasons for the decision related to medical necessity.** Section 1368(a)(5); Rule 1300.68(d)(4).	**Not Corrected**

	UTILIZATION MANAGEMENT (Statewide)	
5	**The Plan does not systematically and routinely analyze utilization data to monitor potential over- and under-utilization of services. (Statewide)** Rule 1300.70(a)(3) and Rule 1300.70(c).	**Not Corrected**
6	**The Plan failed to demonstrate it complies with post-stabilization care requirements. (Northern California)** Sections 1262.8(f)(1), 1371.4(b), 1371.4 (d), 1371.4 (j)(1), 1371.4 (j)(3), 1371.4 (j)(2)(B), (C); 1386(b)(1); Rules 1300.71.4(a), (b)(1) – (3), (d).	**Not Corrected**
	PRESCRIPTION (RX) DRUG COVERAGE (Statewide)	
7	**The Plan does not update its formulary on a monthly basis.** Section 1367.205(a)(1) to (3).	**Not Corrected**

EXHIBIT 9

SUBSCRIBER EDITION

HEALTH & MEDICINE

Kaiser behavioral health care on the hot seat after California complaints

BY CATHIE ANDERSON

UPDATED MAY 23, 2022 9:47 AM

Kaiser Permanente Behavioral health clinicians rallied on Dec. 19, 2019 at the California Capitol before taking to downtown Sacramento streets.
BY **ALYSSA HODENFIELD** | **CATHIE ANDERSON**

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In an unexpected move, the California Department of Managed Health Care informed Kaiser Permanente that it will be examining whether the company is providing adequate mental health care services to its 9.4 million California members.

“This non-routine survey is based on complaints received from enrollees, providers, and other stakeholders concerning the plan’s behavioral health operations,” said Amanda Levy, the department’s deputy director of health policy and stakeholder relations.

Levy said regulators would evaluate Kaiser’s internal and external provider networks, timely access to care, processes for intake and follow-up appointments, appointment scheduling processes, levels of care and associated decision-making processes, medical record documentation and retention practices, and monitoring of urgent appointments.

TOP VIDEOS

Brittney Griner found guilty, sentenced to 9 years by Russian court

Leaders of Kaiser Permanente issued a statement through Steve Shivinsky, the director of national media relations. In part, he said: “We appreciate the DMHC’s

interest and accountability in understanding how we are working to deliver clinically appropriate care to those who rely on us for their mental health services. We welcome the opportunity to review our performance and collaborate on new areas for improvement."

Kaiser's mental health clinicians, represented by the National Union of Healthcare Workers, have complained that their clients face weeks-long waits before they can get successive appointments and grueling schedules that leave clinicians little time to write notes or to connect patients to wraparound services.

"We have been pushing Kaiser Permanente to increase staffing and invest more in behavioral health care so that we can actually address the needs of our patients, but Kaiser keeps refusing," said psychologist Ken Rogers, a leader for the union in the Sacramento region. "Hopefully this investigation will finally force Kaiser to stop denying that it's failing its behavioral health patients and start working with us to improve its services."

In a news release issued Thursday, union leaders pointed to past fines and settlement agreements that the health care giant had signed with the Department of Managed Health Care, including one from 2013 when the company agreed to pay $4 million and to take corrective actions after the agency found it had failed to provide timely access to mental health care.

State records also show that regulators found issues with timely access to behavioral health services and availability of the care during a routine survey in 2016, but by 2019, Kaiser had instituted a corrective action plan that regulators said was working to alleviate the issues.

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CLAIM OFFER

Regulators cited Kaiser for seven unmet deficiencies in the 2019 survey, mainly focused on how the company handled consumer complaints and monitored whether they were effectively resolved.

Regulators were conducting a follow-up inspection to determine whether Kaiser had corrected these deficiencies when it announced the non-routine survey to determine whether the company complied with laws requiring timely access to behavioral health care.

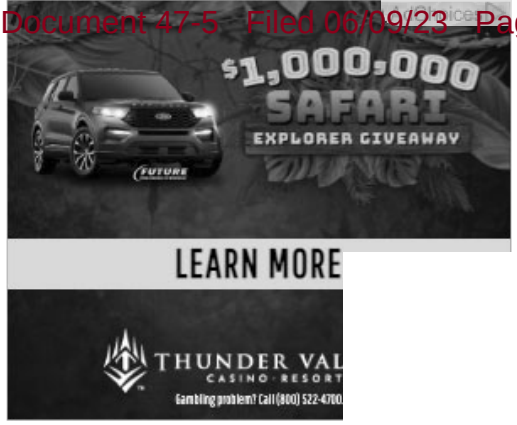
SHARP INCREASE IN KAISER COMPLAINTS

The California Department of Managed Health Care "help center received a 20% increase in behavioral health complaints for Kaiser in 2021 compared to 2020," wrote Rachel Arrezola, a spokesperson for the department, in response to a Bee inquiry. The department "is committed to ensuring enrollees have appropriate access to behavioral health care when they need it."

Kaiser's Shivinsky said: "We believe that a thoughtful, impartial review can help us and other health plans in California address challenges we are all facing. We know that we cannot solve the challenges of the national mental health crisis on our own and look forward to collaboration from across the mental health community."

Both the company and the union noted that California and the nation as a whole have seen a spike in demand for behavioral health services amid the COVID-19 epidemic.

The nonprofit Mental Health America estimated that more than 2.5 million youth in the U.S. have severe depression, and Black, indigenous and other youth of color are at the greatest risk.



In another key measure of mental health, the Centers for Disease Control and Prevention reported earlier this month that fatal overdoses have soared by 15% in 2021 with over 107,000 Americans dying. This follows upon a 30% increase in such deaths in 2020.

NEW CALIFORNIA LAW REQUIRES TIMELY APPOINTMENTS

Union officials said it's past time that Kaiser got its act together in managing behavioral health services. They warned state officials that the company was woefully unprepared to comply with a new state law that goes into effect July 1 requiring that health plans accommodate mental health therapy appointments within 10 business days unless the treating clinician determines that a longer wait would not be detrimental.

Already, union officials said, a 2020 survey of Kaiser clinicians found that, on a daily basis, 65% of respondents are scheduling their patients for return appointments further into the future than is clinically appropriate.

Shivinsky said Kaiser has been on a multiyear journey to improve the way mental health care is delivered, but like other providers, it has faced challenges amid a national shortage of clinicians in the field. The company has expanded its ability to provide virtual care to patients who want it; embedded mental health professionals in primary care clinics, pediatric settings, and emergency departments; and expanded collaborative care programs for patients who have anxiety and depression diagnoses.

"Despite all these efforts, we continue to face the same challenges others do," Shivinsky said. "We haven't solved the problems facing mental health care, and the pandemic has set us all back."

Arrezola said that consumers should file a grievance with their plan if they are not getting timely access to behavioral care. If they are not satisfied with their health plan's response or have been in their plan's grievance system for longer than 30 days for non-urgent issues, she said, they should contact the DMHC Help Center for assistance at (888) 466-2219 or www.HealthHelp.ca.gov.

This story was originally published May 21, 2022 5:25 AM.

FOLLOW MORE OF OUR REPORTING ON HEALTH CARE WORKERS

EXHIBIT 10

Visalia Times Delta

CALIFORNIA

Kaiser therapists flee California health giant as mental health patients languish

Jack Ross and Kristy Hutchings Capital & Main

Published 3:04 p.m. PT Aug. 1, 2022

When Susan Whitney was a therapist at Kaiser Permanente, her colleagues missed working in prison.

Whitney's co-workers first practiced mental health care in the region's penitentiaries before joining the state's largest health care provider. Working conditions for therapists at Kaiser were so deplorable, Whitney says, that her colleagues wanted to go back.

"They can provide better care," says Whitney, who retired from Kaiser in late 2021. "It's a better work environment."

Mental health practitioners at Kaiser are so overburdened with patients that waiting periods between appointments can be six weeks or more, according to therapists who spoke with Capital & Main. (Industry standards mean therapists outside Kaiser generally see patients on a weekly or bi-weekly basis, though cases vary.)

Mental health crisis among youth: California lawmakers target social media addiction

Now California's Department of Managed Health Care (DMHC) has launched a "non-routine survey" to determine whether Kaiser is offering adequate behavioral health care.

When asked about its access issues, Kaiser points to a nationwide shortage of mental health care practitioners.

"The need for mental health care in America has never been greater and at the same time harder to deliver," Kaiser representatives said in May. "Across the United States, mental health experts have reported the demand for mental health services has increased as much as 30% since the beginning of the pandemic."

Kaiser says it has prioritized filling hundreds of therapist vacancies in California.

"We recently launched a $500,000 recruiting initiative to source and hire clinicians to fill more than 1,000 open mental health clinician positions across Kaiser Permanente, more than 400 of which are in California," Yener Balan, Kaiser's vice president of behavioral health and specialty services, told Capital & Main in a March 29 statement.

"The challenge we face is that all mental health providers are drawing from the same, limited pool of talent."

Read more: California makes it easier for low-income residents to get and keep free health coverage

Kaiser, whose mental health care deficiencies have been well documented, turned an $8.1 billion profit in 2021, a company record. In 2021, the Fitch credit ratings agency rated Kaiser bonds AA- for the company's "track record of sound and consistent profitability."

Susan Whitney attributes Kaiser's staffing shortage to "a combination of greed and the lingering stigma over treating mental health the same as physical health."

"I cannot believe that they would treat physical health issues in the same way," she says.

Caseloads reached into hundreds, some say

Emily Ryan, a licensed clinical social worker, began working at Kaiser in Sacramento in 2005. Her caseload at Kaiser was "horrendous," she says.

"I could believe that there is difficulty for them [hiring today], that there's a shortage of every kind of worker right now," she says. "In 2005 there was not. In 2008, when we had the economic crisis, there most certainly was not, and we were having the same exact problems."

Therapist Mickey Fitzpatrick, who worked in the Bay Area town of Pleasanton, says he had caseloads into the hundreds at Kaiser before he left for private practice. "If even a fraction of those new clients wanted to meet as frequently as is recommended, I didn't have the availability to see folks for multiple weeks to months at a time," he says.

In rural Kern County, Kaiser employs 35 mental health workers to serve approximately 100,000 Kaiser members, according to data from the National Union of Healthcare Workers. There is no cap on the number of cases therapists can take on, and they face a regular onslaught of new patients.

“I have co-workers who’ve worked when they were very ill, but they felt like if they canceled one day, their patients would have to wait another six to eight weeks,” says Whitney. “People are waking up in the middle of the night worrying about patients.”

Exodus to more lucrative private practice?

American health plans limit access to mental health care to keep expenses down, according to Richard G. Frank, a senior fellow at the Brookings Institution and director of the USC-Brookings Schaeffer Initiative for Health Policy. Other health care organizations have been accused of undermining their mental health care by not hiring enough therapists — or insufficiently reimbursing the ones they do have for counseling sessions — driving an exodus to more lucrative private practice.

This is by design, says Frank. Mental health patients are more expensive than physical health patients — not because the cost of care is higher, but because mental health patients tend to come with substantial physical health needs, too.

A 2020 study by the consulting company Milliman Inc. reviewed 21 million insurance holders and found that behavioral health patients cost plans 3.5 times more than patients without behavioral health needs.

Experts: The new 988 mental health hotline could make 'all the difference'

“Ever since mental health started being covered by insurance in the ’60s and ’70s, the incentives have been to avoid enrolling people with mental illness in your plan,” says Frank.

Over time, parity laws mandating that health plans offer mental health care on par with their physical health care have grown increasingly strict. On Oct. 8, 2021, Gov. Gavin Newsom signed SB 221, which requires that follow-up appointments for mental health sessions be scheduled within 10 days of the previous session.

When asked about proceeding against Kaiser under the new law, the California Attorney General’s Office declined to comment, citing “a potential or ongoing investigation.”

Regulation and enforcement of health plans in California falls to the Department of Managed Health Care, which fined Kaiser $4 million in 2013 for overbooking its therapists.
Kaiser settled with the DMHC in 2017 following millions of dollars in fines and a litany of enforcement actions imposed against the company. The settlement established a six-point plan to address mental health access issues and forced Kaiser to hire a consultant to oversee the process.

Following the settlement, Kaiser established Connect 2 Care, a system of call centers, to shorten wait times for new mental health patients. Therapists interviewed by Capital & Main said Kaiser created its call centers merely to satisfy regulators, and Connect 2 Care has been criticized by the American Psychological Association.

In May 2022, the agency informed Kaiser of its investigation into the health care giant's mental health services.

Read more: Heat especially harms people with mental and behavioral health conditions, experts say

"We appreciate the DMHC's interest and accountability in understanding how we are working to deliver clinically appropriate care to those who rely on us for their mental health services," Kaiser wrote in a statement.

"Kaiser Permanente is meeting California's regulatory standard for initial appointments for mental health and wellness on average more than 90% of the time. We encourage therapists to document treatment recommendations, including both initial appointments and follow-up appointment frequency, and to escalate any challenges in scheduling to their manager, per the established process."

Kaiser's network of mental health practitioners may be even less robust than the numbers it touts. A 2021 lawsuit filed against Kaiser by the San Diego City Attorney's Office alleged that more than 30% of the therapists listed in Kaiser's directory were not actually available to patients: Some were listed with the wrong contact information, some had retired, some were not practicing within Kaiser's network, and some were not practicing altogether.

"Kaiser's grossly inaccurate provider directories harm their own customers' personal health, as well as their pocketbooks, while unlawfully and unfairly enabling the company to shed more costly enrollees to the detriment of its market competitors," the city of San Diego asserted in its lawsuit.

San Diego also filed lawsuits against two other major providers, Molina Healthcare of California and Health Net, for maintaining inaccurate directories of mental health care practitioners.

Hundreds have left in recent years

Data from the National Union of Healthcare Workers, which represents Kaiser therapists, found practitioners have left Kaiser in steadily increasing numbers over the past three years:

From June 2019 to November 2020, 469 practitioners left Kaiser, with annual turnover rates hovering around 8% per year in Northern California and 5% per year in Southern California. From December 2020 through May 2022, 850 practitioners left Kaiser, and the average annual turnover rate was more than 12% in Northern California and 10% in Southern California.

Kaiser mental health practitioners and experts told Capital & Main that working conditions are to blame for the exodus of therapists from the company. Ex-Kaiser therapist Mickey Fitzpatrick handily beats his old hourly rate, he says, which was $73.73 in April of 2021, after 10 years at the plan. In the Bay Area, therapists regularly charge $250 or more for 50 minute sessions.

“My graduates want to go to Kaiser for work, and they do,” says Dr. Gilbert Newman, vice president for academic affairs at the Wright Institute, a private graduate school for psychology in California. “They often leave Kaiser because they don’t like the work they do. They don’t like being told you can’t see people enough to help them.”

Kaiser therapists can get in trouble with their managers when they recommend clients for regular follow-up appointments. In November of 2021, marriage and family therapist Tanya Veluz was summoned into a meeting with three of her superiors after she recommended patients for return sessions. The managers went through a list of those clients, questioning their need for care.

“They went through each case,” Veluz recalls, “and for a couple where the distress was really high they said, ‘Makes sense, we understand why you would want more support for this case.’ Every other case they challenged my clinical decisions. ‘Well … the questionnaire doesn’t indicate the level of distress you’re asking for.’”

The managers also questioned her estimates for the duration of her patients’ treatment, Veluz says. Trauma patients, Veluz felt, would need sessions for two to six months.

According to Veluz, her manager told her it was impossible to know for how long a patient would need treatment. Veluz disagreed, citing her clinical experience as well as “plenty of research” supporting her diagnoses. She says one manager threatened her license.

When asked about the incident, Kaiser representatives did not directly comment. On July 19, the company said it is on a “multiyear journey to improve the way mental health care is delivered in America today” and has been expanding its virtual care and placing mental health professionals in medical settings. The company has “escalation procedures to support

our therapists if they are unable to schedule a needed follow up appointment" and a "dedicated phone line."

Ken Harlander, a licensed marriage and family therapist, practiced at Kaiser's Bakersfield clinic with Susan Whitney, and left for private practice last year. Harlander avoided delays between appointments at Kaiser by booking returning clients in spots reserved for new patients, which got him summoned to "the principal's office," he says.

"That was what happened if you tried to push back," he says. "When you would ask, 'Why are we selling a product we can't really provide?' you would get no answers."

Richard G. Frank agrees that post-pandemic demand bolsters Kaiser's shortage argument, but says insurance plans' refusal to compete with private practice is the real culprit behind practitioner shortages.

"I think there's a kernel of truth there, but I think it's exaggerated," he says. "What health plans typically claim is that they can't hire all the people they would like to hire at the current rate of pay. That's not the same thing as saying, 'Gee, there are none available.'"

But for Ken Harlander, it wasn't the pay that drove him to private practice — the company's excellent benefits made up for lower hourly wages. Harlander says he left because Kaiser overbooked him and prevented him from doing his job effectively.

"It's just been so good to not work there anymore," he says. "I actually practice good therapy."

Because of its benefits, Kaiser always has willing applicants, according to Harlander. "People would rather work at Kaiser than the county or Medi-Cal work," he says. "They could open slots and hire people away if they wanted to. They wouldn't even have to change their pay structure. If they said we're hiring five therapists, they'd get five candidates right now."

Exhibit 11-A

‘It’s atrocious’: Parents and therapists lambast Kaiser’s youth services

Ariana Bindman, SFGATE
Updated Aug. 16, 2022 4:39 p.m.

Kaiser workers strike at the Oakland Medical Center to protest the HMO's "unethical" working conditions on Aug. 16, 2022.
Ariana Bindman

More than 2,000 mental health clinicians continued to strike at Kaiser Permanente hospitals across Northern California on Tuesday to protest the health care provider’s “unethical” working conditions. On the front lines of the strike at the Oakland Medical Center, SFGATE spoke to several therapists and psychologists who are speaking out on the inhospitable working conditions that are allegedly harming both patients and practitioners.

SFGATE

Alex Klein, a child psychologist who's worked at the Oakland Medical Center for the past seven years, said he is frustrated with Kaiser's current practices and the delays in care.

"If anything, it's been worsening since Kaiser has not been able to make suitable working conditions for clinicians," he said.

According to Klein, his colleagues are burnt out and leaving altogether. As staff dwindles, kids with "significant needs" who should be seen weekly sometimes wait two months or longer for appointments. By failing to support clinicians, he said that Kaiser is subsequently failing to support kids who are suicidal or dealing with conditions like PTSD, OCD, anxiety and depression.

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SFGATE

In response to complaints from the picket line about the lack of staff, Kaiser said in a written statement that it has hired 200 new clinicians since January 2021 and has spent $500,000 to recruit more staff. Representatives also say that Kaiser will continue to prioritize urgent and emergency cases during the strike. "We are working hard to ensure that every patient who needs care this week receives it," they wrote in another statement.

"Despite all that we are doing, we, like others, are challenged to meet the demand and know more must be done," Deb Catsavas, senior vice president of human resources at Kaiser Permanente, said in the statement. "We are focused on continuing to find new ways to meet our members' and patients' mental health needs."

The National Union of Healthcare Workers — which represents the striking clinicians — said enough progress hasn't been made. The union said Kaiser rejected a proposal that would have helped increase staffing and decrease wait times for appointments. Despite Kaiser's statements that it is committed to "bargaining in good faith," therapists said that sometimes the HMO doesn't show up to their bargaining sessions at all.

Meanwhile, Klein said the pandemic is exacerbating the youth mental health crisis, which is the leading cause of disability and poor life outcomes, according to government data. The U.S. Centers for Disease Control and Prevention found that from 2009 to 2019, high school students reported experiencing increased feelings of sadness and hopelessness. The pandemic worsened the crisis. "We've seen a huge increase in anxiety, in depression, particularly with youth — children and teens," Klein continued.

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SFGATE

Jason Lechner, a marriage and family therapist, and Charles Aquilina, a psychologist who works in addiction medicine, both agreed that the pandemic increased the need for mental health services for both kids and adults.

“It made an already difficult problem worse because access to care, access to return appointments and follow-up care was really an issue even before so many people needed it,” Lechner said. Aquilina said that physical isolation and excessive screen time is affecting youth in particular, and that substance abuse among teenagers is also on the rise.

Because of long wait times and staffing issues, some parents said they can no longer rely on Kaiser at all.

One mother, Marie, who requested to not use her full name, called the level of care her teenage son received at the Vallejo Kaiser during a mental health crisis “deplorable.”

SFGATE

“Just to speak to the psychiatrist that was assigned to him took an act of God,” she continue

Top Picks In Shopping

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The 15 best items in Disney's Valentine's Day collection

Even though multiple professionals told her that her son needed to see a mental health practitioner at least two or three times a week, Marie said that Kaiser offered to see him just once a month. She knew her son couldn't afford to wait that long and she put together a patchwork of services outside of Kaiser for him over the course of about six years.

"We spent nearly $500,000 out of pocket until he was 18 years old due to lack of response and quality mental health care from Kaiser," she wrote.

Over the phone, Marie told SFGATE that she took her son to see doctors at Stanford and UCLA, paying $2,400 for three sessions in Northern California and then $45,000 for a month-long evaluation at the University of Utah. Had her friend not given her a $200,000 personal loan, she said, she wouldn't have been able to save her child's life — but even that wasn't enough. Amid other financial troubles during the pandemic, she had to sell her own home.

SFGATE

"We have no retirement now," Marie said. "We spent what we had. But was it worth it? Of course. I always told my son I will do whatever it takes to see him through this."

Barbara McDonald, who spoke with SFGATE for a previous story, had a similar story. She spent $45,000 on services outside of Kaiser due to unpredictable cancellations and delays. "It feels completely negligent," McDonald said.

"They have got to throw away their handbook with how they operate for adolescent psychology," Marie said. "It's atrocious."

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SFGATE

Exhibit 11-B

Bloomberg Government

Kaiser to Boost California Therapist Numbers Under New Contract

By Tiffany Stecker / October 21, 2022 03:00AM ET / Bloomberg Law

Kaiser Permanente will be required to hire more mental health therapists and increase crisis services under a new four-year contract ratified by the therapists' union Thursday.

The agreement, which covers about 2,000 therapists for the nonprofit HMO in Northern California and the state's Central Valley, concludes the longest strike of mental health workers in history.

The standoff began in August with the therapists protesting Kaiser's inability to provide regular and timely behavioral health care to members, with some patients waiting months for follow-up treatment after an initial assessment.

"It took much longer than it should have to reach this agreement, but, in the end, we succeeded in securing important improvements in patient care that Kaiser negotiators told us across the bargaining table that they'd never agree to," Jennifer Browning, a licensed clinical social worker and member of the National Union of Healthcare Workers' bargaining committee, said in a statement.

The agreement is retroactive to September 2021, when the existing contract expired, and will end September 2025. It provides:

- Therapists with two additional hours per week to respond to patient emails and voice messages, contact social services agencies, and perform other duties;
- A 50-cent-per-hour raise for bilingual therapists, and;
- An increase in the duration of initial mental assessments for children, from 60 minutes to 90 minutes.

Must Follow Committee

The agreement doesn't specify how many people Kaiser must hire in the coming years. But it holds management and labor responsible for adopting a plan to better treat specific diagnoses and requires Kaiser to implement the recommendations from those committees. Several of those panels have a mandate to increase staffing, union spokesman Matt Artz said.

California Therapists, Kaiser Agree to End Strike Over Staffing

That requirement could be Kaiser's best chance to offer better care, said Sarah Soroken, a triage and crisis therapist with the provider.

“They can’t just take in the recommendations and not do anything with them,” Soroken said in an interview.

A spokesman for Kaiser Permanente declined to comment at the time of publication.

The union began its California strike on Aug. 15 and accused Kaiser of violating a new state law (S.B. 221) to guarantee timely care for mental health patients. Kaiser members often wait months for follow-up appointments after an initial assessment, according to the HMO’s own data.

Sen. Scott Wiener (D), the author of the timely care law, said that the settlement is a positive step to improve services.

“This resolution seems solid and creates a lot of leverage for the unions to make sure Kaiser is doing better,” he said in an interview.

To contact the reporter on this story: Tiffany Stecker in Sacramento, Calif. at tstecker@bgov.com

EXHIBIT 12

HEALTHCAREDIVE

DIVE BRIEF

California probes Kaiser over enrollee access to mental health appointments

Published Aug. 29, 2022

By Susan Kelly
Contributor

Dive Brief:

- The California Department of Managed Health Care has launched a targeted enforcement investigation into whether Kaiser Permanente health plans are providing patients with timely access to appointments, as required by law, during a strike by mental health clinicians at the system's facilities, a DMHC spokeswoman confirmed in an email to Healthcare Dive on Sunday.
- The probe follows a complaint earlier this month by the National Union of Healthcare Workers to the DMHC that accused Kaiser Foundation Health Plan of illegally canceling behavioral health services for thousands of enrollees in Northern California in response to the impending strike by non-physician clinicians. The strike by DMHC-represented clinicians began on Aug. 15.
- Kaiser Permanente, in an emailed statement, told Healthcare Dive that it is using every resource available to ensure it meets members' mental health needs. "We welcome the opportunity to review the steps we have taken to prepare for and manage

through the union's efforts to disrupt mental health care," spokesman Marc Brown said.

Dive Insight:

The more than 2,000 mental health therapists on strike will remain off the job until Kaiser increases staffing at its clinics and ends "dangerously long" wait times for therapy sessions, according to the NUHW. The union contends Kaiser is breaking California law and violating clinical standards by making patients wait months to start therapy and four to eight weeks between appointments.

California law requires health plans to arrange for care to be provided out of network if timely access to mental health services is unavailable from in-network providers.

DMHC spokeswoman Rachel Arrezola said the department notified Kaiser on Aug. 22 that it had opened an enforcement investigation. The DMHC will continue to monitor the plan closely during the strike to ensure it is in compliance with the law, she said.

"The DMHC is concerned about the potential for immediate harm to enrollees based on the very serious nature of allegations that the plan is not providing timely appointments to enrollees required by the law," Arrezola said.

Brown said 40% of Kaiser's clinicians are caring for members instead of striking, "with more returning each day." In addition, Kaiser Permanente psychiatrists, clinical managers and other licensed clinicians have stepped in to meet with people needing care. Kaiser is also working toward agreements with hundreds of community-based mental health providers to open their schedules

for at least two months to be able to treat more of Kaiser's patients, he said.

"We appreciate the DMHC's interest and accountability in understanding how we are working to deliver clinically appropriate mental health care during NUHW's unnecessary strike," Brown said.

Kaiser Permanente mental health clinicians in Hawaii were planning to begin a strike Monday, joining California therapists in calling for the system to address access-to-care issues.

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Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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REPORT

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ABSTRACT

Background: Transgender healthcare is a rapidly evolving interdisciplinary field. In the last decade, there has been an unprecedented increase in the number and visibility of transgender and gender diverse (TGD) people seeking support and gender-affirming medical treatment in parallel with a significant rise in the scientific literature in this area. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for TGD people through the Standards of Care (SOC). The SOC was initially developed in 1979 and the last version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8.

Aim: The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.

Methods: The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

Results: A total of 18 chapters were developed as part of the SOC-8. They contain recommendations for health care professionals who provide care and treatment for TGD people. Each of the recommendations is followed by explanatory text with relevant references. General areas related to transgender health are covered in the chapters Terminology, Global Applicability, Population Estimates, and Education. The chapters developed for the diverse population of TGD people include Assessment of Adults, Adolescents, Children, Nonbinary, Eunuchs, and Intersex Individuals, and people living in Institutional Environments. Finally, the chapters related to gender-affirming treatment are Hormone Therapy, Surgery and Postoperative Care, Voice and Communication, Primary Care, Reproductive Health, Sexual Health, and Mental Health.

Conclusions: The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and guidance for the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria set forth in this document for gender-affirming medical interventions are clinical guidelines; individual health care professionals and programs may modify these in consultation with the TGD person.

KEYWORDS

adolescents; assessment; children; communication; education; endocrinology; eunuch; gender diverse; health care professional; institutional settings; intersex; mental health; nonbinary; population; postoperative care; primary care; reproductive health; sexual health; SOC8; Standards of Care; surgery; terminology; transgender; voice

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INTRODUCTION

Purpose and use of the Standards of Care

The overall goal of the World Professional Association for Transgender Health's (WPATH) Standards of Care—Eighth Edition (SOC-8) is to provide clinical guidance to health care professionals to assist transgender and gender diverse (TGD) people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment. This assistance may include but is not limited to hormonal and surgical treatments, voice and communication therapy, primary care, hair removal, reproductive and sexual health, and mental health care. Healthcare systems should provide medically necessary gender-affirming health care for TGD people: See Chapter 2—Global Applicability, Statement 2.1.

WPATH is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. Founded in 1979, the organization currently has over 3,000 health care professionals, social scientists, and legal professionals, all of whom are engaged in clinical practice, research, education and advocacy that affects the lives of TGD people. WPATH envisions a world wherein people of all gender identities and gender expressions have access to evidence-based health care, social services, justice, and equality.

One of the main functions of WPATH is to promote the highest standards of health care for individuals through the Standards of Care (SOC) for the health of TGD people. The SOC-8 is based on the best available science and expert professional consensus. The SOC was initially developed in 1979, and the last version was published in 2012.

Most of the research and experience in this field comes from a North American and Western European perspective; thus, adaptations of the SOC-8 to other parts of the world are necessary. Suggestions for approaches to cultural relativity and cultural competence are included in this version of the SOC.

WPATH recognizes that health is not only dependent upon high-quality clinical care but also relies on social and political climates that ensure social tolerance, equality, and the full rights of citizenship. Health is promoted through public policies and legal reforms that advance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy and legal changes. Thus, health care professionals who provide care to TGD people are called upon to advocate for improved access to safe and licensed gender-affirming care while respecting the autonomy of individuals.

While this is primarily a document for health care professionals, individuals, their families, and social institutions may also use the SOC-8 to understand how it can assist with promoting optimal health for members of this diverse population.

The SOC-8 has 18 chapters containing recommendations for health care professionals working with TGD people. Each of the recommendations is followed by explanatory text with relevant references. The recommendations for the initiation of gender-affirming medical and/or surgical treatments (GAMSTs) for adults and adolescents are contained in their respective chapters (see Assessment for Adults and Adolescent chapters). A summary of the recommendations and criteria for GAMST can be found in Appendix D.

Populations included in the SOC-8

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities that exist globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, which may or may not be based on or encompassed by Western conceptualizations of gender or the language used to describe it.

WPATH SOC-8 expands who is included under the TGD umbrella, and the settings in which these guidelines should be applied to promote equity and human rights.

Globally, TGD people encompass a diverse array of gender identities and expressions and have differing needs for gender-affirming care across their lifespan that is related to individual goals and characteristics, available health care resources, and sociocultural and political contexts. When standards of care are absent for certain groups this vacuum can result in a multiplicity of therapeutic approaches, including those that may be counterproductive or harmful. The SOC-8 includes recommendations to promote health and well-being for gender diverse groups that have often been neglected and/or marginalized, including nonbinary people, eunuch, and intersex individuals.

The SOC-8 continues to outline the appropriate care of TGD youth, which includes, when indicated, the use of puberty suppression and, when indicated, the use of gender-affirming hormones.

Worldwide, TGD people commonly experience transphobia, stigmatization, ignorance, and refusal of care when seeking health care services, which contributes to significant health disparities. TGD people often report having to teach their medical providers how to care for them due to the latter's insufficient knowledge and training. Intersectional forms of discrimination, social marginalization, and hate crimes against TGD people lead to minority stress. Minority stress is associated with mental health disparities exemplified by increased rates of depression, suicidality, and non-suicidal self-injuries than rates in cisgender populations. Professionals from every discipline should consider the marked vulnerability of many TGD people. WPATH urges health care authorities, policymakers, and medical societies to discourage and combat transphobia among health care professionals and ensure every effort is made to refer TGD people to professionals with experience and willingness to provide gender-affirming care.

Flexibility in the SOC

The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve.

The SOC-8 supports the role of informed decision-making and the value of harm reduction approaches. In addition, this version of the SOC recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Health care professionals can use the SOC to help patients consider the full range of health services open to them in accordance with their clinical needs for gender expression.

Diversity versus Diagnosis

The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. Unfortunately, gender nonconformity and diversity in gender identity and expression is stigmatized in many societies around the world. Such stigma can lead to prejudice and discrimination, resulting in "minority stress." Minority stress is unique (additive to general stressors experienced by all people), socially based, and chronic, and may make TGD individuals more vulnerable to developing mental health concerns such as anxiety and depression. In addition to prejudice and discrimination in society at large, stigma can contribute to abuse and

neglect in one's interpersonal relationships, which in turn can lead to psychological distress. However, these symptoms are socially induced and are not inherent to being TGD.

While Gender Dysphoria (GD) is still considered a mental health condition in the Diagnostic and Statistical Manual of Mental Disorders, (DSM-5-TR) of the American Psychiatric Association. Gender incongruence is no longer seen as pathological or a mental disorder in the world health community. Gender Incongruence is recognized as a condition in the International Classification of Diseases and Related Health Problems, 11th Version of the World Health Organization (ICD-11). Because of historical and current stigma, TGD people can experience distress or dysphoria that may be addressed with various gender-affirming treatment options. While nomenclature is subject to change and new terminology and classifications may be adopted by various health organizations or administrative bodies, the medical necessity of treatment and care is clearly recognized for the many people who experience dissonance between their sex assigned at birth and their gender identity.

Not all societies, countries, or health care systems require a diagnosis for treatment. However, in some countries these diagnoses may facilitate access to medically necessary health care and can guide further research into effective treatments.

Health care services

The goal of gender-affirming care is to partner with TGD people to holistically address their social, mental, and medical health needs and well-being while respectfully affirming their gender identity. Gender-affirming care supports TGD people across the lifespan—from the very first signs of gender incongruence in childhood through adulthood and into older age—as well as people with concerns and uncertainty about their gender identity, either prior to or after transition.

Transgender health care is greater than the sum of its parts, involving holistic inter- and multidisciplinary care between endocrinology, surgery, voice and communication, primary care, reproductive health, sexual health and mental health disciplines to support gender-affirming interventions as well as preventive care and chronic disease management. Gender-affirming interventions include puberty suppression, hormone therapy, and gender-affirming surgeries among others. It should be emphasized there is no 'one-size-fits-all' approach and TGD people may need to undergo all, some, or none of these interventions to support their gender affirmation. These guidelines encourage the use of a patient-centered care model for initiation of gender- affirming interventions and update many previous requirements to reduce barriers to care.

Ideally, communication and coordination of care should occur between providers to optimize outcomes and the timing of gender-affirming interventions centered on the patient's needs and desires and to minimize harm. In well-resourced settings, multidisciplinary consultation and care coordination is often routine, but many regions worldwide lack facilities dedicated to transgender care. For these regions, if possible, it is strongly recommended that individual care providers create a network to facilitate transgender health care that is not available locally.

Worldwide, TGD people are sometime forced by family members or religious communities to undergo conversion therapy. WPATH strongly recommends against any use of reparative or conversion therapy (see statements 6.5 and 18.10).

Health care settings

The SOC-8 are guidelines rooted in the fundamental rights of TGD people that apply to all settings in which health care is provided regardless of an individual's social or medical circumstances. This includes a recommendation to apply the standards of care for TGD people who are incarcerated or living in other institutional settings.

Due to a lack of knowledgeable providers, untimely access, cost barriers and/or previous stigmatizing health care experiences, many TGD people take non-prescribed hormone therapy. This poses health risks associated with the use of unmonitored therapy in potentially supratherapeutic doses and the potential exposure to blood-borne illnesses if needles are shared for administration. However, for many individuals, it is the only means of acquiring medically necessary

gender-affirming treatment that is otherwise inaccessible. Non-prescribed hormone use should be approached with a harm-reduction lens to ensure individuals are connected with providers who can prescribe safe and monitored hormone therapy.

In some countries, the rights of TGD are increasingly being recognized, and gender clinics are being established that can serve as templates for care. In other countries, however, such facilities are lacking and care may be more fragmented and under-resourced. Nonetheless, different models of care are being pioneered, including efforts to decentralize gender-affirming care within primary care settings and establish telehealth services to reduce barriers and improve access. Regardless of the method of care delivery, the principles of gender-affirming care as outlined in the SOC-8 should be adapted to align with local sociocultural, political, and medical contexts.

Methodology

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility.

While evidence-based research provides the basis for sound clinical practice guidelines and recommendations, it must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated the recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process.

The SOC-8 guidelines committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers, and stakeholders with diverse perspectives and geographic representation. A guideline methodologist assisted with the planning and development of questions and systematic reviews with additional input provided by an international advisory committee and during the public comment period. All committee members completed conflict of interest declarations. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. A detailed overview of the SOC-8 Methodology is included in Appendix A.

SOC-8 Chapters Summary

The SOC-8 represents a significant advancement from previous versions. Changes in this version are based upon a fundamentally different methodology, significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for TGD people beyond hormone therapy and surgery.

These updated guidelines continue the process started with the SOC-7 in 2011 to broaden in scope and move from a narrow focus on psychological requirements for "diagnosing transgenderism" and medical treatments for alleviation of gender dysphoria to gender-affirming care for the whole person. WPATH SOC-8 expands guidelines specifying who is included under the TGD umbrella, what should and should not be offered with gender-affirming care, and the settings in which these guidelines should be applied to promote equity and human rights.

The SOC-8 has several new chapters such as the Assessment of Adults, Education, Eunuchs, and a Nonbinary chapter. In addition, the chapter for children and adolescents of the SOC-7 has been divided into two different chapters. Overall, the SOC-8 is considerably longer than previous versions and provides a more in-depth introduction and recommendations for health care professionals. A summary of every chapter of the SOC-8 can be found below:

Chapter 1—Terminology

This new chapter lays the framework for language used in the SOC-8 and offers consensually agreed upon recommendations for the use of terminology. The chapter provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary (see Appendix B) of common terms and language to provide a framework for use and interpretation of the SOC-8.

Chapter 2—Global Applicability

This chapter references key literature related to development and delivery of health care services, broader advocacy care for TGD people from beyond Western Europe and North America and provides recommendations for adapting and translating the SOC-8 to varied contexts.

Chapter 3—Population Estimates

This chapter updates the population estimates of TGD people in society. Based on the current evidence, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location.

Chapter 4—Education

This new chapter provides a general review of the literature related to education in TGD health care. It offers recommendations at governmental, nongovernmental, institutional and provider levels to increase access to competent, compassionate health care. The intent is to lay the groundwork in the education area and invite a much broader and deeper discussion among educators and health care professionals.

Chapter 5—Assessment of Adults

This new chapter provides guidance on the assessment of TGD adults who are requesting gender-affirming medical and surgical treatments (GAMSTs). It describes and updates the assessment process as part of a patient-centered approach and the criteria that health care professionals may follow in order to recommend GAMSTs to TGD adults.

Chapter 6—Adolescents

This new chapter is dedicated to TGD adolescents, is distinct from the child chapter, and has been created for this 8th edition of the Standards of Care given (1) the exponential growth in adolescent referral rates; (2) the increase in studies available specific to adolescent gender diversity-related care; and (3) the unique developmental and gender-affirming care issues of this age group. This chapter provides recommendations regarding the assessment process of adolescents requiring GAMSTs as well as recommendations when working with TGD youth and their families.

Chapter 7—Children

This new chapter pertains to prepubescent gender diverse children and focuses on developmentally appropriate psychosocial practices and therapeutic approaches.

Chapter 8—Nonbinary

This new chapter in the SOC-8 consists of a broad description of the term nonbinary and its usage from a biopsychosocial, cultural, and intersectional perspective. The need for access to gender-affirming care, specific gender-affirming medical interventions, as well as an appropriate level of support is discussed.

Chapter 9—Eunuchs

This new chapter describes the unique needs of eunuchs, and how the SOC can be applied to this population.

Chapter 10—Intersex

This chapter focuses on the clinical care of intersex individuals. It addresses the evolving terminology, prevalence, and diverse presentations of such individuals and provides recommendations for providing psychosocial and medical care with their evidence-based explanations.

Chapter 11—Institutional Environments

This chapter has been expanded to include both carceral and non-carceral settings and has been built upon the last 3 versions of the SOC. This chapter describes how the SOC-8 can be applied to individuals living in these settings.

Chapter 12—Hormone Therapy

This chapter describes the initiation of gender-affirming hormone therapy, the recommended regimens, screening for health concerns before and during hormone therapy, and specific considerations regarding hormone therapy prior to surgery. It includes an expanded discussion about the safety of gonadotropin releasing hormone (GnRH) agonists in youth, various hormone regimens, monitoring to include the development of potential therapy-related health concerns, and guidance on how hormone providers should collaborate with surgeons.

Chapter 13—Surgery and Postoperative Care

This chapter describes a spectrum of gender-affirming surgical procedures for the diverse and heterogeneous community of individuals who identify as TGD. It provides a discussion about the optimal surgical training in GAS procedures, post-surgical aftercare and follow-up, access to surgery by adults and adolescents, and individually customized surgeries.

Chapter 14—Voice and Communication

This chapter describes professional voice and communication support and interventions that are inclusive of and attentive to all aspects of diversity and no longer limited only to voice feminization and masculinization. Recommendations are now framed as affirming the roles and responsibilities of professionals involved in voice and communication support.

Chapter 15—Primary Care

This chapter discusses the importance of primary care for TGD individuals, including topics of cardiovascular and metabolic health, cancer screening, and primary care systems.

Chapter 16—Reproductive Health

This chapter provides recent data on fertility perspectives and parenthood goals in gender diverse youth and adults, advances in fertility preservation methods (including tissue cryopreservation), guidance regarding preconception and pregnancy care, prenatal counseling, and chest feeding. Contraceptive methods and considerations for TGD individuals are also reviewed.

Chapter 17—Sexual Health

This new chapter acknowledges the profound impact of sexual health on physical and psychological well-being for TGD people. The chapter advocates for sexual functioning, pleasure, and satisfaction to be included in TGD-related care.

Chapter 18—Mental Health

This chapter discusses principles of care for managing mental health conditions in TGD adults and the nexus of mental health care and transition care. Psychotherapy may be beneficial but should not be a requirement for gender-affirming treatment, and conversion treatment should not be offered.

CHAPTER 1 Terminology

This chapter will lay the framework for language used in the SOC-8. It offers recommendations for use of terminology. It provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary of common terms and language to provide a framework for use and interpretation of the SOC-8. See Appendix B for glossary.

Terminology

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, and/or that are not based on or encompassed by Western conceptualizations of gender, or the language used to describe it. TGD is used for convenience as a shorthand for transgender and gender diverse.

The decision to use transgender and gender diverse resulted from an active process and was not without controversy. Discussions centered on avoiding over-emphasis on the term transgender, integrating nonbinary gender identities and experiences, recognizing global variations in understandings of gender, avoiding the term gender nonconforming, and recognizing the changing nature of language because what is current now may not be so in coming years. Thus, the term transgender and gender diverse was chosen with the intent to be most inclusive and to highlight the many diverse gender identities, expressions, experiences, and health care needs of TGD people. A Delphi process was used wherein SOC-8 chapter authors were anonymously and iteratively surveyed over several rounds to obtain consensus on terms. The SOC-8 presents standards of care that strive to be applicable to TGD people globally, no matter how a person self-identifies or expresses their gender.

Context

The language selected in this chapter may not be (nor ever could be) comprehensive of every culture and geographic region/locale. Differences and debates over appropriate terms and specific terminologies are common, and no single term can be used without controversy. The goal of this chapter is to be as inclusive as possible and offer a shared vocabulary that is respectful and reflective of varied experiences of TGD people while remaining accessible to health practitioners and providers, and the public, for the purposes of this document. Ultimately, access to transition-related health care should be based on providing adequate information and obtaining informed consent from the individual, and not on what words TGD people, or their service providers, use to describe their identities. Using language and terminology that is respectful and culturally responsive is a basic foundation in the provision of affirming care, as is reducing the stigma and harm experienced by many TGD people seeking health care. It is vital for service providers to discuss with service users what language is most comfortable for them and to use that language whenever possible.

This chapter explains why current terms are being used in preference to others. Rather than use specific terms for medical, legal, and advocacy groups, the aim is to foster a shared language and understanding in the field of TGD health, and the many related fields (e.g., epidemiology, law), in order to optimize the health of transgender and gender diverse people.

Sex, gender, gender identity, and gender expression are used in the English language as descriptors that can apply to all people—those who are TGD, and those who are not. There are complex reasons why very specific language may be the *most* respectful, *most* inclusive, or *most* accepted by global TGD communities, including the presence or absence of words to describe these concepts in languages other than English; the structural relationship between sex and gender; legal landscapes at the local, national, and international levels; and the consequences of historical and present-day stigma that TGD people face.

Statements of Recommendations

1.1- We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.
1.2- We recommend health care professionals use language in health care settings that uphold the principles of safety, dignity, and respect.
1.3- We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

Because at present, the field of TGD health is heavily dominated by the English language, there are two specific problems that constantly arise in setting the context for terminology. The first problem is that words exist in English that do not exist in other languages (e.g., "sex" and "gender" are only represented by one word in Urdu and many other languages). The second problem is that there are words that exist outside of English that do not have a direct translation into English (e.g., *travesti*, *fa'afafine*, *hijra*, *selrata*, *muxe*, *kathoey*, *transpinoy*, *waria*, *machi*). Practically, this means the heavy influence of English in this field impacts both what terms are widely used and which people or identities are most represented or validated by those terms. The words used also shape the narratives that contribute to beliefs and perceptions. While in past versions of the Standards of Care, World Professional Association for Transgender Health (WPATH) has used only transgender as a broadly defined umbrella term, version 8 broadens this language to use TGD as the umbrella term throughout the document (see Chapter 2—Global Applicability).

Furthermore, the ever-evolving nature of language is impacted by external factors and the social, structural, and personal pressures and violence enacted on TGD people and their bodies. Many of the terms and phrases used historically have been marred by how, when, and why they were used in discussing TGD people, and have thus fallen out of use or are hotly contested among TGD people, with some individuals preferring terms others find offensive. Some wish that these Standards of Care could provide a coherent set of universally accepted terms to describe TGD people, identities, and related health services. Such a list, however, does not and cannot exist without exclusion of some people and without reinforcing structural oppressions, with regards to race, national origin, Indigenous status, socioeconomic status, religion, language(s) spoken, and ethnicity, among other intersectionalities. It is very likely that at least some of the terminology used in SOC-8 will be outdated by the time version 9 is developed. Some people will be frustrated by this reality, but it is hoped it will be seen instead as an opportunity for individuals and communities to develop and refine their own lexicons and for people to develop a still more nuanced understanding of the lives and needs of TGD people, including TGD people's resilience and resistance to oppression.

Finally, law and the work of legal professionals are within the remit of these Standards of Care. As such, language used most widely in international law is included here to help with the development of the functional definitions of these terms and encourage their usage in legal contexts in lieu of more antiquated and/or offensive terms. The currently most thorough document in international human rights law uses the term "gender diverse."[1]

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 1.1

We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.

Culturally relevant language is used to describe TGD people in different global settings. For example, the concepts of sex, gender, and gender diversity differ across contexts, as does the language used to describe them. Thus, the language used when caring

for TGD people in Thailand is not going to be the same as that used for TGD care in Nigeria. When applying the Standards of Care globally, we recommend health care professionals (HCPs) utilize local language and terms to deliver care in their specific cultural and/or geographical locale.

Gender affirmation refers to the process of recognizing or affirming TGD people in their gender identity—whether socially, medically, legally, behaviorally, or some combination of these (Reisner, Poteat et al., 2016). Health care that is gender-affirming or trans-competent utilizes culturally specific language in caring for TGD people. Gender-affirming care is not synonymous with transition-related care. Provision of transition-related care, such as medical gender affirmation via hormones or surgery, does not alone ensure provision of gender-affirming care, nor does it indicate the quality or safety of the health care provided.

Consultation and partnerships with TGD communities can help to ensure relevancy and inclusivity of the language used in providing health care locally in a particular context and setting.

Statement 1.2

We recommend health care professionals use language in health care settings that upholds the principles of safety, dignity, and respect.

Safety, dignity, and respect are basic human rights (International Commission of Jurists, 2007). We recommend HCPs utilize language and terminology that uphold these human rights when providing care for TGD people. Many TGD people have experienced stigma, discrimination, and mistreatment in health care settings, resulting in suboptimal care and poor health outcomes (Reisner, Poteat et al., 2016; Safer et al., 2016; Winter, Settle et al., 2016). Such experiences include misgendering, being refused care or denied services when sick or injured and having to educate HCPs to be able to receive adequate care (James et al., 2016). Consequently, many TGD people feel unsafe accessing health care. They may avoid health care systems and seek other means of getting health-related needs met, such as taking hormones without a medical prescription or monitoring and relying on peers for medical advice. Furthermore, previous negative experiences in health care settings are associated with future avoidance of care among TGD people.

Many TGD people have been treated unjustly, with prejudice, and without dignity or respect by HCPs, and lack of trust is often a barrier to care. Using language grounded in the principles of safety, dignity, and respect in health care settings is paramount to ensure the health, well-being, and rights of TGD people globally. Language is a significant component of gender-affirming care, but language alone does not resolve or mitigate the systematic abuse and sometimes violence TGD people face globally in care settings. Language is but one important step toward patient/client-centered and equitable health care among TGD people. Other concrete actions HCPs can take include obtaining informed consent and refraining from making assumptions about a person's needs based on their gender or TGD status.

Statement 1.3

We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

In providing health care to TGD people, we recommend HCPs discuss with their patients what language or terminology they prefer be used when referring to them. This discussion includes asking TGD people how they would like to be addressed in terms of name and pronouns, how they self-identify their gender, and about the language that should be used to describe their body parts. Utilizing affirming language or terminology is a key component of TGD-affirming care (Lightfoot et al., 2021; Vermeir et al., 2018). Furthermore, these discussions and communications can serve to build rapport and reduce the mistrust many TGD people feel toward HCPs and experience within health care systems. Discussions and usage of language or terminology can also facilitate engagement and retention in care that is not specifically TGD-related, such as uptake of routine preventive screenings and any necessary medical follow-up of findings. In electronic health records, organ/anatomical inventories can be standardly used to inform appropriate clinical care, rather than relying solely on assigned sex at birth and/or gender identity designations.

HCPs and health care settings can implement standardized procedures to facilitate these conversations such as: using intake forms that include chosen pronouns and name, inviting

all staff (regardless of gender, i.e., cisgender, TGD) to use pronouns in introductions, having pronouns accompany names on a document for all patients, and not using gendered honorifics (e.g., Ms., Mr.). Policies for HCPs and health care settings can be put in place to ensure a TGD person's privacy and right to confidentiality, including when they disclose being a TGD person, and if/how to appropriately document. For example, a clinic policy may be to record this information as private and confidential between HCPs and patients/clients, and that it should only be disclosed on a "need to know" basis.

Note

1. A/73/152, Report of the Independent Expert on protection against violence and discrimination based on sexual orientation and gender identity

CHAPTER 2 Global Applicability

People who defy cultural boundaries of sex and gender have existed in cultures worldwide since ancient times, sometimes acknowledged in local language terms (Feinberg, 1996). In contrast to the more recent pathologization of gender diversity as an illness, some cultures traditionally celebrated and welcomed this diversity (e.g., Nanda, 2014; Peletz, 2009). Today, the English language umbrella term transgender and gender diverse (TGD) describes a huge variety of gender identities and expressions, and therefore a population with diverse health care experiences and needs. Together, TGD people represent important aspects of human diversity the World Professional Association for Transgender Health (WPATH) asserts should be valued and celebrated. TGD people continue to make vital contributions to the societies in which they live, although often these are unrecognized.

Disturbingly, many TGD people in the modern world experience stigma, prejudice, discrimination, harassment, abuse and violence, resulting in social, economic and legal marginalization, poor mental and physical health, and even death—a process that has been characterized as a stigma-sickness slope (Winter, Diamond et al., 2016). Experiences such as these (and the anticipation or fear of encountering such experiences) leads to what Meyer has described as minority stress (Meyer, 2003; see also Bockting et al., 2013 writing specifically about TGD people), and are associated with poor physical (e.g. Rich et al, 2020) and psychological (e.g., Bränström et al., 2022; Scandurra et al., 2017; Shipherd et al., 2019, Tan et al., 2021) health outcomes.

Violence against TGD people is a particular problem. Seen from a global perspective, it is widespread, diverse in nature (emotional, sexual and physical, e.g., see Mujugira et al., 2021), and involves a range of perpetrators (including State actors). Statistics on murder, the form of violence most extreme in its consequences, are alarming. Worldwide, there were over 4,000 documented killings between January 2008 and September 2021; a statistic widely regarded as flawed by under-reporting (TGEU, 2020).

Since the publication of the Standards of Care Version 7 (SOC-7), there have been dramatic changes in perspectives on TGD people and their health care. Mainstream global medicine no longer classifies TGD identities as a mental disorder. In the Diagnostic and Statistical Manual Version 5 (DSM-5) from the American Psychiatric Association (APA, 2013), the diagnosis of *Gender Dysphoria* focuses on any distress and discomfort that accompanies being TGD, rather than on the gender identity itself. A text revision (DSM-5-TR) was published in 2022. In the International Classification of Diseases, Version 11 (ICD-11), the diagnostic manual of the World Health Organization (WHO, 2019b), the *Gender Incongruence* diagnosis is placed in a chapter on sexual health and focuses on the person's experienced identity and any need for gender-affirming treatment that might stem from that identity. Such developments, involving a depathologization (or more precisely a de-psychopathologization) of transgender identities, are fundamentally important on a number of grounds. In the field of health care, they may have helped support a care model that emphasizes patients' active participation in decision-making about their own health care, supported by primary health care professionals (HCPs) (Baleige et al., 2021). It is reasonable to suppose these developments may also promote more socially inclusive policies such as legislative reform regarding gender recognition that facilitates a rights-based approach, without imposing requirements for diagnosis, hormone therapy and/or surgery. TGD people who have changed gender markers on key documents enjoy better mental health (e.g., Bauer et al., 2015; Scheim et al., 2020). A more rights-based approach in this area may contribute greatly to the overall health and well-being of TGD people (Arístegui et al., 2017).

Previous editions of the SOC have revealed much of the recorded clinical experience and knowledge in this area is derived from North American and Western European sources. They have focused on gender-affirming health care in high income countries that enjoy relatively well-resourced health care systems (including those with trained mental health providers, endocrinologists, surgeons and other specialists) and where services are often funded publicly or (at least for some patients) through private insurance.

For many countries, health care provision for TGD people is aspirational; with resourcing in this area limited or non-existent, and services often unavailable, inappropriate, difficult to access and/or unaffordable. Few if any HCPs (primary or specialist) may exist. Funding for gender-affirming health care may be absent, with patients often bearing the full costs of whatever health care they access. Health care providers often lack clinical and/or cultural competence in this area. Training for work with these patients may be limited (e.g., Martins et al., 2020). For all these reasons and because of mainstream "Western" medicine's historical view of TGD people as mentally disordered (a perspective that has only recently changed), TGD people have commonly found themselves disempowered as health care consumers.

Health care providers have found the relevant literature is largely North American and European, which present particular challenges for persons working in health care systems that are especially poorly resourced. Recent initiatives that often involve TGD stakeholders as partners are changing this situation somewhat by providing a body of knowledge about good practice in other regions, including how to provide effective, culturally-competent TGD health care in low- and middle-income countries outside the global north.

Within the field, a wide range of valuable health care resources have been developed in recent years. Dahlen et al (2021) review twelve international clinical practice guidelines; over half those reviewed originate from professional bodies based in North America (e.g., Hembree et al., 2017) or Europe (e.g., T'Sjoen et al., 2020). Three are from WHO (the most recent being WHO, 2016). Nowadays, there are numerous other resources, not on Dahlen et al.'s list, that explicitly draw on expertise from regions outside North America and Europe. Examples can be found in Asia and the Pacific (APTN, 2022; Health Policy Project et al., 2015), the Caribbean (PAHO, 2014), Thailand, Australia (Telfer et al., 2020), Aotearoa New Zealand (Oliphant et al., 2018), and South Africa (Tomson et al., 2021) (see also TRANSIT (UNDP et al., 2016)). These resources have commonly been created through the initiatives of or in partnership with TGD communities locally or internationally. This partnership approach, focused on meeting local needs in culturally safe and competent ways, can also have broad international relevance. Some of these publications may be of particular value to those planning, organizing and delivering services in low-income, low-resource countries. There are likely to be other resources published in languages other than English of which we are unaware.

Globally, TGD identities may be associated with differing conceptual frameworks of sex, gender, and sexuality and exist in widely diverse cultural (and sometimes spiritual) contexts and histories. Considering the complex relationships between social and cultural factors, the law, and the demand for and provisions of gender-affirming health care, the SOC-8 should be interpreted through a lens that is appropriate for and within the context of each HCP's individual practice while maintaining alignment to the core principles that underscore it (APTN and UNDP, 2012; Health Policy Project et al., 2015; PAHO, 2014).

It is within this context and by drawing broadly on the experiences of TGD people and health care providers internationally that we consider the global applicability of SOC-8 within this chapter. We set out key considerations for HCPs and conclude by recommending core principles and practices fundamental to contemporary health care for TGD people, regardless of where they live or whether there are resources available to those who seek to provide such health care.

Statement 2.1

We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.

Medical necessity is a term common to health care coverage and insurance policies globally. A common definition of medical necessity as used by insurers or insurance companies is "Health care services that a physician and/or health care professional, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with generally accepted standards of medical practice; (b) clinically

Statements of Recommendations

2.1- We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.
2.2- We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.
2.3- We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.
2.4- We recommend translations of the SOC focus on cross-cultural, conceptual, and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.
2.5- We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles
- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights including the right to bodily and mental integrity, autonomy and self-determination; freedom from discrimination, and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care
- Involve transgender and gender diverse people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and the capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion and avoid providing any direct or indirect support for such approaches or services.

Principles around delivering competent services
- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services including those related to administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches
- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease." The treating HCP asserts and documents that a proposed treatment is medically necessary for treatment of the condition (American Medical Association, 2016).

Generally, "accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, designated Medical Specialty Societies and/or legitimate Medical Colleges' recommendations, and the views of physicians and/or HCPs practicing in relevant clinical areas.

Medical necessity is central to payment, subsidy, and/or reimbursement for health care in parts of the world. The treating HCP may assert and document that a given treatment is medically necessary for the prevention or treatment of the condition. If health policies and practices challenge the medical necessity of a treatment, there may be an opportunity to appeal to a governmental agency or other entity for an independent medical review.

It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical

interventions. In many countries, medically necessary gender-affirming care is documented by the treating health professional as treatment for Gender Incongruence (HA60 in ICD-11; WHO, 2019b) and/or as treatment for Gender Dysphoria (F64.0 in DSM-5-TR; APA, 2022).

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments (e.g., Ainsworth & Spiegel, 2010; Aires et al., 2020; Aldridge et al., 2020; Almazan & Keuroghlian, 2021; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Buncamper et al., 2016; Cardoso da Silva et al., 2016; Eftekhar Ardebili, 2020; Javier et al., 2022; Lindqvist et al., 2017; Mullins et al., 2021; Nobili et al., 2018; Owen-Smith et al., 2018; Özkan et al., 2018; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Yang, Zhao et al., 2016). Gender-affirming interventions may also include hair removal/transplant procedures, voice therapy/surgery, counseling, and other medical procedures required to effectively affirm an individual's gender identity and reduce gender incongruence and dysphoria. Additionally, legal name and sex or gender change on identity documents can also be beneficial and, in some jurisdictions, are contingent on medical documentation that patients may call on practitioners to produce.

Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria (e.g., Aires et al., 2020; Aldridge et al., 2020; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Bertrand et al., 2017; Buncamper et al., 2016; Claes et al., 2018; Eftekhar Ardebili, 2020; Esmonde et al., 2019; Javier et al., 2022; Lindqvist et al., 2017; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Mullins et al., 2021; Nobili et al., 2018; Olson-Kennedy, Rosenthal et al., 2018; Özkan et al., 2018; Poudrier et al., 2019; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Wolter et al., 2015; Wolter et al., 2018).

Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of TGD individuals. In other words, governments should ensure health care services for TGD people are established, extended or enhanced (as appropriate) as elements in any Universal Health Care, public health, government-subsidized systems, or government-regulated private systems that may exist. Health care systems should ensure ongoing health care, both routine and specialized, is readily accessible and affordable to all citizens on an equitable basis.

Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

Statement 2.2

We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.

TGD people identify in many different ways worldwide, and those identities exist within a cultural context. In English speaking countries, TGD people variously identify as *transsexual,*

trans, gender nonconforming, gender queer or diverse, nonbinary, or indeed *transgender and/or gender diverse,* as well as by other identities; including (for many identifying inside the gender binary) *male* or *female.* (e.g., James et al., 2016; Strauss et al., 2017; Veale et al., 2019).

Elsewhere, identities include but are not limited to *travesti* (across much of Latin America), *hijra* (across much of South Asia), *khwaja sira* (in Pakistan), *achout* (in Myanmar), *maknyah, paknyah* (in Malaysia), *waria* (Indonesia) *kathoey, phuying kham phet, sao praphet song* (Thailand), *bakla, transpinay, transpinoy* (Philippines), *fa'afafine* (Samoa), *mahu* (French Polynesia, Hawai'i), *leiti* (Tonga), *fakafifine* (Niue), *pinapinaaine* (Tuvalu and Kiribati), *vakasalewalewa* (Fiji), *palopa* (Papua Niugini), *brotherboys* and *sistergirls* (Aboriginal and Torres Strait Islander people in Australia), and *akava'ine* (Cook Islands) (e.g., APTN and UNDP, 2012; Health Policy Project et al., 2015; Kerry, 2014). There are also a large number of *two spirit* identities across North America (e.g., *nadleehi* in Navajo (Diné) culture) (Sheppard & Mayo, 2013). The identities to which each of these terms refer are often culturally complex and may exist in a spiritual or religious context. Depending on the cultures and the identities concerned, some may be regarded as so-called "third genders" lying beyond the gender binary (e.g., Graham, 2010; Nanda, 2014; Peletz, 2009). Some TGD identities are less firmly established than others. In many places worldwide, the visibility of transgender men and nonbinary trans masculine identities is relatively recent, with few or no applicable traditional terms in local languages (Health Policy Project et al., 2015). Regardless of where or with whom HCPs work (including those working with ethnic minority persons, migrants and refugees), they need to be aware of the cultural context in which people have grown up and live as well as the consequences for health care.

Worldwide the availability, accessibility, acceptability and quality of health care vary greatly, with resulting inequities within and across countries (OECD, 2019). In some countries, formal health care systems exist alongside established traditional and folk health care systems, with indigenous models of health underpinning the importance of holistic health care (WHO, 2019a). HCPs should be aware of the traditions and realities within which health care is available and provide support that is sensitive to the local needs and identities of TGD people and provide them with culturally competent and safe care.

Statement 2.3

We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.

TGD people's lived experiences vary greatly, depending on a range of factors, including social, cultural (including spiritual), legal, economic and geographic. When TGD people live in environments that affirm their gender and/or cultural identities, then these experiences can be very positive. Families are particularly important in this regard (e.g., Pariseau et al., 2019; Yadegarfard et al., 2014; Zhou et al., 2021). However, when viewed from a global perspective, the circumstances in which TGD people live are often challenging. They are commonly denied widely accepted rights in international human rights law. These include rights to education, health and protection from medical abuses, work and an adequate standard of living, housing, freedom of movement and expression, privacy, security, life, family, freedom from arbitrary deprivation of liberty, fair trial, treatment with humanity while in detention, and freedom from torture, inhuman or degrading treatment or punishment (International Commission of Jurists, 2007, 2017).

It is widely accepted that denial of rights can impact sexual and gender minority health and well-being (e.g., OHCHR et al., 2016; WHO, 2015). We therefore reaffirm here the importance of the rights listed above for TGD people and note WPATH's previous rights advocacy, including through numerous policy documents (e.g., WPATH, 2016, 2017, 2019). HCPs can play an important role in rights advocacy, including the right to quality gender-affirming health care that is appropriate, affordable, and accessible.

Across the world, a large number of studies detail the challenges TGD people face in their lives, and the impact on their health and well-being (e.g., Aurat Foundation, 2016;

Bhattacharya & Ghosh, 2020; Chumakov et al., 2021; Coleman et al., 2018; Heylens, Elaut et al., 2014; Human Rights Watch, 2014; James et al, 2016; Lee, Operario et al., 2020; Luz et al., 2022; McNeil et al., 2012, 2013; Motmans et al., 2017; Muller et al., 2019; Scandurra et al., 2017; Strauss et al., 2019; Suen et al., 2017; Valashany & Janghorbani, 2019; Veale et al., 2019; Wu et al., 2017). The research shows TGD people often experience stigma and prejudice as well as discrimination and harassment, abuse and violence, or they live in anticipation and fear of such actions. Social values and attitudes hostile to TGD people, often communicated to young people in school curricula (e.g., Olivier & Thurasukam, 2018), are also expressed in family rejection (e.g., Yadegarfard et al., 2014), and perpetuated in laws, policies and practices that limit freedom to express one's gender identity and sexuality and hinder access to housing, public spaces, education, employment and services (including health care). The end result is TGD people are commonly deprived of a wide range of opportunities available to their cisgender counterparts and are pushed to the margins of society, without family supports. To make matters worse, across much of the world TGD people's access to legal gender recognition is restricted or non-existent (e.g., ILGA World, 2020a; TGEU, 2021; UNDP and APTN, 2017). In some countries, such barriers nowadays draw on support from "gender-critical theorists" (as critiqued by e.g., Madrigal-Borloz, 2021; Zanghellini, 2020).

Gender identity change efforts (gender reparative or gender conversion programs aimed at making the person cisgender) are widespread, cause harm to TGD people (e.g., APTN, 2020a, 2020b, 2020c, 2021; Bishop, 2019; GIRES et al., 2020; Turban, Beckwith et al., 2020), and (like efforts targeting sexual orientation) are considered unethical (e.g., APS, 2021; Trispiotis and Purshouse, 2021; Various, 2019, 2021). These efforts may be viewed as a form of violence. The UN independent expert on protection against violence and discrimination based on sexual orientation and gender identity has called for a global ban on such practices (Madrigal-Borloz, 2020). An increasing number of jurisdictions are outlawing such work (ILGA World, 2020b).

Inequities arise from a range of factors, including economic considerations and values underpinning the provision of health care systems, particularly with regard to the emphasis placed on public-, private- and self-funding of health care. Lack of access to appropriate and affordable health care can lead to a greater reliance on informal knowledge systems. This includes information about self-administration of hormones, which, in many cases, is undertaken without necessary medical monitoring or supervision (e.g., Do et al., 2018; Liu et al., 2020; Rashid et al., 2022; Reisner et al., 2021; Winter & Doussantousse, 2009).

In some parts of the world, large numbers of transgender women employ silicone as a means of modifying their bodies, drawing on the services of silicone "pumpers" and/or attending pumping "parties", often within their communities. The immediate results of silicone pumping contrast with significant downstream health risks (e.g., Aguayo-Romero et al., 2015; Bertin et al., 2019; Regmi et al., 2021), particularly where industrial silicone or other injectable substances have been used and where surgical removal may be difficult.

Finally, sexual health outcomes for TGD people are poor. HIV prevalence for transgender women reporting to clinical organizations in metropolitan areas is approximately 19% worldwide, which is 49 times higher than the background prevalence rate in the general population (Baral et al., 2013). Sexual health outcomes for transgender men are also problematic (e.g., Mujugira et al., 2021).

Statement 2.4

We recommend translations of the SOC focus on cross-cultural, conceptual and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.

Much of the research literature on TGD people is produced in high-income and English-speaking countries. global northern perspectives about TGD people (including those related to health care needs and provision) dominate this literature. A May 2021 Scopus database search undertaken by the current authors shows 99% of the literature on transgender health care comes out of Europe, North America, Australia, or New Zealand. Overall, 96% of the literature is in the English language. TGD people of the Global

South have received relatively little attention in the English language literature, and the work of those HCPs who interact with them has often gone unrecognized and unpublished or has not been translated into English. Applying resources produced in the global north risks overlooking the relevance and nuance of local knowledge, cultural frameworks and practices, and missed opportunities to learn from the work of others.

When translating the principles set out in the SOC, we recommend following best practice guidelines for language translation to ensure high quality written resources are produced that are culturally and linguistically appropriate to the local situation. It is important translators have knowledge about TGD identities and cultures to check that literal translations are culturally competent and safe for local TGD people. It is also important translation should follow established processes for quality assurance (Centers for Medicare & Medicaid Services, 2010; Sprager & Martinez, 2015)

Statement 2.5

We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles

- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care, for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights, including the right to bodily and mental integrity, autonomy, and self-determination; freedom from discrimination and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care

- Involve TGD people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion, and avoid providing any direct or indirect support for such approaches or services

Principles around delivering competent services

- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services, including those associated with administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches

- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

We have already cited research detailing the broad range of challenges TGD people may face; social economic and legal obstacles, as well those related to health care access. While overall health care services are diverse across the world (in terms of availability, accessibility, and quality), those services available to TGD people are often inadequate. Numerous reports from diverse regions worldwide show, while TGD people may report positive health care experiences, many others do not (e.g., Callander et al., 2019; Costa, da Rosa Filho et al., 2018; Do et al., 2018; Gourab et al., 2019; Health Policy Project et al., 2015; Liu et al., 2020; Motmans et al., 2017; Muller et al., 2019; PAHO, 2014; Reisner et al., 2021; Strauss et al., 2017; TGEU, 2017). Mainstream health care options often do not meet their needs for general, sexual, or gender-affirming health care. Standard patient management procedures at clinics and hospitals often fail to recognize the gender identities of their TGD patients (including where outside of the binary their patients identify). Patients may be housed in wards that are gender inappropriate for them, putting them at risk of sexual harassment. TGD patients often encounter unsupportive or hostile attitudes from HCPs and ancillary staff and may even be refused service. Of great concern, HCPs in some parts of the world are involved in gender identity change efforts of the sort described earlier in this chapter.

Throughout the world, there are many other barriers to the provision of gender-affirming health care. Health care professionals may often be unwilling to provide the services TGD people seek. In some countries, there may be laws or regulations inhibiting or preventing them from doing so. When general practitioners and other health care providers do not have access to clear guidelines in their own language, they may be deterred from providing services. Even in situations where health care is available, patients may find it is difficult to access because of distance, gatekeeping practices, supply and demand issues that result in long wait lists or cost increases. Indeed, gender-affirming procedures may not be incorporated into a universal health care provision or be covered by private insurance, even though similar procedures may be covered for cisgender patients.

For all these reasons, many TGD people avoid formal health care services whenever they can. Their own communities commonly fill the void, acting as important resources for their members. They provide social and emotional support, often in an otherwise hostile environment. In addition, they often act as reservoirs of shared information about available options for health care, including parallel and informal health care options outside of (and more accessible and affordable than) mainstream medicine. As we saw earlier in this chapter, this often includes sharing of information about silicone and other injectable substances for bodily transformation and about hormones that are self-administered without necessary medical monitoring or supervision. WHO notes TGD individuals who self-administer gender-affirming hormones would benefit from access to evidence-based information, quality products, and sterile injection equipment (WHO, 2021). Access to such information can form part of a broader harm reduction approach (e.g., Idrus & Hyman, 2014).

Putting the important core principles outlined above into practice can improve health care experiences and promote respect for TGD people in all local contexts. This can occur regardless of the realities of a health care system (including the cultural, social, legal, economic context in which health care is provided), the level of provision available, or the TGD people seeking such services.

CHAPTER 3 Population Estimates

In the previous edition of its Standards of Care, Version 7, World Professional Association for Transgender Health (WPATH) identified only a small number of articles attempting to estimate the size of the transgender and gender diverse (TGD) population and characterized the state-of-the-science as "a starting point" requiring further systematic study (Coleman et al., 2012). Since then, the literature on this topic has expanded considerably as evidenced by a number of recent reviews that have sought to synthesize the available evidence (Arcelus et al., 2015; Collin et al., 2016; Goodman et al., 2019; Meier & Labuski, 2013; Zhang et al., 2020).

In reviewing epidemiologic data pertaining to the TGD population, it may be best to avoid the terms "incidence" and "prevalence." Avoiding these and similar terms may preclude inappropriate pathologizing of TGD people (Adams et al., 2017; Bouman et al., 2017). Moreover, the term "incidence" may not be applicable in this situation because it assumes TGD status has an easily identifiable time of onset, a prerequisite for calculating incidence estimates (Celentano & Szklo, 2019). For all the above reasons, we recommend using the terms "number" and "proportion" to signify the absolute and the relative size of the TGD population.

Perhaps the most important consideration in reviewing this literature is the variable definition applied to the TGD population (Collin et al., 2016; Meier & Labuski, 2013). In clinic-based studies, the data on TGD people are typically limited to individuals who received transgender-related diagnoses or counseling or those who requested or underwent gender-affirming therapy, whereas survey-based research typically relies on a broader, more inclusive definition based on self-reported gender identities.

Another methodological consideration in assessing the size and distribution of the TGD population is the need to understand what constitutes the sampling frame. As noted in recent reviews (Goodman et al., 2019; Zhang et al., 2020), many of the published studies, especially those conducted more than a decade ago, first assessed the number of patients seen at a particular clinical center and then divided that number by an approximated population size. This was unlikely to produce an accurate estimate because the numerator in the calculations is not necessarily included in the denominator, and the true size of the denominator often remains unknown.

With these considerations in mind, it is advisable to focus specifically on recent (published within the last decade) peer-reviewed studies that utilized sound methodology in identifying TGD people within a well-defined sampling frame. For all of the above reasons, the present chapter is focused on studies that met the following inclusion criteria 1) appeared in press in 2009 or later; 2) used a clear definition of TGD status; 3) calculated proportions of TGD people based on a well-defined population denominator; and 4) were peer-reviewed. These types of studies can provide more accurate contemporary estimates.

The available studies can be assigned into three groups 1) those that reported proportions of TGD people among individuals enrolled in large health care systems; 2) those that presented results from population surveys of predominantly adult participants; and 3) those that were based on surveys of youth conducted in schools. Of these three categories, the most informative and methodologically sound studies are summarized below. Additional details about these and other similar studies can be found in recent literature reviews (Goodman et al., 2019; Zhang et al., 2020).

Among studies that estimated the size of the TGD population enrolled in large health care systems, all were conducted in the US, and all relied on information obtained from electronic health records. Four of those health system-based studies relied exclusively on diagnostic codes to ascertain the TGD population; two studies (Blosnich et al., 2013; Kauth et al., 2014) used data from the Veterans Health Affairs system, which provides care to over 9 million people, and two studies (Dragon et al., 2017; Ewald et al., 2019) used claims data from Medicare, the federal health insurance program that primarily covers people 65 years of age or older. The proportions of TGD people reported in these diagnostic code-based studies ranged from approximately 0.02% to 0.03%. Another more recent publication also used Medicare data along with commercial insurance claims to identify TGD people and applied expanded inclusion criteria to supplement

diagnostic codes with information on procedures and hormone therapy (Jasuja et al., 2020). Using this methodology, the proportion of TGD people among all persons enrolled in the participating health plans was 0.03%. The sixth health systems-based study (Quinn et al., 2017) was conducted at Kaiser Permanente plans in the states of Georgia and California; these plans provide care to approximately 8 million members enrolled through employers, government programs, or individually. The TGD population in the Kaiser Permanente study was ascertained across all age groups using both diagnostic codes and free-text clinical notes. The proportions of TGD people identified at Kaiser Permanente were higher than the corresponding proportions reported in the Veterans Health Affairs and Medicare studies with the most recent estimates ranging from 0.04 to 0.08%.

In contrast to results from the health system-based studies, findings from surveys that relied on self-reported TGD status produced much higher estimates. Two US studies took advantage of the Behavioral Risk Factor Surveillance Study (BRFSS), which is an annual telephone survey conducted in all 50 states and US territories (Conron et al., 2012; Crissman et al., 2017). The first study used data from the 2007–2009 BRFSS cycles in the state of Massachusetts, and the second study used the 2014 BRFSS data from 19 states and the territory of Guam. Both studies reported that approximately 0.5% of adult participants (at least 18 years of age) responded *"Yes"* to the question *"Do you consider yourself to be transgender?"*

An internet-based survey administered to a sample of the Dutch population 15–70 years of age (Kuyper & Wijsen, 2014) asked participants to score the following two questions using a 5-point Likert scale: *"Could you indicate to which degree you psychologically experience yourself as a man?"* and *"Could you indicate to which degree you psychologically experience yourself as a woman?"* The respondents were considered "gender ambivalent" if they gave the same score to both statements and "gender incongruent" when they reported a lower score for their sex assigned at birth than for their gender identity. The proportions of participants reporting incongruent and ambivalent gender identity were 1.1% and 4.6%, respectively, for persons who were assigned male at birth (AMAB), and 0.8% and 3.2%, respectively, for persons assigned female at birth (AFAB).

A similarly designed study estimated the proportion of TGD residents in the Flanders region of Belgium using a sample drawn from the country's National Register (Van Caenegem, Wierckx et al., 2015). Participants were asked to score the following statements: *"I feel like a woman"* and *"I feel like a man"* on a 5-point Likert scale. Using the same definitions applied in the Dutch study (Kuyper & Wijsen, 2014), the proportion of gender incongruent individuals was 0.7% for AMAB people and 0.6% for AFAB people. The corresponding estimates for gender ambivalence among AMAB and AFAB people were 2.2% and 1.9%, respectively.

A more recent population-based study evaluated the proportion of TGD people among approximately 50,000 adult residents of Stockholm County, Sweden (Åhs et al., 2018). The numerator was determined by asking participants the following question: *"I would like hormones or surgery to be more like someone of a different sex."* Two additional items were designed to identify individuals experiencing gender incongruence: *"I feel like someone of a different sex"* and *"I would like to live as or be treated as someone of a different sex."* The need for either hormone therapy or gender-affirming surgery was reported by 0.5% of participants. Individuals who expressed feeling like someone of a different sex and those who wanted to live as or be treated as a person of another sex constituted 2.3% and 2.8% of the total sample, respectively.

Population-based data outside of North America and Western Europe are less common. One recent study offers valuable data from a large representative survey of 6,000 adults in Brazil (Spizzirri et al., 2021). Gender identity of participants was assessed based on the following three questions 1) *"Which of the following options best describes how you currently feel?"* (Options: I feel I am a man, I feel I am a woman, and I feel I am neither a man nor a woman); 2) *"What is the sex on your birth certificate?"* (Options: male, female, and undetermined); and 3) *"Which of*

these situations do you most closely relate to?" (Options: I was born male, but I have felt female since childhood; I was born female, but I have felt male since childhood; I was born male, and I feel comfortable with my body; I was born female, and I feel comfortable with my body). Based on the responses to these three questions, the authors determined 1.9% of the survey respondents were TGD (0.7% defined as transgender, and 1.2% defined as nonbinary).

The literature on the population proportions of TGD youth (persons under 19 years of age) includes several survey studies conducted in schools. A 2012 national cross-sectional survey in New Zealand collected information on TGD identity among high school students (Clark et al., 2014). Among over 8,000 survey participants, 1.2% self-identified as TGD and 2.5% reported they were not sure. Another study of schoolchildren was based on a 2016 survey of 9th and 11th grade students (ages 14–18 years) in the US state of Minnesota (Eisenberg et al., 2017). Of the nearly 81,000 survey respondents, 2.7% reported being TGD. A more recent study (Johns et al., 2019) presented results of the Youth Risk Behavior Survey (YRBS), which is conducted biennially among local, state, and nationally representative samples of US high school students in grades 9–12 (approximate age range 13–19 years). The 2017 YRBS cycle was carried out in 10 states and 9 large urban areas and included the following sequence: "*Some people describe themselves as transgender when their sex at birth does not match the way they think or feel about their gender. Are you transgender*?" Among nearly 120,000 participants across the 19 sites, 1.8% responded "*Yes, I am transgender,*" and 1.6% responded "*I am not sure if I am transgender.*"

Another recently published school-based study in the US presented results of a 2015 survey conducted in Florida and California with the aim of identifying gender diverse children and adolescents in a sample of just over 6,000 students in grades 9–12 (Lowry et al., 2018). "High gender-nonconforming" was used to define AMAB children who reported being very/mostly/somewhat feminine or AFAB children who reported being very/mostly/somewhat masculine. Based on these definitions, the proportions of TGD participants were reported to be 13% among AMAB students, 4% among AFAB students, and 8.4% overall.

Only one study examined the proportion of self-identified TGD children in a younger age group. Shields et al. analyzed the data from a 2011 survey of 2,700 students in grades 6–8 (age range 11–13 years) across 22 San Francisco public middle schools (Shields et al., 2013). Thirty-three children self-identified as TGD based on the question *"What is your gender?"* where the possible responses were *"female, male, or transgender."* The resulting proportion of transgender survey respondents was 1.3%. However, this definition would exclude TGD persons self-identifying as nonbinary and those who do not explicitly identify as transgender.

Taken together, these data indicate among health system-based studies that relied on diagnostic codes or other evidence documented in the medical records (Blosnich et al., 2013; Dragon et al., 2017; Ewald et al., 2019; Kauth et al., 2014; Quinn et al., 2017), the proportions of TGD people reported in recent years (2011–2016) ranged from 0.02% to 0.08%. By contrast, when the TGD status was ascertained based on self-report, the corresponding proportions were orders of magnitude higher and reasonably consistent, if the studies used similar definitions. When the surveys specifically inquired about "transgender" identity, the estimates ranged from 0.3% to 0.5% among adults and from 1.2% to 2.7% in children and adolescents. When the definition was expanded to include broader manifestations of gender diversity, such as gender incongruence or gender ambivalence, the corresponding proportions were higher: 0.5% to 4.5% among adults and 2.5% to 8.4% among children and adolescents.

As reviewed elsewhere (Goodman et al., 2019), another noteworthy observation is the continuous increase in both the size and the composition of the TGD population with upward trends in the proportion of TGD people observed in health care systems, through population-based surveys, as well as in the data on legal gender recognition. The higher estimates observed in more recent literature support some of the previous publications indicating the size of TGD population was

Summary of reported proportions of TGD people in the general population

Health systems-based studies: 0.02–0.1%
Survey-based studies of adults: 0.3–0.5% (transgender), 0.3–4.5% (all TGD)
Survey-based studies of children and adolescents: 1.2–2.7% (transgender), 2.5–8.4% (all TGD)

likely underestimated in earlier studies (Olyslager & Conway, 2008).

The temporal trends in AMAB to AFAB ratio have also been reported in studies analyzing referrals to clinics as well as data from integrated health systems; this ratio has changed from predominantly AMAB in previous decades to predominantly AFAB in recent years, especially among TGD youth (Aitken et al., 2015; de Graaf, Carmichael et al., 2018; de Graaf, Giovanardi et al. 2018; Steensma et al., 2018; Zhang et al., 2021). The trend towards a greater proportion of TGD people in younger age groups and the age-related differences in the AMAB to AFAB ratio likely represent the "cohort effect," which reflects sociopolitical advances, changes in referral patterns, increased access to health care and to medical information, less pronounced cultural stigma, and other changes that have a differential impact across generations (Ashley 2019d; Pang et al., 2020; Zhang et al., 2020).

Despite recent improvements in the quality of published studies, an important limitation of the existing literature is the relative paucity of peer-reviewed publications from regions outside of Western Europe or North America. Some of the relevant information on global estimates can be obtained from reports supported by the governments or non-governmental organizations (Fisher et al., 2019; Kasianczuk & Trofymenko, 2020), but these reports may be difficult to systematically identify and evaluate until they appear in peer-reviewed literature. Other barriers to evaluating the global distribution of the TGD populations include inadequate access to demographic data and over-representation of English-language journals in the world literature.

These limitations notwithstanding, the available highest-quality data clearly indicate TGD people represent a sizable and growing proportion of the general population. Based on the credible evidence available to date, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location. Accurate estimates of the proportion, distribution, and composition of the TGD population as well as a projection of resources required to adequately support the health needs of TGD people should rely on systematically collected high-quality data, which are now increasingly available. Continuous and routine collection of these data is needed to decrease variability and minimize over- and under-estimation of the reported results. For example, far more accurate and precise estimates should become available when population censuses begin systematically collecting and reporting data on sex assigned at birth and gender identity, including asexual and nonbinary categories, using the now well-validated two-step method. The first such census-based estimate was released by the national statistical office of Canada. Based on the 2021 census data, 100,815 of 30.5 million Canadians self-identified as transgender or nonbinary; this accounted for 0.33% of the population 15 years of age or older (Statistics Canada, 2022). Consistent with the published literature, the proportions of transgender and nonbinary people were much higher for Generation Z (born between 1997 and 2006, 0.79%) and millennials (born between 1981 and 1996, 0.51%) than for Generation X (born between 1966 and 1980, 0.19%), baby boomers (born between 1946 and 1965, 0.15%), and the Interwar and Greatest Generations (born in 1945 or earlier, 0.12%). While these results represent the highest quality data available to date, it is not clear how the population proportions reported in Canada may compare with those in other countries. The variability in the definitions of what constitutes the TGD population and the differences in data collection methods can be reduced further by improving international collaborations.

CHAPTER 4 Education

This chapter will provide a general review of the literature related to education in transgender and gender diverse (TGD) health care. Recommendations are offered at governmental, nongovernmental, institutional, and provider levels with the goal of increasing access to competent, compassionate health care. In turn, this increased access should improve health outcomes in TGD populations. As this is a novel chapter in the World Professional Association for Transgender Health (WPATH) Standards of Care, the intent is to lay the groundwork for the education area and invite a broader and deeper discussion among educators and health professionals.

Health professionals involved in transgender care encompass a broad range of disciplines. Health professional education varies considerably by country or region in terms of structure, licensure, and policy. Published literature on education in TGD health care is predominantly from North America, Europe, Australia and New Zealand. This chapter does not provide a review of the education literature for each discipline, the needs specific to each discipline (which can be found in the relevant chapters), or the needs specific to each country/region's health education system. Greater understanding and research are needed on the intersection of health education systems, licensure, and transgender health across the world.

On a global level, TGD health education is imperative if national and international health disparities are to be addressed. Cultural competency related to TGD communities continues to be lacking. The World Bank Group (2018) reports widespread discrimination, harassment, violence, and abuse affecting TGD people. They also report TGD people face the highest rates of violence and discrimination (World Bank Group, 2018). Although many higher income countries have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018).

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing education—historically have ignored TGD cultural or clinical education. The Joint Commission (US) has recommended health care organizations "provide educational programs and forums that support the unique needs of the LGBT community" and "offer educational opportunities that address LGBT health issues" (The Joint Commission, 2011). However, this is not enforced.

On an individual level, several questions need answers. What type of education interventions can most effectively address transphobia and lead to long-standing changes in attitudes? What interventions translate into increasing the number of care providers in this area as well as the number of TGD people receiving care? Does clinical exposure increase the confidence of providers over time? What educational interventions lead to improved health outcomes in the TGD population and, if so, when and how did these interventions accomplish this? Although health professions have begun to incorporate TGD health into education using a variety of modalities and at varying levels of training, efforts differ by health profession and are neither systemic nor systematic in nature (e.g., Brennan et al., 2012; Chinn, 2013; Eliason et al., 2010; Lim et al., 2015; Obedin-Maliver et al., 2011; Rondahl, 2009).

Attaining cultural humility with the full appreciation of the intersectionality of humanity is an ultimate educational goal. That said, this initial call for education is focused on building the foundation in cultural awareness and cultural competency that is currently weak or non-existent in much of the world.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

4.1- We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity and respect.
4.2- We recommend all members of the health care workforce receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.
4.3- We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Recommendation 4.1

We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity and respect.

Article 1 of the United Nations Universal Declaration of Human Rights states, "All human beings are born free and equal in dignity and rights" (United Nations, 1948). Only recently has this fundamental statement included the recognition that TGD rights are human rights (UNOCHR, 2018). Globally, training at all levels about TGD communities continues to be lacking. As recently as 2002, only 3% of Fortune 500 companies had antidiscrimination protection for TGD employees, and none offered insurance coverage for gender-affirming health care (Human Rights Campaign Foundation, 2017). By 2022, 91% of Fortune 500 companies included gender identity in US non-discrimination policies, and 66% offered TGD-inclusive insurance coverage. However, only 72% provide any form of lesbian, gay, bisexual, transgender and queer/questioning (LGBTQ) cultural knowledge training for their workforce (Human Rights Campaign Foundation, 2022). This lack of understanding fosters discrimination across the board. Taken together, these inconsistencies negatively affect the health of individuals and communities and exacerbate the health disparities and inequities they face. In Britain, only 28% of TGD workers felt the senior leadership were committed to TGD equality; only 21% of TGD employees would consider reporting transphobic harassment in the workplace (Stonewall, 2018). For those who are openly TGD, 34% were excluded by their co-workers, 35% were abused by customers, 24% were denied promotion due to their gender identity, and 11% were fired (Stonewall, 2018). In southeastern Europe, the World Bank stated there is widespread discrimination, harassment, violence, and abuse, and TGD people in that region faced the highest rates of violence and discrimination (World Bank Group, 2018). Often the discrimination went unreported with 60% of individuals not filing a report because of a lack of faith the complaint would be addressed, a fear of further discrimination or ridicule, and a reluctance to be outed (World Bank Group, 2018). Although many countries in the region have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018). It is the responsibility of the governmental, nongovernmental, and private agencies in these countries with anti-discrimination laws to ensure the rights of the TGD population. They are, therefore, obligated to find ways in which discrimination and stigma can be decreased. One of these is through education. Local cultures that foster anti-TGD attitudes are often a barrier to this needed education. Although cultural competency trainings have led to equivocal results, Shepherd (2019) recommends that providing cultural knowledge training that prioritizes local cultural issues and focuses on the values of openness, non-judgment, and responsiveness may lead to the desired results. Implementing cultural knowledge training requires a leadership willing to prioritize the training and to dedicate the time, money, and human capital to delivering initial and ongoing training.

Recommendation 4.2

We recommend all members of the health care workforce receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing

education—historically have ignored TGD cultural or clinical education. Factors contributing to this lack of inclusion include lack of faculty knowledge, experience, comfort with the subject matter, faculty bias, limited space within the existing curriculum, and lack of guidance on how to integrate the topics (McDowell & Bower, 2016). Research into the lack of and the need for such education does not specifically address TGD health concerns. Rather, the existing literature subsumes TGD health education within the broader discussion of the lack of LGBTQ-focused cultural and clinical-competency training. As an example, nursing baccalaureate programs included only an average of 2.12 hours of instruction on LGBTQ health (Lim et al., 2015). A fair assumption is that the amount of time devoted to TGD-specific health issues constituted only a fraction of this time.

Within the broader context of LGBTQ competency, the lack of TGD cultural- and clinical-competency training is a long-known shortfall of health care education (Aldridge et al., 2021). In the US, the Department of Health and Human Services' *Healthy People 2020,* (United States Department of Health and Human Services (2013, April 10)), the National Academy of Medicine (The Institute of Medicine, 2011), and the Joint Commission (The Joint Commission, 2011) all recognized lack of education negatively impacts the ability of LGBTQ people, including TGD individuals, to obtain appropriate, medically necessary care. The UK's House of Commons Women and Equalities Committee found lack of education contributed to TGD health disparities in the National Health Service (House of Commons Women and Equalities Committee, 2015, December 8). The lack of TGD health care education has been identified in the US (Obedin-Maliver et al., 2011), UK (Tollemache et al., 2021), South Africa (de Vries et al., 2020; Taylor et al., 2018; Wilson et al., 2014), Canada (Bauer et al., 2014), Australia (Riggs & Bartholomaeus, 2016), Sweden, Spain, Serbia, Poland (Burgwal et al., 2021), and Pakistan (Martins et al., 2020) among other countries.

In addition to developing curriculum, Shepherd (2022) states both clinical and organizational components are necessary to improve clinical encounters and consumer satisfaction. On an organizational level, it must be feasible as well as locally and practically oriented (Shepherd, 2022). On an individual level, in addition to knowledge training, health care professionals are better served employing generic traits that focus on the values of openness, non-judgment, and responsiveness (Shepherd, 2018).

Recommendation 4.3.

We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Each health profession has its own educational institutions, administrative, and licensing bodies, which vary by country and specialization within the profession. No major health professional organizations, educational institutions, or licensing bodies appear to require training in TGD health. While these organizations increasingly recommend including LGBTQ intersex health, rarely do they specify competencies, skills, or learning objectives for working with TGD people within their specialty. Published material on health professional education in TGD health is focused primarily on nursing, medicine, and mental health and is predominantly from North America, Europe, Australia, and New Zealand. An increased understanding of transgender health and medical/health professional education systems and requirements globally is essential.

Despite the increasing visibility of TGD people, access to knowledgeable and culturally- competent health professionals remain an overwhelming need around the world (James et al., 2016; Lerner et al., 2020; Müller, 2017). Lack of knowledgeable providers is a major barrier to gender-affirming care for transgender persons (Puckett et al., 2018; Safer et al., 2016) and contributes to large health disparities (Giffort & Underman, 2016; Reisman et al., 2019). The lack of adequate professional education in TGD health is a global problem (Do & Nguyen, 2020; Martins et al., 2020; Parameshwaran et al., 2017) that occurs at all levels of training (Dubin et al., 2018) and traverses health disciplines (Glick et al., 2020; Gunjawate et al., 2020; Johnson & Federman,

2014) and medical specialties (Fung et al., 2020; Korpaisarn and Safer, 2018).

Challenges remain as studies to date have small sample sizes, involve one-time training, include multiple disciplines at multiple career levels, focus on short-term outcomes, and often cover all LGBTQI topics rather than TGD-specific ones that are usually acquired post-licensure and are not the focus of most currently studied educational interventions (Dubin et al., 2018).

To successfully implement the recommendations, institutions may need to consider developing 1) systemic and systematic approaches to developing and implementing competencies for each health discipline across the professional lifespan; 2) standardized assessments for learners, with input from the TGD community; and 3) allotment of curricular resources, including trained faculty, as well as time in accordance with clear, consensual learning objectives (Dubin et al., 2018; Pratt-Chapman, 2020). In addition, evaluations of these interventions should not only focus on outcomes but also strive to understand how, when, and why these outcomes are occurring (Allen et al., 2021).

CHAPTER 5 Assessment of Adults

This chapter provides guidance for the assessment of transgender and gender diverse (TGD) adults who are requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs) to better align their body with their gender identity (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1).

TGD adults are people at or above the age of majority in their country, who have some form of gender diversity. The developmental elements of the adolescent chapter, including the importance of parental/caregiver involvement, may be relevant for the care of young adults too, even if they are above the age of majority.

This chapter includes all forms of gender identities and transitions including, but not limited to, male, female, gender diverse, nonbinary, agender, and eunuch. The population of TGD adults is heterogeneous and will vary according to their clinical need, biological, psychological, and social situations, as well as their access to health care. As such, any assessment for GAMSTs will need to be adapted to the scientific, clinical, and community knowledge base of the presenting gender identity as well as local circumstances. This chapter recognizes individuals may experience different local levels of clinical or regulatory oversight when the state or others are providing health care.

An individual's gender identity is an internal identification and experience. The role of the assessor is to assess for the presence of gender incongruence and identify any co-existing mental health concerns, to offer information about GAMSTs, to support the TGD person in considering the effects/risks of GAMSTs, and to assess if the TGD person has the capacity to understand the treatment being offered and if the treatment is likely to be of benefit. The assessor can also assist a TGD person to consider choices that could improve their GAMST outcomes. The GAMST assessment approach described in this chapter recognizes the lived experience and self-knowledge of the TGD person and the clinical knowledge of the assessing health care professional (HCP). Consequently, with this approach, the decision to move forward with GAMSTs is shared between the TGD person and the assessing HCP, with both playing a key part in collaborative decision-making.

Some systems use a model of care for TGD adults seeking GAMSTs that prioritizes the TGD adult as the decision maker with the HCP acting as an advisor, barring serious contraindications. These models are used when considering hormone therapy rather than surgery and are often called "informed consent" models (Deutsch, 2011, 2016a). Many such models utilize an abbreviated assessment that focuses primarily on the ability of a TGD person to grant informed consent and to utilize information about GAMSTs to inform their medical decision-making. There is significant variability in such models across jurisdictions, systems, and HCPs (Deutsch, 2011; Morenz et al., 2020). Informed consent models have been used for some time for hormone prescription in many local settings.

This chapter is intended to offer flexible global guidance that must be adapted to local circumstances. HCPs will need to determine which assessment approaches best meet the needs in their local settings. The evaluation of these approaches is best undertaken in collaboration with TGD people.

Since TGD people represent a diverse array of gender identities and expressions and have differing needs for GAMSTs, no single assessment process will fit every person or every situation. Some TGD people may need a comparatively brief assessment process for GAMSTs. For TGD adults with a complex presentation or for those who are requesting less common treatments or treatments with limited research evidence, more comprehensive assessments with different members of a multidisciplinary team will be required. Assessments may be in person or through telehealth. While psychometric assessment tools have been used in some instances, they are not a required part of the assessment for GAMSTs. Counseling or psychotherapy can be helpful when requested by a TGD person. However, counseling or psychotherapy specifically focused on their TGD identity is not a requirement for the assessment or initiation of GAMSTs. Genital exams are not a prerequisite for initiation of GAMTs and should be performed only when clinically indicated.

GAMSTs can be delivered in diverse settings. Settings will depend on available health care systems within each country and may include nationalized/public health care, private sector settings, community health care settings, and charitable institutions. Local and regional circumstances may therefore influence the availability of health care. Regardless of the setting, health care offered to TGD people should be of the highest possible quality. World Professional Organization for Transgender Health (WPATH) advocates for assessment and treatment to be readily available. Access to assessment and treatment for TGD people seeking GAMSTs is critical given the clear medical necessity of these interventions and the profound benefits they offer to TGD people (Aldridge et al., 2020; Byne et al., 2012). The guidance in this chapter will need to be adapted according to local, as well as individual, clinical, and social circumstances.

The statements below are based on significant background literature, including literature demonstrating the strong positive impact of access to GAMSTs; available empirical evidence; a favorable risk-benefit ratio; and consensus of professional best practice. The empirical evidence base for the

Statements of Recommendations

5.1- We recommend health care professionals assessing transgender and gender diverse adults for physical treatments:
5.1.a- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.
5.1.b- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.
5.1.c- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.
5.1.d- Are able to assess capacity to consent for treatment.
5.1.e- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.
5.1.f- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.
5.2- We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):
5.3- We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:
5.3.a- Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.
5.3.b- Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.
5.3.c- Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.
5.3.d- Ensure that any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.e- Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.f- Assess the capacity to consent for the specific physical treatment prior to the initiation of this treatment.
5.3.g- Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.
5.4- We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.
5.5- We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.
5.6- We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).
5.7- We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professional in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

assessment of TGD adults is limited. It primarily includes an assessment approach that uses specific criteria that are examined by an HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research (Olsen-Kennedy et al., 2016). This is understandable given the complexity and ethical considerations of allocating patients in need of care to different assessment groups and the lack of funding for research and other resources to assess long-term outcomes of assessment approaches.

The creation of this guidance has been a complex undertaking. The criteria in this chapter have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to care. It is hoped that future research will explore the effectiveness of this model as well as evolving assessment models for hormone therapy and for surgery that will allow continued improvements to be made.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 5.1.

We recommend health care professional assessing transgender and gender diverse adults for gender-affirming treatments:

Statement 5.1.a

Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.

TGD people, as with all other people seeking health care, should have the highest quality of care accessible that is commensurate with the quality of care provided to all people utilizing health services (The Yogyakarta Principles, 2017). As this will vary around the globe, the nature of the professional completing an assessment for GAMSTs will vary according to the nature of health care in the local setting as well as the regulatory requirements set by licensing and registration boards. It is important the health care provided includes an assessment conducted by a competent, statutorily regulated HCP who has the competence to identify gender incongruence and conditions that can be mistaken for gender incongruence and who can support the TGD person throughout the assessment process (RCGP, 2019). Assessors must be able to refer to HCPs licensed to provide GAMSTs.

HCPs should have at a minimum a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training and be statutorily regulated; examples include a mental health professional (MHP), general medical practitioner, nurse, or other qualified HCP. In some settings, statutorily regulated HCPs with lower levels of qualification may practice under the clinical supervision of a qualified HCP who takes ultimate clinical responsibility for the quality and accuracy of the completed GAMST assessment. For additional information see Chapter 4—Education.

Accessing a competent, statutorily regulated, HCP with expertise in GAMST assessment can sometimes be difficult. Consequently, ensuring continuity of care and minimizing gaps in accessible care or significantly delayed care (e.g., a long waiting list) may require that a statutorily regulated HCP without expertise provide care and support the assessment of a TGD person for GAMSTs. Avoiding unnecessary delays in care is critically important. However, TGD people should be supported to access care with an experienced HCP as soon as possible (RCGP, 2019).

Established practice requires the competence to identify and diagnose gender incongruence (Hembree et al., 2017; Reed et al., 2016; T'Sjoen et al., 2020) and the ability to identify differentials or conditions that may be mistaken as gender incongruence (Byne et al., 2018; Dhejne et al., 2016; Hembree et al., 2017). Established practice also strongly emphasizes the need for ongoing continuing education in the assessment and provision of care of TGD people (American Psychological Association, 2015; T'Sjoen et al., 2020). For more information see Chapter 4—Education.

Statement 5.1.b

For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health

Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.

In some countries, a diagnosis of gender incongruence may be necessary to access GAMSTs (as described below). HCPs assessing TGD people in those countries should be competent to diagnose gender incongruence using the most current classification system necessary for TGD people to access GAMSTs. The ICD-11 (WHO, 2019a) is a classification system that focuses on the TGD person's experienced identity and any need for GAMSTs and does not consider a TGD identity to be a mental illness.

Statement 5.1.c

Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.

Gender diversity is a natural variation in people and is not inherently pathological (American Psychological Association, 2015). However, assessment is best provided by an HCP who possesses some expertise in mental health in order to identify conditions that can be mistaken for gender incongruence. Such conditions are rare and, when present, are often psychological in nature (Byne et al., 2012; Byne et al., 2018; Hembree et al., 2017).

The need to include an HCP with some expertise in mental health does not require the inclusion of a psychologist, psychiatrist, or social worker in each assessment. Instead, a general medical practitioner, nurse, or other qualified HCP could also fulfill this requirement if they have sufficient expertise to identify gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity, assist a TGD person in care planning and preparation for GAMSTs, and refer to a mental health professional (MHP), if needed. As discussed in greater depth in the mental health chapter, MHPs have an important role to play in the care of TGD people. For example, the prejudice and discrimination experienced by some TGD people (Robles et al., 2016) can lead to depression, anxiety, or worsening of other mental health conditions. In such cases, an MHP can diagnose, clarify, and treat mental health conditions. MHPs and HCPs with expertise in mental health are well-placed to assess for GAMSTs, as well as to support TGD people who require or request mental health input or support during their transition. For additional information see Chapter 18—Mental Health.

Statement 5.1.d

Are able to assess capacity to consent for treatment.

An assessment for GAMSTs must include an examination of the TGD person's ability to consent to the proposed treatment. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes. It also requires the ability to retain that information for the purposes of making the decision (using aids as necessary) as well as the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007).

Some TGD individuals will have the capacity to grant consent immediately during the assessment. Some TGD individuals may need a longer process to be able to consent through ongoing discussion and the practice of medical decision-making skills. The presence of psychiatric illness or mental health symptoms do not pose a barrier to GAMSTs unless the psychiatric illness or mental health symptoms affect the TGD person's capacity to consent to the specific treatment being requested or affect their ability to receive treatment. This is especially important because GAMSTs have been found to reduce mental health symptomatology for TGD people (Aldridge et al., 2020).

Health care systems can consider GAMSTs for individuals who may not be able to directly consent if an appropriate legal guardian or regulator-approved independent decision maker with the power to determine health care treatment grants consent and confirms the proposed treatment is in alignment with the TGD individual's needs and wishes.

Statement 5.1.e

Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity. For supporting text, see Statement 5.1.f.

Statement 5.1.f

Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.

As in any other area of clinical practice, it is vital HCPs who are providing assessment for the initiation of GAMSTs are knowledgeable and experienced in the health care of TGD people. If this is not possible in the local context, the HCP providing the assessment should work closely with an HCP who is knowledgeable and experienced. As part of their clinical practice, HCPs should commit to ongoing training in TGD health care, become a member of relevant professional bodies, attend relevant professional meetings, workshops or seminars, consult with an HCP with relevant experience, and/or engage with the TGD community. This is particularly important in TGD health care as it is a relatively new field, and the knowledge and terminology are constantly changing (American Psychological Association, 2015; Thorne, Yip et al., 2019). Consequently, keeping up to date in the areas of TGD health is vital for anyone involved in an assessment for GAMSTs.

Statement 5.2

We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

If required and if possible, assessment for GAMST should be conducted by a multidisciplinary team (Costa, Rosa-e-Silva et al., 2018; Hembree et al., 2017; Karasic & Fraser, 2018; T'Sjoen et al., 2020) with team members who have timely and adequate contact with one another. This could include an MHP, an endocrinologist, a primary care provider, a surgeon, a voice and communication specialist, TGD peer navigator, and others. In some cases, a multidisciplinary team may not be required; however, should a multidisciplinary team be needed, it is critical HCPs be able to access colleagues from different disciplines in a timely manner to complete the GAMST assessment and best support the needs of the TGD person. It is also critical TGD people be supported with follow-up appointments with any HCP who was involved during the assessment for GAMSTs, prior to, during, and after the initiation of gender-affirming treatments.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):

Statement 5.3

We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:

Statement 5.3.a

Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.

To access GAMSTs, a TGD person's gender incongruence must be marked and sustained. This can include a need for GAMSTs and a desire to be accepted as a person of the experienced gender. Consequently, a consideration of the nature, length and consistency of gender incongruence is important. This can include such factors as a change of name and identity documents, telling others about one's gender, health care documentation, or changes in gender expression. However, marked and sustained gender incongruence can exist in the absence of disclosure to others by the TGD person (Brumbaugh-Johnson & Hull, 2019; Saeed et al., 2018; Sequeira et al., 2020). An abrupt or superficial change in gender identity or lack of persistence is insufficient to initiate gender- affirming treatments, and further assessment is recommended. In such circumstances, ongoing assessment is helpful to ensure the consistency and persistence of gender incongruence before GAMSTs are initiated.

While marked and sustained gender incongruence should be present, it is not necessary for TGD people to experience severe levels of distress regarding their gender identity to access gender- affirming treatments. In fact, access to gender-affirming treatment can act as a prophylactic measure to prevent distress (Becker et al., 2018; Giovanardi et al., 2021; Nieder et al., 2021; Nobili et al., 2018; Robles et al., 2016). A TGD adult can have sustained gender incongruence without significant distress and still benefit from GAMSTs.

Established clinical practice examines the persistence of gender incongruence when considering the initiation of GAMSTs (Chen & Loshak, 2020). In a review of 200 clinical notes, Jones, Brewin et al. (2017) identified the importance of the "stability of gender identity" when planning care. Providing GAMSTs to TGD people with persistent gender incongruence has been associated with low rates of patient regret and high rates of patient satisfaction (Becker et al., 2018; El-Hadi et al., 2018; Staples et al., 2020; Wiepjes et al., 2018). However, while the ICD 11 (WHO, 2019a) requires the presence of marked and persistent gender incongruence for a diagnosis of gender incongruence to be made, there is little specific evidence concerning the length of persistence required for treatment in adults. HCPs involved in an assessment of a TGD person for GAMSTs are encouraged to give due consideration to the life stage, history, and current circumstances of the adult being assessed.

Statement 5.3.b

Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.

A diagnosis of gender incongruence may be necessary in some regions to access transition-related care. When a diagnosis is necessary to access GAMSTs, the assessment for GAMSTs will involve determining and assigning a diagnosis. In these instances, HCPs should have competence using the latest International Classification of Diseases and Related Health Problems (ICD) (WHO, 2019a). In regions where a diagnosis is necessary to access health care, a diagnosis of HA60 *Gender Incongruence of Adolescence or Adulthood* should be determined prior to gender-affirming interventions. Gender-affirming interventions secondary to a diagnosis of *HA6Z Gender Incongruence, Unspecified* may be considered in the context of a more comprehensive assessment by the multidisciplinary team.

There is evidence the use of rigid assessment tools for "transition readiness" may reduce access to care and are not always in the best interest of the TGD person (MacKinnon et al., 2020). Therefore, in situations where the assignment of a diagnosis is mandatory to access care, the process should be approached with trust and transparency between the HCP and the TGD individual requesting GAMST, with the needs of the TGD individual in mind. Indeed, high quality relationships between TGD people and their HCPs are associated with lower emotional distress and better outcomes (Kattari et al., 2016). Because many TGD people fear HCPs will erroneously conflate transgender identity with mental illness (Ellis et al., 2015), a diagnostic assessment should be undertaken with sensitivity to facilitate the best relationship between the provider and the TGD individual.

Statement 5.3.c

Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.

In rare cases, TGD individuals might have a condition that may be mistaken for gender incongruence or may have another reason for seeking treatment aside from the alleviation of gender incongruence. In these cases, and when there is ambiguity regarding the diagnosis of gender incongruence, a more detailed and comprehensive assessment is important. For example, further assessment might be required to determine if gender incongruence persists outside of an acute psychotic episode. If gender incongruence persists after an acute psychotic episode resolves, GAMSTs may be considered as long as the TGD person has the capacity to consent to and undergo the specific treatment. If gender incongruence does not persist and only occurs during such an episode, treatment should not be considered. It is important such circumstances be identified and excluded prior to the initiation of GAMSTs (Byne et al., 2012, 2018; Hembree et al., 2017). It is important to understand, however, TGD people may present with gender incongruence and with a mental health condition, autistic spectrum disorder, or other neurodiversity (Glidden et al., 2016). Indeed, some mental health conditions, such as anxiety (Bouman et al., 2017), depression (Heylens, Elaut et al., 2014; Witcomb et al., 2018), and self-harm (Arcelus et al., 2016; Claes et al., 2015) are more prevalent in TGD people who have not accessed GAMSTs. Recent longitudinal studies suggest mental health symptoms experienced by TGD people tend to improve following GAMSTs (Aldridge et al., 2020; Heylens, Verroken et al., 2014;

White Hughto & Reisner, 2016). There is no evidence to suggest a benefit of withholding GAMSTs from TGD people who have gender incongruence simply on the basis that they have a mental health or neurodevelopmental condition. For more information see Chapter 18—Mental Health.

Statement 5.3.d

Ensure any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

Like their cisgender counterparts, TGD people may have mental health problems. Treatment for mental health problems can and should occur in conjunction with GAMSTs when medical transition is needed. It is vital gender-affirming care is not impeded unless, in some extremely rare cases, there is robust evidence that doing so is necessary to prevent significant decompensation with a risk of harm to self or others. In those cases, it is also important to consider the risks delaying GAMSTs poses to a TGD person's mental and physical health (Byne et al., 2018).

In general, social and medical transition of TDG people are both associated with a reduction in mental health problems (Aldridge et al., 2020; Bouman et al., 2017; Durwood et al., 2017; Glynn et al., 2016; Hughto & Reisner, 2016; Wilson et al., 2015; Witcomb et al., 2018). Unfortunately, the loss of social support and the physical and financial stress that can be associated with the initiation of GAMSTs may exacerbate pre-existing mental health problems and warrant additional support from the treating HCP (Budge et al., 2013; Yang, Wang et al., 2016). An assessment of mental health symptoms can improve transition outcomes, particularly when the assessment is used to facilitate access to psychological and social support during transition (Byne et al., 2012). A delay of transition in rare circumstances may be considered if, for example, the TGD person is unable to engage with the process of transition or would be unable to manage aftercare following surgery, even with support. Where a delay in GAMST as a last resort has been found to be necessary, the HCP should offer resources and support to improve mental health and facilitate re-engagement with the GAMST process as soon as practicable. It should be noted access to medical transition for TGD people facilitates social transition and improves safety in public (Rood et al., 2017). In turn, the degree to which TGD people's appearance conforms to their gender identity is the best predictor of quality of life and mental health outcomes following medical transition (Austin & Goodman, 2017). Delaying access to GAMSTs due to the presence of mental health problems may exacerbate symptoms (Owen-Smith et al., 2018) and damage rapport; consequently, this should be done only when all other avenues have been exhausted.

Statement 5.3.e

Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

In rare cases, GAMSTs, such as hormonal and surgical interventions, may have iatrogenic consequences or may exacerbate pre-existing physical health conditions (Hembree et al., 2017). In these instances, care should be taken, whenever possible, to manage pre-existing physical health conditions while initiating (if appropriate) or continuing gender-affirming treatments. Any interruptions in treatment should be as brief as possible and with treatment re-initiated as soon as practicable. Limited data and inconsistent findings suggest an association between cardiovascular and metabolic risks and hormone therapy in TGD adults (Getahun, 2018; Iwamoto, Defreyne et al., 2019; Iwamoto et al., 2021; Spanos et al., 2020). Because of the possible harm related to long-term treatment and the probable benefits expected from the preventive measures applied before and during hormone treatment, a careful assessment of physical health conditions prior to initiation of treatment is important. Some specific conditions, such as a history of hormone-sensitive cancer, may require further assessment and management that may preclude hormone treatment (Center of Excellence for Transgender Health, 2016; Hembree et al., 2017).

Similar concerns may be present for TGD adults who wish to access surgical interventions. Each gender-affirming surgical intervention has specific risks and potentially unfavorable consequences (Bryson & Honig, 2019; Nassiri et al., 2020; Remington et al., 2018). However, intervention-specific risks associated with the presence of specific physical conditions have not been well researched. Thus, the kinds of medical concerns raised by TGD people during the assessment are typically no different from those of any other surgical candidate.

Taking into consideration the mental and physical health disparities (Brown & Jones, 2016) and barriers to health care (Safer et al., 2016) experienced by TGD people, the assessment of physical conditions by HCPs should not be limited to a history of medical interventions. If the TGD person has physical health conditions, it is important these conditions are managed while initiating or continuing GAMSTs whenever possible. Any interruption in treatment should be made with a view toward re-initiating treatment as soon as practicable. It is also important HCPs develop a treatment strategy for managing physical conditions that facilitates health and promotes consistent adherence to a treatment plan.

Statement 5.3.f

Assess the capacity to consent for the specific gender-affirming treatments prior to the initiation of this treatment.

The practice of informed consent to treatment is central to the provision of health care. Informed consent is couched in the ethical principle that recipients of health care should understand the health care they receive and any potential consequences that could result. The importance of informed consent is embedded in many legislative and regulatory practices that guide HCPs around the world (Jefford & Moore, 2008). It is not possible to know all the potential consequences of a health care treatment; instead, considering what would be "reasonable" to expect is often used as a minimum criterion for consent (Jefford & Moore, 2008; Spatz et al., 2016) and remains the case with GAMSTs. Being able to consent to a health care procedure or clinical intervention requires several complex cognitive processes. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes in addition to the ability to retain that information for the purposes of making the decision (using aids as necessary) and the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007). It is vital the TGD person and the assessing HCP consider a priori the nature of the treatment sought and the potential positive and negative effects it may have on the biological, psychological, and social domains of the TGD person's life.

It is important to recognize mental illness, in particular symptoms of cognitive impairment or psychosis, can impact a person's ability to grant consent for GAMSTs (Hostiuc et al., 2018). However, the presence of such symptoms does not necessarily equate to an inability to give consent because many people with significant mental health symptoms are able to understand the risks and benefits of treatment enough to make an informed decision (Carpenter et al., 2000). Instead, it is important a careful assessment is carried out that examines each TGD person's ability to comprehend the nature of the specific GAMST being considered, consider treatment options, including risks and benefits, appreciate the potential short- and long-term consequences of the decision, and communicate their choice in order to receive the treatment (Grootens-Wiegers et al., 2017).

There may be instances in which an individual lacks the capacity to consent to health care, such as during an acute episode of psychosis or in situations where an individual has long-term cognitive impairment. However, limits to capacity to consent to treatment should not prevent individuals from receiving appropriate GAMSTs. For some, understanding the risks and benefits may require the use of repeated explanations in jargon-free language over time or the use of diagrams to facilitate explanation and aid comprehension. A comprehensive and thorough assessment undertaken by the multidisciplinary health care team can further inform this process. For others, an alternative decision maker, such as a legal guardian or regulator-approved,

independent decision maker may need to be appointed. These situations need to be considered on a case-by-case basis with the aim of ensuring the most affirmative and least restrictive health care is provided to the individual. Also see Chapter 11—Institutional Environments.

Statement 5.3.g

Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.

As gender-affirming medical interventions often affect reproductive capacity, HCPs should ensure a TGD person is aware of the implications for reproduction of the treatments and is familiar with gamete storage and assistive reproductive options. Gender-affirming hormone treatments have been shown to impact reproductive functions and fertility, although the consequences are heterogenous for people of all birth-assigned sexes (Adeleye et al., 2019; Jindarak et al., 2018; Taub et al., 2020). There may be individual differences and fluctuations in these effects on TGD adults. It is therefore essential that HCPs inform a TGD person about the possible impact of the treatment on their reproductive potential during the assessment and as part of the evaluation of the person's capacity to consent for GAMSTs. Reproductive options should be considered and discussed prior to the initiation of gender-affirming treatments. Because the literature is unclear about the possibility of conception while on hormone therapy, information about the necessity of using contraception to avoid unwanted pregnancy and the different methods of contraception available may need to be provided (Light et al., 2014; Schubert & Carey,2020).

Cross-sectional studies in clinical and nonclinical samples from different populations consistently report TGD adults express parental desire and wish to pursue fertility preservation with varying rates that are related to age, gender, and the duration of gender-affirming hormone treatment (Auer et al., 2018; De Sutter et al., 2002; Defreyne, Van Schuvlenbergh et al., 2020; Wierckx, Stuyver et al., 2012). In a small sample, provision of fertility information was found to have an influence on decision-making related to the use of fertility preservation (Chen et al., 2019). Although there was no comparison made between groups who did and did not receive fertility counseling, high fertility preservation rates occurred following comprehensive fertility counseling among transgender individuals (Amir et al., 2020). Further, one study suggested consultation with a specialist reduced regret related to the decision about whether to pursue fertility preservation procedures (Vyas et al., 2021). For more information see Chapter 16—Reproductive Health.

Statement 5.4

We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.

Social transition can be extremely beneficial to many TGD people although not all TGD people are able to socially transition or wish to socially transition (Bränström & Pachankis, 2021; Koehler et al., 2018; Nieder, Eyssel et al., 2020). Consequently, some TGD people seek gender-affirming interventions after social transition, some before, some during, and some in the absence of social transition.

Social transition and gender identity disclosure can improve the mental health of a TGD person seeking gender-affirming interventions (Hughto et al., 2020; McDowell et al., 2019). In addition, chest and facial surgeries prior to hormone therapy can facilitate social transition (Altman, 2012; Davis & Colton Meier, 2014; Olson-Kennedy, Warus et al. 2018; Van Boerum et al., 2019). As part of the assessment process, HCPs should discuss which social role is most comfortable for the TGD person, if a social transition is planned, and the timing for any planned social transition (Barker & Wylie, 2008). It is imperative during the assessment process, HCPs are respectful of the wide diversity of gendered social roles, including nonbinary as well as binary identities and presentations, which vary

according to cultural, local community, and individual understandings.

Not everyone who requests GAMSTs will wish to or be able to socially transition. Little is known about TGD people who do not socially transition before, during, or after medical treatment, as this has not been systematically studied. The most frequent reasons that have been identified for avoiding social transition are fear of being abandoned by family or friends, fearing economic loss (Bradford et al., 2013), and being discriminated against and stigmatized (Langenderfer-Magruder et al., 2016; McDowell et al., 2019; White Hughto et al., 2015). However, some people do not pursue social transition because they feel hormonal or surgical treatments offer enough subjective improvement to reduce gender dysphoria.

If there is no clear plan for social transition or if social transition is unwanted, additional assessment is important to determine the specific nature and advisability of the treatment request, especially if surgical treatment is requested. Additional assessment can offer the TGD person an opportunity to consider the possible effects of not socially transitioning while still obtaining GAMSTs. Given the lack of data on health outcomes for TGD people who do not socially transition (Evans et al., 2021; Levine, 2009; Turban, Loo et al., 2021), GAMSTs should be approached cautiously in such circumstances.

Statement 5.5

We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.

Previous versions of the SOC guidelines have required TGD individuals to be assessed for GAMSTs by two qualified HCPs. It was believed having two independent opinions was best practice as it ensured safety for both TGD people and HCPs. For example, it was assumed that seeing two HCPs offered assuredness for both TGD people and their assessing HCPs when pursuing irreversible medical interventions.

However, the limited research in the area indicates two opinions are largely unnecessary. For example, Jones, Brewin et al. (2017) reviewed the case notes of experienced HCPs working within a state-funded gender service and found there was an overwhelming correlation between both opinions—arguably making one of them redundant. Further, Bouman et al. (2014) determined the requirement for two independent assessors reflected paternalism in health care services and raised a potential breach of the autonomy of TGD individuals. The authors posited when clients are adequately prepared and assessed under the care of a multidisciplinary team, a second independent assessment is unnecessary.

Consequently, if written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), TGD people seeking treatments including hormones, and genital, chest, facial and other gender-affirming surgeries require a single written opinion/signature from an HCP competent to independently assess and diagnose (Bouman et al., 2014; Yuan et al, 2021). Further written opinions/signatures may be requested where there is a specific clinical need.

Statement 5.6

We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

The Endocrine Society Clinical Practice Guidelines advise a period of consistent hormone treatment prior to genital surgery (Hembree et al., 2017). While there was limited supportive research, this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery. For example, there can be changes in sexual desire after genital surgery that removes the testicles (Lawrence, 2005; Wierckx, Van de Peer et al., 2014). In this context, reversible testosterone suppression can offer a TGD person a period of time to experience the absence of testosterone and decide if this feels right for

them. It should be noted the effects of reduced estrogen on a TGD person's sexual desire and functioning following an oophorectomy is less well documented.

Surgery that removes gonads is an irreversible procedure that leads to loss of fertility and loss of the effects of endogenous sex steroids. Both effects must be discussed as a component of the assessment process. For additional information see Chapter 16—Reproductive Health. Of course, hormones are not clinically indicated for TGD adults who do not want them or in cases where they are contraindicated due to health reasons. For more information see Chapter 13—Surgery and Postoperative Care.

Statement 5.7

We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professionals in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

Many TGD adults may consider a range of identities and elements of gender presentation while they are exploring their gender identity and are considering transition options. Accordingly, people may spend some time in a gender identity or presentation before they discover it does not feel comfortable and later adapt it or shift to an earlier identity or presentation (Turban, King et al., 2021). Some TGD adults may also experience a change in gender identity over time so that their needs for medical treatment evolve. This is a healthy and reasonable process for determining the most comfortable and congruent way of living, which is informed by the person's gender identity and the context of their life. This process of identity exploration should not necessarily be equated with regret, confusion, or poor decision-making because a TGD adult's gender identity may change without devaluing previous transition decisions (MacKinnon et al., 2021; Turban, Loo et al., 2021). TGD adults should be assisted in this exploration and any other changes in their identity (Expósito-Campos, 2021). While exploration continues, gender-affirming treatments that are irreversible should be avoided until clarity about long-term goals and outcomes is achieved.

The decision to detransition appears to be rare (Defreyne, Motmans et al., 2017; Hadje-Moussa et al., 2019; Wiepjes et al., 2018). Estimates of the number of people who detransition due to a change in identity are likely to be overinflated due to research blending different cohorts (Expósito-Campos, 2021). For example, detransition research cohorts often include TGD adults who chose to detransition because of a change in their identity as well as TGD adults who chose to detransition without a change in identity. While little research has been conducted to systematically examine variables that correlate with a TGD adult's decision to halt a transition process or to detransition, a recent study found the vast majority of TGD people who opted to detransition did so due to external factors, such as stigma and lack of social support and not because of changes in gender identity (Turban, King et al., 2021). TGD adults who have not experienced a change in identity may choose to halt transition or to detransition because of oppression, violence, and social/relational conflict, surgical complications, health concerns, physical contraindications, a lack of resources, or dissatisfaction with the results (Expósito-Campos, 2021). In such cases, MHPs are well placed to assist the TGD person with these challenges.

While the choice to detransition is proportionally rare, it is expected an overall increase in the number of adults who identify as TGD would result in an increase in the absolute number of people seeking to halt or reverse a transition. However, while the absolute numbers may increase, the percentage of people seeking to halt or reverse permanent physical changes should remain static and low. The existence of these rare requests must not be used as a justification to interrupt critical, medically necessary care, including hormone and surgical treatments, for the vast majority of TGD adults.

Due to the limited research in this area, clinical guidance is based primarily on individual case studies and the expert opinion of HCPs

working with TGD adults (Expósito-Campos, 2021; Richards & Barrett, 2020). Accordingly, if a TGD adult has undergone permanent physical changes and seeks to undo them, the assessing HCP should be a member of a comprehensive multidisciplinary assessment team. A multidisciplinary team allows for the contribution of additional viewpoints from HCPs experienced in transgender health. In collaboration with the TGD adult, the multidisciplinary team is encouraged to thoroughly understand the motivations for the original treatment and for the decision to detransition. Any concerns with the previous physical changes should be carefully explored and a significant effort made to ensure similar concerns are not replicated by the reversal.

To ensure the greatest likelihood of satisfaction and comfort with a reversal of permanent physical changes, the TGD adult and the multidisciplinary team should explore the role of social transition in the assessment and in preparation for the reversal. In such instances, it is highly likely a prolonged period of living in role will be necessary before further physical changes are recommended. HCPs should support the TGD adult through any social changes, as well as any feelings of failure, shame, depression, or guilt in deciding to make such a change. In addition, people should be supported in coping with any prejudice or social difficulties they may have experienced that could have led to a decision to detransition or that may have resulted from such a decision. It is also important to help the person remain engaged with health care throughout the process (Narayan et al., 2021).

While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition (Aldridge et al., 2020; Byne et al., 2012; Gorin-Lazard et al., 2012; Owen-Smith et al., 2018; White Hughto & Reisner, 2016), some TGD adults may decompensate or experience a worsened condition following transition. Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition (Hall et al., 2021; Littman, 2021); however, this occurrence appears to be rare (Hall et al., 2021; Wiepjes et al., 2018). In cases where people decompensate after physical or social transition and then remain in a poorer biological, psychological, or social state than they were in prior to transition, serious consideration should be given as to whether transition is helpful at this time, for this person, or both. In cases where treatment is no longer supported, assistance should be arranged to support the person to manage the process of stopping treatment and to manage any concomitant difficulties (Narayan et al., 2021).

It is vital that people who detransition, for any reason, be supported. It should be remembered, however, this is a rare occurrence and the literature shows consistently positive outcomes for the vast majority of TGD adults who transition to a gender that is comfortable for them, including those who receive GAMSTs (Byne et al., 2012; Green & Fleming, 1990; Lawrence, 2003; Motmans et al., 2012; Van de Grift, Elaut et al., 2018).

CHAPTER 6 Adolescents

Historical context and changes since previous Standards of Care

Specialized health care for transgender adolescents began in the 1980s when a few specialized gender clinics for youth were developed around the world that served relatively small numbers of children and adolescents. In more recent years, there has been a sharp increase in the number of adolescents requesting gender care (Arnoldussen et al., 2019; Kaltiala, Bergman et al., 2020). Since then, new clinics have been founded, but clinical services in many places have not kept pace with the increasing number of youth seeking care. Hence, there are often long waitlists for services, and barriers to care exist for many transgender youth around the world (Tollit et al., 2018).

Until recently, there was limited information regarding the prevalence of gender diversity among adolescents. Studies from high school samples indicate much higher rates than earlier thought, with reports of up to 1.2% of participants identifying as transgender (Clark et al., 2014) and up to 2.7% or more (e.g., 7–9%) experiencing some level of self-reported gender diversity (Eisenberg et al., 2017; Kidd et al., 2021; Wang et al., 2020). These studies suggest gender diversity in youth should no longer be viewed as rare. Additionally, a pattern of uneven ratios by assigned sex has been reported in gender clinics, with adolescents assigned female at birth (AFAB) initiating care 2.5–7.1 times more frequently as compared to adolescents who are assigned male at birth (AMAB) (Aitken et al., 2015; Arnoldussen et al., 2019; Bauer et al., 2021; de Graaf, Carmichael et al., 2018; Kaltiala et al., 2015; Kaltiala, Bergman et al., 2020).

A specific World Professional Association for Transgender Health's (WPATH) Standards of Care section dedicated to the needs of children and adolescents was first included in the 1998 WPATH Standards of Care, 5th version (Levine et al., 1998). Youth aged 16 or older were deemed potentially eligible for gender-affirming medical care, but only in select cases. The subsequent 6th (Meyer et al., 2005) and 7th (Coleman et al., 2012) versions divided medical-affirming treatment for adolescents into three categories and presented eligibility criteria regarding age/puberty stage—namely fully reversible puberty delaying blockers as soon as puberty had started; partially reversible hormone therapy (testosterone, estrogen) for adolescents at the age of majority, which was age 16 in certain European countries; and irreversible surgeries at age 18 or older, except for chest "masculinizing" mastectomy, which had an age minimum of 16 years. Additional eligibility criteria for gender-related medical care included a persistent, long (childhood) history of gender "non-conformity"/dysphoria, emerging or intensifying at the onset of puberty; absence or management of psychological, medical, or social problems that interfere with treatment; provision of support for commencing the intervention by the parents/caregivers; and provision of informed consent. A chapter dedicated to transgender and gender diverse (TGD) adolescents, distinct from the child chapter, has been created for this 8th edition of the Standards of Care given 1) the exponential growth in adolescent referral rates; 2) the increased number of studies specific to adolescent gender diversity-related care; and 3) the unique developmental and gender-affirming care issues of this age group.

Non-specific terms for gender-related care are avoided (e.g., gender-affirming model, gender exploratory model) as these terms do not represent unified practices, but instead heterogenous care practices that are defined differently in various settings.

Adolescence overview

Adolescence is a developmental period characterized by relatively rapid physical and psychological maturation, bridging childhood and adulthood (Sanders, 2013). Multiple developmental processes occur simultaneously, including pubertal-signaled changes. Cognitive, emotional, and social systems mature, and physical changes associated with puberty progress. These processes do not all begin and end at the same time for a given individual, nor do they occur at the same age for all persons. Therefore, the lower and upper borders of adolescence are imprecise and cannot be defined exclusively by age. For example, physical pubertal changes may

begin in late childhood and executive control neural systems continue to develop well into the mid-20s (Ferguson et al., 2021). There is a lack of uniformity in how countries and governments define the age of majority (i.e., legal decision-making status; Dick et al., 2014). While many specify the age of majority as 18 years of age, in some countries it is as young as 15 years (e.g., Indonesia and Myanmar), and in others as high as 21 years (e.g., the U.S. state of Mississippi and Singapore).

For clarity, this chapter applies to adolescents from the start of puberty until the legal age of majority (in most cases 18 years), however there are developmental elements of this chapter, including the importance of parental/caregiver involvement, that are often relevant for the care of transitional-aged young adults and should be considered appropriately.

Cognitive development in adolescence is often characterized by gains in abstract thinking, complex reasoning, and metacognition (i.e., a young person's ability to think about their own feelings in relation to how others perceive them; Sanders, 2013). The ability to reason hypothetical situations enables a young person to conceptualize implications regarding a particular decision. However, adolescence is also often associated with increased risk-taking behaviors. Along with these notable changes, adolescence is often characterized by individuation from parents and the development of increased personal autonomy. There is often a heightened focus on peer relationships, which can be both positive and detrimental (Gardner & Steinberg, 2005). Adolescents often experience a sense of urgency that stems from hypersensitivity to reward, and their sense of timing has been shown to be different from that of older individuals (Van Leijenhorst et al., 2010). Social-emotional development typically advances during adolescence, although there is a great variability among young people in terms of the level of maturity applied to inter- and intra-personal communication and insight (Grootens-Wiegers et al., 2017). For TGD adolescents making decisions about gender-affirming treatments—decisions that may have lifelong consequences—it is critical to understand how all these aspects of development may impact decision-making for a given young person within their specific cultural context.

Gender identity development in adolescence

Our understanding of gender identity development in adolescence is continuing to evolve. When providing clinical care to gender diverse young people and their families, it is important to know what is and is not known about gender identity during development (Berenbaum, 2018). When considering treatments, families may have questions regarding the development of their adolescent's gender identity, and whether or not their adolescent's declared gender will remain the same over time. For some adolescents, a declared gender identity that differs from the assigned sex at birth comes as no surprise to their parents/caregivers as their history of gender diverse expression dates back to childhood (Leibowitz & de Vries, 2016). For others, the declaration does not happen until the emergence of pubertal changes or even well into adolescence (McCallion et al., 2021; Sorbara et al., 2020).

Historically, social learning and cognitive developmental research on gender development was conducted primarily with youth who were not gender diverse in identity or expression and was carried out under the assumption that sex correlated with a specific gender; therefore, little attention was given to gender identity development. In addition to biological factors influencing gender development, this research demonstrated psychological and social factors also play a role (Perry & Pauletti, 2011). While there has been less focus on gender identity development in TGD youth, there is ample reason to suppose, apart from biological factors, psychosocial factors are also involved (Steensma, Kreukels et al., 2013). For some youth, gender identity development appears fixed and is often expressed from a young age, while for others there may be a developmental process that contributes to gender identity development over time.

Neuroimaging studies, genetic studies, and other hormone studies in intersex individuals demonstrate a biological contribution to the development of gender identity for some

individuals whose gender identity does not match their assigned sex at birth (Steensma, Kreukels et al., 2013). As families often have questions about this very issue, it is important to note it is not possible to distinguish between those for whom gender identity may seem fixed from birth and those for whom gender identity development appears to be a developmental process. Since it is impossible to definitively delineate the contribution of various factors contributing to gender identity development for any given young person, a comprehensive clinical approach is important and necessary (see Statement 3). Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups. Conceptualization of gender identity by shifting from dichotomous (e.g., binary) categorization of male and female to a dimensional gender spectrum along a continuum (APA, 2013) would also be necessary.

Adolescence may be a critical period for the development of gender identity for gender diverse young people (Steensma, Kreukels et al., 2013). Dutch longitudinal clinical follow-up studies of adolescents with childhood gender dysphoria who received puberty suppression, gender-affirming hormones, or both, found that none of the youth in adulthood regretted the decisions they had taken in adolescence (Cohen-Kettenis & van Goozen, 1997; de Vries et al., 2014). These findings suggest adolescents who were comprehensively assessed and determined emotionally mature enough to make treatment decisions regarding gender- affirming medical care presented with stability of gender identity over the time period when the studies were conducted.

When extrapolating findings from the longer-term longitudinal Dutch cohort studies to present-day gender diverse adolescents seeking care, it is critical to consider the societal changes that have occurred over time in relation to TGD people. Given the increase in visibility of TGD identities, it is important to understand how increased awareness may impact gender development in different ways (Kornienko et al., 2016). One trend identified is that more young people are presenting to gender clinics with nonbinary identities (Twist & de Graaf, 2019). Another phenomenon occurring in clinical practice is the increased number of adolescents seeking care who have not seemingly experienced, expressed (or experienced and expressed) gender diversity during their childhood years. One researcher attempted to study and describe a specific form of later-presenting gender diversity experience (Littman, 2018). However, the findings of the study must be considered within the context of significant methodological challenges, including 1) the study surveyed parents and not youth perspectives; and 2) recruitment included parents from community settings in which treatments for gender dysphoria are viewed with scepticism and are criticized. However, these findings have not been replicated. For a select subgroup of young people, susceptibility to social influence impacting gender may be an important differential to consider (Kornienko et al., 2016). However, caution must be taken to avoid assuming these phenomena occur prematurely in an individual adolescent while relying on information from datasets that may have been ascertained with potential sampling bias (Bauer et al., 2022; WPATH, 2018). It is important to consider the benefits that social connectedness may have for youth who are linked with supportive people (Tuzun et al., 2022)(see Statement 4).

Given the emerging nature of knowledge regarding adolescent gender identity development, an individualized approach to clinical care is considered both ethical and necessary. As is the case in all areas of medicine, each study has methodological limitations, and conclusions drawn from research cannot and should not be universally applied to all adolescents. This is also true when grappling with common parental questions regarding the stability versus instability of a particular young person's gender identity development. While future research will help advance scientific understanding of gender identity development, there may always be some gaps. Furthermore, given the ethics of self-determination in care, these gaps should not leave the TGD adolescent without important and necessary care.

Research evidence of gender-affirming medical treatment for transgender adolescents

A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical

and surgical treatments (GAMSTs) (see medically necessary statement in the Global chapter, Statement 2.1), over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment in adolescents is not possible. A short narrative review is provided instead.

At the time of this chapter's writing, there were several longer-term longitudinal cohort follow-up studies reporting positive results of early (i.e., adolescent) medical treatment; for a significant period of time, many of these studies were conducted through one Dutch clinic (e.g., Cohen-Kettenis & van Goozen, 1997; de Vries, Steensma et al., 2011; de Vries et al., 2014; Smith et al., 2001, 2005). The findings demonstrated the resolution of gender dysphoria is associated with improved psychological functioning and body image satisfaction. Most of these studies followed a pre-post methodological design and compared baseline psychological functioning with outcomes after the provision of medical gender-affirming treatments. Different studies evaluated individual aspects or combinations of treatment interventions and included 1) gender-affirming hormones and surgeries (Cohen-Kettenis & van Goozen, 1997; Smith et al., 2001, 2005); 2) puberty suppression (de Vries, Steensma et al., 2011); and 3) puberty suppression, affirming hormones, and surgeries (de Vries et al., 2014). The 2014 long-term follow-up study is the only study that followed youth from early adolescence (pretreatment, mean age of 13.6) through young adulthood (posttreatment, mean age of 20.7). This was the first study to show gender-affirming treatment enabled transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with satisfactory objective and subjective outcomes in adulthood (de Vries et al., 2014). While the study employed a small (n = 55), select, and socially supported sample, the results were convincing. Of note, the participants were part of the Dutch clinic known for employing a multidisciplinary approach, including provision of comprehensive, ongoing assessment and management of gender dysphoria, and support aimed at emotional well-being.

Several more recently published longitudinal studies followed and evaluated participants at different stages of their gender-affirming treatments. In these studies, some participants may not have started gender-affirming medical treatments, some had been treated with puberty suppression, while still others had started gender-affirming hormones or had even undergone gender-affirming surgery (GAS) (Achille et al., 2020; Allen et al., 2019; Becker-Hebly et al., 2021; Carmichael et al., 2021; Costa et al., 2015; Kuper et al., 2020, Tordoff et al., 2022). Given the heterogeneity of treatments and methods, this type of design makes interpreting outcomes more challenging. Nonetheless, when compared with baseline assessments, the data consistently demonstrate improved or stable psychological functioning, body image, and treatment satisfaction varying from three months to up to two years from the initiation of treatment.

Cross-sectional studies provide another design for evaluating the effects of gender-affirming treatments. One such study compared psychological functioning in transgender adolescents at baseline and while undergoing puberty suppression with that of cisgender high school peers at two different time points. At baseline, the transgender youth demonstrated lower psychological functioning compared with cisgender peers, whereas when undergoing puberty suppression, they demonstrated better functioning than their peers (van der Miesen et al., 2020). Grannis et al. (2021) demonstrated transgender males who started testosterone had lower internalizing mental health symptoms (depression and anxiety) compared with those who had not started testosterone treatment.

Four additional studies followed different outcome designs. In a retrospective chart study, Kaltiala, Heino et al. (2020) reported transgender

adolescents with few or no mental health challenges prior to commencing gender-affirming hormones generally did well during the treatment. However, adolescents with more mental health challenges at baseline continued to experience the manifestations of those mental health challenges over the course of gender-affirming medical treatment. Nieder et al. (2021) studied satisfaction with care as an outcome measure and demonstrated transgender adolescents were more satisfied the further they progressed with the treatments they initially started. Hisle-Gorman et al. (2021) compared health care utilization pre- and post-initiation of gender-affirming pharmaceuticals as indicators of the severity of mental health conditions among 3,754 TGD adolescents in a large health care data set. Somewhat contrary to the authors' hypothesis of improved mental health, mental health care use did not significantly change, and psychotropic medication prescriptions increased. In a large non-probability sample of transgender-identified adults, Turban et al. (2022) found those who reported access to gender-affirming hormones in adolescence had lower odds of past-year suicidality compared with transgender people accessing gender- affirming hormones in adulthood.

Providers may consider the possibility an adolescent may regret gender-affirming decisions made during adolescence, and a young person will want to stop treatment and return to living in the birth-assigned gender role in the future. Two Dutch studies report low rates of adolescents (1.9% and 3.5%) choosing to stop puberty suppression (Brik et al., 2019; Wiepjes et al., 2018). Again, these studies were conducted in clinics that follow a protocol that includes a comprehensive assessment before the gender-affirming medical treatment is started. At present, no clinical cohort studies have reported on profiles of adolescents who regret their initial decision or detransition after irreversible affirming treatment. Recent research indicate there are adolescents who detransition, but do not regret initiating treatment as they experienced the start of treatment as a part of understanding their gender-related care needs (Turban, 2018). However, this may not be the predominant perspective of people who detransition (Littman, 2021; Vandenbussche, 2021). Some adolescents may regret the steps they have taken (Dyer, 2020). Therefore, it is important to present the full range of possible outcomes when assisting transgender adolescents. Providers may discuss this topic in a collaborative and trusting manner (i.e., as a "potential future experience and consideration") with the adolescent and their parents/caregivers before gender-affirming medical treatments are started. Also, providers should be prepared to support adolescents who detransition. In an internet convenience sample survey of 237 self-identified detransitioners with a mean age of 25.02 years, which consisted of over 90% of birth assigned females, 25% had medically transitioned before age 18 and 14% detransitioned before age 18 (Vandenbussche, 2021). Although an internet convenience sample is subject to selection of respondents, this study suggests detransitioning may occur in young transgender adolescents and health care professionals should be aware of this. Many of them expressed difficulties finding help during their detransition process and reported their detransition was an isolating experience during which they did not receive either sufficient or appropriate support (Vandenbussche, 2021).

To conclude, although the existing samples reported on relatively small groups of youth (e.g., n = 22-101 per study) and the time to follow-up varied across studies (6 months–7 years), this emerging evidence base indicates a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment. Further, rates of reported regret during the study monitoring periods are low. Taken as a whole, the data show early medical intervention—as part of broader combined assessment and treatment approaches focused on gender dysphoria and general well-being—can be effective and helpful for many transgender adolescents seeking these treatments.

Ethical and human rights perspectives

Medical ethics and human rights perspectives were also considered while formulating the

Statements of Recommendations

6.1- We recommend health care professionals working with gender diverse adolescents:
6.1.a- Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.
6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.
6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.
6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.
6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.
6.2- We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.
6.3- We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.
6.4- We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.
6.5- We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.
6.6- We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including a review of the benefits and risks.
6.7- We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.
6.8- We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender- related surgery until the transition is made to adult care.
6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.
6.10- We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.
6.11- We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):
6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:
6.12.a- The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.
6.12.b- The experience of gender diversity/incongruence is marked and sustained over time.
6.12.c- The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.
6.12.d- The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.
6.12.e- The adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.
6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.
6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

adolescent SOC statements. For example, allowing irreversible puberty to progress in adolescents who experience gender incongruence is not a neutral act given that it may have immediate and lifelong harmful effects for the transgender young person (Giordano, 2009; Giordano & Holm, 2020; Kreukels & Cohen-Kettenis, 2011). From a human rights perspective, considering gender diversity as a normal and expected variation within the broader diversity of the human experience, it is an adolescent's right to participate in their own decision-making

process about their health and lives, including access to gender health services (Amnesty International, 2020).

Short summary of statements and unique issues in adolescence

These guidelines are designed to account for what is known and what is not known about gender identity development in adolescence, the evidence for gender-affirming care in adolescence, and the unique aspects that distinguish adolescence from other developmental stages.

Identity exploration: A defining feature of adolescence is the solidifying of aspects of identity, including gender identity. Statement 6.2 addresses identity exploration in the context of gender identity development. Statement 6.12.b accounts for the length of time needed for a young person to experience a gender diverse identity, express a gender diverse identity, or both, so as to make a meaningful decision regarding gender-affirming care.

Consent and decision-making: In adolescence, consent and decision-making require assessment of the individual's emotional, cognitive, and psychosocial development. Statement 6.12.c directly addresses emotional and cognitive maturity and describes the necessary components of the evaluation process used to assess decision-making capacity.

Caregivers/parent involvement: Adolescents are typically dependent on their caregivers/parents for guidance in numerous ways. This is also true as the young person navigates through the process of deciding about treatment options. Statement 6.11 addresses the importance of involving caregivers/parents and discusses the role they play in the assessment and treatment. No set of guidelines can account for every set of individual circumstances on a global scale.

Statement 6.1

We recommend health care professionals working with gender diverse adolescents:

a. **Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.**
b. **Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.**
c. **Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.**
d. **Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.**
e. **Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.**

When assessing and supporting TGD adolescents and their families, care providers/health care professionals (HCPs) need both general as well as gender-specific knowledge and training. Providers who are trained to work with adolescents and families play an important role in navigating aspects of adolescent development and family dynamics when caring for youth and families (Adelson et al., 2012; American Psychological Association, 2015; Hembree et al., 2017). Other chapters in these standards of care describe these criteria for professionals who provide gender care in more detail (see Chapter 5—Assessment for Adults; Chapter 7—Children; or Chapter 13—Surgery and Postoperative Care). Professionals working with adolescents should understand what is and is not known regarding adolescent gender identity development, and how this knowledge base differs from what applies to adults and prepubertal children. Among HCPs, the mental health professional (MHP) has the most appropriate training and dedicated clinical time to conduct an assessment and elucidate treatment priorities and goals when working with transgender youth, including those seeking gender-affirming medical/surgical care. Understanding and managing the dynamics of family members who may share differing perspectives regarding the history and needs of the

young person is an important competency that MHPs are often most prepared to address.

When access to professionals trained in child and adolescent development is not possible, HCPs should make a commitment to obtain training in the areas of family dynamics and adolescent development, including gender identity development. Similarly, considering autistic/neurodivergent transgender youth represent a substantial minority subpopulation of youth served in gender clinics globally, it is important HCPs seek additional training in the field of autism and understand the unique elements of care autistic gender diverse youth may require (Strang, Meagher et al., 2018). If these qualifications are not possible, then consultation and collaboration with a provider who specializes in autism and neurodiversity is advised.

Statement 6.2

We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.

Adolescence is a developmental period that involves physical and psychological changes characterized by individuation and the transition to independence from caregivers (Berenbaum et al., 2015; Steinberg, 2009). It is a period during which young people may explore different aspects of identity, including gender identity.

Adolescents differ regarding the degree to which they explore and commit to aspects of their identity (Meeus et al., 2012). For some adolescents, the pace to achieving consolidation of identity is fast, while for others it is slower. For some adolescents, physical, emotional, and psychological development occur over the same general timeline, while for others, there are certain gaps between these aspects of development. Similarly, there is variation in the timeline for gender identity development (Arnoldussen et al., 2020; Katz-Wise et al., 2017). For some young people, gender identity development is a clear process that starts in early childhood, while for others pubertal changes contribute to a person's experience of themselves as a particular gender (Steensma, Kreukels et al., 2013), and for many others a process may begin well after pubertal changes are completed. Given these variations, there is no one particular pace, process, or outcome that can be predicted for an individual adolescent seeking gender-affirming care.

Therefore, HCPs working with adolescents should promote supportive environments that simultaneously respect an adolescent's affirmed gender identity and also allows the adolescent to openly explore gender needs, including social, medical, and physical gender-affirming interventions should they change or evolve over time.

Statement 6.3

We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

Given the many ways identity may unfold during adolescence, we recommend using a comprehensive biopsychosocial assessment to guide treatment decisions and optimize outcomes. This assessment should aim to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care. As mentioned in Statement 6.1, MHPs have the most appropriate training, experience, and dedicated clinical time required to obtain the information discussed here. The assessment process should be approached collaboratively with the adolescent and their caregiver(s), both separately and together, as described in more detail in Statement 6.11. An assessment should occur prior to any medically necessary medical or surgical intervention under consideration (e.g., puberty blocking medication, gender-affirming hormones, surgeries). See medically necessary statement in Chapter 2—Global Applicability, Statement 2.1; see also Chapter 12—Hormone Therapy and Chapter 13—Surgery and Postoperative Care.

Youth may experience many different gender identity trajectories. Sociocultural definitions and experiences of gender continue to evolve over time, and youth are increasingly presenting with a range of identities and ways of describing their experiences and gender-related needs (Twist & de

Graaf, 2019). For example, some youth will realize they are transgender or more broadly gender diverse and pursue steps to present accordingly. For some youth, obtaining gender-affirming medical treatment is important while for others these steps may not be necessary. For example, a process of exploration over time might not result in the young person self-affirming or embodying a different gender in relation to their assigned sex at birth and would not involve the use of medical interventions (Arnoldussen et al., 2019).

The most robust longitudinal evidence supporting the benefits of gender-affirming medical and surgical treatments in adolescence was obtained in a clinical setting that incorporated a detailed comprehensive diagnostic assessment process over time into its delivery of care protocol (de Vries & Cohen-Kettenis, 2012; de Vries et al., 2014). Given this research and the ongoing evolution of gender diverse experiences in society, a comprehensive diagnostic biopsychosocial assessment during adolescence is both evidence-based and preserves the integrity of the decision-making process. In the absence of a full diagnostic profile, other mental health entities that need to be prioritized and treated may not be detected. There are no studies of the long-term outcomes of gender-related medical treatments for youth who have not undergone a comprehensive assessment. Treatment in this context (e.g., with limited or no assessment) has no empirical support and therefore carries the risk that the decision to start gender-affirming medical interventions may not be in the long-term best interest of the young person at that time.

As delivery of health care and access to specialists varies globally, designing a particular assessment process to adapt existing resources is often necessary. In some cases, a more extended assessment process may be useful, such as for youth with more complex presentations (e.g., complicating mental health histories (Leibowitz & de Vries, 2016)), co-occurring autism spectrum characteristics (Strang, Powers et al., 2018), and/or an absence of experienced childhood gender incongruence (Ristori & Steensma, 2016). Given the unique cultural, financial, and geographical factors that exist for specific populations, providers should design assessment models that are flexible and allow for appropriately timed care for as many young people as possible, so long as the assessment effectively obtains information about the adolescent's strengths, vulnerabilities, diagnostic profile, and individual needs. Psychometrically validated psychosocial and gender measures can also be used to provide additional information.

The multidisciplinary assessment for youth seeking gender-affirming medical/surgical interventions includes the following domains that correspond to the relevant statements:

- **Gender Identity Development:** Statements 6.12.a and 6.12.b elaborate on the factors associated with gender identity development within the specific cultural context when assessing TGD adolescents.
- **Social Development and Support; Intersectionality:** Statements 6.4 and 6.11 elaborate on the importance of assessing gender minority stress, family dynamics, and other aspects contributing to social development and intersectionality.
- **Diagnostic Assessment of Possible Co-Occurring Mental Health and/or Developmental Concerns:** Statement 6.12.d elaborates on the importance of understanding the relationship that exists, if at all, between any co-occurring mental health or developmental concerns and the young person's gender identity/gender diverse expression.
- **Capacity for Decision-Making:** Statement 6.12.c elaborates on the assessment of a young person's emotional maturity and the relevance when an adolescent is considering gender affirming-medical/surgical treatments.

Statement 6.4

We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.

Multiple studies and related expert consensus support the implementation of approaches that promote acceptance and affirmation of gender diverse youth across all settings, including families, schools, health care facilities, and all other organizations and communities with which they

interact (e.g., Pariseau et al., 2019; Russell et al., 2018; Simons et al., 2013; Toomey et al., 2010; Travers et al., 2012). Acceptance and affirmation are accomplished through a range of approaches, actions, and policies we recommend be enacted across the various relationships and settings in which a young person exists and functions. It is important for the family members and community members involved in the adolescent's life to work collaboratively in these efforts unless their involvement is considered harmful to the adolescent. Examples proposed by Pariseau et al. (2019) and others of acceptance and affirmation of gender diversity and contemplation and expression of identity that can be implemented by family, staff, and organizations include:

1. Actions that are supportive of youth drawn to engaging in gender-expansive (e.g., nonconforming) activities and interests;
2. Communications that are supportive when youth express their experiences about their gender and gender exploration;
3. Use of the youth's asserted name/pronouns;
4. Support for youth wearing clothing/uniforms, hairstyles, and items (e.g., jewelry, makeup) they feel affirm their gender;
5. Positive and supportive communication with youth about their gender and gender concerns;
6. Education about gender diversity issues for people in the young person's life (e.g., family members, health care providers, social support networks), as needed, including information about how to advocate for gender diverse youth in community, school, health care, and other settings;
7. Support for gender diverse youth to connect with communities of support (e.g., LGBTQ groups, events, friends);
8. Provision of opportunities to discuss, consider, and explore medical treatment options when indicated;
9. Antibullying policies that are enforced;
10. Inclusion of nonbinary experiences in daily life, reading materials, and curricula (e.g., books, health, and sex education classes, assigned essay topics that move beyond the binary, LGBTQ, and ally groups);
11. Gender inclusive facilities that the youth can readily access without segregation from nongender diverse peers (e.g., bathrooms, locker rooms).

We recommend HCPs work with parents, schools, and other organizations/groups to promote acceptance and affirmation of TGD identities and expressions, whether social or medical interventions are implemented or not as acceptance and affirmation are associated with fewer negative mental health and behavioral symptoms and more positive mental health and behavioral functioning (Day et al., 2015; de Vries et al., 2016; Greytak et al., 2013; Pariseau et al., 2019; Peng et al., 2019; Russell et al., 2018; Simons et al., 2013; Taliaferro et al., 2019; Toomey et al., 2010; Travers et al., 2012). Russell et al. (2018) found mental health improvement increases with more acceptance and affirmation across more settings (e.g., home, school, work, and friends). Rejection by family, peers, and school staff (e.g., intentionally using the name and pronoun the youth does not identify with, not acknowledging affirmed gender identity, bullying, harassment, verbal and physical abuse, poor relationships, rejection for being TGD, eviction) was strongly linked to negative outcomes, such as anxiety, depression, suicidal ideation, suicide attempts, and substance use (Grossman et al., 2005; Klein & Golub; 2016; Pariseau et al., 2019; Peng et al., 2019; Reisner, Greytak et al., 2015; Roberts et al., 2013). It is important to be aware that negative symptoms increase with increased levels of rejection and continue into adulthood (Roberts et al., 2013).

Neutral or indifferent responses to a youth's gender diversity and exploration (e.g., letting a child tell others their chosen name but not using the name, not telling family or friends when the youth wants them to disclose, not advocating for the child about rejecting behavior from school staff or peers, not engaging or participating in other support mechanisms (e.g., with psychotherapists and support groups) have also been found to have negative consequences, such as increased depressive symptoms (Pariseau et al., 2019). For these reasons, it is important not to ignore a youth's gender questioning or delay consideration of the youth's gender-related

care needs. There is particular value in professionals recognizing youth need individualized approaches, support, and consideration of needs around gender expression, identity, and embodiment over time and across domains and relationships. Youth may need help coping with the tension of tolerating others' processing/adjusting to an adolescent's identity exploration and changes (e.g., Kuper, Lindley et al., 2019). It is important professionals collaborate with parents and others as they process their concerns and feelings and educate themselves about gender diversity because such processes may not necessarily reflect rejection or neutrality but may rather represent efforts to develop attitudes and gather information that foster acceptance (e.g., Katz-Wise et al., 2017).

Statement 6.5

We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.

Some health care providers, secular or religious organizations, and rejecting families may undertake efforts to thwart an adolescent's expression of gender diversity or assertion of a gender identity other than the expression and behavior that conforms to the sex assigned at birth. Such efforts at blocking reversible social expression or transition may include choosing not to use the youth's identified name and pronouns or restricting self-expression in clothing and hairstyles (Craig et al., 2017; Green et al., 2020). These disaffirming behaviors typically aim to reinforce views that a young person's gender identity/expression must match the gender associated with the sex assigned at birth or expectations based on the sex assigned at birth. Activities and approaches (sometimes referred to as "treatments") aimed at trying to change a person's gender identity and expression to become more congruent with the sex assigned at birth have been attempted, but these approaches have not resulted in changes in gender identity (Craig et al., 2017; Green et al., 2020). We recommend against such efforts because they have been found to be ineffective and are associated with increases in mental illness and poorer psychological functioning (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020).

Much of the research evaluating "conversion therapy" and "reparative therapy" has investigated the impact of efforts to change gender expression (masculinity or femininity) and has conflated sexual orientation with gender identity (APA, 2009; Burnes et al., 2016; Craig et al., 2017). Some of these efforts have targeted both gender identity and expression (AACAP, 2018). Conversion/reparative therapy has been linked to increased anxiety, depression, suicidal ideation, suicide attempts, and health care avoidance (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020). Although some of these studies have been criticized for their methodologies and conclusions (e.g., D'Angelo et al., 2020), this should not detract from the importance of emphasizing efforts undertaken a priori to change a person's identity are clinically and ethically unsound. We recommend against any type of conversion or attempts to change a person's gender identity because 1) both secular and religion-based efforts to change gender identity/expression have been associated with negative psychological functioning that endures into adulthood (Turban, Beckwith et al., 2020); and 2) larger ethical reasons exist that should underscore respect for gender diverse identities.

It is important to note potential factors driving a young person's gender-related experience and report of gender incongruence, when carried out in the context of supporting an adolescent with self-discovery, is not considered reparative therapy as long as there is no a priori goal to change or promote one particular gender identity or expression (AACAP, 2018; see Statement 6.2). To ensure these explorations are therapeutic, we recommend employing affirmative consideration and supportive tone in discussing what steps have been tried, considered, and planned for a youth's gender expression. These discussion topics may include what felt helpful or affirming, what felt unhelpful or distressing and why. We recommend employing affirmative responses to these steps and discussions, such as those identified in SOC-8 Statement 6.4.

Statement 6.6

We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including review of the benefits and risks.

TGD youth may experience distress related to chest and genital anatomy. Practices such as chest binding, chest padding, genital tucking, and genital packing are reversible, nonmedical interventions that may help alleviate this distress (Callen-Lorde, 2020a, 2020b; Deutsch, 2016a; Olson-Kennedy, Rosenthal et al., 2018; Transcare BC, 2020). It is important to assess the degree of distress related to physical development or anatomy, educate youth about potential nonmedical interventions to address this distress, and discuss the safe use of these interventions.

Chest binding involves compression of the breast tissue to create a flatter appearance of the chest. Studies suggest that up to 87% of trans masculine patients report a history of binding (Jones, 2015; Peitzmeier, 2017). Binding methods may include the use of commercial binders, sports bras, layering of shirts, layering of sports bras, or the use of elastics or other bandages (Peitzmeier, 2017). Currently, most youth report learning about binding practices from online communities composed of peers (Julian, 2019). Providers can play an important role in ensuring youth receive accurate and reliable information about the potential benefits and risks of chest binding. Additionally, providers can counsel patients about safe binding practices and monitor for potential negative health effects. While there are potential negative physical impacts of binding, youth who bind report many benefits, including increased comfort, improved safety, and lower rates of misgendering (Julian, 2019). Common negative health impacts of chest binding in youth include back/chest pain, shortness of breath, and overheating (Julian, 2019). More serious negative health impacts such as skin infections, respiratory infections, and rib fractures are uncommon and have been associated with chest binding in adults (Peitzmeier, 2017). If binding is employed, youth should be advised to use only those methods considered safe for binding—such as binders specifically designed for the gender diverse population—to reduce the risk of serious negative health effects. Methods that are considered unsafe for binding include the use of duct tape, ace wraps, and plastic wrap as these can restrict blood flow, damage skin, and restrict breathing. If youth report negative health impacts from chest binding, these should ideally be addressed by a gender-affirming medical provider with experience working with TGD youth.

Genital tucking is the practice of positioning the penis and testes to reduce the outward appearance of a genital bulge. Methods of tucking include tucking the penis and testes between the legs or tucking the testes inside the inguinal canal and pulling the penis back between the legs. Typically, genitals are held in place by underwear or a gaff, a garment that can be made or purchased. Limited studies are available on the specific risks and benefits of tucking in adults, and none have been carried out in youth. Previous studies have reported tight undergarments are associated with decreased sperm concentration and motility. In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh, 2019) although there are no definitive studies evaluating these adverse outcomes. Further research is needed to determine the specific benefits and risks of tucking in youth.

Statement 6.7

We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.

When discussing the available options of menstrual-suppressing medications with gender diverse youth, providers should engage in shared decision-making, use gender-inclusive language (e.g., asking patients which terms they utilize to refer to their menses, reproductive organs, and genitalia) and perform physical exams in a sensitive, gender-affirmative manner (Bonnington et al., 2020; Krempasky et al., 2020). There is no formal research evaluating how menstrual

suppression may impact gender incongruence and/or dysphoria. However, the use of menstrual suppression can be an initial intervention that allows for further exploration of gender-related goals of care, prioritization of other mental health care, or both, especially for those who experience a worsening of gender dysphoria from unwanted uterine bleeding (see Statement 6.12d; Mehringer & Dowshen, 2019). When testosterone is not used, menstrual suppression can be achieved via a progestin. To exclude any underlying menstrual disorders, it is important to obtain a detailed menstrual history and evaluation prior to implementing menstrual-suppressing therapy (Carswell & Roberts, 2017). As part of the discussion about menstrual-suppressing medications, the need for contraception and information regarding the effectiveness of menstrual-suppressing medications as methods of contraception also need to be addressed (Bonnington et al., 2020). A variety of menstrual suppression options, such as combined estrogen-progestin medications, oral progestins, depot and subdermal progestin, and intrauterine devices (IUDs), should be offered to allow for individualized treatment plans while properly considering availability, cost and insurance coverage, as well as contraindications and side effects (Kanj et al., 2019).

Progestin-only hormonal medication are options, especially in trans masculine or nonbinary youth who are not interested in estrogen-containing medical therapies as well as those at risk for thromboembolic events or who have other contraindications to estrogen therapy (Carswell & Roberts, 2017). Progestin-only hormonal medications include oral progestins, depo-medroxyprogesterone injection, etonogestrel implant, and levonorgestrel IUD (Schwartz et al., 2019). Progestin-only hormonal options vary in terms of efficacy in achieving menstrual suppression and have lower rates of achieving amenorrhea than combined oral contraception (Pradhan & Gomez-Lobo, 2019). A more detailed description of the relevant clinical studies is presented in Chapter 12—Hormone Therapy. HCPs should not make assumptions regarding the individual's preferred method of administration as some trans masculine youth may prefer vaginal rings or IUD implants (Akgul et al., 2019). Although hormonal medications require monitoring for potential mood lability, depressive effects, or both, the benefits and risks of untreated menstrual suppression in the setting of gender dysphoria should be evaluated on an individual basis. Some patients may opt for combined oral contraception that includes different combinations of ethinyl estradiol, with ranging doses, and different generations of progestins (Pradhan & Gomez-Lobo, 2019). Lower dose ethinyl estradiol components of combined oral contraceptive pills are associated with increased breakthrough uterine bleeding. Continuous combined oral contraceptives may be used to allow for continuous menstrual suppression and can be delivered as transdermal or vaginal rings.

The use of gonadotropin releasing hormone (GnRH) analogues may also result in menstrual suppression. However, it is recommended gender diverse youth meet the eligibility criteria (as outlined in Statement 6.12) before this medication is considered solely for this purpose (Carswell & Roberts, 2017; Pradhan & Gomez-Lobo, 2019). Finally, menstrual-suppression medications may be indicated as an adjunctive therapy for breakthrough uterine bleeding that may occur while on exogenous testosterone or as a bridging medication while awaiting menstrual suppression with testosterone therapy. When exogenous testosterone is employed as a gender-affirming hormone, menstrual suppression is typically achieved in the first six months of therapy (Ahmad & Leinung, 2017). However, it is vital adolescents be counseled ovulation and pregnancy can still occur in the setting of amenorrhea (Gomez et al., 2020; Kanj et al., 2019).

Statement 6.8

We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender-related surgery until the transition is made to adult care.

HCPs with expertise in child and adolescent development, as described in Statement 6.1, play an important role in the continuity of care for

young people over the course of their gender-related treatment needs. Supporting adolescents and their families necessitates approaching care using a developmental lens through which understanding a young person's evolving emotional maturity and care needs can take place over time. As gender-affirming treatment pathways differ based on the needs and experiences of individual TGD adolescents, decision-making for these treatments (puberty suppression, estrogens/androgens, gender-affirmation surgeries) can occur at different points in time within a span of several years. Longitudinal research demonstrating the benefits of pubertal suppression and gender-affirming hormone treatment (GAHT) was carried out in a setting where an ongoing clinical relationship between the adolescents/families and the multidisciplinary team was maintained (de Vries et al., 2014).

Clinical settings that offer longer appointment times provide space for adolescents and caregivers to share important psychosocial aspects of emotional well-being (e.g., family dynamics, school, romantic, and sexual experiences) that contextualize individualized gender-affirming treatment needs and decisions as described elsewhere in the chapter. An ongoing clinical relationship can take place across settings, whether that be within a multidisciplinary team or with providers in different locations who collaborate with one another. Given the wide variability in the ability to obtain access to specialized gender care centers, particularly for marginalized groups who experience disparities with access, it is important for the HCP to appreciate the existence of any barriers to care while maintaining flexibility when defining how an ongoing clinical relationship can take place in that specific context.

An ongoing clinical relationship that increases resilience in the youth and provides support to parents/caregivers who may have their own treatment needs may ultimately lead to increased parental acceptance—when needed—which is associated with better mental health outcomes in youth (Ryan, Huebner et al., 2009).

Statement 6.9

We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

TGD adolescents with gender dysphoria/gender incongruence who seek gender-affirming medical and surgical treatments benefit from the involvement of health care professionals (HCPs) from different disciplines. Providing care to TGD adolescents includes addressing 1) diagnostic considerations (see Statements 6.3, 6.12a, and 6.12b) conducted by a specialized gender HCP (as defined in Statement 6.1) whenever possible and necessary; and 2) treatment considerations when prescribing, managing, and monitoring medications for gender-affirming medical and surgical care, requiring the training of the relevant medical/surgical professional. The list of key disciplines includes but is not limited to adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, social work, support staff, and the surgical team.

The evolving evidence has shown a clinical benefit for transgender youth who receive their gender-affirming treatments in multidisciplinary gender clinics (de Vries et al., 2014; Kuper et al., 2020; Tollit et al., 2019). Finally, adolescents seeking gender-affirming care in multidisciplinary clinics are presenting with significant complexity necessitating close collaboration between mental health, medical, and/or surgical professionals (McCallion et al., 2021; Sorbara et al., 2020; Tishelman et al., 2015).

As not all patients and families are in the position or in a location to access multidisciplinary care, the lack of available disciplines should not preclude a young person from accessing needed care in a timely manner. When disciplines are available, particularly in centers with existing multidisciplinary teams, disciplines, or both, it is recommended efforts be made to include the relevant providers when developing a gender care team. However, this does not mean all disciplines are necessary to provide care to a particular youth and family.

If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST) for an adolescent, only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical HCPs and MHPs (American Psychological Association, 2015; Hembree et al., 2017; Telfer et al., 2018). Further assessment results and written opinions may be requested when there is a specific clinical need or when team members are in different locations or choose to write their own summaries. For further information see Chapter 5—Assessment for Adults, Statement 5.5.

Statement 6.10

We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to the initiation of treatment, of the reproductive effects, including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.

While assessing adolescents seeking gender-affirming medical or surgical treatments, HCPs should discuss the specific ways in which the required treatment may affect reproductive capacity. Fertility issues and the specific preservation options are more thoroughly discussed in Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

It is important HCPs understand what fertility preservation options exist so they can relay the information to adolescents. Parents are advised to be involved in this process and should also understand the pros and cons of the different options. HCPs should acknowledge adolescents and parents may have different views around reproductive capacity and may therefore come to different decisions (Quain et al., 2020), which is why HCPs can be helpful in guiding this process.

HCPs should specifically pay attention to the developmental and psychological aspects of fertility preservation and decision-making competency for the individual adolescent. While adolescents may think they have made up their minds concerning their reproductive capacity, the possibility their opinions about having biologically related children in the future might change over time needs to be discussed with an HCP who has sufficient experience, is knowledgeable about adolescent development, and has experience working with parents.

Addressing the long-term consequences on fertility of gender-affirming medical treatments and ensuring transgender adolescents have realistic expectations concerning fertility preservation options or adoption cannot not be addressed with a one-time discussion but should be part of an ongoing conversation. This conversation should occur not only before initiating any medical intervention (puberty suppression, hormones, or surgeries), but also during further treatment and during transition.

Currently, there are only preliminary results from retrospective studies evaluating transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assumptions about what future adult goals an adolescent may have. Research in childhood cancer survivors found participants who acknowledged missed opportunities for fertility preservation reported distress and regret surrounding potential infertility (Armuand et al., 2014; Ellis et al., 2016; Lehmann et al., 2017). Furthermore, individuals with cancer who did not prioritize having biological children before treatment have reported "changing their minds" in survivorship (Armuand et al., 2014).

Given the complexities of the different fertility preservation options and the challenges HCPs may experience discussing fertility with the adolescent and the family (Tishelman et al., 2019), a fertility consultation is an important consideration for every transgender adolescent who pursues medical-affirming treatments unless the local situation is such that a fertility consultation is not covered by insurance or public health care plans, is not available locally, or the individual circumstances make this unpreferable.

Statement 6.11

We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents

involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

When there is an indication an adolescent might benefit from a gender-affirming medical or surgical treatment, involving the parent(s) or primary caregiver(s) in the assessment process is recommended in almost all situations (Edwards-Leeper & Spack, 2012; Rafferty et al., 2018). Exceptions to this might include situations in which an adolescent is in foster care, child protective services, or both, and custody and parent involvement would be impossible, inappropriate, or harmful. Parent and family support of TGD youth is a primary predictor of youth well-being and is protective of the mental health of TGD youth (Gower, Rider, Coleman et al., 2018; Grossman et al., 2019; Lefevor et al., 2019; McConnell et al., 2015; Pariseau et al., 2019; Ryan, 2009; Ryan et al., 2010; Simons et al., 2013; Wilson et al., 2016). Therefore, including parent(s)/caregiver(s) in the assessment process to encourage and facilitate increased parental understanding and support of the adolescent may be one of the most helpful practices available.

Parent(s)/caregiver(s) may provide key information for the clinical team, such as the young person's gender and overall developmental, medical, and mental health history as well as insights into the young person's level of current support, general functioning, and well-being. Concordance or divergence of reports given by the adolescent and their parent(s)/caregiver(s) may be important information for the assessment team and can aid in designing and shaping individualized youth and family supports (De Los Reyes et al., 2019; Katz-Wise et al., 2017). Knowledge of the family context, including resilience factors and challenges, can help providers know where special supports would be needed during the medical treatment process. Engagement of parent(s)/caregiver(s) is also important for educating families about various treatment approaches, ongoing follow-up and care needs, and potential treatment complications. Through psychoeducation regarding clinical gender care options and participation in the assessment process, which may unfold over time, parent(s)/caregiver(s) may better understand their adolescent child's gender-related experience and needs (Andrzejewski et al., 2020; Katz-Wise et al., 2017).

Parent/caregiver concerns or questions regarding the stability of gender-related needs over time and implications of various gender-affirming interventions are common and should not be dismissed. It is appropriate for parent(s)/caregiver(s) to ask these questions, and there are cases in which the parent(s)/caregiver(s)' questions or concerns are particularly helpful in informing treatment decisions and plans. For example, a parent/caregiver report may provide critical context in situations in which a young person experiences very recent or sudden self-awareness of gender diversity and a corresponding gender treatment request, or when there is concern for possible excessive peer and social media influence on a young person's current self-gender concept. Contextualization of the parent/caregiver report is also critical, as the report of a young person's gender history as provided by parent(s)/caregiver(s) may or may not align with the young person's self-report. Importantly, gender histories may be unknown to parent(s)/caregiver(s) because gender may be internal experience for youth, not known by others unless it is discussed. For this reason, an adolescent's report of their gender history and experience is central to the assessment process.

Some parents may present with unsupportive or antagonistic beliefs about TGD identities, clinical gender care, or both (Clark et al., 2020). Such unsupportive perspectives are an important therapeutic target for families. Although challenging parent perspectives may in some cases seem rigid, providers should not assume this is the case. There are many examples of parent(s)/caregiver(s) who, over time with support and psychoeducation, have become increasingly accepting of their TGD child's gender diversity and care needs.

Helping youth and parent(s)/caregiver(s) work together on important gender care decisions is a primary goal. However, in some cases, parent(s)/caregiver(s) may be too rejecting of their adolescent child and their child's gender needs to be part of the clinical evaluation process. In these situations, youth may require the engagement of larger systems of advocacy and support to move

forward with the necessary support and care (Dubin et al., 2020).

Statement 6.12

We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:

Statement 6.12.a

The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.

When working with TGD adolescents, HCPs should realize while a classification may give access to care, pathologizing transgender identities may be experienced as stigmatizing (Beek et al., 2016). Assessments related to gender health and gender diversity have been criticized, and controversies exist around diagnostic systems (Drescher, 2016).

HCPs should assess the overall gender-related history and gender care-related needs of youth. Through this assessment process, HCPs may provide a diagnosis when it is required to get access to transgender-related care.

Gender incongruence and gender dysphoria are the two diagnostic terms used in the World Health Organization's International Classification of Diseases (ICD) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM), respectively. Of these two widely used classification systems, the DSM is for psychiatric classifications only and the ICD contains all diseases and conditions related to physical as well as mental health. The most recent versions of these two systems, the DSM-5 and the ICD-11, reflect a long history of reconceptualizing and de-psychopathologizing gender-related diagnoses (American Psychiatric Association, 2013; World Health Organization, 2019a). Compared with the earlier version, the DSM-5 replaced gender identity disorder with gender dysphoria, acknowledging the distress experienced by some people stemming from the incongruence between experienced gender identity and the sex assigned at birth. In the most recent revision, the DSM-5-TR, no changes in the diagnostic criteria for gender dysphoria are made. However, terminology was adapted into the most appropriate current language (e.g., birth-assigned gender instead of natal-gender and gender-affirming treatment instead of gender reassignment (American Psychiatric Association, 2022). Compared with the ICD 10th edition, the gender incongruence classification was moved from the Mental Health chapter to the Conditions Related to Sexual Health chapter in the ICD-11. When compared with the DSM-5 classification of gender dysphoria, one important reconceptualization is distress is not a required indicator of the ICD-11 classification of gender incongruence (WHO, 2019a). After all, when growing up in a supporting and accepting environment, the distress and impairment criterion, an inherent part of every mental health condition, may not be applicable (Drescher, 2012). As such, the ICD-11 classification of gender incongruence may better capture the fullness of gender diversity experiences and related clinical gender needs.

Criteria for the ICD-11 classification gender incongruence of adolescence or adulthood require a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a need to "transition" to live and be accepted as a person of the experienced gender. For some, this includes hormonal treatment, surgery, or other health care services to enable the individual´s body to align as much as required, and to the extent possible, with the person's experienced gender. Relevant for adolescents is the indicator that a classification cannot be assigned "prior to the onset of puberty." Finally, it is noted "that gender variant behaviour and preferences alone are not a basis for assigning the classification" (WHO, ICD-11, 2019a).

Criteria for the DSM-5 and DSM-5-TR classification of gender dysphoria in adolescence and adulthood denote "a marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration' (criterion A, fulfilled when 2 of 6 subcriteria are manifest; DSM-5, APA, 2013; DSM 5-TR, APA, 2022).

Of note, although a gender-related classification is one of the requirements for receiving medical gender-affirming care, such a classification alone does not indicate a person needs medical-affirming care. The range of youth experiences of gender incongruence necessitates professionals provide a range of treatments or interventions based on the individual's needs. Counseling, gender exploration, mental health assessment and, when needed, treatment with MHPs trained in gender development may all be indicated with or without the implementation of medical-affirming care.

Statement 6.12.b

The experience of gender diversity/incongruence is marked and sustained over time.

Identity exploration and consolidation are experienced by many adolescents (Klimstra et al., 2010; Topolewska-Siedzik & Cieciuch, 2018). Identity exploration during adolescence may include a process of self-discovery around gender and gender identity (Steensma, Kreukels et al., 2013). Little is known about how processes that underlie consolidation of gender identity during adolescence (e.g., the process of commitment to specific identities) may impact a young person's experience(s) or needs over time.

Therefore, the level of reversibility of a gender-affirming medical intervention should be considered along with the sustained duration of a young person's experience of gender incongruence when initiating treatment. Given potential shifts in gender-related experiences and needs during adolescence, it is important to establish the young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones or surgeries. Puberty suppression treatment, which provides more time for younger adolescents to engage their decision-making capacities, also raises important considerations (see Statement 6.12f and Chapter 12—Hormone Therapy) suggesting the importance of a sustained experience of gender incongruence/diversity prior to initiation. However, in this age group of younger adolescents, several years is not always practical nor necessary given the premise of the treatment as a means to buy time while avoiding distress from irreversible pubertal changes. For youth who have experienced a shorter duration of gender incongruence, social transition-related and/or other medical supports (e.g., menstrual suppression/androgen blocking) may also provide some relief as well as furnishing additional information to the clinical team regarding a young person's broad gender care needs (see Statements 6.4, 6.6, and 6.7).

Establishing evidence of persistent gender diversity/incongruence typically requires careful assessment with the young person over time (see Statement 6.3). Whenever possible and when appropriate, the assessment and discernment process should also include the parent(s)/caregiver(s) (see Statement 6.11). Evidence demonstrating gender diversity/incongruence sustained over time can be provided via history obtained directly from the adolescent and parents/caregivers when this information is not documented in the medical records.

The research literature on continuity versus discontinuity of gender-affirming medical care needs/requests is complex and somewhat difficult to interpret. A series of studies conducted over the last several decades, including some with methodological challenges (as noted by Temple Newhook et al., 2018; Winters et al., 2018) suggest the experience of gender incongruence is not consistent for all children as they progress into adolescence. For example, a subset of youth who experienced gender incongruence or who socially transitioned prior to puberty over time can show a reduction in or even full discontinuation of gender incongruence (de Vries et al., 2010; Olson et al., 2022; Ristori & Steensma, 2016; Singh et al., 2021; Wagner et al., 2021). However, there has been less research focused on rates of continuity and discontinuity of gender incongruence and gender-related needs in pubertal and adolescent populations. The data available regarding broad unselected gender-referred pubertal/adolescent cohorts (from the Amsterdam transgender clinic) suggest that, following extended assessments over time, a subset of adolescents with gender incongruence presenting for gender care elect not to pursue gender-affirming medical care

(Arnoldussen et al., 2019; de Vries, Steensma et al., 2011). Importantly, findings from studies of gender incongruent pubertal/adolescent cohorts, in which participants who have undergone comprehensive gender evaluation over time, have shown persistent gender incongruence and gender-related need and have received referrals for medical gender care, suggest low levels of regret regarding gender-related medical care decisions (de Vries et al., 2014; Wiepjes et al., 2018). Critically, these findings of low regret can only currently be applied to youth who have demonstrated sustained gender incongruence and gender-related needs over time as established through a comprehensive and iterative assessment (see Statement 6.3).

Statement 6.12.c

The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.

The process of informed consent includes communication between a patient and their provider regarding the patient's understanding of a potential intervention as well as, ultimately, the patient's decision whether to receive the intervention. In most settings, for minors, the legal guardian is integral to the informed consent process: if a treatment is to be given, the legal guardian (often the parent[s]/caregiver[s]) provides the informed consent to do so. In most settings, assent is a somewhat parallel process in which the minor and the provider communicate about the intervention and the provider assesses the level of understanding and intention.

A necessary step in the informed consent/assent process for considering gender-affirming medical care is a careful discussion with qualified HCPs trained to assess the emotional and cognitive maturity of adolescents. The reversible and irreversible effects of the treatment, as well as fertility preservation options (when applicable), and all potential risks and benefits of the intervention are important components of the discussion. These discussions are required when obtaining informed consent/assent. Assessment of cognitive and emotional maturity is important because it helps the care team understand the adolescent's capacity to be informed.

The skills necessary to assent/consent to any medical intervention or treatment include the ability to 1) comprehend the nature of the treatment; 2) reason about treatment options, including the risks and benefits; 3) appreciate the nature of the decision, including the long-term consequences; and 4) communicate choice (Grootens-Wiegers et al., 2017). In the case of gender- affirming medical treatments, a young person should be well-informed about what the treatment may and may not accomplish, typical timelines for changes to appear (e.g., with gender-affirming hormones), and any implications of stopping the treatment. Gender-diverse youth should fully understand the reversible, partially reversible, and irreversible aspects of a treatment, as well as the limits of what is known about certain treatments (e.g., the impact of pubertal suppression on brain development (Chen and Loshak, 2020)). Gender-diverse youth should also understand, although many gender-diverse youth begin gender- affirming medical care and experience that care as a good fit for them long-term, there is a subset of individuals who over time discover this care is not a fit for them (Wiepjes et al., 2018). Youth should know such shifts are sometimes connected to a change in gender needs over time, and in some cases, a shift in gender identity itself. Given this information, gender diverse youth must be able to reason thoughtfully about treatment options, considering the implications of the choices at hand. Furthermore, as a foundation for providing assent, the gender-diverse young person needs to be able to communicate their choice.

The skills needed to accomplish the tasks required for assent/consent may not emerge at specific ages per se (Grootens-Wiegers et al., 2017). There may be variability in these capacities related to developmental differences and mental health presentations (Shumer & Tishelman, 2015) and dependent on the opportunities a young person has had to practice these skills (Alderson, 2007). Further, assessment of emotional and cognitive maturity must be conducted separately for each gender-related treatment decision (Vrouenraets et al., 2021).

The following questions may be useful to consider in assessing a young person's emotional and

cognitive readiness to assent or consent to a specific gender-affirming treatment:

- Can the young person think carefully into the future and consider the implications of a partially or fully irreversible intervention?
- Does the young person have sufficient self-reflective capacity to consider the possibility that gender-related needs and priorities can develop over time, and gender-related priorities at a certain point in time might change?
- Has the young person, to some extent, thought through the implications of what they might do if their priorities around gender do change in the future?
- Is the young person able to understand and manage the day-to-day short- and long-term aspects of a specific medical treatment (e.g., medication adherence, administration, and necessary medical follow-ups)?

Assessment of emotional and cognitive maturity may be accomplished over time as the care team continues to engage in conversations about the treatment options and affords the young person the opportunity to practice thinking into the future and flexibly consider options and implications. For youth with neurodevelopmental and/or some types of mental health differences, skills for future thinking, planning, big picture thinking, and self-reflection may be less-well developed (Dubbelink & Geurts, 2017). In these cases, a more careful approach to consent and assent may be required, and this may include additional time and structured opportunities for the young person to practice the skills necessary for medical decision-making (Strang, Powers et al., 2018).

For unique situations in which an adolescent minor is consenting for their own treatment without parental permission (see Statement 6.11), extra care must be taken to support the adolescent's informed decision-making. This will typically require greater levels of engagement of and collaboration between the HCPs working with the adolescent to provide the young person appropriate cognitive and emotional support to consider options, weigh benefits and potential challenges/costs, and develop a plan for any needed (and potentially ongoing) supports associated with the treatment.

Statement 6.12.d

The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and/or gender-affirming medical treatments have been addressed.

Evidence indicates TGD adolescents are at increased risk of mental health challenges, often related to family/caregiver rejection, non-affirming community environments, and neurodiversity-related factors (e.g., de Vries et al., 2016; Pariseau et al., 2019; Ryan et al., 2010; Weinhardt et al., 2017). A young person's mental health challenges may impact their conceptualization of their gender development history and gender identity-related needs, the adolescent's capacity to consent, and the ability of the young person to engage in or receive medical treatment. Additionally, like cisgender youth, TGD youth may experience mental health concerns irrespective of the presence of gender dysphoria or gender incongruence. In particular, depression and self-harm may be of specific concern; many studies reveal depression scores and emotional and behavioral problems comparable to those reported in populations referred to mental health clinics (Leibowitz & de Vries, 2016). Higher rates of suicidal ideation, suicide attempts, and self-harm have also been reported (de Graaf et al., 2020). In addition, eating disorders occur more frequently than expected in non-referred populations (Khatchadourian et al., 2013; Ristori et al., 2019; Spack et al., 2012). Importantly, TGD adolescents show high rates of autism spectrum disorder/characteristics (Øien et al., 2018; van der Miesen et al., 2016; see also Statement 6.1d). Other neurodevelopmental presentations and/or mental health challenges may also be present, (e.g., ADHD, intellectual disability, and psychotic disorders (de Vries, Doreleijers et al., 2011; Meijer et al., 2018; Parkes & Hall, 2006).

Of note, many transgender adolescents are well-functioning and experience few if any mental health concerns. For example, socially transitioned pubertal adolescents who receive medical

gender- affirming treatment at specialized gender clinics may experience mental health outcomes equivalent to those of their cisgender peers (e.g., de Vries et al., 2014; van der Miesen et al., 2020). A provider's key task is to assess the direction of the relationships that exist between any mental health challenges and the young person's self-understanding of gender care needs and then prioritize accordingly.

Mental health difficulties may challenge the assessment and treatment of gender-related needs of TGD adolescents in various ways:

1. First, when a TGD adolescent is experiencing acute suicidality, self-harm, eating disorders, or other mental health crises that threaten physical health, safety must be prioritized. According to the local context and existing guidelines, appropriate care should seek to mitigate the threat or crisis so there is sufficient time and stabilization for thoughtful gender-related assessment and decision-making. For example, an actively suicidal adolescent may not be emotionally able to make an informed decision regarding gender-affirming medical/surgical treatment. If indicated, safety-related interventions should not preclude starting gender-affirming care.
2. Second, mental health can also complicate the assessment of gender development and gender identity-related needs. For example, it is critical to differentiate gender incongruence from specific mental health presentations, such as obsessions and compulsions, special interests in autism, rigid thinking, broader identity problems, parent/child interaction difficulties, severe developmental anxieties (e.g., fear of growing up and pubertal changes unrelated to gender identity), trauma, or psychotic thoughts. Mental health challenges that interfere with the clarity of identity development and gender-related decision-making should be prioritized and addressed.
3. Third, decision-making regarding gender-affirming medical treatments that have life-long consequences requires thoughtful, future-oriented thinking by the adolescent, with support from the parents/caregivers, as indicated (see Statement 6.11). To be able to make such an informed decision, an adolescent should be able to understand the issues, express a choice, appreciate and give careful thought regarding the wish for medical-affirming treatment (see Statement 6.12c). Neurodevelopmental differences, such as autistic features or autism spectrum disorder (see Statement 6.1d, e.g., communication differences; a preference for concrete or rigid thinking; differences in self-awareness, future thinking and planning), may challenge the assessment and decision-making process; neurodivergent youth may require extra support, structure, psychoeducation, and time built into the assessment process (Strang, Powers et al., 2018). Other mental health presentations that involve reduced communication and self-advocacy, difficulty engaging in assessment, memory and concentration difficulties, hopelessness, and difficulty engaging in future-oriented thinking may complicate assessment and decision-making. In such cases, extended time is often necessary before any decisions regarding medical-affirming treatment can be made.
4. Finally, while addressing mental health concerns is important during the course of medical treatment, it does not mean all mental health challenges can or should be resolved completely. However, it is important any mental health concerns are addressed sufficiently so that gender -affirming medical treatment can be provided optimally (e.g., medication adherence, attending follow-up medical appointments, and self-care, particularly during a postoperative course).

Statement 6.12.e

The adolescent has been informed of the reproductive effects, including the potential loss of fertility, and available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.

For guidelines regarding the clinical approach, the scientific background, and the rationale, see Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

Statement 6.12.f

The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.

The onset of puberty is a pivotal point for many gender diverse youth. For some, it creates an intensification of their gender incongruence, and for others, pubertal onset may lead to gender fluidity (e.g., a transition from binary to nonbinary gender identity) or even attenuation of a previously affirmed gender identity (Drummond et al., 2008; Steensma et al., 2011, Steensma, Kreukels et al., 2013; Wallien & Cohen-Kettenis, 2008). The use of puberty-blocking medications, such as GnRH analogues, is not recommended until children have achieved a minimum of Tanner stage 2 of puberty because the experience of physical puberty may be critical for further gender identity development for some TGD adolescents (Steensma et al., 2011). Therefore, puberty blockers should not be implemented in prepubertal gender diverse youth (Waal & Cohen-Kettenis, 2006). For some youth, GnRH agonists may be appropriate in late stages or in the post-pubertal period (e.g., Tanner stage 4 or 5), and this should be highly individualized. See Chapter 12—Hormone Therapy for a more comprehensive review of the use of GnRH agonists.

Variations in the timing of pubertal onset is due to multiple factors (e.g., sex assigned at birth, genetics, nutrition, etc.). Tanner staging refers to five stages of pubertal development ranging from prepubertal (Tanner stage 1) to post-pubertal, and adult sexual maturity (Tanner stage 5) (Marshall & Tanner, 1969, 1970). For assigned females at birth, pubertal onset (e.g., gonadarche) is defined by the occurrence of breast budding (Tanner stage 2), and for birth-assigned males, the achievement of a testicular volume of greater than or equal to 4 mL (Roberts & Kaiser, 2020). An experienced medical provider should be relied on to differentiate the onset of puberty from physical changes such as pubic hair and apocrine body odor due to sex steroids produced by the adrenal gland (e.g., adrenarche) as adrenarche does not warrant the use of puberty-blocking medications (Roberts & Kaiser, 2020). Educating parents and families about the difference between adrenarche and gonadarche helps families understand the timing during which shared decision-making about gender-affirming medical therapies should be undertaken with their multidisciplinary team.

The importance of addressing other risks and benefits of pubertal suppression, both hypothetical and actual, cannot be overstated. Evidence supports the existence of surgical implications for transgender girls who proceed with pubertal suppression (van de Grift et al., 2020). Longitudinal data exists to demonstrate improvement in romantic and sexual satisfaction for adolescents receiving puberty suppression, hormone treatment and surgery (Bungener et al., 2020). A study on surgical outcomes of laparoscopic intestinal vaginoplasty (performed because of limited genital tissue after the use of puberty blockers) in transgender women revealed that the majority experienced orgasm after surgery (84%), although a specific correlation between sexual pleasure outcomes and the timing of pubertal suppression initiation was not discussed in the study (Bouman, van der Sluis et al., 2016), nor does the study apply to those who would prefer a different surgical procedure. This underscores the importance of engaging in discussions with families about the future unknowns related to surgical and sexual health outcomes.

Statement 6.12.g

The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, breast growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). To

ensure sufficient time for psychological adaptations to the physical change during an important developmental time for the adolescent, 12 months of hormone treatment is suggested. Depending upon the surgical result required, a period of hormone treatment may need to be longer (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty, breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of hormone therapy on the proposed surgery. In addition, for individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Consideration of ages for gender-affirming medical and surgical treatment for adolescents

Age has a strong, albeit imperfect, correlation with cognitive and psychosocial development and may be a useful objective marker for determining the potential timing of interventions (Ferguson et al., 2021). Higher (i.e., more advanced) ages may be required for treatments with greater irreversibility, complexity, or both. This approach allows for continued cognitive/emotional maturation that may be required for the adolescent to fully consider and consent to increasingly complex treatments (see Statement 6.12c).

A growing body of evidence indicates providing gender-affirming treatment for gender diverse youth who meet criteria leads to positive outcomes (Achille et al., 2020; de Vries et al., 2014; Kuper et al., 2020). There is, however, limited data on the optimal timing of gender-affirming interventions as well as the long-term physical, psychological, and neurodevelopmental outcomes in youth (Chen et al., 2020; Chew et al., 2018; Olson-Kennedy et al., 2016). Currently, the only existing longitudinal studies evaluating gender diverse youth and adult outcomes are based on a specific model (i.e., the Dutch approach) that involved a comprehensive initial assessment with follow-up. In this approach, pubertal suppression was considered at age 12, GAHT at age 16, and surgical interventions after age 18 with exceptions in some cases. It is not clear if deviations from this approach would lead to the same or different outcomes. Longitudinal studies are currently underway to better define outcomes as well as the safety and efficacy of gender-affirming treatments in youth (Olson-Kennedy, Garofalo et al., 2019; Olson-Kennedy, Rosenthal et al., 2019). While the long-term effects of gender-affirming treatments initiated in adolescence are not fully known, the potential negative health consequences of delaying treatment should also be considered (de Vries et al., 2021). As the evidence base regarding outcomes of gender-affirming interventions in youth continues to grow, recommendations on the timing and readiness for these interventions may be updated.

Previous guidelines regarding gender-affirming treatment of adolescents recommended partially reversible GAHT could be initiated at approximately 16 years of age (Coleman et al., 2012; Hembree et al., 2009). More recent guidelines suggest there may be compelling reasons to initiate GAHT prior to the age of 16, although there are limited studies on youth who have initiated hormones prior to 14 years of age (Hembree et al., 2017). A compelling reason for earlier initiation of GAHT, for example, might be to avoid prolonged pubertal suppression, given potential bone health concerns and the psychosocial implications of delaying puberty as described in more detail in Chapter 12—Hormone Therapy (Klink, Caris et al., 2015; Schagen et al., 2020; Vlot et al., 2017; Zhu & Chan, 2017). Puberty is a time of significant brain and cognitive development. The potential neurodevelopmental impact of extended pubertal suppression in gender diverse youth has been specifically identified as an area in need of continued study (Chen et al., 2020). While GnRH analogs have been shown to be safe when used for the treatment of precocious puberty, there are concerns delaying exposure to sex hormones (endogenous or exogenous) at a time of peak bone mineralization may lead to decreased bone mineral density. The potential decrease in bone mineral density as well as the clinical significance of any decrease requires continued study (Klink, Caris et al., 2015; Lee, Finlayson et al.,

2020; Schagen et al., 2020). The potential negative psychosocial implications of not initiating puberty with peers may place additional stress on gender diverse youth, although this has not been explicitly studied. When considering the timing of initiation of gender-affirming hormones, providers should compare the potential physical and psychological benefits and risks of starting treatment with the potential risks and benefits of delaying treatment. This process can also help identify compelling factors that may warrant an individualized approach.

Studies carried out with trans masculine youth have demonstrated chest dysphoria is associated with higher rates of anxiety, depression, and distress and can lead to functional limitations, such as avoiding exercising or bathing (Mehringer et al., 2021; Olson-Kennedy, Warus et al., 2018; Sood et al., 2021). Testosterone unfortunately does little to alleviate this distress, although chest masculinization is an option for some individuals to address this distress long-term. Studies with youth who sought chest masculinization surgery to alleviate chest dysphoria demonstrated good surgical outcomes, satisfaction with results, and minimal regret during the study monitoring period (Marinkovic & Newfield, 2017; Olson-Kennedy, Warus et al., 2018). Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined by a multidisciplinary team experienced in adolescent and gender development (see relevant statements in this chapter). The duration or current use of testosterone therapy should not preclude surgery if otherwise indicated. The needs of some TGD youth may be met by chest masculinization surgery alone. Breast augmentation may be needed by trans feminine youth, although there is less data about this procedure in youth, possibly due to fewer individuals requesting this procedure (Boskey et al., 2019; James, 2016). GAHT, specifically estrogen, can help with development of breast tissue, and it is recommended youth have a minimum of 12 months of hormone therapy, or longer as is surgically indicated, prior to breast augmentation unless hormone therapy is not clinically indicated or is medically contraindicated.

Data are limited on the optimal timing for initiating other gender-affirming surgical treatments in adolescents. This is partly due to the limited access to these treatments, which varies in different geographical locations (Mahfouda et al., 2019). Data indicate rates of gender-affirming surgeries have increased since 2000, and there has been an increase in the number of TGD youth seeking vaginoplasty (Mahfouda et al., 2019; Milrod & Karasic, 2017). A 2017 study of 20 WPATH-affiliated surgeons in the US reported slightly more than half had performed vaginoplasty in minors (Milrod & Karasic, 2017). Limited data are available on the outcomes for youth undergoing vaginoplasty. Small studies have reported improved psychosocial functioning and decreased gender dysphoria in adolescents who have undergone vaginoplasty (Becker et al., 2018; Cohen-Kettenis & van Goozen, 1997; Smith et al.,2001). While the sample sizes are small, these studies suggest there may be a benefit for some adolescents to having these procedures performed before the age of 18. Factors that may support pursuing these procedures for youth under 18 years of age include the increased availability of support from family members, greater ease of managing postoperative care prior to transitioning to tasks of early adulthood (e.g., entering university or the workforce), and safety concerns in public spaces (i.e., to reduce transphobic violence) (Boskey et al., 2018; Boskey et al., 2019; Mahfouda et al., 2019). Given the complexity and irreversibility of these procedures, an assessment of the adolescent's ability to adhere to postsurgical care recommendations and to comprehend the long-term impacts of these procedures on reproductive and sexual function is crucial (Boskey et al., 2019). Given the complexity of phalloplasty, and current high rates of complications in comparison to other gender-affirming surgical treatments, it is not recommended this surgery be considered in youth under 18 at this time (see Chapter 13—Surgery and Postoperative Care).

Additional key factors that should be taken into consideration when discussing the timing of interventions with youth and families are addressed in detail in statements 6.12a-f. For a summary of the criteria/recommendations for medically necessary gender-affirming medical treatment in adolescents, see Appendix D.

CHAPTER 7 Children

These Standards of Care pertain to prepubescent gender diverse children and are based on research, ethical principles, and accumulated expert knowledge. The principles underlying these standards include the following 1) childhood gender diversity is an expected aspect of general human development (Endocrine Society and Pediatric Endocrine Society, 2020; Telfer et al., 2018); 2) childhood gender diversity is not a pathology or mental health disorder (Endocrine Society and Pediatric Endocrine Society, 2020; Oliphant et al., 2018; Telfer et al., 2018); 3) diverse gender expressions in children cannot always be assumed to reflect a transgender identity or gender incongruence (Ehrensaft, 2016; Ehrensaft, 2018; Rael et al., 2019); 4) guidance from mental health professionals (MHPs) with expertise in gender care for children can be helpful in supporting positive adaptation as well as discernment of gender-related needs over time (APA, 2015; Ehrensaft, 2018; Telfer et al., 2018); 5) conversion therapies for gender diversity in children (i.e., any "therapeutic" attempts to compel a gender diverse child through words, actions, or both to identify with, or behave in accordance with, the gender associated with the sex assigned at birth are harmful and we repudiate their use (APA, 2021; Ashley, 2019b, Paré, 2020; SAMHSA, 2015; Telfer et al., 2018; UN Human Rights Council, 2020).

Throughout the text, the term "health care professional" (HCP) is used broadly to refer to professionals working with gender diverse children. Unlike pubescent youth and adults, prepubescent gender diverse children are not eligible to access medical intervention (Pediatric Endocrine Society, 2020); therefore, when professional input is sought, it is most likely to be from an HCP specialized in psychosocial supports and gender development. Thus, this chapter is uniquely focused on developmentally appropriate psychosocial practices, although other HCPs, such as pediatricians and family practice HCPs may also find these standards useful as they engage in professional work with gender diverse children and their families.

This chapter employs the term "gender diverse" given that gender trajectories in prepubescent children cannot be predicted and may evolve over time (Steensma, Kreukels et al., 2013). At the same time, this chapter recognizes some children will remain stable in a gender identity they articulate early in life that is discrepant from the sex assigned at birth (Olson et al., 2022). The term, "gender diverse" includes transgender binary and nonbinary children, as well as gender diverse children who will ultimately not identify as transgender later in life. Terminology is inherently culturally bound and evolves over time. Thus, it is possible terms used here may become outdated and we will find better descriptors.

This chapter describes aspects of medical necessary care intended to promote the well-being and gender-related needs of children (see medically necessary statement in the Global Applicability chapter, Statement 2.1). This chapter advocates everyone employs these standards, to the extent possible. There may be situations or locations in which the recommended resources are not fully available. HCPs/teams lacking resources need to work toward meeting these standards. However, if unavoidable limitations preclude components of these recommendations, this should not hinder providing the best services currently available. In those locations where some but not all recommended services exist, choosing not to implement potentially beneficial care services risks harm to a child (Murchison et al., 2016; Telfer et al., 2018; Riggs et al., 2020). Overall, it is imperative to prioritize a child's best interests.

A vast empirical psychological literature indicates early childhood experiences frequently set the stage for lifelong patterns of risk and/or resilience and contribute to a trajectory of development more or less conducive to well-being and a positive quality of life (Anda et al., 2010; Masten & Cicchetti, 2010; Shonkoff & Garner, 2012). The available research indicates, in general, gender diverse youth are at greater risk for experiencing psychological difficulties (Ristori & Steensma, 2016) than age- matched cisgender peers as a result of encountering destructive experiences, including trauma and maltreatment stemming from gender diversity-related rejection and other harsh, non-accepting interactions (Barrow & Apostle, 2018; Giovanardi et al., 2018; Gower, Rider, Brown et al., 2018; Grossman & D'Augelli, 2006; Hendricks & Testa, 2012; Reisner, Greytak

et al., 2015; Roberts et al., 2014; Tishelman & Neumann-Mascis, 2018). Further, literature indicates prepubescent children who are well accepted in their gender diverse identities are generally well-adjusted (Malpas et al., 2018; Olson et al., 2016). Assessment and treatment of children typically emphasizes an *ecological* approach, recognizing children need to be safe and nurtured in each setting they frequent (Belsky, 1993; Bronfenbrenner, 1979; Kaufman & Tishelman, 2018; Lynch & Cicchetti, 1998; Tishelman et al., 2010; Zielinski & Bradshaw, 2006). Thus, the perspective of this chapter draws on basic psychological literature and knowledge of the unique risks to gender diverse children and emphasizes the integration of an ecological approach to understanding their needs and to facilitating positive mental health in all gender care. This perspective prioritizes fostering well-being and quality of life for a child throughout their development. Additionally, this chapter also embraces the viewpoint, supported by the substantial psychological research cited above, that psychosocial gender-affirming care (Hidalgo et al., 2013) for prepubescent children offers a window of opportunity to promote a trajectory of well-being that will sustain them over time and during the transition to adolescence. This approach potentially can mitigate some of the common mental health risks faced by transgender and gender diverse (TGD) teens, as frequently described in literature (Chen et al., 2021; Edwards-Leeper et al., 2017; Haas et al., 2011; Leibowitz & de Vries, 2016; Reisner, Bradford et al., 2015; Reisner, Greytak et al., 2015).

Developmental research has focused on understanding various aspects of gender development in the earliest years of childhood based on a general population of prepubescent children. This research has typically relied on the assumption that child research participants are cisgender (Olezeski et al., 2020) and has reported gender identity stability is established in the preschool years for the general population of children, most of whom are likely not gender diverse (Kohlberg, 1966; Steensma, Kreukels et al., 2013). Recently, developmental research has demonstrated gender diversity can be observed and identified in young prepubescent children (Fast & Olson, 2018; Olson & Gülgöz, 2018; Robles et al., 2016). Nonetheless, empirical study in this area is limited, and at this time there are no psychometrically sound assessment measures capable of reliably and/or fully ascertaining a prepubescent child's self-understanding of their own gender and/or gender-related needs and preferences (Bloom et al., 2021). Therefore, this chapter emphasizes the importance of a nuanced and individualized clinical approach to gender assessment, consistent with the recommendations from various guidelines and literature (Berg & Edwards-Leeper, 2018; de Vries & Cohen-Kettenis, 2012; Ehrensaft, 2018; Steensma & Wensing-Kruger, 2019). Research and clinical experience have indicated gender diversity in prepubescent children may, for some, be fluid; there are no reliable means of predicting an individual child's gender evolution (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013), and the gender-related needs for a particular child may vary over the course of their childhood.

It is important to understand the meaning of the term "assessment" (sometimes used synonymously with the term "evaluation"). There are multiple contexts for assessment (Krishnamurthy et al., 2004) including rapid assessments that take place during an immediate crisis (e.g., safety assessment when a child may be suicidal) and focused assessments when a family may have a circumscribed question, often in the context of a relatively brief consultation (Berg & Edwards-Leeper, 2018). The term assessment is also often used in reference to "diagnostic assessment," which can also be called an "intake" and is for the purpose of determining whether there is an issue that is diagnosable and/or could benefit from a therapeutic process. This chapter focus on comprehensive assessments, useful for understanding a child and family's needs and goals (APA, 2015; de Vries & Cohen-Kettenis, 2012; Srinath et al., 2019; Steensma & Wensing-Kruger, 2019). This type of psychosocial assessment is not necessary for all gender diverse children, but may be requested for a number of reasons. Assessments may present a useful opportunity to start a process of support for a gender diverse child and their family, with the understanding that gender diverse children benefit when their family dynamics include

Statements of Recommendations

7.1- We recommend health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess a general knowledge of gender diversity across the life span.
7.2- We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.
7.3- We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.
7.4- We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.
7.5- We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.
7.6- We recommend health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning, and language skills.
7.7- We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).
7.8- We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.
7.9- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.
7.10- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age-appropriate psychoeducation about gender development.
7.11- We recommend that health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.
7.12- We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.
7.13- We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.
7.14- We recommend the health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.
7.15- We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

acceptance of their gender diversity and parenting guidance when requested. Comprehensive assessments are appropriate when solicited by a family requesting a full understanding of the child's gender and mental health needs in the context of gender diversity.

In these circumstances, family member mental health issues, family dynamics, and social and cultural contexts, all of which impact a gender diverse child, should be taken into consideration (Barrow & Apostle, 2018; Brown & Mar, 2018; Cohen-Kettenis et al., 2003; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Ristori & Steensma, 2016; Tishelman & Neumann-Mascis, 2018). This is further elaborated upon in the text below.

It is important HCPs working with gender diverse children strive to understand the child and the family's various aspects of identity and experience: racial, ethnic, immigrant/refugee status, religious, geographic, and socio-economic, for example, and be respectful and sensitive to cultural context in clinical interactions (Telfer et al., 2018). Many factors may be relevant to culture and gender, including religious beliefs, gender-related expectations, and the degree to which gender diversity is accepted (Oliphant et al., 2018). Intersections between gender diversity, sociocultural diversity, and minority statuses can be sources of strength, social stress, or both (Brown & Mar, 2018; Oliphant et al., 2018; Riggs & Treharne, 2016).

Each child, family member, and family dynamic is unique and potentially encompasses multiple cultures and belief patterns. Thus, HCPs of all disciplines should avoid stereotyping based on preconceived ideas that may be incorrect or biased (e.g., that a family who belongs to a religious organization that is opposed to appreciating gender diversity will necessarily be unsupportive of their child's gender diversity) (Brown & Mar, 2018). Instead, it is essential to approach each family openly and understand each family member and family pattern as distinct.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 7.1

We recommend the health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess general knowledge of gender diversity across the life span.

HCPs working with gender diverse children should acquire and maintain the necessary training and credentials relevant to the scope of their role as professionals. This includes licensure, certification, or both by appropriate national and/or regional accrediting bodies. We recognize the specifics of credentialing and regulation of professionals vary globally. Importantly, basic licensure, certification, or both may be insufficient in and of itself to ensure competency working with gender diverse children, as HCPs specifically require in-depth training and supervised experience in childhood gender development and gender diversity to provide appropriate care.

Statement 7. 2

We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.

HCPs should receive training and supervised expertise in general child and family mental health across the developmental spectrum from toddlerhood through adolescence, including evidence-based assessment and intervention approaches. Gender diversity is not a mental health disorder; however, as cited above, we know mental health can be adversely impacted for gender diverse children (e.g., through gender minority stress) (Hendricks & Testa, 2012) that may benefit from exploration and support; therefore, mental health expertise is highly recommended. Working with children is a complex endeavor, involving an understanding of a child's developmental needs at various ages, the ability to comprehend the forces impacting a child's well-being both inside and outside the family (Kaufman & Tishelman, 2018), and an ability to fully assess when a child is unhappy or experiencing significant mental health difficulties, related or unrelated to gender. Research has indicated high levels of adverse experiences and trauma in the gender diverse community of children, including susceptibility to rejection or even maltreatment (APA, 2015; Barrow & Apostle, 2018; Giovanardi et al., 2018; Reisner, Greytak et al., 2015; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). HCPs need to be cognizant of the potential for adverse experiences and be able to initiate effective interventions to prevent harm and promote positive well-being.

Statement 7.3

We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.

The experience of gender diversity in autistic children as well as in children with other forms of neurodivergence may present extra clinical complexities (de Vries et al., 2010; Strang, Meagher et al., 2018). For example, autistic children may find it difficult to self-advocate for their gender-related needs and may communicate in highly individualistic ways (Kuvalanka et al., 2018; Strang, Powers et al., 2018). They may have varied interpretations of gender-related experiences given common differences in communication and thinking style. Because of the unique needs of gender diverse neurodivergent children, they may be at high risk for being misunderstood (i.e., for their communications to be misinterpreted). Therefore, professionals providing support to these children can best serve them by receiving training and developing expertise in autism and related neurodevelopmental presentations and/or collaborating with autism specialists (Strang, Meagher et al., 2018). Such training is especially relevant as research has documented

higher rates of autism among gender diverse youth than in the general population (de Vries et al., 2010; Hisle-Gorman et al., 2019; Shumer et al., 2015).

Statement 7.4

We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.

Continuing professional development regarding gender diverse children and families may be acquired through various means, including through readings (journal articles, books, websites associated with gender knowledgeable organizations), attending on-line and in person trainings, and joining peer supervision/consultation groups (Bartholomaeus et al., 2021).

Continuing education includes 1) maintaining up-to-date knowledge of available and relevant research on gender development and gender diversity in prepubescent children and gender diversity across the life span; 2) maintaining current knowledge regarding best practices for assessment, support, and treatment approaches with gender diverse children and families. This is a relatively new area of practice and health care professionals need to adapt as new information emerges through research and other avenues (Bartholomaeus et al., 2021).

Statement 7.5

We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.

A comprehensive assessment, when requested by a family and/or an HCP can be useful for developing intervention recommendations, as needed, to benefit the well-being of the child and other family members. Such an assessment can be beneficial in a variety of situations when a child and/or their family/guardians, in coordination with providers, feel some type of intervention would be helpful. Neither assessments nor interventions should ever be used as a means of covertly or overtly discouraging a child's gender diverse expressions or identity. Instead, with appropriately trained providers, assessment can be an effective means of better understanding how to support a child and their family without privileging any particular gender identity or expression. An assessment can be especially important for some children and their families by collaborating to promote a child's gender health, well-being, and self-fulfillment.

A comprehensive assessment can facilitate the formation of an individualized plan to assist a gender diverse prepubescent children and family members (de Vries & Cohen-Kettenis, 2012; Malpas et al., 2018; Steensma & Wensing-Kruger, 2019; Telfer et al., 2018; Tishelman & Kaufman, 2018). In such an assessment, integrating information from multiple sources is important to 1) best understand the child's gender needs and make recommendations; and 2) identify areas of child, family/caregiver, and community strengths and supports specific to the child's gender status and development as well as risks and concerns for the child, their family/caregivers and environment. Multiple informants for both evaluation and support/intervention planning purposes may include the child, parents/caregivers, extended family members, siblings, school personnel, HCPs, the community, broader cultural and legal contexts and other sources as indicated (Berg & Edwards-Leeper, 2018; Srinath, 2019).

An HCP conducting an assessment of gender diverse children needs to explore gender-related issues but must also take a broad view of the child and the environment, consistent with the ecological model described above (Bronfenbrenner, 1979) to fully understand the factors impacting a child's well-being and areas of gender support and risk (Berg & Edwards-Leeper, 2018; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Tishelman & Neumann-Mascis, 2018). This includes understanding the strengths and challenges experienced by the child/family and that are present in the environment. We advise HCPs conducting an assessment with gender diverse children to consider incorporating multiple assessment domains, depending on the child and the family's needs and circumstances. Although some of the latter listed domains below do not directly address the child's gender (see items 7–12 below), they need to be accounted for in a gender assessment, as indicated by clinical judgment, to understand the complex web of factors

that may be affecting the child's well-being in an integrated fashion, including gender health, consistent with evaluation best practices a (APA, 2015; Berg & Edwards-Leeper, 2018; Malpas et al., 2018) and develop a multi-pronged intervention when needed.

Summarizing from relevant research and clinical expertise, assessment domains often include 1) a child's asserted gender identity and gender expression, currently and historically; 2) evidence of dysphoria, gender incongruence, or both; 3) strengths and challenges related to the child, family, peer and others' beliefs and attitudes about gender diversity, acceptance and support for child; 4) child and family experiences of gender minority stress and rejection, hostility, or both due to the child's gender diversity; 5) level of support related to gender diversity in social contexts (e.g., school, faith community, extended family); 6) evaluation of conflict regarding the child's gender and/or parental/caregiver/sibling concerning behavior related to the child's gender diversity; 7) child mental health, communication and/or cognitive strengths and challenges, neurodivergence, and/or behavioral challenges causing significant functional difficulty; 8) relevant medical and developmental history; 9) areas that may pose risks (e.g., exposure to domestic and/or community violence, any form of child maltreatment; history of trauma; safety and/or victimization with peers or in any other setting; suicidality); 10) co-occurring significant family stressors, such as chronic or terminal illness, homelessness or poverty; 11) parent/caregiver and/or sibling mental health and/or behavioral challenges causing significant functional difficulty; and 12) child's and family's strengths and challenges.

A thorough assessment incorporating multiple forms of information gathering is helpful for understanding the needs, strengths, protective factors, and risks for a specific child and family across environments (e.g., home/school). Methods of information gathering often include 1) interviews with the child, family members and others (e.g., teachers), structured and unstructured; 2) caregiver and child completed standardized measures related to gender; general child well-being; child cognitive and communication skills and developmental disorders/disabilities; support and acceptance by parent/caregiver, sibling, extended family and peers; parental stress; history of childhood adversities; and/or other issues as appropriate (APA, 2020; Berg & Edwards-Leeper, 2018; Kaufman & Tishelman, 2018; Srinath, 2019).

Depending on the family characteristics, the developmental profile of the child, or both, methods of information gathering also may also benefit from including the following 1) child and/or family observation, structured and unstructured; and 2) structured and visually supported assessment techniques (worksheets; self-portraits; family drawings, etc.) (Berg & Edwards-Leeper, 2018).

Statement 7.6

We recommend that health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning and language skills.

Given the complexities of assessing young children who, unlike adults, are in the process of development across a range of domains (cognitive, social, emotional, physiological), it is important to consider the developmental status of a child and gear assessment modalities and interactions to the individualized abilities of the child. This includes tailoring the assessment to a child's developmental stage and abilities (preschoolers, school age, early puberty prior to adolescence), including using language and assessment approaches that prioritize a child's comfort, language skills, and means of self-expression (Berg & Edwards-Leeper, 2018; Srinath, 2019). For example, relevant developmental factors, such as neurocognitive differences (e.g., autism spectrum conditions), and receptive and expressive language skills should be considered in conducting the assessment. Health care professionals may need to consult with specialists for guidance in cases in which they do not possess the specialized skills themselves (Strang et al., 2021).

Statement 7.7

We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).

HCPs conducting an assessment with gender diverse children and families need to account for developmental, emotional, and environmental factors that may constrain a child's, caregiver's, sibling or other's report or influence their belief systems related to gender (Riggs & Bartholomaeus, 2018). As with all child psychological assessments, environmental and family/caregiver reactions (e.g., punishment), and/or cognitive and social factors may influence a child's comfort and/or ability to directly discuss certain factors, including gender identity and related issues (Srinath, 2019). Similarly, family members may feel constrained in freely expressing their concerns and ideas depending on family conflicts or dynamics and/or other influences (e.g., cultural/religious; extended family pressure) (Riggs & Bartholomaeus, 2018).

Statement 7.8

We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.

The goal of psychotherapy should never be aimed at modifying a child's gender identity (APA, 2021; Ashley, 2019b; Paré, 2020; SAMHSA, 2015; UN Human Rights Council, 2020), either covertly or overtly. Not all gender diverse children or their families need input from MHPs as gender diversity is not a mental health disorder (Pediatric Endocrine Society, 2020; Telfer et al., 2018). Nevertheless, it is often appropriate and helpful to seek psychotherapy when there is distress or concerns are expressed by parents to improve psychosocial health and prevent further distress (APA, 2015). Some of the common reasons for considering psychotherapy for a gender diverse child and family include the following 1) A child is demonstrating significant conflicts, confusion, stress or distress about their gender identity or needs a protected space to explore their gender (Ehrensaft, 2018; Spivey and Edwards-Leeper, 2019); 2) A child is experiencing external pressure to express their gender in a way that conflicts with their self-knowledge, desires, and beliefs (APA, 2015); 3) A child is struggling with mental health concerns, related to or independent of their gender (Barrow & Apostle, 2018); 4) A child would benefit from strengthening their resilience in the face of negative environmental responses to their gender identity or presentation (Craig & Auston, 2018; Malpas et al., 2018); 5) A child may be experiencing mental health and/or environmental concerns, including family system problems that can be misinterpreted as gender congruence or incongruence (Berg & Edwards-Leeper, 2018); and 6) A child expresses a desire to meet with an MHP to get gender-related support. In these situations, the psychotherapy will focus on supporting the child with the understanding that the child's parent(s)/caregiver(s) and potentially other family members will be included as necessary (APA, 2015; Ehrensaft, 2018; McLaughlin & Sharp, 2018). Unless contraindicated, it is extremely helpful for parents/guardians to participate in some capacity in the psychotherapy process involving prepubescent children as family factors are often central to a child's well-being. Although relatively unexplored in research involving gender diverse children, it may be important to attend to the relationship between siblings and the gender diverse child (Pariseau et al., 2019; Parker & Davis-McCabe, 2021).

HCPs should employ interventions tailor-made to the individual needs of the child that are designed to 1) foster protective social and emotional coping skills to promote resilience in the face of potential negative reactions to the child's gender identity, expressions, or both (Craig & Austin, 2016; Malpas et al., 2018; Spencer, Berg et al., 2021); 2) collaboratively problem-solve social challenges to reduce gender minority stress (Barrow & Apostle, 2018; Tishelman & Neumann-Mascis, 2018); 3) strengthen environmental supports for the child and/or members of the immediate and extended family (Kaufman & Tishelman, 2018); and 4) provide the child an opportunity to further understand their internal gender experiences (APA, 2015; Barrow& Apostle, 2018; Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). It is helpful for HCPs to develop a relationship with a gender diverse child and family that can endure over time as needed. This enables the child/family to establish a long-term trusting relationship throughout childhood whereby the HCP can offer support and guidance as a child matures and as potentially

different challenges or needs emerge for the child/family (Spencer, Berg et al., 2021; Murchison et al., 2016). In addition to the above and within the limits of available resources, when a child is neurodivergent, an HCP who has the skill set to address both neurodevelopmental differences and gender is most appropriate (Strang et al., 2021).

As outlined in the literature, there are numerous reasons parents/caregivers, siblings, and extended family members of a prepubescent child may find it useful to seek psychotherapy for themselves (Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). As summarized below, some of these common catalysts for seeking such treatment occur when one or more *family members* 1) desire education around gender development (Spivey & Edwards-Leeper, 2019); 2) are experiencing significant confusion or stress about the child's gender identity, expression, or both (Ashley, 2019c; Ehrensaft, 2018); 3) need guidance related to emotional and behavioral concerns regarding the gender diverse child (Barrow & Apostle, 2018; 4) need support to promote affirming environments outside of the home (e.g., school, sports, camps) (Kaufman & Tishelman, 2018); 5) are seeking assistance to make informed decisions about social transition, including how to do so in a way that is optimal for a child's gender development and health (Lev & Wolf-Gould, 2018); 6) are seeking guidance for dealing with condemnation from others, including political entities and accompanying legislation, regarding their support for their gender diverse child (negative reactions directed toward parents/caregivers can sometimes include rejection and/or harassment/abuse from the social environment arising from affirming decisions (Hidalgo & Chen, 2019); 7) are seeking to process their own emotional reactions and needs about their child's gender identity, including grief about their child's gender diversity and/or potential fears or anxieties for their child's current and future well-being (Pullen Sansfaçon et al., 2019); and 8) are emotionally distressed and/or in conflict with other family members regarding the child's gender diversity (as needed, HCPs can provide separate sessions for parents/caregivers, siblings and extended family members for support, guidance, and/or psychoeducation) (McLaughlin & Sharp, 2018; Pullen Sansfaçon et al., 2019; Spivey & Edwards-Leeper, 2019).

Statement 7.9

We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.

Consistent with the ecological model described above and, as appropriate, based on individual/family circumstances, it can be extremely helpful for HCPs to prioritize coordination with important others (e.g., teachers, coaches, religious leaders) in a child's life to promote emotional and physical safety across settings (e.g., school settings, sports and other recreational activities, faith-based involvement) (Kaufman & Tishelman, 2018). Therapeutic and/or support groups are often recommended as a valuable resource for families/caregivers and/or gender diverse children themselves (Coolhart, 2018; Horton et al., 2021; Malpas et al., 2018; Murchison et al., 2016).

Statement 7.10

We recommend HCPs offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age appropriate psycho-education about gender development.

Parents/caregivers and their gender diverse child should have the opportunity to develop knowledge regarding ways in which families/caregivers can best support their child to maximize resilience, self-awareness, and functioning (APA, 2015; Ehrensaft, 2018; Malpas, 2018; Spivey & Edwards-Leeper, 2019). It is neither possible nor is it the role of the HCP to predict with certainty the child's ultimate gender identity; instead, the HCP's task is to provide a safe space for the child's identity to develop and evolve over time without attempts to prioritize any particular developmental trajectory with regard to gender (APA, 2015; Spivey & Edwards-Leeper, 2019). Gender diverse children and early adolescents have different needs and experiences than older adolescents, socially and physiologically, and those differences should be reflected in the individualized approach HCPs

provide to each child/family (Keo-Meir & Ehrensaft, 2018; Spencer, Berg et al., 2021).

Parents/caregivers and their children should also have the opportunity to develop knowledge about gender development and gender literacy through age-appropriate psychoeducation (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy involves understanding the distinctions between sex designated at birth, gender identity, and gender expression, including the ways in which these three factors uniquely come together for a child (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). As a child gains gender literacy, they begin to understand their body parts do not necessarily define their gender identity and/or their gender expression (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy also involves learning to identify messages and experiences related to gender within society. As a child gains gender literacy, they may view their developing gender identity and gender expression more positively, promoting resilience and self-esteem, and diminishing risk of shame in the face of negative messages from the environment. Gaining gender literacy through psychoeducation may also be important for siblings and/or extended family members who are important to the child (Rider, Vencill et al., 2019; Spencer, Berg et al., 2021).

Statement 7.11

We recommend health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender-affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.

As a child matures and approaches puberty, HCPs should prioritize working with children and their parents/caregivers to integrate psychoeducation about puberty, engage in shared decision-making about potential gender-affirming medical interventions, and discuss fertility-related and other reproductive health implications of medical treatments (Nahata, Quinn et al., 2018; Spencer, Berg et al., 2021). Although only limited empirical research exists to evaluate such interventions, expert consensus and developmental psychological literature generally support the notion that open communication with children about their bodies and preparation for physiological changes of puberty, combined with gender-affirming acceptance, will promote resilience and help to foster positive sexuality as a child matures into adolescence (Spencer, Berg et al., 2019). All these discussions may be extended (e.g., starting earlier) to include neurodivergent children, to ensure there is enough time for reflection and understanding, especially as choices regarding future gender- affirming medical care potentially arise (Strang, Jarin et al., 2018). These discussions could include the following topics:

- Review of body parts and their different functions;
- The ways in which a child's body may change over time with and without medical intervention;
- The impact of medical interventions on later sexual functioning and fertility;
- The impact of puberty suppression on potential later medical interventions;
- Acknowledgment of the current lack of clinical data in certain areas related to the impacts of puberty suppression;
- The importance of appropriate sex education prior to puberty.

These discussions should employ developmentally appropriate language and teaching styles, and be geared to the specific needs of each individual child (Spencer, Berg et al., 2021).

Statement 7.12

We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.

Gender social transition refers to a process by which a child is acknowledged by others and has the opportunity to live publicly, either in all situations or in certain situations, in the gender identity they affirm and has no singular set of parameters or actions (Ehrensaft et al., 2018).

Gender social transition has often been conceived in the past as binary—a girl transitions to a boy, a boy to a girl. The concept has expanded to include children who shift to a nonbinary or individually shaped iteration of gender identity (Chew et al., 2020; Clark et al., 2018). Newer research indicates the social transition process may serve a protective function for some prepubescent children and serve to foster positive mental health and well-being (Durwood et al., 2017; Gibson et al., 2021; Olson et al., 2016). Thus, recognition that a child's gender may be fluid and develop over time (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013) is not sufficient justification to negate or deter social transition for a prepubescent child when it would be beneficial. Gender identity evolution may continue even after a partial or complete social transition process has taken place (Ashley, 2019e; Edwards-Leeper et al., 2018; Ehrensaft, 2020; Ehrensaft et al., 2018; Spivey & Edwards-Leeper, 2019). Although empirical data remains limited, existing research has indicated children who are most assertive about their gender diversity are most likely to persist in a diverse gender identity across time, including children who socially transition prior to puberty (Olson et al., 2022; Rae et al., 2019; Steensma, McGuire et al., 2013). Thus, when considering a social transition, we suggest parents/caregivers and HCPs pay particular attention to children who consistently and often persistently articulate a gender identity that does not match the sex designated at birth. This includes those children who may explicitly request or desire a social acknowledgement of the gender that better matches the child's articulated gender identity and/or children who exhibit distress when their gender as they know it is experienced as incongruent with the sex designated at birth (Rae et al., 2019; Steensma, Kreukels et al., 2013).

Although there is a dearth of empirical literature regarding best practices related to the social transition process, clinical literature and expertise provides the following guidance that prioritizes a child's best interests (Ashley, 2019e; Ehrensaft, 2018; Ehrensaft et al, 2018; Murchison et al., 2016; Telfer et al., 2018): 1) social transition should originate from the child and reflect the child's wishes in the process of making the decision to initiate a social transition process; 2) an HCP may assist exploring the advantages/benefits, plus potential challenges of social transition; 3) social transition may best occur in all or in specific contexts/settings only (e.g., school, home); and 4) a child may or may not choose to disclose to others that they have socially transitioned, or may designate, typically with the help of their parents/caregivers, a select group of people with whom they share the information.

In summary, social transition, when it takes place, is likely to best serve a child's well-being when it takes place thoughtfully and individually for each child. A child's social transition (and gender as well) may evolve over time and is not necessarily static, but best reflects the cross-section of the child's established self-knowledge of their present gender identity and desired actions to express that identity (Ehrensaft et al., 2018).

A social transition process can include one or more of a number of different actions consistent with a child's affirmed gender (Ehrensaft et al., 2018), including:

- Name change;
- Pronoun change;
- Change in sex/gender markers (e.g., birth certificate; identification cards; passport; school and medical documentation; etc.);
- Participation in gender-segregated programs (e.g., sports teams; recreational clubs and camps; schools; etc.);
- Bathroom and locker room use;
- Personal expression (e.g., hair style; clothing choice; etc.);
- Communication of affirmed gender to others (e.g., social media; classroom or school announcements; letters to extended families or social contacts; etc.).

Statement 7.13

We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.

It is important children who have engaged in social transition be afforded the same opportunities as other children to continue considering

meanings and expressions of gender throughout their childhood years (Ashley 2019e; Spencer, Berg et al., 2021). Some research has found children may experience gender fluidity or even detransition after an initial social transition. Research has not been conclusive about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition—due to gender evolution, or potentially other reasons (e.g., safety concerns; gender minority stress) (Olson et al., 2022; Steensma, Kreukels et al., 2013). A recent research report indicates in the US, detransition occurs with only a small percentage of youth five years after a binary social transition (Olson et al., 2022); further follow-up of these young people would be helpful. Replication of these findings is important as well since this study was conducted with a limited and self-selected participant pool in the US and thus may not be applicable to all gender diverse children. In summary, we have limited ability to know in advance the ways in which a child's gender identity and expressions may evolve over time and whether or why detransition may take place for some. In addition, not all gender diverse children wish to explore their gender (Telfer et al., 2018). Cisgender children are not expected to undertake this exploration, and therefore attempts to force this with a gender diverse child, if not indicated or welcomed, can be experienced as pathologizing, intrusive and/or cisnormative (Ansara & Hegarty, 2012; Bartholomaeus et al., 2021; Oliphant et al., 2018).

Statement 7.14

We recommend health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.

Social transition in prepubescent children consists of a variety of choices, can occur as a process over time, is individualized based on both a child's wishes and other psychosocial considerations (Ehrensaft, 2018), and is a decision for which possible benefits and challenges should be weighted and discussed.

A social transition may have potential benefits as outlined in clinical literature (e.g., Ehrensaft et al., 2018) and supported by research (Fast & Olson, 2018; Rae et al., 2019). These include facilitating gender congruence while reducing gender dysphoria and enhancing psychosocial adjustment and well-being (Ehrensaft et al., 2018). Studies have indicated socially transitioned gender diverse children largely mirror the mental health characteristics of age matched cisgender siblings and peers (Durwood et al., 2017). These findings differ markedly from the mental health challenges consistently noted in prior research with gender diverse children and adolescents (Barrow & Apostle, 2018) and suggest the impact of social transition may be positive. Additionally, social transition for children typically can only take place with the support and acceptance of parents/caregivers, which has also been demonstrated to facilitate well-being in gender diverse children (Durwood et al., 2021; Malpas et al., 2018; Pariseau et al., 2019), although other forms of support, such as school-based support, have also been identified as important (Durwood et al., 2021; Turban, King et al., 2021). HCPs should discuss the potential benefits of a social transition with children and families in situations in which 1) there is a consistent, stable articulation of a gender identity that is incongruent with the sex assigned at birth (Fast & Olson, 2018). This should be differentiated from gender diverse expressions/behaviors/interests (e.g., playing with toys, expressing oneself through clothing or appearance choices, and/or engaging in activities socially defined and typically associated with the other gender in a binary model of gender) (Ehrensaft, 2018; Ehrensaft et al., 2018); 2) the child is expressing a strong desire or need to transition to the gender they have articulated as being their authentic gender (Ehrensaft et al., 2018; Fast & Olson, 2018; Rae et al., 2019); and 3) the child will be emotionally and physically safe during and following transition (Brown & Mar, 2018). Prejudice and discrimination should be considerations, especially in localities where acceptance of gender diversity is limited or prohibited (Brown & Mar, 2018; Hendricks & Testa, 2012; Turban, King et al., 2021). Of note, there can also be possible risks to a gender diverse child who does not socially transition, including 1) being ostracized or bullied for being perceived as not conforming to prescribed community

gender roles and/or socially expected patterns of behavior; and 2) living with the internal stress or distress that the gender they know themselves to be is incongruent with the gender they are being asked to present to the world.

To promote gender health, the HCP should discuss the potential challenges of a social transition. One concern often expressed relates to fear that a child will preclude considering the possible evolution of their gender identity as they mature or be reluctant to initiate another gender transition even if they no longer feel their social transition matches their current gender identity (Edwards-Leeper et al., 2016; Ristori & Steensma, 2016). Although limited, recent research has found some parents/caregivers of children who have socially transitioned may discuss with their children the option of new gender iterations (for example, reverting to an earlier expression of gender) and are comfortable about this possibility (Olson et al., 2019). Another often identified social transition concern is that a child may suffer negative sequelae if they revert to the former gender identity that matches their sex designated at birth (Chen et al., 2018; Edwards-Leeper et al., 2019; Steensma & Cohen-Kettenis, 2011). From this point of view, parents/caregivers should be aware of the potential developmental effect of a social transition on a child.

HCPs should provide guidance to parents/caregivers and supports to a child when a social gender transition is being considered or taking place by 1) providing consultation, assessment, and gender supports when needed and sought by the parents/caregivers; 2) aiding family members, as needed, to understand the child's desires for a social transition and the family members' own feelings about the child's expressed desires; 3) exploring with, and learning from, the parents/caregivers whether and how they believe a social transition would benefit their child both now and in their ongoing development; 4) providing guidance when parents/caregivers are not in agreement about a social transition and offering the opportunity to work together toward a consistent understanding of their child's gender status and needs; 5) providing guidance about safe and supportive ways to disclose their child's social transition to others and to facilitate their child transitioning in their various social environments (e.g., schools, extended family); 6) facilitating communication, when desired by the child, with peers about gender and social transition as well as fortifying positive peer relationships; 7) providing guidance when social transition may not be socially accepted or safe, either everywhere or in specific situations, or when a child has reservations about initiating a transition despite their wish to do so; there may be multiple reasons for reservations, including fears and anxieties; 8) working collaboratively with family members and MHPs to facilitate a social transition in a way that is optimal for the child's unfolding gender development, overall well-being, and physical and emotional safety; and 9) providing psychoeducation about the many different trajectories the child's gender may take over time, leaving pathways open to future iterations of gender for the child, and emphasizing there is no need to predict an individual child's gender identity in the future (Malpas et al., 2018).

All of these tasks incorporate enhancing the quality of communication between the child and family members and providing an opportunity for the child to be heard and listened to by all family members involved. These relational processes in turn facilitate the parents/caregivers' success in making informed decisions about the advisability and/or parameters of a social transition for their child (Malpas et al., 2018).

One role of HCPs is to provide guidance and support in situations in which children and parents/caregivers wish to proceed with a social transition but conclude that the social environment would not be accepting of those choices, by 1) helping parents/caregivers define and extend safe spaces in which the child can express their authentic gender freely; 2) discussing with parents/caregivers ways to advocate that increase the likelihood of the social environment being supportive in the future, if this is a realistic goal; 3) intervening as needed to help the child/family with any associated distress and/or shame brought about by the continued suppression of authentic gender identity and the need for secrecy; and 4) building both the child's and the family's resilience, instilling the understanding that if the social environment is having difficulty accepting a child's social transition and affirmed gender identity, it is not because of some shortcoming in the child but because of

insufficient gender literacy in the social environment (Ehrensaft et al., 2018).

Statement 7.15

We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

All children have the right to be supported and respected in their gender identities (Human Rights Campaign, 2018; Paré, 2020; SAMHSA, 2015). As noted above, gender diverse children are a particularly vulnerable group (Barrow & Apostle, 2018; Cohen-Kettenis et al., 2003; Giovanardi et al., 2018; Gower, Rider, Coleman et al., 2018; Grossman & D'Augelli, 2007; Hendricks & Testa, 2012; Reisner, Greytak et al., 2015; Ristori & Steensma, 2016; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). The responsibilities of HCPs as advocates encompass acknowledging social determinants of health are critical for marginalized minorities (Barrow & Mar, 2018; Hendricks & Testa, 2012). Advocacy is taken up by all HCPs in the form of child and family support (APA, 2015; Malpas et al., 2018). Some HCPs may be called on to move beyond their individual offices or programs to advocate for gender diverse children in the larger community, often in partnership with stakeholders, including parents/caregivers, allies, and youth (Kaufman & Tishelman, 2018; Lopez et al., 2017; Vanderburgh, 2009). These efforts may be instrumental in enhancing children's gender health and promoting their civil rights (Lopez et al., 2017).

HCP's voices may be essential in schools, in parliamentary bodies, in courts of law, and in the media (Kuvalanka et al., 2019; Lopez et al., 2017; Whyatt-Sames, 2017; Vanderburgh, 2009). In addition, HCPs may have a more generalized advocacy role in acknowledging and addressing the frequent intentional or unintentional negating of the experience of gender diverse children that may be transmitted or communicated by adults, peers, and in media (Rafferty et al., 2018). Professionals who possess the skill sets and find themselves in appropriate situations can provide clear de-pathologizing statements on the needs and rights of gender diverse children and on the damage caused by discriminatory and transphobic rules, laws, and norms (Rafferty et al., 2018).

CHAPTER 8 Nonbinary

Nonbinary is used as an umbrella term referring to individuals who experience their gender as outside of the gender binary. The term nonbinary is predominantly but not exclusively associated with global north contexts and may sometimes be used to describe indigenous and non-Western genders. The term nonbinary includes people whose genders are comprised of more than one gender identity simultaneously or at different times (e.g., bigender), who do not have a gender identity or have a neutral gender identity (e.g., agender or neutrois), have gender identities that encompass or blend elements of other genders (e.g., polygender, demiboy, demigirl), and/or who have a gender that changes over time (e.g., genderfluid) (Kuper et al., 2014; Richards et al., 2016; Richards et al., 2017; Vincent, 2019). Nonbinary people may identify to varying degrees with binary-associated genders, e.g., nonbinary man/woman, or with multiple gender terms, e.g., nonbinary and genderfluid (James et al., 2016; Kuper et al., 2012). Nonbinary also functions as a gender identity in its own right (Vincent, 2020). It is important to acknowledge this is not an exhaustive list, the same identities can have different meanings for different people, and the use of terms can vary over time and by location.

Genderqueer, first used in the 1990s, is an identity category somewhat older than nonbinary—which first emerged in approximately the late 2000s (Nestle et al., 2002; Wilchins, 1995). Genderqueer may sometimes be used synonymously with nonbinary or may communicate a specific consciously politicized dimension to a person's gender. While transgender is used in many cultural contexts as an umbrella term inclusive of nonbinary people, not all nonbinary people consider themselves to be transgender for a range of reasons, including because they consider being transgender to be exclusively within the gender binary or because they do not feel "trans enough" to describe themselves as transgender (Garrison, 2018). Some nonbinary people are unsure or ambivalent about whether they would describe themselves as transgender (Darwin, 2020; Vincent, 2019).

In the context of the English language, nonbinary people may use the pronouns they/them/theirs, or neopronouns which include e/em/eir, ze/zir/hir, er/ers/erself among others (Moser & Devereux, 2019; Vincent, 2018). Some nonbinary people use a combination of pronouns (either deliberately mixing usage, allowing free choice, or changing with social context), or prefer to avoid gendered pronouns entirely, instead using their name. Additionally, some nonbinary people use she/her/hers, or he/him/his, sometimes or exclusively, whilst in some regions in the world descriptive language for nonbinary people does not (yet) exist. In contexts outside of English, a wide range of culturally specific linguistic adaptations and evolutions can be observed (Attig, 2022; Kirey-Sitnikova, 2021; Zimman, 2020). Also of note, some languages use one pronoun that is not associated with sex or gender while others gender all nouns. These variations in language are likely to influence nonbinary people's experience of gender and how they interact with others.

Recent studies suggest nonbinary people comprise roughly 25% to over 50% of the larger transgender population, with samples of youth reporting the highest percentage of nonbinary people (Burgwal et al., 2019; James et al., 2016; Watson, 2020). In recent studies of transgender adults, nonbinary people tend to be younger than transgender men and transgender women and in studies of both youth and adults, nonbinary people are more likely to have been assigned female at birth (AFAB). However, these findings should be interpreted with caution as there are likely a number of complex, sociocultural factors influencing the quality, representativeness, and accuracy of this data (Burgwal et al., 2019; James et al., 2016; Watson, 2020; Wilson & Meyer, 2021) (see also Chapter 3—Population Estimates).

Understanding gender identities and gender expressions as a non-linear spectrum

Nonbinary genders have long been recognized historically and cross-culturally (Herdt, 1994; McNabb, 2017; Vincent & Manzano, 2017). Many gender identity categories are culturally specific and cannot be easily translated from their context, either linguistically or in relation to the Western paradigm of gender. Historical settler colonial interactions with indigenous people with

non-Western genders remain highly relevant as cultural erasure and the intersections of racism and cisnormativity may detrimentally inform the social determinants of health of indigenous gender diverse people. From the 1950s, gender was used to reference the socially constructed categorization of behaviors, activities, appearance, etc. in relation to a binary model of male/man/masculine, and female/woman/feminine within contemporary Western contexts. However, gender now has a wider range of possible meanings, appreciating interrelated yet distinguishable concepts, including gendered biology (sex), gender roles, gender expression, and gender identity (Vincent, 2020). Aspects of gender expression that might traditionally be understood culturally as "masculine", "feminine", or "androgynous" may be legitimately expressed among people of any and all gender identities, whether nonbinary or not. For example, a nonbinary individual presenting in a feminine manner cannot be taken to imply they will necessarily later identify as a woman or access interventions associated with transgender women, such as vaginoplasty. A person's gender nonconformity in relation to cultural expectations should neither be viewed as a cause for concern nor assumed to be indicative of clinical complexity—for example, a nonbinary person assigned male at birth (AMAB) wearing feminine-coded clothing, using she/her pronouns, but keeping a masculine-coded first name.

Modeling gender as a spectrum offers greater nuance than a binary model. However, there remain significant limitations in a linear spectrum model that can lead to uncritical generalizations about gender. For example, while it is intuitive to position the "binary options" (man/male, woman/female) at either end of such a continuum, doing so situates masculinity as oppositional to femininity, failing to accommodate gender neutrality, the expression of masculinity and femininity simultaneously, and genderqueer or non-Western concepts of gender. It is essential HCPs do not view nonbinary genders as "partial" articulations of transgender manhood (in nonbinary people AFAB) or transgender womanhood (in nonbinary people AMAB), or definitively as "somewhere along the spectrum of masculinity/femininity"; some nonbinary individuals consider themselves outside male/female dichotomization altogether. A *non-linear* spectrum indicates differences of gender expression, identity, or needs around gender affirmation between clients should not be compared for the purposes of situating them along a linear spectrum. Additionally, the interpretation of gender expression is subjective and culturally defined, and what may be experienced or viewed as highly feminine by one person may not be viewed as such by another (Vincent, 2020). HCPs benefit from avoiding assumptions about how each client conceptualizes their gender and by being prepared to be led by a given client's personal understanding of gender as it relates to the client's gender identity, expression, and any need for medical care.

The gender development process experienced by all transgender and gender diverse (TGD) people regardless of their relationship to a gender binary appear to share similar themes (e.g., awareness, exploration, meaning making, integration), but the timing, progression, and personal experiences associated with each of these processes vary both within and across groups of transgender and nonbinary people (Kuper, Wright et al., 2018; Kuper, Lindley et al., 2019; Tatum et al., 2020). Sociocultural and intersectional perspectives can be helpful at contextualizing gender development and social transition, including how individual experiences are shaped by the social and cultural context and how they interact with additional domains of identity and personal experience.

The need for access to gender-affirming care

Some nonbinary people seek gender-affirming care to alleviate gender dysphoria or incongruence and increase body satisfaction through medically necessary interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). Some nonbinary people may feel a certain treatment is necessary for them—see also Chapter 5—Assessment of Adults (Beek et al., 2015; Jones et al., 2019; Köhler et al., 2018), whilst others do not (Burgwal & Motmans, 2021; Nieder, Eyssel et al., 2020), and the proportion of nonbinary people who seek gender-affirming care and the specific goals of

that care, remains unclear. It is the role of the health care professional to provide information about existing medical options (and their availability) that might help alleviate gender dysphoria or incongruence and increase body satisfaction without making assumptions about which treatment options may best fit each individual person.

Motivations for accessing (or not accessing) gender-affirming medical interventions, including hormone treatment, surgeries, or both are heterogeneous and potentially complex (Burgwal & Motmans, 2021; Vincent, 2019, 2020) and should be explored collaboratively before making decisions about physical interventions. The need of an individual to access gender-affirming medical procedures cannot be predicted by their gender role, expression, or identity. For example, some transgender women have no need of vaginoplasty, while some nonbinary individuals AMAB may need and benefit from that same intervention. Further, nonbinary people seeking gender-affirming care associated closely with a transition pathway from their assigned sex/gender to the other binarily-recognized category (i.e., estrogen therapy and vaginoplasty for someone AMAB) does not undermine the validity of their nonbinary identity.

While barriers to care remain widespread for many transgender people, nonbinary people appear to experience particularly high rates of difficulty accessing both mental health and gender-affirming medical care (Clark et al., 2018; James, 2016). Many nonbinary people report having experiences with health care professionals who were not affirming of their nonbinary gender, including experiences where health care professionals convey beliefs that their gender is not valid, or they are fundamentally more difficult to provide care for (Valentine, 2016; Vincent, 2020). Nonbinary people may face provider assumptions that they do not need or want gender-affirming treatment (Kcomt et al., 2020; Vincent, 2020) and have described experiencing pressure to present themselves as transgender men or transgender women (within a binary framework of gender) in order to access treatment (Bradford et al., 2019; Taylor et al., 2019). At times, nonbinary people find themselves educating the provider from whom they are seeking services despite the inappropriateness of providers relying primarily on their patients for education (Kcomt et al., 2020). In comparison to transgender men and transgender women, Burgwal and Motmans (2021) found that nonbinary people experienced more fear of prejudice from health care providers, less confidence in the services provided, and greater difficulty knowing where to go to for care. Studies in both Europe and US have shown that nonbinary individuals tend to delay care more often than binary transgender men or transgender women, with fear of insensitive or incompetent treatment being the most cited reason (Burgwal & Motmans, 2021; Grant et al., 2011). Nonbinary people also appear less likely to disclose their gender identity to their health care providers than other transgender people (Kcomt et al., 2020).

The need for an appropriate level of support

Providing gender-affirming care to nonbinary people goes beyond the provision of specific gender-affirming interventions such as hormone therapy or surgery and involves supporting the overall health and development of nonbinary people. Minority stress models have been adapted to conceptualize how the gender-related stressors experienced by transgender people are associated with physical and mental health disparities (Delozier et al., 2020; Testa et al., 2017). Nonbinary people appear to experience minority stressors that are both similar to and unique from those experienced by transgender men and transgender women. Johnson (2020) reported that experiences of invalidation are particularly high among nonbinary people, e.g., statements or actions conveying a belief that nonbinary identities are not "real" or are the result of a "fad" or "phase," and nonbinary people appear less likely than transgender men and transgender women to have their correct pronouns used by others. Similarly, nonbinary people have described feeling "invisible" to others (Conlin, 2019; Taylor, 2018) and one study found that nonbinary youth reported lower levels of self-esteem in comparison to young transgender men and transgender women (Thorne, Witcomb et al., 2019).

While many TGD people report experiences of discrimination, victimization, and interpersonal rejection (James, 2016) including bullying within

samples of youth (Human Rights Campaign, 2018; Witcomb et al., 2019), the prevalence of these experiences may vary across groups and appears influenced by additional intersecting characteristics. For example, Newcomb (2020) found transgender women and nonbinary youth AMAB experienced higher levels of victimization than transgender men and nonbinary youth AFAB, with nonbinary youth AMAB reporting the highest levels of traumatic stress. In a second study, Poquiz (2021) found transgender men and transgender women experienced higher levels of discrimination than nonbinary people. This intersectional complexity is also likely contributing to the variability in findings from studies comparing the physical and mental health of nonbinary and transgender men and transgender women, with some studies indicating more physical and mental health concerns among nonbinary people, some reporting less concerns, and some reporting no difference between groups (Scandurra, 2019).

Given nonbinary identity narratives may be less widely available than more binary-oriented identity narratives, nonbinary people may have less resources available to explore and articulate their gender-related sense of self. For example, this might include access to community spaces and interpersonal relationships where nonbinary identity can be explored, or access to language and concepts that allow more nuanced consideration of nonbinary experiences (Bradford et al., 2018; Fiani & Han, 2019; Galupo et al., 2019). Clinical guidance is now developing to assist providers in adapting gender-affirming therapeutic care to meet these unique experiences of nonbinary people (Matsuno, 2019; Rider, Vencill et al., 2019).

Gender-affirming medical interventions for nonbinary people

In contexts where a particular medical intervention does not have established precedent, it is important that before the intervention is considered, the individual is provided with an overview of the available information, including recognition of potential knowledge limits. It is equally important to undertake and document a comprehensive discussion of the physical changes needed and the potential limitations in achieving those attributes, as well as the implication that any given intervention may or may not enhance an individual's ability to express their gender.

With regards to estrogen therapy for nonbinary people AMAB, it is important to note the possibility of breast growth cannot be avoided (Seal, 2017). Although the extent of growth is highly variable, this should be made clear if a nonbinary person seeks some of the other changes associated with estrogen therapy (such as softening of skin and reduction in facial hair growth) but does not want or is ambivalent about breast growth. Likewise, for nonbinary people AFAB who may wish to access testosterone to acquire some changes but not others, it should be recognized that if facial hair development is needed, genital growth is inevitable (Seal, 2017). The time frame for taking testosterone means these changes are likely also to be accompanied by an irreversible vocal pitch drop, although the extent of each is individual (Vincent, 2019; Ziegler et al., 2018). A vocal pitch drop without the development of body hair is another such challenge. For some nonbinary people, hair removal is a very important part of their gender affirmation (Cocchetti, Ristori, Romani et al., 2020).

If hormonal therapy is discontinued and gonads are retained, many physical changes will revert to pre-hormone therapy status as gonadal hormones once again take effect, including reversal of amenorrhea and body hair development in nonbinary people AFAB and reduction in muscular definition and erectile dysfunction in nonbinary people AMAB. Other changes will be permanent such as "male-pattern" baldness, genital growth, and facial hair growth in nonbinary people AFAB or breast development in nonbinary people AMAB (Hembree et al., 2017). These will require further interventions to reverse, such as electrolysis or mastectomy and are sometimes described as "partially reversible" (Coleman et al., 2012). As the implications of using low-dose hormone therapy are not documented in this patient population, it is important to consider monitoring for cardiovascular risk and bone health if low-dose hormone therapy is used. For more detailed information see Chapter 12—Hormone Therapy.

If neither testosterone nor estrogen expression is needed, inhibition of estrogen and/or testosterone

Statements of Recommendations

8.1- We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their experience of gender.
8.2- We recommend health care professionals consider gender-affirming medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."
8.3- We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment, unless hormone therapy is required to achieve the desired surgical result.
8.4- We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

production is possible. The implications of this with regards to increased cardiovascular risk, reduced bone mineralization, and risk of depression should be discussed and measures taken to mitigate risk (Brett et al., 2007; Vale et al., 2010; Wassersug & Johnson, 2007). For more information see also Chapter 9—Eunuchs and Chapter 12—Hormone Therapy. Exploration of medical and/or social transition independently of each other and options to explore hormones, surgery, or both independently of each other should be available to everyone, whether the person is a transgender man, transgender woman, or a nonbinary person.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 8.1

We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their nonbinary experiences of gender.

An individualized assessment with a nonbinary person starts with an understanding of how they experience their own gender and how this impacts their goals for the care they are seeking. How individuals conceptualize their gender-related experiences are likely to vary across groups and cultures and may incorporate experiences associated with other intersecting aspects of identity (e.g., age, sexuality, race, ethnicity, socioeconomic status, disability status) (Kuper et al., 2014; Subramanian et al., 2016).

HCPs should avoid making a priori assumptions about any client's gender identity, expression, or needs for care. They should also be mindful that a client's nonbinary experience of gender may or may not be relevant to the assessment and treatment-related goals. The extent to which the client's gender is relevant to their treatment goals should determine the level of detail at which their gender identity is explored. For example, when seeking care for a presenting concern wholly unrelated to gender, simply determining the correct name and pronouns may be sufficient (Knutson et al., 2019). When addressing a concern for which current or past hormonal or surgical status is relevant, more detail may be needed, even if the concern is not specifically gender-related.

Clinical settings need to be welcoming, reflective of the diversity of genders, and affirm the experiences of gender of nonbinary people to be culturally competent. Ensuring clinic and provider information (e.g., websites), forms (e.g., intake surveys), and other materials are inclusive of nonbinary identities and experiences conveys that nonbinary people are welcome and recognized (Hagen & Galupo, 2014). Using free text fields for gender identity and pronouns is more inclusive than using a list of response options. Ensuring privacy at the reception desk, setting up alternatives for listing legal names in digital databases (in cultural contexts where this is necessary), installing gender-neutral toilets, and setting up alternatives to calling out the legal name in the waiting room are additional examples of transgender and gender diverse (TGD) cultural competency (Burgwal et al., 2021). In care settings, it is important preferences for names, pronouns, and other gender-related terms are asked and used both initially and on a regular basis as they may vary over time and circumstance.

HCPs are encouraged to adopt an approach that focuses on strengths and resilience.

Increasingly, critiques are emerging regarding HCPs over-focus on gender-related distress as it is also important to consider experiences of increased comfort, joy, and self-fulfilment that can result from self-affirmation and access to care (Ashley, 2019a; Benestad, 2010). In addition to utilizing diagnoses when/where required to facilitate access to care, HCPs are encouraged to collaboratively explore with clients this broader range of potential gender-related experiences and how they may fit with treatment options (Motmans et al., 2019). For all TGD people, resiliency factors such as supportive relationships, participation in communities that include similar others, and identity pride are essential to consider as they are associated with a range of positive health outcomes (Bowling et al., 2019; Budge, 2015; Johns et al., 2018).

Awareness of the limitations that exist in the tools providers have historically used to assess transgender people's experience of dysphoria is important as they may be particularly pronounced for many nonbinary people. Most gender-related measures assume clients experience their gender in a binary way, among other concerns (e.g., Recalled Gender Identity Scale, Utrecht Gender Dysphoria Scale). While several newer measures have been developed in an attempt to better capture the experiences of nonbinary people (McGuire et al., 2018; McGuire et al., 2020), open-ended discussion is likely to provide a deeper and more accurate understanding of each individual's unique experiences of dysphoria and their associated care needs. Similarly, while more recent iterations of diagnostic categories (i.e., "gender dysphoria" in the DSM 5 and "gender incongruence" in ICD-11) were intended to be inclusive of people with nonbinary experiences of gender, they may not adequately capture the full diversity and scope of experiences of gender-related distress, particularly for nonbinary people. In addition to distress associated with aspects of one's physical body and presentation (including features that may be existing or absent), distress may arise from how one experiences their own gender, how one's gender is perceived within social situations, and from experiences of minority stress associated with one's gender (Winters & Ehrbar, 2010). Nonbinary peoples' experiences in each of these areas may or may not be similar to those of transgender men or women.

A person-centered approach for affirming care includes specific discussion of how different interventions may or may not shift the client's comfort with their own experience of gender, and how their gender is perceived by others. Nonbinary people can face challenges in reconciling their personal identities with the limits of the medical treatments available and can also encounter confusion and intolerance from society regarding their gender presentations (Taylor et al., 2019). Emerging research suggests the medical treatment needs of nonbinary people are particularly diverse, with some reporting needs for treatments that have typically been associated with transition trajectories historically associated with transgender men and women and some reporting alternative approaches (e.g., low dose hormone therapy, surgery without hormone therapy), some reporting a lack of interest in medical treatment, and some reporting feeling unsure about their needs (Burgwal & Motmans, 2021; James et al., 2016). Conceptualizing assessment as an ongoing process is particularly important given gender-related experiences and associated needs may shift throughout the lifespan. Given the ongoing evolution in treatment options and knowledge of treatment effects, particularly for nonbinary people, clients will benefit from providers who regularly seek up-to-date knowledge and convey these updates to their clients.

Statement 8.2

We recommend health care professionals consider medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."

Previous requirements for accessing hormonal treatment and surgery, such as "living in a gender role that is congruent with one's gender identity," do not reflect the lived experiences of many TGD people (Coleman et al., 2012). Due to the entrenched nature of the gender binary in most contemporary Western cultures, one can typically only be understood by others as a man or woman within most settings (Butler, 1993). Hence, the visibility and understanding of nonbinary embodiments and expressions is limited. This is due to gendered cues

being almost always understood in reference to a gender binary (Butler, 1993). Presently, it can be difficult for nonbinary people to be reliably recognized as their gender via visual cues associated with their gender expression (e.g., clothing, hair). However, androgyny or gender nonconformity may be communicated by the mixing or combining of cultural markers with traditionally masculine or feminine connotations. Because there is no commonly recognized "nonbinary category" within most contemporary Western, global north cultural contexts, nonbinary visibility often necessitates explicit sharing of one's gender with others or the use of cues that may be interpreted as gender nonconformity (but not necessarily nonbinary).

For these reasons, framing access to medical care in the context of someone experiencing a "social gender transition" where they are "living in a gender role that is congruent with one's gender identity" is not in line with the way many TGD people understand themselves and their personal transition process. For some, "living in a gender role that is congruent with one's gender identity" does not involve changes in name, pronouns, or gender expression even as medical intervention may be necessary. Even if a person is able to live in ways that are congruent with their gender identity, it may be difficult for an outside observer to assess this without learning directly from that person how they understand their own experience in this regard. Expectation of "social gender transition" may be unhelpful when considering eligibility for gender- affirming care, such as hormones and surgery, and rigid expectations of what a "social gender role transition" "should" look like can be a barrier to care for nonbinary people. There is no logical requirement gender-affirming medical interventions can only be done once a person legally changes their name, changes the gender marker on their identity documents, or wears or refrains from wearing particular items of clothing. Nonbinary people may struggle to access recognition of their genders on formal documentation, which may negatively affect their mental health or well-being (Goetz & Arcomano, 2021). TGD people may benefit from specific support in accessing (or retaining) their gender marker of preference. A requirement that someone disclose their gender identity in all circles of their lives (family, work, school, etc.) in order to access medical care may not be consistent with their goals and can place them at risk if it is not safe to do so.

Statement 8.3

We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment unless hormone therapy is required to achieve the desired surgical result.

The trajectory of "hormones before surgery" is an option across a range of surgical interventions. Some nonbinary people will seek gender-affirming surgical treatment to alleviate gender incongruence and increase body satisfaction (Beek et al., 2015; Burgwal & Motmans, 2021; Jones et al., 2019; Koehler et al., 2018), but do not want hormonal treatment or are unable to undergo hormonal therapy due to other medical reasons (Nieder, Eyssel et al., 2020). Currently, it is unknown for which proportion of nonbinary people these options apply.

Perhaps the surgery which has some specific association with nonbinary people (rather than sought by transgender men or undergone by some cisgender women) is mastectomy in nonbinary people AFAB who have not taken testosterone—although testosterone is not a requirement for this type of surgery—and some nonbinary people AFAB may need breast reduction (McTernan et al., 2020). An example of a surgery for which at least a period of hormone therapy may be necessary is metoidioplasty that enhances the enlarged clitoris produced by testosterone therapy. See Chapter 13—Surgery and Postoperative Care for more detail on whether hormone therapy is necessary for various surgeries. Procedures addressing the internal reproductive system include hysterectomy, unilateral or bilateral salpingo-oophorectomy, and vaginectomy. Hormone therapy is not required for any of these procedures, but hormone replacement therapy (either with estrogens, testosterone, or both) is advisable in those individuals undergoing a total gonadectomy to prevent adverse effects on their cardiovascular and musculoskeletal systems (Hembree et al., 2017; Seal, 2017). For phalloplasty, while there is no surgical requirement per se for a minimum period of testosterone

treatment, virilization (or the absence of virilization) of the clitoris and labia minora may impact the choice of surgical technique and influence surgical options. For more information see Chapter 13—Surgery and Postoperative Care.

Nonbinary AMAB clients should be informed commencing estrogen therapy post-surgically with no prior history of estrogen therapy may influence (perhaps adversely) the surgical result (Kanhai, Hage, Asscheman et al., 1999; Kanhai, Hage, Karim et al., 1999). Nonbinary people AMAB requesting a bilateral orchiedectomy do not require estrogen therapy to achieve a better outcome (Hembree et al., 2017). In these contexts, it is good practice to inform clients of the risks and benefits of hormone replacement therapy (estrogens, testosterone, or both) in preventing adverse effects on the cardiovascular and musculoskeletal system as well as alternative treatment options, such as calcium plus vitamin D supplementation to prevent osteoporosis (Hembree et al., 2017; Seal, 2017; Weaver et al., 2016). See also Chapter 9—Eunuchs for those who choose to forgo hormone replacement therapy. In the case of vaginoplasty, individuals should be advised lack of testosterone-blocking therapy may cause postoperative hair growth in the vagina when hair-bearing skin graft and flaps have been used (Giltay & Gooren, 2000).

Additional surgical requests for nonbinary people AMAB include penile-preserving vaginoplasty, vaginoplasty with preservation of the testicle(s), and procedures resulting in an absence of external primary sexual characteristics (i.e., penectomy, scrotectomy, orchiectomy, etc.). The surgeon and individual seeking treatment are advised to engage in discussions so as to understand the individual's goals and expectations as well as the benefits and limitations of the intended (or requested) procedure, to make decisions on an individualized basis and collaborate with other health care providers who are involved (if any).

Statement 8.4.

We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

All nonbinary individuals who seek gender-affirming hormonal therapies should be offered information and guidance about fertility options (Hembree et al., 2017; De Roo et al., 2016; Defreyne, Elaut et al., 2020; Defreyne, van Schuvlenbergh et al., 2020; Nahata et al., 2017; Quinn et al., 2021). It is important to discuss the potential impact of hormone therapy on fertility prior to initiation. This discussion should include fertility preservation options, the extent to which fertility may or may not be regained if hormone therapy is ceased, and the fact that hormone therapy per se is not birth control. For more information see Chapter 16—Reproductive Health.

Recent studies suggest that nonbinary individuals are less likely to access care and make their needs for potential interventions heard (Beek et al., 2015; Taylor et al., 2019). As such, it stands to reason that any gender diverse individual should be offered information on current options and techniques for fertility preservation, ideally prior to commencing hormonal treatment as the quality of the sperm or eggs may be impacted by exposure to hormones (Hamada et al., 2015; Payer et al., 1979). However, this should in no way preclude making inquiries and seeking more information at a later time, as there is evidence that fertility is still possible for individuals taking estrogen and testosterone (Light et al., 2014). A decision by a nonbinary or gender diverse person that fertility preservation or counseling is not needed should not be used as a basis for denying or delaying access to hormonal treatment.

CHAPTER 9 Eunuchs

Among the many people who benefit from gender-affirming medical care, those who identify as eunuchs are among the least visible. The 8th version of the Standards of Care (SOC) includes a discussion of eunuch individuals because of their unique presentation and their need for medically necessary gender-affirming care (see Chapter 2—Global Applicability, Statement 2.1).

Eunuch individuals are those assigned male at birth (AMAB) and wish to eliminate masculine physical features, masculine genitals, or genital functioning. They also include those whose testicles have been surgically removed or rendered nonfunctional by chemical or physical means and who identify as eunuch. This identity-based definition for those who embrace the term eunuch does not include others, such as men who have been treated for advanced prostate cancer and reject the designation of eunuch. We focus here on those who identify as eunuchs as part of the gender diverse umbrella.

As with other gender diverse individuals, eunuchs may also seek castration to better align their bodies with their gender identity. As such, eunuch individuals are gender nonconforming individuals who have needs requiring medically necessary gender-affirming care (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008).

Eunuch individuals identify their gender identities in various ways. Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation. The focus of this chapter is on the treatment and care for those who identify as eunuchs. Health care professionals (HCPs) will encounter eunuchs requesting hormonal interventions, castration, or both to become eunuchs. These individuals may also benefit from a eunuch community because of the identification—with or without actual castration.

While there is a 4000-year history of eunuchs in society, the greatest wealth of information about contemporary eunuch-identified people is found within the large online peer-support community that congregates on sites such as the Eunuch Archive (www.eunuch.org), which was established in 1998. The moderators of this site attempt to maintain both medical and historical accuracy in its discussion forums, although there is certainly misinformation as well. According to the website, as of January 2022, there have been over 130,000 registered members from various parts of the world and frequently over 90% of those reading the site are "guests" rather than members. The website lists over 23,000 threads and nearly 220,000 posts. For example, two threads giving instructions for self-castration by injection of different toxins directly into the testicles have about 2,500 posts each, and each has been read well over one million times. Beginning in 2001, there have been 20 annual international gatherings of the Eunuch Archive community in Minneapolis in addition to many regional gatherings elsewhere. While the topic of castration is of interest to the great majority of people who participate in the discussions, it is a minority of the membership who seriously seek or have undergone castration. Many former Eunuch Archive members have achieved their goals and no longer participate.

Because of misconceptions and prejudice about historic eunuchs, the invisibility of contemporary eunuchs, and the social stigma that affects all gender and sexual minorities, few eunuch individuals come out publicly as eunuch and many will tell no one and will share only with like-minded people in an online community or are known as such only to close family and friends (Wassersug & Lieberman, 2010). The stereotypes of eunuchs are often highly negative (Lieberman 2018), and eunuchs may suffer the same minority stress as other stigmatized groups (Wassersug & Lieberman, 2010). Research into minority stress affecting gender diverse people should therefore include eunuchs.

The current set of recommendations is directed at professionals working with individuals who identify as eunuchs (Johnson & Wassersug, 2016; Vale et al., 2010) requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs). Although not a specific diagnostic category in the ICD or DSM, eunuch is a useful construct as it speaks to the specifics of eunuch experience while also connecting it to the experience of gender incongruence more broadly. Eunuch individuals will present themselves clinically in various ways. They wish for

Statements of Recommendations

9.1- We recommend health care professionals and other users of the Standards of Care 8th guidelines should apply the recommendations in ways that meet the needs of eunuch individuals
9.2- We recommend health care professionals should consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.
9.3- We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.
9.4- We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

a body that is compatible with their eunuch identity—a body that does not have fully functional male genitalia. Some other eunuch individuals feel acute discomfort with their male genitals and need to have them removed to feel comfortable in their bodies (Johnson et al., 2007; Roberts et al., 2008). Others are indifferent to having male external genitalia as long as they are only physically present and do not function to produce androgens and male secondary sexual features (Brett et al., 2007). Hormonal means may be used to suppress the production of androgens, although orchiectomy provides a permanent solution for those not wishing genital functioning (Wibowo et al., 2016). Some eunuch individuals desire lower testosterone levels achieved with orchiectomy, but many will elect some form of hormone replacement to prevent adverse effects associated with hypogonadism. Most who elect hormone therapy choose either a full or partial replacement dose of testosterone. A smaller number elect estrogen.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 9.1.

We recommend health care professionals and other users of the Standards of Care, Version 8 guidelines should apply the recommendations in ways that meet the needs of eunuch individuals.

Eunuch individuals are part of the population of gender diverse people who experience gender incongruence and may also seek gender-affirming care. Like other transgender and gender diverse (TGD) individuals, eunuchs require access to affirming care to gain comfort with their gendered self. Each section of the SOC addresses the needs of diverse individuals, and eunuchs can be included within that group. They may have commonality with some nonbinary individuals in that social transition may not be a desired option, and hormone therapy may not play the same role as it might in a social transition or transition within the binary (Wassersug & Lieberman, 2010).

Like other gender diverse individuals, eunuch individuals may be aware of their identity in childhood or adolescence. Due to the lack of research into the treatment of children who may identify as eunuchs, we refrain from making specific suggestions.

Eunuch individuals may seek medical or surgical care (hormone suppression, orchiectomy, and, in some cases, penectomy) to achieve physical, psychological, or sexual changes (Wassersug & Johnson, 2007). It is important all patients, including both eunuchs and those seeking castration, establish and maintain a relationship with an HCP that is built upon trust and mutual understanding. Given a lack of awareness of eunuchs within the general medical community and the fear among many individuals seeking castration they will not be accepted, many do not receive appropriate primary care and screening tests (Jäggi et al., 2018). Increased awareness and education among medical providers will help address the need to be informed about the need to include eunuchs in discussions of gender diversity (Deutsch, 2016a). It goes without saying that eunuchs require and deserve the same primary care services as the general population. The topic of screening tests for cancers, such as prostate and breast, is an important area for

discussion as the risks of hormone-related cancers are likely different among male-assigned people whose testosterone and estrogen levels are not in the male range. Due to a lack of studies looking at the prevalence and incidence of hormone-related cancers in the eunuch population, there is no evidence to guide how often to screen for hormone-related cancers with prostate exams, PSA measurements, mammograms, etcetera.

The large literature on prostate cancer patients who have been medically or surgically castrated provides information about some of the effects of post-pubertal castration (such as potential osteoporosis, depression, or metabolic syndrome), but voluntary eunuchs may interpret the results very differently from those castrated for medical reasons. Chemical or surgical castration may be experienced as a source of distress to cis men with prostate cancer, while the same treatment may be affirming and a source of comfort for eunuch individuals. Similarly, transmasculine people who have a mastectomy to gain comfort with their bodies experience that surgery differently from ciswomen who undergo mastectomy to treat breast cancer (Koçan & Gürsoy, 2016; van de Grift et al., 2016). The prostate cancer information is well summarized by Wassersug et al. (2021) who provide references that explore the large literature on the subject. Such information on the effects of castration should be made available to those seeking castration.

Following an assessment as per the SOC-8, medical options requested by the patient can be considered and prescribed, if appropriate. These options can be tailored to the individual to create a plan that reflects their specific needs and preferences. The number and type of interventions applied and the order in which these take place may differ from person to person. These options are consistent with both the assessment and surgery chapters of the SOC-8. Treatment options for eunuchs to consider include:

- Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual, or androgynous;
- Orchiectomy to stop testicular production of testosterone;
- Orchiectomy with or without penectomy to alter their body to match their self-image;
- Orchiectomy followed by hormone replacement with testosterone or estrogen.

Per statement 5.6 in Chapter 5—Assessment of Adults, eunuch individuals seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

Statement 9.2.

We recommend health care professionals consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.

The same assessment process recommended in the SOC-8 ought to apply to eunuchs (see Chapter 5—Assessment of Adults). The Eunuch Archive has a large number of posts from individuals finding great difficulty in seeking medical providers who will perform castration surgery. There are a large number of eunuch individuals who have performed self-surgery or have had surgery performed by people who are not credentialed medical providers (Johnson & Irwig, 2014). There are also clinical reports of eunuch individuals who have self-castrated and accounts of patients who have misled medical providers to obtain castration (Hermann & Thorstenson, 2015; Mukhopadhyay & Chowdhury, 2009). There is no doubt when members of this population are denied access to quality medical treatment, they will take actions that may cause them great harm, such as bleeding and infection that may require hospital admission (Hay, 2021; Jackowich et al., 2014; Johnson & Irwig, 2014). Because of these serious problems and harm caused through self-surgery, surgery by unqualified practitioners or the unsupervised use of medications that affect hormones, it is important health care providers create a welcoming environment and consider various treatment options after careful assessment

to avoid the problems that lack of access to treatment and withholding treatment will cause.

When desired, castration can be achieved either chemically or surgically. For some, chemical castration can be an appropriate trial prior to undergoing surgical castration to determine how the individual feels when hypogonadal (Vale et al., 2010). Chemical castration is usually reversible if the medications are discontinued (Wassersug et al., 2021). The most common types of medications used to lower testosterone levels are antiandrogens and estrogen.

The two most commonly used antiandrogens, cyproterone acetate and spironolactone, are oral. Estrogen is sometimes prescribed for prostate cancer patients to lower serum testosterone levels via negative feedback at the hypothalamus and pituitary gland. Estrogens and antiandrogens may not fully suppress testosterone levels into the female or castrate range, and oral estrogens increase the risk of venous thromboembolism. Although not commonly used due to cost, gonadotropin releasing hormone (GnRH) agonists are a very effective method for suppressing the production of sex steroids and fertility (Hembree et al., 2017). When selecting a medication, we advise using those which have been studied in multiple transgender populations (i.e., estrogen, cyproterone acetate, GnRH agonists) rather than medications with little to no peer-reviewed scientific studies (i.e., bicalutamide, rectal progesterone, etc.) (Angus et al., 2021; Butler et al., 2017; Efstathiou et al., 2019; Tosun et al., 2019).

Many eunuch individuals pursue hormone replacement therapy following castration as they do not desire the complete suppression of hormone levels and consequent problems, such as the increased risk of osteoporosis. The two main options for replacement of sex steroids are testosterone and estrogen that may be used in full or partial replacement doses. The majority elect testosterone as they present as male and are not interested in feminization. A minority elect estrogen at a high enough dose to prevent osteoporosis, but low enough avoid most feminization. They may identify as nonbinary, agender, or other (Johnson et al., 2007; Johnson & Wassersug, 2016).

Although studies on hormone replacement therapy in eunuchs are lacking, findings from cisgender men treated for prostate cancer can be informative regarding the effects of hormone therapy. In a randomized controlled trial of 1,694 cisgender men treated for locally advanced or metastatic prostate cancer, one group received a GnRH agonist and the other received transdermal estrogen (Langley et al., 2021). Cisgender men who received the GnRH agonist developed signs and symptoms of both androgen and estrogen deficiency, whereas men who received the estrogen patch only developed androgen-depleting symptoms. Both groups had high rates of sexual side effects (91%), and weight gain was similar among the groups. Compared with cisgender men receiving the GnRH agonist, cisgender men treated with estrogen patches had a higher self-reported quality of life, lower rates of hot flushes (35% vs. 86%), and higher rates of gynecomastia (86% vs. 38%). Metabolically, cisgender men receiving estrogen patches had favorable changes with a lower mean fasting glucose, fasting total cholesterol, systolic and diastolic blood pressure. Conversely, cisgender men receiving the GnRH agonist experienced the opposite effects. Based on this study, eunuchs may consider a low dose of transdermal estrogen therapy to avoid adverse estrogen-depleting effects, which include hot flashes, fatigue, metabolic effects, and loss of bone mineral density (Hembree et al., 2017; Langley et al., 2021). For further information see Chapter 12—Hormone Therapy.

Statement 9.3.

We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.

A frequent topic on the discussion boards of the Eunuch Archive is the difficulty of finding practitioners who are able to understand their needs. Eunuchs and those seeking castration usually are less visible than other gender minorities (Wassersug & Lieberman, 2010). Due to stigma and fear of rejection by the medical community, they may not voluntarily disclose their identity and desires to their medical or mental health providers. In some environments, medical providers may not be aware eunuchs exist and may not even know they have treated eunuch-identified patients.

The SOC section on assessment is applicable to eunuch individuals. Like other gender diverse individuals, those seeking castration can engage in an informed consent process in which qualified providers conduct assessments to ensure individuals are capable of providing informed consent prior to medical interventions and to ensure a mental health problem is not the etiology of the desire. As with other sexual and gender minorities, working with eunuchs requires an understanding that they are a diverse population, and that each person is eunuch in their own way (Johnson et al., 2007). The person seeking services benefits from the professional's accepting stance, open inquiry, suspension of judgment, and flexible expectations, combined with professional competency and expertise.

To provide appropriate treatment, providers must establish trust and respect by creating an inclusive environment for eunuch-identified people. For eunuch-identified individuals, the ideal intake form would ask the assigned sex and identified gender and offer multiple gender options, including "eunuch" and "other." Individuals may identify with more than one option and should be able to select more than one.

HCPs may be involved in the assessment, psychotherapy (if desired), preparation, and follow-up for medical and surgical gender-affirming interventions. They may also provide support for partners and families. Eunuch-identified individuals who want the support of a qualified mental health provider will benefit from a therapist who meets the experience and criteria set out in Chapter 4—Education.

While some individuals seeking or considering castration come to counseling or therapy because they want emotional support or help with decision-making, many come to providers for an assessment in preparation for specific medical interventions (Vale et al., 2010).

Statement 9.4.

We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

Several research studies have contributed to our knowledge of contemporary eunuch-identified people and have explored demographic characteristics and sexuality (Handy et al., 2015; Vale et al., 2013; Wibowo et al., 2012, 2016). Medical and MHPs should assume eunuchs are sexual people capable of sexual activity, pleasure, and relationships, unless they report otherwise (Wibowo et al., 2021). Research has shown there is great diversity among eunuchs regarding the level of desire, type of preferred physical or sexual contact, and nature of preferred relationships (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008). While some enjoy active sex lives with or without romantic relationships, others identify as asexual or aromantic and are relieved by the loss of libido achieved through surgical or chemical castration (Brett et al., 2007). Each person is different, and one's genital status does not determine sexual or romantic attraction (Walton et al., 2016; Yule et al., 2015).

Regardless of the type of chemical suppression or surgery a person has undergone, they may be capable of sexual pleasure and sexual activity. Contrary to popular belief, eunuchs are not necessarily asexual or nonsexual (Aucoin & Wassersug, 2006). Safe sex education is necessary for all people who engage in sexual activity that could involve an exchange of body fluids. See Chapter 17—Sexual Health for information regarding sex education and safe sex options for people with diverse genders and sexualities. In addition, fertility preservation should be discussed when considering medical interventions that might impact the possibilities for future parenthood. For more considerations see Chapter 16—Reproductive Health.

CHAPTER 10 Intersex

The Standards of Care, Version 7 included a chapter on the applicability of the standards to people with physical intersexuality who become gender-dysphoric and/or change their gender because they differ from transgender individuals without intersexuality in phenomenological presentation, life trajectories, prevalence, etiology, and stigma risks. The current chapter provides an update and adds recommendations on the medically necessary clinical approach to the management of individuals with intersexuality in general (see medical necessity statement in Chapter 2—Global Applicability, Statement 2.1). Because a newborn with an atypical sexual differentiation may already present with clinical challenges, including the need for family education and support from early on, the decision-making on gender assignment, subsequent clinical gender management, components of which—especially genital surgery—may be controversial, and a later risk of gender dysphoria development and gender change that is markedly increased (Sandberg & Gardner, 2022).

Terminology

"Intersex" (from Latin, literal translation "between the sexes") is a term grounded in the binary system of sex underlying mammalian (including human) reproduction. In medicine, the term is colloquially applied to individuals with markedly atypical, congenital variations in the reproductive tract. Some variations, often labeled "genital ambiguity," preclude the simple recognition of somatic sex as male or female and, in resource-rich societies, may require a comprehensive physical, endocrine, and genetic work-up, before a sex/gender is "assigned." In recent years "intersex" has also become an identity label adopted by some individuals with intersex conditions and a subset of (non-intersex) individuals with a nonbinary gender identity (Tamar-Mattis et al., 2018).

At a 2005 international consensus conference on intersex management, intersex conditions were subsumed under a new standard medical term, "Disorders of Sex Development" (DSD), defined as "congenital conditions in which development of chromosomal, gonadal, or anatomical sex is atypical" (Hughes et al., 2006). DSD covers a much wider range of conditions than those traditionally included under intersexuality and comprises conditions such as Turner syndrome and Klinefelter syndrome, which are much more prevalent. In addition, many affected individuals dislike the term "disorder," viewing it as inherently stigmatizing (Carpenter, 2018; Griffiths, 2018; Johnson et al., 2017; Lin-Su, et al., 2015; Lundberg et al., 2018; Tiryaki et al., 2018). Health care professionals (HCPs) also vary in their acceptance of the term (Miller et al., 2018). The wide-spread alternative reading of DSD as "Differences in Sex Development" can be seen as less pathologizing, but is semantically unsatisfactory as this term does not distinguish the typical genital differences between males and females from atypical sexual differentiation. Other recent attempts to come up with less obviously stigmatizing terms such as "Conditions Affecting Reproductive Development" (CARD; Delimata et al., 2018) or "Variations of/in Sex Characteristics" (VSC; Crocetti, et al., 2021) are also not specific to intersexuality.

Given these definitional issues, in this chapter we are using the term "intersexuality" (or "intersex") to refer to congenital physical manifestations only. This is done for both descriptive clarity and historical continuity. This choice is not meant to indicate an intention on our part to take sides in the ongoing discussion regarding the concept of sex/gender as a bipolar system or as a continuum, which may vary with considerations of context and utility (Meyer-Bahlburg, 2019). In 21st century societies, the concepts of sex and gender are in a process of evolution.

Prevalence

The prevalence of intersex conditions depends on the definition used. Obvious genital atypicality ("ambiguous genitalia") occurs with an estimated frequency ranging from approximately 1:2000—1:4500 people (Hughes et al., 2007). The most inclusive definitions of DSD estimate a prevalence of up to 1.7% (Blackless et al., 2000). Although these numbers are high in aggregate, the individual conditions associated with the intersex variations tend to be much rarer. For instance, androgen insensitivity syndrome (AIS) occurs in approximately 1 in 100,000 46,XY births (Mendoza & Motos, 2013), and classic congenital adrenal

hyperplasia (CAH) in approximately 1 in 15,000 46,XX births (Therrell, 2001). Prevalence figures for individual syndromes may vary dramatically between countries and ethnic groups.

Presentation

The presentation of individuals with intersex traits varies widely. Intersexuality can be recognized during prenatal ultrasound imaging, although most individuals will be identified during genital examinations at birth. In resource-rich societies, such children will undergo extensive medical diagnostic procedures within the first weeks of life. Taking into consideration the specific medical diagnosis, physical and hormonal findings, and information from long-term follow-up studies about gender outcome, joint decision-making between the health-care team and the parents generally leads to the newborn being assigned to the male or female sex/gender. Some individuals with intersexuality come to the attention of specialists only around the age of puberty, for instance, when female-raised adolescents are evaluated for primary amenorrhea.

HCPs assisting individuals with both intersexuality and gender uncertainty need to be aware that the medical context in which such individuals have grown up is typically very different from that of non-intersex TGD people. There are many different syndromes of intersexuality, and each syndrome can vary in its degree of severity. Thus, hormonal and surgical treatment approaches vary accordingly.

Some physical manifestations of intersexuality may require early urgent intervention, as in cases of urinary obstruction or of adrenal crisis in CAH. Most physical variations among individuals with intersexuality neither impair function, at least in the early years, nor risk safety for the individual. Yet, the psychosocial stigma associated with atypical genital appearance often motivates early genital surgery (commonly labeled 'corrective' or 'normalizing') long before the individual reaches the age of consent. This approach is highly controversial because it conflicts with ethical principles supporting a person's autonomy (Carpenter, 2021; Kon, 2015; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). In addition, among the manifestations without immediate safety concerns, some individuals, when older, may opt for a range of medical interventions to optimize function and appearance. The specifics of medical treatments are far beyond the scope of what can be addressed in this chapter, and the interested reader should consult the respective endocrine and surgical literature.

Some intersex conditions are associated with a greater variability in long-term gender identity outcome than others (Dessens et al., 2005). For instance, the incidence of a non-cisgender gender identity in 46,XX individuals with CAH assigned female may be as high as 5–10% (Furtado et al., 2012). The substantial biological component underlying gender identity is a critical factor that must be considered when offering psychosocial, medical, and surgical interventions for individuals with intersex conditions.

There is also ample evidence people with intersexuality and their families may experience psychosocial distress (de Vries et al., 2019; Rosenwohl-Mack et al., 2020; Wolfe-Christensen et al., 2017), in part related to psychosocial stigma (Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg, Reyes-Portillo et al., 2017; Meyer-Bahlburg et al., 2018).

Intersexuality in the psychiatric nomenclature

Since 1980, the American psychiatric nomenclature recognized individuals with intersexuality who meet the criteria for gender identity variants; however, their diagnostic categorization changed with successive DSM editions. For instance, in DSM-III (American Psychiatric Association, 1980), the Axis-I category of "transsexualism" could not be applied to such individuals in adulthood, but such children were labeled "gender identity disorder of childhood," with the medical intersex condition to be specified in Axis III. In DSM-IV-TR (American Psychiatric Association, 2000), individuals with intersexuality were excluded from the Axis-I category of "gender identity disorder" regardless of age and, instead, grouped with other conditions under the category "gender identity disorder not otherwise specified." In DSM-5 (American Psychiatric Association, 2013), which moved away from the multiaxial

Statements of Recommendations

10.1- We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.
10.2- We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.
10.3- We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.
10.4- We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.
10.5- We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.
10.6- We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.
10.7- We suggest health care professionals refer children/individuals with intersexuality and their families to mental-health providers as well as peer and other psychosocial supports as indicated.
10.8- We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.
10.9- We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.
10.10- We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.
10.11- We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.
10.12- We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

system, "gender identity disorder" was re-defined as "gender dysphoria" and applied regardless of age and intersex status, but individuals with intersexuality received the added specification "with a disorder of sex development" (Zucker et al., 2013). The just published text revision of DSM-5 (American Psychiatric Association, 2022) keeps the term gender dysphoria. Note, however, the recent revision of the International Classification of Diseases [ICD-11; World Health Organization, 2019a] has moved "gender incongruence" from the chapter "Mental, Behavioral, or Neurodevelopmental Disorders" to a new chapter "Conditions Related to Sexual Health."

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 10.1

We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.

Intersexuality, a subcategory of DSD, is a complex congenital condition that requires the involvement of experts from various medical and behavioral disciplines (Hughes et al., 2006). Team composition and function can vary depending on team location, local resources, diagnosis, and the needs of the individual with intersexuality and her/his/their family. The ideal team includes pediatric subspecialists in endocrinology, surgery and/or urology, psychology/psychiatry, gynecology, genetics, and, if available, personnel trained in social work, nursing, and medical ethics (Lee et al., 2006). The structure of the team can be in line with 1) the traditional multidisciplinary medical model; 2) the interprofessional model; or 3) the transdisciplinary model. Although these structures can appear similar, they are in fact very different and can exert varying influences on how the team functions (Sandberg & Mazur, 2014). The 2006 Consensus Statement makes no decision about which model is best—multidisciplinary, interdisciplinary, or transdisciplinary—and only states the models "imply different degrees of collaboration and professional

autonomy" (Lee, Nordenström et al., 2016). Since the publication of the Consensus Statement in 2006, such teams have been created both in Europe and in the US. A listing of teams in the US can be found on the DSD-Translational Network (DSD-TRN) website. There are also teams in a number of European countries (Thyen et al., 2018). While there are barriers to the creation of teams as noted by Sandberg and Mazur (2014), multidisciplinary teams help address a number of problems that have undermined the successful care of individuals with an intersex diagnosis and their families, such as the scattered nature of services, the limited or absent communication between professionals, and the resulting fragmented nature of the explanations individuals receive that cause more confusion than clarity.

Most individuals born with intersexuality will be identified at birth or shortly thereafter, while others will be identified at later times in the life cycle, for example at puberty (see Brain et al., 2010, Table 1). When this happens the team approach will be modified based on the diagnosis and the age of the person. In some circumstances, the composition of the team can be expanded to include other specialists as needed.

It has been reported children seen by a multidisciplinary team were significantly more likely to receive nearly the full range of services rather than only those services offered by a single provider (Crerand et al., 2019). Parents who received such care positively endorsed psychosocial services and the team approach and reported receiving more information than those who did not interact with such a team (Crerand et al., 2019).

Statement 10.2

We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.

Results from interviews with medical trainees (Liang et al., 2017; Zelin et al., 2018) and from programmatic self-audits and surveys (DeVita et al., 2018; Khalili et al., 2015) suggest medical training programs are not adequately preparing practitioners to provide competent care to individuals presenting with gender dysphoria and intersexuality. Professional and stakeholder attendees of intersex-specific events have identified ongoing education and collaboration as an important professional development need (Bertalan et al., 2018; Mazur et al., 2007). This may be especially true for adult care providers who may have less clinical guidance or support in assisting those individuals who are transitioning from pediatric to adult care (Crouch & Creighton, 2014).

However, there are few guidelines for training or assessing practitioner competency in managing these topics, and those that are available primarily apply to mental health professionals (MHPs) (Hollenbach et al., 2014), with the exception of a primary care guide (National LGBTQIA + Health Education Center, 2020).

For HCPs wanting to improve their competency, seeking consultation from experts may be an option when formal education or empirical guidelines are otherwise unavailable. Given the relative widespread adoption of multidisciplinary expert teams in the treatment of intersexuality (Pasterski et al., 2010), individuals serving on these teams are well positioned to consult with and educate other health care staff who may not have received adequate training (Hughes et al., 2006). Therefore, it is recommended the training of other professionals be a central component of team development (Auchus et al., 2010) and members of multidisciplinary teams receive training specific to team-based work, including strategies for engaging in interprofessional learning (Bisbey, et al., 2019; Interprofessional Education Collaborative Expert Panel, 2011).

Statement 10.3

We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.

Full disclosure of medical information to families of children with intersex conditions through education and counseling should begin at the time of diagnosis and should be consistent with guidance from multiple international consensus guidelines. One of the most challenging issues presented by a newborn with intersexuality, particularly

when associated with noticeable genital ambiguity, is sex assignment and from the parents' perspective, the gender of rearing (Fisher, Ristori et al., 2016). Given this is a very stressful situation for most parents, it is generally recommended the decisions about sex/gender should be made as quickly as a thorough diagnostic evaluation permits (Houk & Lee, 2010). However, the criteria for sex/gender decisions have changed over time. In the second half of the 20th century, the decisions were biased towards female assignment, because feminizing genital surgery was seen as easier and less side-effect prone than masculinizing surgery. Yet, in certain intersex conditions, for instance 46,XY 5α-RD-2 deficiency, female sex/gender assignment was found to be associated with high rates of later gender dysphoria and gender change (Yang et al., 2010). Therefore, since the International Consensus Conference on Intersex Management in 2005, sex/gender assignment takes into consideration the gradually accumulating data on long-term gender outcome in the diverse conditions of intersexuality.

The practice of disclosure seeks to enable more fully informed decision-making about care. Additionally, while shame and stigma surrounding intersexuality is associated with poorer psychosocial outcomes, open and proactive communication of health information has been proposed as a strategy to reduce those risks (de Vries et al., 2019). Depending on the person's diagnosis and developmental stage, intersex conditions may differentially impact individuals and their health care needs. Intersex-health-related communication must therefore be continuous and tailored to the individual. Research on decision-making in intersex care suggests families are influenced by how clinical teams communicate (Timmermans et al., 2018). In keeping with the SOC, we encourage providers to adopt normalizing, affirming language and attitudes across education and counseling functions. For example, describing genital atypia as a "variation" or "difference" is more affirming than using the terms "birth defect" or "abnormality."

All HCPs involved in an individual's care can provide essential education and information to families. In multidisciplinary teams, the type of education may align with an HCP's area of expertise, for example, a surgeon educating the individual on their anatomy, an endocrinologist teaching the specifics of hormonal development, or an MHP conveying the spectrums of gender and sexual identity. Other HCPs may need to provide comprehensive education. Families should receive information that is pertinent to the individual's specific intersex variation, when known. All HCPs can supplement this information with patient-centered resources available from support groups. People with intersexuality have also been hired as team members to provide education using their lived experience.

Consensus guidelines also recommend families be offered ongoing peer and professional psychosocial support (Hughes et al., 2006) that may involve counseling with a focus on problem-solving and anticipatory guidance (Hughes et al., 2006). For example, families may seek guidance in educating other people—siblings, extended family, and caregivers—about the specific intersex condition of an individual. Other families may need support or mental health care to manage the stress of intersex treatment. Adolescents may benefit from guidance on how to disclose information to peers as well as from support when navigating dating and sex. Providing counseling may also involve guiding families and individuals of all ages through a shared decision-making process around medical or surgical care. Providers may employ decision aids to support this process (Sandberg et al., 2019; Weidler et al., 2019).

Statement 10.4

We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.

Communicating health information is a multi-directional process that includes the transfer of information from providers to patients, from parents to patients, as well as from patients back to their providers (Weidler & Peterson, 2019). While much emphasis has been placed on communicating to parents around issues of diagnosis and surgical decision-making, youth with DSD have reported barriers to engaging with health care providers and may not always turn

to their parents for support (Callens et al., 2021). To prepare individuals to be fully engaged and autonomous in their treatment, it is critical both providers and parents communicate continuously with children/individuals.

Providers must set an expectation as soon as possible for ongoing, open communication between all parties, especially since parents may experience distress due to the uncertainty associated with DSD and may seek quick fixes (Crissman et al., 2011; Roberts et al., 2020). Models of shared decision-making as well as related decisional tools have been developed to support ongoing communication between HCPs and families/individuals (Karkazis et al., 2010; Sandberg et al., 2019; Siminoff & Sandberg, 2015; Weidler et al., 2019). In addition to setting an expectation for dialogue, providers can also set the tone of communication. Providers can help parents and individuals tolerate diagnostic uncertainty while simultaneously providing education on anatomic variations, modeling openness to gender and sexual identity, and welcoming the child's/individual's questions. As they age, children/individuals may have questions or need age-appropriate information on issues of sex, menstruation, fertility, the need for hormone treatment (adrenal/sex), bone health, and cancer risk.

Parents also play a critical role in educating their children and may be the first people to disclose health information to their child (Callens et al., 2021). As part of expectation-setting around communication, providers should prepare parents to educate their child and members of their support system about the intersex diagnosis and treatment history. Some parents report difficulties in knowing how much to disclose to others as well as to their own children (Crissman et al., 2011; Danon & Kramer, 2017). The stress parents experience while raising children with an intersex condition is increased when parents adopt an approach that minimizes disclosure/discussion of their child's diagnosis (Crissman et al., 2011). The level of stress also varies by developmental stage, with parents of adolescents reporting higher rates of stress (Hullman et al., 2011). Therefore, HCPs should assist parents in developing strategies specific to their child's developmental stage that address their psychosocial or cultural concerns and values (Danon & Kramer, 2017; Weidler & Peterson, 2019). Finally, broader research on sexuality and gender variance has found—counter to the associations between shame/stigma and negative health outcomes—supportive family behaviors (including talking with children about their identity and connecting them with peers) predicted greater self-esteem and better health outcomes in individuals (Ryan et al., 2010).

Statement 10.5

We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.

Psychological, social, and cultural constructs all intersect with biological factors to form an individual's gender identity. As a group, individuals with intersexuality show increased rates of gender nonconforming behavior, gender-questioning, and cross-gender wishes in childhood, dependent in part on the discrepancy between the prenatal sex-hormonal milieu in which the fetal brain has differentiated and the sex assigned at birth (Callens et al., 2016; Hines, et al., 2015; Meyer-Bahlburg et al., 2016; Pasterski et al., 2015). Gender identity problems are observed at different rates in individuals with different intersex conditions (de Vries et al., 2007). More recently, some individuals have been documented to develop a nonbinary identity, at least privately (Kreukels et al., 2018). Although the majority of people with intersexuality may not experience gender dysphoria or wishes for gender transition, they may still have feelings of uncertainty and unanswered questions regarding their gender (Kreukels et al., 2018). Questions about gender identity may arise from such factors as genital appearance, pubertal development, and knowledge of items such as the diagnostic term of the medical condition, gonadal status, sex chromosome status, and a history of genital surgery. Therefore, HCPs need to be accessible for clients to discuss such questions and feelings, openly converse about gender diversity, and adopt a less binary approach to gender. HCPs are advised to guide parents as well in supporting their children in exploring gender.

Furthermore, such support should not be confined to the childhood years. Rather, individuals should be given the opportunity to explore their gender identity throughout their lifetime, because different phases may come with new questions regarding gender (for example, puberty/adolescence, childbearing age). Children in general may have questions regarding their gender identity at salient points during their maturation and evolution. When faced with additional stressors, for example, genital ambiguity, genital examinations and procedures, as well as the intersectionality of cultural bias and influences, individuals with intersexuality may need support and should be encouraged to seek educated professional assistance and guidance when needed. Also, HCPs should inquire regularly to determine if their clients with intersexuality need such support. When people experience gender incongruence, gender-affirming interventions may be considered. Procedures that should be applied in such interventions are described in other chapters.

Statement 10.6

We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.

Individuals with intersexuality are reported to experience stigma, feelings of shame, guilt, anger, sadness and depression (Carroll et al., 2020; Joseph et al., 2017; Schützmann et al., 2009). Higher levels of psychological problems are observed in this population than in the general population (Liao & Simmonds, 2014; de Vries et al., 2019). In addition, parental fear of stigmatization and adjustment to their child's diagnosis must not be overlooked by the clinical team. Parents may benefit from supportive counseling to assist them both in managing clinical decision-making (Fleming et al., 2017; Rolston et al., 2015; Timmermans et al., 2019) as well as understanding the impact of clinical decisions on their view of their child (Crissman et al., 2011; Fedele et al., 2010).

Thyen et al. (2005) found repeated genital examinations appear to be correlated with shame, fear and pain and may increase the likelihood of developing post-traumatic stress disorder (PTSD) later in life (Alexander et al., 1997; Money & Lamacz, 1987). Exposure to repeated genital examinations, fear of medical interventions, and parental and physician secrecy about being intersex ultimately undermine the self-empowerment and self-esteem of the person with intersexuality (Meyer-Bahlburg et al., 2018; Thyen et al., 2005; Tishelman et al., 2017; van de Grift, Cohen-Kettenis et al., 2018). For recommendations on how to conduct genital examinations to minimize adverse psychological side effects see Tishelman et al. (2017).

There is an active movement within the intersex community to alleviate stigma and to return human rights and dignity to intersex people rather than viewing them as medical anomalies and curiosities (Yogyakarta Principles, 2007, 2017). Chase (2003) summarizes the major reasons for the intersex advocacy movement and outlines how stigma and emotional trauma are the outcome of ignorance and the perceived need for secrecy. Public awareness of intersex conditions is very limited, and images and histories of individuals with intersexuality are still presented as "abnormalities of nature". We, therefore, advise HCPs to actively educate their colleagues, individuals with intersexuality, their families, and communities, raise public awareness, and increase knowledge about intersexuality. Societal awareness and knowledge regarding intersexuality may help reduce discrimination and stigmatization. Tools and education/information materials may also help individuals with intersexuality disclose their condition, if desired (Ernst et al., 2016).

HCPs should be able to recognize and address stigmatization in their clients (Meyer-Bahlburg et al., 2018) and should encourage people with intersexuality of various ages to connect via support groups. There is a need for developing specific techniques/methods for assisting clients to cope with stigma related to intersex.

Statement 10.7

We suggest health care professionals refer children/individuals with intersexuality and their families to mental health professionals as well as peer and other psychosocial supports as indicated.

For almost all parents, the birth of a child with intersexuality is entirely unexpected and comes as a shock. Their inability to respond immediately to the ubiquitous question, "Is your baby a boy or a girl?", their lack of knowledge about the child's condition, the uncertainty regarding the child's future, and the pervasive intersex stigma are likely to cause distress, sometimes to the level of PTSD and may lead to prolonged anxiety and depression (Pasterski et al., 2014; Roberts et al., 2020; Wisniewski & Sandberg, 2015). This situation may affect parental care and long-term outcome of their child with intersexuality (Schweizer et al., 2017). As these children grow up, they are also at risk of experiencing intersex stigma in its three major forms (enacted, anticipated, internalized) in all spheres of life (Meyer-Bahlburg et al., 2018), along with other potential difficulties such as body image problems, gender-atypical behavior, and gender identity questioning. Many may face the additional challenge presented by the awareness of the incongruence between their assigned gender and biological characteristics such as sexual karyotype, gonads, past and/or current sex-hormonal milieu, and reproductive tract configuration. This situation may also adversely affect the individuals' mental health (Godfrey, 2021; Meyer-Bahlburg, 2022). A recent online study of a very large sample of LGBTQ youth indicated that LGBTQ youth who categorized themselves as having a physical intersex variation had a rate of mental health problems that was higher than the rate in LGBTQ youth without intersexuality (Trevor Project, 2021). As intersex conditions are rare, parents of such children and later the individuals themselves may experience their situation as unique and very difficult for others to understand. Thus, based on clinical experience, there is a consensus among HCPs who are experienced in intersex care, that social support is a crucial component of intersex care, not only through professional support by MHPs (Pasterski et al., 2010), but also, importantly, through support groups of individuals with intersex conditions (Baratz et al., 2014; Cull & Simmonds, 2010; Hughes et al., 2006; Lampalzer et al., 2021). A detailed international listing of DSD and intersex peer support and advocacy groups with their websites has been provided by Lee, Nordenström et al. (2016). Given the heterogeneity of intersex conditions and treatment regimens, an individual with intersexuality may find it most helpful to associate with a support group that includes members with the same or similar condition as that of the individual. It is important HCPs specializing in intersex care also collaborate closely with such support groups so that occasional differences in opinions regarding specific aspects of care can be resolved through detailed discussions. Close contacts between HCPs and support groups also facilitate community-based participatory research that benefits both sides.

Statement 10.8

We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.

While many people with intersexuality have a gender identity in line with their XX or XY karyotype, there is sufficient heterogeneity that HCPs should be able to provide customized approaches. For example, among XX individuals with virilizing CAH, a larger than expected minority have a male gender identity (Dessens et al., 2005). Among XY individuals with partial androgen insensitivity syndrome, gender identity can vary significantly (Babu & Shah, 2021). Furthermore, among XY individuals with 5α-reductase-2 (5α-RD-2) deficiency and with 17-beta-hydroxysteroid dehydrogenase-3 deficiency who are assigned the female sex at birth, a large fraction (56–63% and 39–64%, respectively) change from a typical female gender role to a typical male gender role as they age (Cohen-Kettenis, 2005).

People with intersexuality have a wide range of medical options open to them depending on their gender identity and its alignment with anatomy. These options include puberty suppression medication, hormonal treatment, and surgeries, all customized to the unique circumstances of the individual (Weinand & Safer, 2015; Safer & Tangpricha, 2019) (for further information see Chapter 6—Adolescents and Chapter 12—Hormone Therapy). Specifically, when functional gonads are present, puberty may be temporarily suspended by using gonadotropin-releasing hormone (GnRH) analogues. Such intervention can

facilitate the necessary passage of time needed by the individual to explore gender identity and to actively participate in sex designation, especially for conditions in which sex role change is common (i.e., in female-raised individuals with 5α-RD-2 deficiency; Cocchetti, Ristori, Mazzoli et al., 2020; Fisher, Castellini et al., 2016).

HCPs can counsel individuals and their families directly if the providers have sufficient expertise and can leverage expertise needed to determine both a course of treatment appropriate for the individual and the logistics involved in implementing the chosen therapeutic option.

Statement 10.9

We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.

International human rights organizations have increasingly expressed their concerns that surgeries performed before a child can participate meaningfully in decision-making may endanger the child's human rights to autonomy, self-determination, and an open future (e.g., Human Rights Watch, 2017). Numerous medical and intersex advocacy organizations as well as several countries have joined these international human rights groups in recommending the delay of surgery when medically feasible (Dalke et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). However, it is important to note some anatomic variations, such as obstruction of urinary flow or exposure of pelvic organs, pose an imminent risk to physical health (Mouriquand et al., 2016). Others, such as menstrual obstruction or long-term malignancy risk in undescended testes, have eventual physical consequences. A third group of variations, i.e., variations in the appearance of external genitals or vaginal depth, pose no immediate or long-term physical risk. The above recommendation addresses only those anatomic variations that, if left untreated, have no immediate adverse physical consequences and where delaying surgical treatment poses no physical health risk.

Non-urgent surgical care for individuals with these variations is complex and often contested, particularly when an individual is an infant or a young child and cannot yet participate in the decision-making process. Older people with intersexuality have reported psychosocial and sexual health problems, including depression, anxiety, and sexual and social stigma (de Vries et al., 2019; Rosenwohl-Mack et al., 2020). Some studies have suggested individuals with a specific variation (e.g., 46,XX CAH) agree with surgery being performed before adolescence (Bennecke et al., 2021). Recent studies suggest some adolescents and adults are satisfied with the appearance and function of the genitals after childhood surgery (Rapp et al., 2021). A child's genital difference can also become a source of stress for parents, and there is research that reports a correlation of surgery to create binary genitals with a limited amount of reduction in parental distress (Wolfe-Christensen et al., 2017), although a minority of parents may report decisional regret (Ellens et al., 2017). Consequently, some organizations recommend surgery be offered to very young children (American Urological Association, 2019; Pediatric Endocrine Society, 2020).

This shows the division within the medical field regarding its management guidelines for early genital surgery. The authors of this chapter also did not reach complete consensus. Some intersex specialists consider it potentially harmful to insist on a universal deferral of early genital surgery for genital variations without immediate medical risks. Reasons supporting this view include 1) intersex conditions are highly heterogeneous with respect to type and severity as well as associated gonadal structure, function, and malignancy risk; 2) societies and families vary tremendously in gender norms and intersex stigma potential; 3) early surgery may present certain technical advantages; and 4) a review of surveys of individuals with intersexuality (most of whom had previously undergone genital surgery) show the majority endorse surgery before the age of consent, especially in the case of individuals with 46,XX CAH and less strongly for individuals with XY intersex conditions (Meyer-Bahlburg, 2022). Experts supporting this view call for an individualized approach to

decisions regarding genital surgery and its timing. This approach has been adopted by medical societies with high rates of intersex specialists (Bangalore Krishna et al., 2021; Pediatric Endocrine Society, 2020; Speiser et al., 2018; Stark et al., 2019) and by certain support organizations (CARES Foundation; Krege et al., 2019).

Nonetheless, long-term outcome studies are limited and most studies reporting positive outcomes lack a non-surgical comparison group (Dalke, et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). There is also no evidence surgery protects children with intersex conditions from stigma (Roen, 2019). Adults with intersexuality do experience stigma, depression, and anxiety related to their genitalia, but can also experience stigma whether or not they have surgery (Ediati et al., 2017; Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg et al., 2018). There is also evidence surgeries may lead to significant cosmetic, urinary, and sexual complications extending into adulthood (Gong & Cheng, 2017; National Academies of Sciences, Engineering, and Medicine, 2020). Recent studies suggest some groups of individuals may have particularly negative experiences with gonadectomy, although this risk has to be weighed against that of gonadal malignancy (Duranteau et al., 2020; Rapp et al., 2021). People with intersex conditions are also far more likely than the general population to be transgender, to be gender diverse, or to have gender dysphoria (Almasri et al., 2018; Pasterski et al., 2015). Genital surgeries of young children may therefore irreversibly reinforce a binary sex assignment that is not aligned with the persons' future. These findings, together with human rights perspectives, support the call for the delay in the decision for surgery until the individual can decide for him/her/themselves.

Systematic long-term follow-up studies are urgently needed to compare individuals with the same intersex conditions who differ in the age at surgery or have had no surgery with regard to gender identity, mental health, and general quality of life.

Statement 10.10

We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.

Intersex conditions are rare, and intersex genital and gonadal anatomy are heterogeneous. Surgeries have been associated with a risk of significant long-term complications (e.g., National Academies of Sciences, Engineering, and Medicine, 2020), and most surgical training programs do not prepare trainees to provide this specialized care (Grimstad, Kremen et al., 2021). In recognition of the complexity of surgical care across the lifespan, standards produced by expert and international consensus recommend this care be provided by multidisciplinary teams of experts (Krege et al, 2019; Lee, Nordenström et al., 2016; Pediatric Endocrine Society, 2020). Therefore, we advise surgical care be limited to intersex-specialized, multidisciplinary settings that include surgeons experienced in intersex care.

Statement 10.11

We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.

Individuals with certain intersex conditions may have reproductively functional genitalia but experience infertility due to atypical gonadal development. Others may have functioning gonads with viable germ cells but an inability to achieve natural fertility secondary to incongruent internal or external genitalia (van Batavia & Kolon, 2016). Pubertal suppression, hormonal treatment with sex steroid hormones, and gender affirming surgeries may all have an adverse impact on future fertility. The potential consequences of the treatment and fertility preservation options should therefore be reviewed and discussed.

Individuals with functioning testes should be advised prolonged treatment with estrogen and suppression of testosterone, as studied in TGD people without intersexuality, may cause testicular atrophy and a reduction in sperm count (Mattawanon et al., 2018). Although interruption

of such gender affirming hormonal treatment may improve sperm quality, a complete reversal of semen impairment cannot be guaranteed (Sermondade et al., 2021). The principal fertility preservation option for individuals with functioning testes is cryopreservation of sperm collected through masturbation or vibratory stimulation (de Roo et al., 2016). Although there are no data for success in humans, there is a proposal to offer direct testicular extraction and cryopreservation of immature testicular tissue to adolescents who have not yet undergone spermarche (Mattawanon et al., 2018).

Individuals with functioning ovaries should be advised testosterone therapy usually results in cessation of both menses and ovulation, often within a few months of initiating therapy. There are major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility. In transgender people, one study reported testosterone treatment may be associated with the development of polycystic ovarian morphology (Grynberg et al., 2010). However, other researchers have not found evidence of polycystic ovarian syndrome (PCOS) among transgender men receiving gender affirming hormone therapy based on metabolic (Chan et al., 2018) or histologic parameters (de Roo et al., 2017). Individuals with an intact uterus and functioning ovaries may regain their fertility potential if testosterone therapy is discontinued.

Fertility preservation options in post-pubertal people with intersexuality and functioning ovaries include hormonal stimulation for mature oocyte cryopreservation or ovarian tissue cryopreservation. Alternatively, stimulated oocyte extraction has been reported even for a transgender man continuing testosterone therapy (Greenwald, 2021). Similarly, oocyte cryopreservation after ovarian stimulation has been reported in a transgender boy receiving GnRHa therapy (Rothenberg et al., 2019). It should be noted ovarian stimulation, temporary cessation of GnRHa, testosterone treatment, or both, as well as gynecological procedures, can all be psychologically distressing to individuals, with the stress reaction being influenced by mental health, gender identity, and other medical experience. Applicability of certain interventions may depend on the support of other people in the individual's social network, including potential partners.

Statement 10.12

We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

For people with intersex characteristics, the likelihood of infertility may be recognized in infancy, childhood, adolescence as well as in adulthood, without first engaging in attempts to conceive. For many individuals, a diagnosis of infertility accompanies the intersex diagnosis (Jones, 2019). For some individuals, assisted heterologous fertilization (e.g., oocyte or sperm donation) may be an option. Multiple adoption pathways exist. Some may require commitment and a considerable investment of time. Individuals who are either not interested in engaging in the efforts to achieve fertility previously described or for whom fertility is not possible can benefit from early exposure to the options available for adoption and alternative parenthood. While uterus transplantation has had preliminary success in people with Mullerian agenesis (Richards et al., 2021), there is no protocol to date that avoids exposure of the developing fetus to the risks associated with the medications used to avoid transplant rejection.

CHAPTER 11 Institutional Environments

This chapter addresses care for transgender and gender diverse (TGD) individuals who reside in institutions. By definition, institutions are facilities or establishments in which people live and receive care in a congregate or large group setting, where individuals may or may not have freedom of movement, individual consent, or agency. Carceral facilities (correctional facilities, immigration detention centers, jails, juvenile detention centers) and noncarceral facilities (long-term care facilities, in-patient psychiatric facilities, domiciliaries, hospice/palliative care, assisted living facilities) are residential institutions where health care access for transgender persons may be provided. Much of the evidence in support of proper care of TGD persons comes from carceral settings. However, the recommendations put forth here apply to all institutions that house TGD individuals, both carceral and noncarceral (Porter et al., 2016). All of the recommendations of the Standards of Care apply equally to people living in both types of institutions. People should have access to these medically necessary treatments irrespective of their housing situation within an institution (Brown, 2009). Care for an institutionalized person must consider the individual does not have the access that non-institutionalized persons have to securing care on their own. For that reason, institutionalized persons must be supported in being able to receive the Standards of Care established by the World Professional Association for Transgender Health (WPATH).

TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care (see Chapter 2—Global Applicability, Statement 2.1), which is ranked as their number one concern while incarcerated (Brown, 2014; Emmer et al., 2011). The systemic racial inequities inherent in many carceral environments (Sawyer, 2020), racial disparities in health outcomes (Nowotny et al., 2017), and the overrepresentation of TGD people of color in some facilities (Reisner et al., 2014) punctuate a need for facility leadership to attend to transitional care access issues. Controlled studies show clinically significant health and mental health disparities for justice-involved transgender people compared to matched groups of transgender people who have not been incarcerated or jailed (Brown and Jones, 2015). Too often the agencies, structures, and personnel that provide care are lacking in knowledge, training, and capacity to care for gender diverse people (Clark et al., 2017). Discrimination against TGD residents in palliative care settings, including hospice, is common, and the needs of TGD patients or their surrogates have been ignored in these settings (Stein et al., 2020). This is one reason why lesbian, gay, bisexual and transgender (LGBT)

Statements of Recommendations

11.1- We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8 apply equally to people living in institutions.
11.2- We suggest institutions provide all staff with training on gender diversity.
11.3- We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so without undue delay and in accordance with the SOC-8.
11.4- We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with the SOC-8 when sought by the individual, without undue delay.
11.5- We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.
11.6- We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.
11.7- We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations rather than solely their anatomy or sex assignment at birth.
11.8- We recommend institutional personnel establish housing policies that ensure the safety of TGD residents without segregating or isolating these individuals.
11.9- We recommend institutional personnel allow TGD residents the private use of shower and toilet facilities upon request.

patients may choose to hide their sexual and/or gender identity when they enter a nursing home, despite the fact that prior to their admission to the facility they had been living publicly as a LGBT-identified person (Carroll, 2017; Serafin et al., 2013).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable. The majority of the available literature related to institutions focuses on those who are incarcerated in jails, prisons, or other carceral environments. Literature about other institutional types were also considered and referenced where available. We hope future investigations will address this relative lack of data from noncarceral institutions. The recommendations summarized above are generalizable to a variety of institutional settings that have characteristics in common, including extended periods of stay, loss of or limited agency, and reliance on institutional staff for some or all of the basic necessities of life.

Statement 11.1

We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8, apply equally to TGD people living in institutions.

Just as people living in institutions require and deserve mental and medical health care in general and in specialty areas, we recognize TGD people are in these institutions and thus need care specific to TGD concerns. We recommend the application of the Standards of Care (SOC) to people living in institutions as basic principles of health care and ethics (Beauchamp & Childress, 2019; Pope & Vasquez, 2016). Additionally, numerous courts have long upheld the need to provide TGD-informed care based in the WPATH SOC to people living in institutions as well (e.g., Koselik v. Massachusetts, 2002; Edmo v. Idaho Department of Corrections, 2020). Agencies that provide staffing for long-term, in-home services should also be aware of the applicability of the Standards of Care.

Statement 11.2

We suggest institutions provide all staff with training on gender diversity.

Because TGD care affects a small percentage of the population, it requires specialized training as outlined in this SOC Version 8. While the level of training will vary based on the staff member's role within the institutional setting, all staff will need training in addressing residents appropriately while other clinical staff may need more intensive training and/or consultation. These training recommendations also apply to agencies that supply staffing for in-home, long-term care. Misgendering institutionalized residents, not allowing for gender appropriate clothing, shower facilities, or housing, and not using chosen names communicates a lack of respect for TGD residents who may experience repeated indignities as emotionally traumatic, depressing, and anxiety-producing. By providing all institutional staff with training on gender diversity and basic competence in transgender-related health care issues, these harms can be prevented (Hafford-Letchfield et al., 2017). Surveys indicate individuals working with incarcerated individuals as well as in workers in noncarceral settings like palliative care have significant knowledge gaps (Stein et al., 2020; White et al., 2016). Hafford-Letchfied et al. (2017) showed benefit to training residential long-term care staff when such training began with "recognizing LBGT issues" and existed in "care homes". If the assigned health care providers lack the expertise to assess and/or treat gender diverse persons under their charge, outside consultation should be sought from professionals with expertise in the provision of gender-affirming health care (Brömdal et al., 2019; Sevelius and Jenness, 2017).

Statement 11.3

We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so

without undue delay and in accordance with the SOC-8.

TGD persons may be admitted to institutions in need of evaluation for gender-affirming hormonal care or may develop this need after they have resided in an institutional setting for varying degrees of time. It is not uncommon for TGD persons to be denied access to hormonal care for months or years after making such needs known or to be undertreated and poorly monitored, delaying the necessary titration of medications for safety and efficacy (Keohane, 2018; Kosilek v. Massachusetts, 2002; Monroe v. Baldwin et al., 2019). This can result in significant negative mental health outcomes to include depression, anxiety, suicidality, and surgical self-treatment risks (Brown, 2010). As with all medically necessary health care, access to gender-affirming hormone therapies should be provided in a timely fashion when indicated for a TGD resident, in both carceral and noncarceral institutional environments. Medical professionals shall appropriately titrate hormones based on laboratory results and clinical outcomes to ensure results are within the range of recommended standards within the field of endocrinology. Such labs shall be taken at a frequency so as not to delay appropriate titration.

TGD elderly people living in long-term care facilities have unique needs (Boyd, 2019; Caroll, 2017; Porter, 2016). When elderly individuals request hormonal treatment, while physicians should assess pre-existing conditions, rarely do such conditions absolutely contraindicate administering hormones in this population (Ettner, 2013). People with gender incongruence in institutions may also have coexisting mental health conditions (Brown and Jones, 2015; Cole et al., 1997). These conditions should be evaluated and treated appropriately as part of the overall assessment. Persons receiving hormones must be closely medically monitored to avoid potential drug interactions and polypharmacy (Hembree et al., 2017).

TGD persons who enter an institution on an appropriate regimen of gender-affirming hormone therapy should be continued on the same or similar therapies and monitored according to the SOC Version 8. A "freeze frame" approach is inappropriate and dangerous (Kosilek v. Massachusetts, 2002). A "freeze frame" approach is the outmoded practice of denying hormones to people who are not already on them or keeping TGD persons on the same dose of hormones throughout their institutionalization that they were receiving upon admission, even if that dose was an initiation (low) dose. TGD persons who are deemed appropriate for de novo gender-affirming hormone therapy should be started on such therapy just as they would be outside of an institution (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009). The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a significant likelihood of negative outcomes (Brown, 2010; Sundstrom and Fields v. Frank, 2011), such as surgical self-treatment by autocastration, depressed mood, increased gender dysphoria, and/or suicidality (Brown, 2010; Maruri, 2011).

If an individual in an institution does receive gender-affirming hormones and/or surgeries, decisions regarding housing in sex-segregated facilities may need to be reassessed for the safety and well-being of the TGD person (Ministry of Justice [UK], 2016).

Statement 11.4

We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with SOC-8, when sought by the individual, without undue delay.

TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009; Edmo v. Idaho Department of Corrections, 2020). The consequences of denial or lack of access to gender- affirming surgeries for residents of institutions who cannot access such care outside of their institutions may be serious, including substantial worsening of gender dysphoria symptoms, depression, anxiety, suicidality, and the possibility of surgical self-treatment

(e.g., autocastration or autopenectomy; Brown, 2010; Edmo v. Idaho Department of Corrections, 2020; Maruri, 2011). It is not uncommon for residents of institutions to be denied access to evaluation for gender-affirming surgery as well as denial of the treatment itself, even when medically necessary (Kosilek v. Massachusetts/Dennehy, 2012; Edmo v. Idaho Department of Corrections, 2020). The denial of medically necessary evaluations for and the provision of gender-affirming surgical treatments and necessary aftercare is inappropriate and inconsistent with these Standards of Care.

Statement 11.5

We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.

Gender expression refers to people having hairstyles, grooming products, clothing, names, and pronouns associated with their gender identity in their culture and/or community (American Psychological Association, 2015; Hembree et al., 2017). Gender expression is the norm among most people within a culture or a community. Social transition is the process of TGD persons beginning and continuing to express their gender identity in ways that are authentic and socially perceptible. Often, social transition involves behavior and public presentation differing from what is usually expected for people assigned a given legal gender marker at birth. A gender marker is the legal label for a person's sex that is typically assigned or designated at birth on official documents (American Psychological Association, 2015). This is most commonly recorded as male or female but also intersex or "X" in some nations and jurisdictions. TGD individuals need the same rights to gender expression afforded cisgender people living both outside and inside institutional settings. Staff acceptance of social transition also sets a tone of respect and affirmation that may enhance respect and affirmation with others residing in the institution, thereby increasing safety and reducing some aspects of gender incongruence.

Research indicates social transition and congruent gender expression have a significant beneficial effect on the mental health of TGD people (Bockting & Coleman, 2007; Boedecker, 2018; Devor, 2004; Glynn et al., 2016; Russell et al., 2018). To allow for expressing gender identity, these recommendations include being allowed to wear gender congruent clothing and hairstyles, to obtain and use gender-appropriate hygiene and grooming products, to be addressed by a chosen name or legal last name (even if unable to change the assigned name legally yet), and to be addressed by a pronoun consistent with one's identity. These elements of gender expression and social transition, individually or collectively as indicated by the individual's needs, reduce gender dysphoria/incongruence, depression, anxiety, self-harm ideation and behavior, suicidal ideation and attempts (Russell et al., 2018). Furthermore, these elements of congruent gender expression enhance well-being and functioning (Glynn et al., 2016).

Statement 11.6

We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.

Given that an increasing percentage of people openly identify as gender diverse, there is a need to develop and implement practices and policies that meet the needs of these people irrespective of where they live (McCauley et al., 2017). For example, institutions should utilize medical and administrative records systems for their residents that track gender markers consistent with gender identity and not solely sex assigned at birth. In developing these recommendations, there was recognition that gender expansiveness can challenge some institutional norms where TGD people live. However, all institutions have the responsibility to provide for the safety and well-being of all persons living therein (Australia, 2015; Corrective Services New South Wales, 2015; Edmo v. Idaho Department of Corrections, 2020; Kosilek v. Massachusetts, 2002; NCCHC, 2015). Sevelius and colleagues (2020) demonstrated correct pronoun usage is gender-affirming for

transgender women and correlates with positive mental health and HIV-related health outcomes. If a resident of an institution has legally changed names, the institutional records should be changed to reflect those changes.

Statement 11.7

We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations, rather than solely their anatomy or sex assignment at birth.

The separation of people based on sex assigned at birth, a policy almost universally implemented in institutional settings (Brown and McDuffie, 2009; Routh et al., 2017), can create an inherently dangerous environment (Ledesma & Ford, 2020). Gender diverse people are extremely vulnerable to stigmatization, victimization, neglect, violence, and sexual abuse (Banbury, 2004; Beck, 2014; Jenness and Fenstermaker, 2016; Malkin & DeJong, 2018; Oparah, 2012; Stein et al., 2020). This systemic sex-segregated rigidity often fails to keep TGD people safe and may impede access to gender-affirming health care (Stohr, 2015). As a result, institutions should follow procedures that routinely evaluate the housing needs and preferences of TGD inmates (e.g., Federal Bureau of Prisons, 2016). Likewise, the Prison Rape Elimination Act specifically cites TGD individuals as a vulnerable population and directs prisons nationwide in the US to consider the housing preferences of these inmates (Bureau of Justice Assistance, 2017).

Statement 11.8

We recommend institutional personnel establish housing policies that ensure the safety of transgender and gender diverse residents without segregating or isolating these individuals.

Assigning placement for a TGD resident solely on the basis of their genital anatomy or sex assigned at birth is misguided and places people at risk for physical and/or psychological harm (Scott, 2013; Simopoulos & Khin, 2014; Yona & Katri, 2020). It is well established within carceral settings, transgender individuals are far more likely than other prisoners to be sexually harassed, assaulted, or both (James et al., 2016; Jenness & Fenstermaker, 2016; Malkin & DeJong, 2019). While placement decisions need to address security concerns, shared decision-making that includes the input of the individual should be made on a case-by-case basis (Federal Bureau of Prisons, 2016; Jenness and Smyth, 2011). Some transgender women prefer to reside in a male facility while others feel safer in a female facility. Given the range of gender identities, expression and transition status is so heterogeneous among gender diverse people, keeping residents safe requires flexible decision-making processes (Yona & Katri, 2020). One of the fears older LBGT individuals have living in long-term care is mistreatment by roommates (Jablonski et al., 2013). Consequently, housing in nursing homes and assisted living facilities should consider assigning rooms to elders based on their self-identified gender without regard to birth assignment or surgical history and in collaboration with the TGD patient.

Solitary confinement, sometimes referred to as administrative segregation in carceral facilities, refers to physical isolation of individuals during which they are confined in their cells for approximately twenty-three hours each day. The use of isolation is employed in some carceral facilities as a disciplinary measure as well as a means of protecting prisoners who are considered a risk to themselves or others or who are at risk of sexual assault by other inmates. However, isolating prisoners for safety concerns, if necessary, should be brief, as isolation can cause severe psychological harm and gross disturbances of functioning (Ahalt et al., 2017; Scharff Smith, 2006). National prison standards organizations as well as The United Nations consider isolation longer than 15 days to be torture (NCCHC, 2016; United Nations, 2015).

Statement 11.9

We recommend institutional personnel allow transgender and gender diverse residents the private use of shower and toilet facilities, upon request.

The necessity and importance of privacy is universal irrespective of gender identity. TGD

individuals report avoiding public restrooms, limiting the amount they eat and drink so as not to have to use a public facility, often leading to urinary tract infections and kidney-related problems (James et al., 2016). TGD individuals in institutions are often deprived of privacy in bathroom and shower use, which can result in psychological harm and/or physical and sexual abuse (Bartels and Lynch, 2017; Brown, 2014; Cook-Daniels, 2016; Mann, 2006). Similarly, in carceral environments, pat downs, strip searches and body cavity searches should be conducted by staff members of the same sex with the understanding this may not be possible in extreme emergencies. The incidental viewing of searches by other employees should be avoided (Bureau of Justice Assistance, 2017). Private use of shower and toilet facilities for incarcerated transgender people is also required by some laws, including for instance the United States' federal Prison Rape Elimination Act in the US.

The population of aging/older TGD persons who need to be served by institutions is increasing (Carroll, 2017; Witten & Eyler, 2016). Many long-term care and other facilities catering to the needs of the aging need to take into consideration the needs of their non-cisgender residents (Ettner, 2016; Ettner & Wiley, 2016). Surveys of HCPs working with elders in hospice and palliative care settings as well as other long-term care facilities report patients who identify as TGD often do not get their basic needs met, are discriminated against in their medical care access, or are physically and/or emotionally abused (Stein et al., 2020) A survey of retirement and residential care providers in Australia found little experience with or understanding of the issues facing this population. Indeed, many elderly TGD residents admitted to concealing their gender identity, bowing to the fear of insensitive treatment or frank discrimination (Cartwright et al., 2012; Cook-Daniels, 2016; Grant et al., 2012; Horner et al., 2012; Orel & Fruhauf, 2015).

CHAPTER 12 Hormone Therapy

Transgender and gender diverse (TGD) persons may require medically necessary gender-affirming hormone therapy (GAHT) to achieve changes consistent with their embodiment goals, gender identity, or both (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). This chapter describes hormone therapy recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to initiation of hormone therapy for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Ever since the first World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) was published in 1979 and in subsequent updates of the SOC, including SOC version 7, GAHT has been accepted as medically necessary (Coleman et al., 2012). WPATH endorsed the Endocrine Society's guidelines for GAHT for TGD persons in 2009 and 2017 (Hembree et al., 2009; Hembree et al., 2017). The European Society for Sexual Medicine has also published a position statement on hormone management in adolescent and adult TGD people (T'Sjoen et al., 2020). When provided under medical supervision, GAHT in adults is safe (Tangpricha & den Heijer, 2017; Safer & Tangpricha, 2019). However, there are some potential long-term risks, and careful monitoring and screening are required to reduce adverse events (Hembree et al., 2017; Rosenthal, 2021).

In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017). Health care professionals (HCPs) can use serum testosterone and/or estradiol levels to monitor most sex steroid treatments. However, conjugated estrogens or synthetic estrogen use cannot be monitored. The assumption that the estrone/estradiol ratio should be monitored was not supported in a recent cohort study as there was no relationship between estrone concentration and change in body fat or breast development seen in a European cohort of 212 adult transgender women during a 1-year follow-up of hormone treatment (Tebbens et al., 2021). This study demonstrated higher estrone concentrations or higher estrone/estradiol ratios are not associated with antagonistic effects on feminization (fat percentage and breast development) (Tebbens et al., 2021). Thus, monitoring of the estrone to estradiol ratio is not supported by the current published evidence. Previously used conjugated estrogens have been abandoned in favor of bioidentical estrogens. Even if several studies have shown a significantly greater risk of thromboembolic and cardiovascular complications with the use of oral conjugated estrogens compared with oral estradiol in postmenopausal women, no randomized controlled trials have taken place, either in postmenopausal women or in transgender people undergoing estrogen treatment (Smith et al., 2014).

The approach to GAHT differs and depends on the developmental stage of the individual at the time of initiation of hormone therapy as well as their treatment goals. Hormone therapy is not recommended for children who have not begun endogenous puberty. In eligible youth (as per Chapter 6—Adolescents) who have reached the early stages of puberty, the focus is usually to delay further pubertal progression with gonadotropin releasing hormone agonists (GnRHas) until an appropriate time when GAHT can be introduced. In these cases, pubertal suppression is considered medically necessary. Eligible adults may initiate GAHT if they fulfill the criteria as per Chapter 5—Assessment for Adults. In addition, health care providers should discuss fertility goals and fertility preservation procedures prior to initiating GAHT. See Chapter 16—Reproductive Health.

GAHT with feminine embodiment goals typically consists of estrogen and an androgen-lowering medication (Hembree et al., 2017). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence the potential benefits of progesterone administration outweigh the potential risks (Iwamoto, T'Sjoen et al., 2019). Masculinizing GAHT typically consists of testosterone. Both WPATH and the Endocrine Society recommend monitoring levels of sex

hormones. While GAHT is customized to meet the individual needs of the TGD person, typically hormone levels are maintained at a concentration sufficient to support good bone health and are not supraphysiologic (Hembree et al., 2017; Rosen et al., 2019).

Statements of Recommendations

12.1- We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents after they first exhibit physical changes of puberty (Tanner stage 2).
12.2- We recommend health care professionals use gonadotropin releasing hormone (GnRH) agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated.
12.3- We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are either not available or are cost prohibitive.
12.4- We suggest health care professionals prescribe GnRH agonists for suppression of sex steroids without concomitant sex steroid hormone replacement in eligible* transgender and gender diverse adolescents seeking such intervention and who are well into or have completed pubertal development (past Tanner stage 3) but are either unsure about or do not want to begin sex steroid hormone therapy.
12.5- We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment for eligible* transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent.
12.6- We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at levels appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.
12.7- We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.
12.8- We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care required for transgender and gender diverse adolescents.
12.9- We recommend health care professionals institute regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.
12.10- We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about the options available for fertility preservation prior to initiating puberty suppression and prior to treating with hormone therapy.
12.11- We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment for transgender and gender diverse people.
12.12- We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of the physical changes induced by sex hormonal treatment.
12.13- We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment.
12.14- We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age > 45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended.
12.15- We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as a component of gender-affirming hormonal treatment.
12.16- We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gender diverse people with testes who are taking estrogen as part of a hormonal treatment plan if the individual's goal is to approximate circulating sex hormone concentrations in cisgender women.
12.17- We recommend health care professionals monitor hematocrit (or hemoglobin) in transgender and gender diverse people treated with testosterone.
12.18- We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery.
12.19- We suggest health care professionals counsel transgender and gender diverse people about the various options available for gender-affirmation surgery unless surgery is not indicated or is medically contraindicated.
12.20- We recommend health care professionals initiate and continue gender-affirming hormone therapy for eligible* transgender and gender diverse people who require this treatment due to demonstrated improvement in psychosocial functioning and quality of life.
12.21- We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

** For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents and Appendix D.*

In most cases, GAHT is maintained throughout life. It is not known if doses of GAHT should be reduced in older TGD people. Discontinuation of hormone therapy may result in bone loss in TGD individuals and will definitely do so in individuals whose gonads have been removed (Wiepjes et al., 2020). Routine primary care should also be performed (see Chapter 15—Primary Care). Epidemiology studies have reported an increased incidence of cardiovascular disease and venous thromboembolism (VTE) in TGD people receiving estrogen, most notably in older people and with different preparations of GAHT (Irwig, 2018; Maraka et al., 2017). TGD individuals treated with testosterone may also have increased adverse cardiovascular risks and events, such as increased myocardial infarction, blood pressure, decreased HDL-cholesterol, and excess weight (Alzahrani et al., 2019; Irwig, 2018; Kyinn et al., 2021). Health care professionals (HCPs) should discuss lifestyle and pharmacologic therapy with patients who are at the highest risk of developing cardiovascular disease (see Chapter 15—Primary Care). Polycythemia is another disorder that may present in TGD people taking testosterone (Antun et al., 2020). Therefore, it is important to continuously monitor for the development of conditions that can be exacerbated by GAHT throughout life (Hembree et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Gender-Affirming Hormone Therapy in Youth

The following sections will discuss hormone therapy in TGD youth. Depending on the developmental stage of the youth, this hormone therapy generally comprises two phases, namely pubertal suppression followed by the addition of GAHT. During the first phase, pubertal development is halted to allow the youth to explore their gender identity and embodiment goals to prepare for the next phase, which may include GAHT. This section will discuss the recommendations for the use of gonadotropin releasing hormone agonists (GnRHas) as well as alternate approaches to pubertal suppression and will be followed by recommendations for GAHT. Sections that are applicable to youth and adults will follow in the next section.

Statement 12.1

We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents only after they first exhibit physical changes of puberty (Tanner stage 2).

In general, the goal of GnRHa administration in TGD adolescents is to prevent further development of the endogenous secondary sex characteristics corresponding to the sex designated at birth. Since this treatment is fully reversible, it is regarded as an extended time for adolescents to explore their gender identity by means of an early social transition (Ashley, 2019e). Treatment with GnRHas also has therapeutic benefit since it often results in a vast reduction in the level of distress stemming from physical changes that occur when endogenous puberty begins (Rosenthal, 2014; Turban, King et al., 2020).

For those prepubertal TGD children who have been persistent in their gender identity, any amount of permanent development of secondary sex characteristics could result in significant distress. While one might consider use of a GnRHa to prevent initiation of puberty in such individuals who remain at Tanner Stage 1, this use of GnRHa has not been recommended (Hembree et al., 2017). When a child reaches an age where pubertal development would normally begin (typically from 7-8 to 13 years for those with ovaries and from 9 to 14 years for those with testes), it would be appropriate to screen the child more frequently, perhaps at 4-month intervals, for signs of pubertal development (breast budding or testicular volume > 4 cc). Given the typical tempo of pubertal development (3.5–4 years for completion), it would be very unlikely for permanent pubertal changes to develop if one is only in puberty for 4 months or less. Thus, with frequent follow-up, the initiation of puberty can easily be detected before there are irreversible physical changes, and GnRHa can be started at that time with great efficacy. Of note, following initiation of a GnRHa, there is typically

a regression of one Tanner stage. Thus, if there is only Tanner stage 2 breast development, it typically fully regresses to the prepubertal Tanner stage 1; the same is typically true with Tanner stage 2 testes (often not even discernable to the patient and is not associated with development of secondary sex characteristics).

Given GnRHas work through GnRH receptor desensitization, if there's no uptick in endogenous GnRH stimulation of the pituitary (the first biochemical sign of puberty), there's no need for GnRH receptor desensitization. In addition, because of the wide variability in the timing of the start of puberty (as noted above), it is hard to justify using a GnRHa that might have some unknown risk if there's no physiological benefit before pubertal onset. Using a GnRHa with a child at Tanner stage 1 would only be indicated in cases of constitutional delay in growth and puberty, likely alongside the start of GAHT.

However, the use of a GnRHa could be considered in a child who, due to a constitutional delay in growth and puberty, starts GAHT while still in Tanner Stage 1. Initiating GAHT may activate the hypothalamic-pituitary gonadal axis in the beginning but may also mask the effects on the body of this activation. To avoid body changes with the potential to exacerbate an individual's gender incongruence, the GnRHa can be started as an adjunctive therapy to the GAHT shortly after the initiation of the GAHT to provide for pubertal development of the identified phenotype.

In addition, the suppression of the development of secondary sex characteristics is most effective when sex hormonal treatment is initiated in early to mid-puberty when compared with the initiation of sex hormonal treatment after puberty is completed (Bangalore-Krisha et al., 2019). Correspondingly, for adolescents who have already completed endogenous puberty and are considering starting GAHT, GnRHas can be used to inhibit physical functions, such as menses or erections, and can serve as a bridge until the adolescent, guardian(s) (if the adolescent is not able to consent independently), and treatment team reach a decision (Bangalore-Krishna et al., 2019; Rosenthal, 2021).

The onset of puberty occurs through reactivation of the hypothalamic-pituitary-gonadal axis. Clinical assessment of the stages of puberty is based on physical features that reflect that reactivation. In individuals with functioning ovaries, Tanner stage 2 is characterized by the budding of the mammary gland. The development of the mammary gland occurs from exposure to estrogen produced by the ovaries. In individuals with functioning testes, Tanner stage 2 is characterized by an increase in testicular volume (typically greater than 4 ml). The growth of the testes is mediated through the gonadotropins luteinizing hormone (LH) and follicle stimulating hormone (FSH). In the later stages, the testes produce enough testosterone to induce masculinization of the body.

Statement 12.2

We recommend health care professionals use GnRH agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated. For supporting text, see Statement 12.4.

Statement 12.3

We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are not available or are cost prohibitive. For supporting text, see Statement 12.4.

Statement 12.4.

We suggest health care professionals prescribe GnRH agonists to suppress sex steroids without concomitant sex steroid hormone replacement in eligible transgender and gender diverse adolescents seeking such intervention who are well into or have completed pubertal development (past Tanner stage 3) but are unsure about or do not wish to begin sex steroid hormone therapy.

GnRHas reduce gonadotrophin and sex steroid concentrations in TGD adolescents and thus halt the further development of secondary sex characteristics (Schagen et al., 2016). Their use is generally safe with the development of hypertension being the only short-term adverse event reported in the literature (Delemarre-van de Waal & Cohen-Kettenis, 2006; Klink, Bokenkamp et al., 2015). GnRHas prevent the pituitary gland from

secreting LH and FSH (Gava et al., 2020). When the gonadotropins decrease, the gonad is no longer stimulated to produce sex hormones (estrogens or androgens), and the sex hormone levels in the blood decrease to prepubertal levels. GnRHa treatment leads to partial regression of the initial stages of the already developed secondary sex characteristics (Bangalore et al., 2019). TGD adolescents with functioning ovaries will experience diminished growth of breast tissue, and if treatment is started at Tanner stage 2, the breast tissue may disappear completely (Shumer et al., 2016). Menarche can be prevented or discontinued following the administration of GnRHas in adolescents with a uterus. In TGD adolescents with functioning testes, testicular volume will regress to a lower volume.

When GnRHa treatment is started in adolescents at the later phases of pubertal development, some physical changes of pubertal development, such as late-stage breast development in TGD adolescents with functioning ovaries and a lower voice and growth of facial hair in TGD adolescents with functioning testes, will not regress completely, although any further progression will be stopped (Delemarre-van de Waal & Cohen-Kettenis, 2006). GnRHas have been used since 1981 for the treatment of central precocious puberty (Comite et al., 1981; Laron et al., 1981), and their benefits are well established (please also see the statements in Chapter 6—Adolescents). The use of GnRHas in individuals with central precocious puberty is regarded as both safe and effective, with no known long-term adverse effects (Carel et al., 2009). However, the use of GnRHas in TGD adolescents is considered off-label because they were not initially developed for this purpose. Nonetheless, data from adolescents prescribed GnRHas in a similar dose and fashion demonstrate effectiveness in delaying the onset of puberty although the long-term effects on bone mass have not been well established (Klink, Caris et al., 2015). Although long-term data are more limited in TGD adolescents than in adolescents with precocious puberty, data collection specifically in this population are ongoing (Klaver et al., 2020; Lee, Finlayson et al., 2020; Millington et al., 2020; Olson-Kennedy, Garofalo et al., 2019).

We recognize even though GnRHas are a medically necessary treatment, they may not be available for eligible adolescents because it is not covered by health insurance plans in some countries or may be cost-prohibitive. Therefore, other approaches should be considered in these cases, such as oral or injectable progestin formulations. In addition, for adolescents older than 14 years, there are currently no data to inform HCPs whether GnRHas can be administered as monotherapy (and for what duration) without posing a significant risk to skeletal health. This is because the skeleton will not have any exposure to adequate levels of sex steroid hormones (Rosenthal, 2021).

A prolonged hypogonadal state in adolescence, whether due to medical conditions such as hypergonadotropic hypogonadism, iatrogenic causes such as GnRHa monotherapy or physiological conditions such as conditional delay of growth and development, is often associated with an increased risk of poor bone health later in life (Bertelloni et al., 1998; Finkelstein et al., 1996). However, bone mass accrual is a multifactorial process that involves a complex interplay between endocrine, genetic, and lifestyle factors (Anai et al., 2001). When deciding on the duration of GnRHa monotherapy, all contributing factors should be considered, including factors such as pretreatment bone mass, bone age, and pubertal stage from an endocrine perspective and height gain, as well as psychosocial factors such as mental maturity and developmental stage relative to one's adolescent cohort and the adolescent's individual treatment goals (Rosenthal, 2021). For these reasons, a multidisciplinary team and an ongoing clinical relationship with the adolescent and the family should be maintained when initiating GnRHa treatment (see Statements 6.8, 6.9, and 6.12 in Chapter 6—Adolescents). The clinical course of the treatment, e.g., the development of bone mass during GnRHa treatment and the adolescent's response to treatment, can help to determine the length of GnRHa monotherapy.

Statement 12.5

We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment in eligible*

transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent. For supporting text, see Statement 12.6.

Statement 12.6

We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at a level appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.

Sex steroid hormone therapy generally comprises two treatment regimens, depending on the timing of the GnRHa treatment. When GnRHa treatment is started in the early stages of endogenous pubertal development, puberty corresponding with gender identity or embodiment goals is induced with doses of sex steroid hormones similar to those used in peripubertal hypogonadal adolescents. In this context, adult doses of sex steroid hormones are typically reached over approximately a 2-year period (Chantrapanichkul et al., 2021). When GnRHa treatment is started in late- or postpubertal transgender adolescents, sex steroid hormones can be given at a higher starting dose and increased more rapidly until a maintenance dose is achieved, resembling treatment protocols used in transgender adults (Hembree et al., 2017). An additional advantage of GnRHa treatment is sex steroid hormones do not have to be administered in supraphysiological doses, which would otherwise be needed to suppress endogenous sex steroid production (Safer & Tangpricha, 2019). For TGD individuals with functioning testes, GnRHa treatment (or another testosterone-blocking medication) should be continued until such time as the TGD adolescent/young adult ultimately undergoes gonadectomy, if this surgical procedure is pursued as a medically necessary part of their gender-affirming care. Once adult levels of testosterone are reached in TGD individuals with functioning ovaries who have been initially suppressed with GnRHa's, testosterone alone at physiological doses is typically sufficient to lower ovarian estrogen secretion, and GnRHas can be discontinued as discussed below (Hembree et al., 2017). For TGD adolescents with functioning ovaries who are new to care, GAHT can be accomplished with physiological doses of testosterone alone without the need for concomitant GnRHa administration (Hembree et al., 2017).

Gender-affirming sex steroid hormone therapy induces the development of secondary sex characteristics of the gender identity. Also, the rate of bone mineralization, which decreases during treatment with GnRHa's, rapidly recovers (Klink, Caris et al., 2015). During GnRHa treatment in early-pubertal TGD adolescents, the bone epiphyseal plates are still unfused (Kvist et al., 2020; Schagen et al., 2020). Following the initiation of sex steroid hormone treatment, a growth spurt can occur, and bone maturation continues (Vlot et al., 2017). In postpubertal TGD adolescents, sex steroid hormone treatment will not affect height since the epiphyseal plates have fused, and bone maturation is complete (Vlot et al., 2017).

In TGD adolescents with functioning testes, the use of 17-ß-estradiol for pubertal induction is preferred over that of synthetic estrogens, such as the more thrombogenic ethinyl estradiol (see Appendix D (Asscheman et al., 2015). It is still necessary to either continue GnRHa's to suppress endogenous testosterone production or transition to another medication that suppresses endogenous testosterone production (Rosenthal et al., 2016). Breast development and a female-typical fat distribution are among a number of physical changes that occur in response to estrogen treatment. See Appendix C—Table 1.

For TGD adolescents seeking masculinizing treatment, androgens are available as injectable preparations, transdermal formulations, and subcutaneous pellets. For pubertal induction, the use of testosterone-ester injection is generally recommended by most experts initially because of cost, availability, and experience (Shumer et al., 2016). It is advised to continue GnRHas at least until a maintenance level of testosterone is reached. In response to androgen treatment, virilization of the body occurs, including a lowering of the voice, more muscular development particularly in the upper body, growth of facial and body hair, and clitoral enlargement (Rosenthal et al., 2016). See Appendix C—Table 1.

In almost all situations, parental/caregiver consent should be obtained. Exceptions to this recommendation, in particular when caregiver or parental involvement is determined to be harmful to the adolescent, are described in more detail in Chapter 6—Adolescents (see Statement 6.11) where the rationale for involving parents/caregivers in the consent process is also described.

Statement 12.7

We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.

Menstrual suppression is a treatment option commonly needed by TGD individuals who experience distress related to menses or the anticipation of menarche. Statement 6.7 in Chapter 6—Adolescents describes this in more detail. To achieve amenorrhea, menstrual suppression can be initiated as a solo option before initiating testosterone or alongside testosterone therapy (Carswell & Roberts, 2017). Some youth, who are not ready for testosterone therapy or are not yet at an appropriate pubertal/developmental stage to begin such treatment, will benefit from the induction of amenorrhea (Olson-Kennedy, Rosenthal et al., 2018). Adolescents who experience an exacerbation of dysphoria related to the onset of puberty may elect to be treated with GnRHas for pubertal suppression (also see the Adolescents chapter).

Progestogens may be effective in adolescents whose goal is solely menstrual suppression. Continuous administration of progestin-only oral pills (including the contraceptive and noncontraceptive options), medroxyprogesterone injections, or levonorgestrel intrauterine device can be used for induction of amenorrhea (Pradhan & Gomez-Lobo, 2019). TGD individuals with functioning ovaries who start testosterone therapy may have 1–5 menstrual cycles before amenorrhea is achieved (Taub et al., 2020). Once amenorrhea is achieved, some TGD individuals with functioning ovaries may also choose to continue progestin treatment for birth control if relevant to their sexual practices.

TGD individuals with functioning ovaries and a uterus should be counseled about the potential for breakthrough menstrual bleeding in the first few months after initiating menstrual suppression. With GnRHa therapy, breakthrough bleeding may occur 2–3 weeks after initiation of the medication. For individuals seeking contraception or for those who continue to experience menstrual bleeding on progestin therapy, an estrogen combination with progestin may be considered for the maintenance of amenorrhea, yet they should be counseled on the possible side effect of breast development (Schwartz et al., 2019).

Statement 12.8

We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care of transgender and gender diverse adolescents.

As with the care of adolescents, we suggest where possible a multidisciplinary expert team of medical and mental health professionals (MHPs) be assembled to manage this treatment. In adolescents who pursue GAHT (given this is a partly irreversible treatment), we suggest initiating treatment using a schedule of gradually increasing doses after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and has established the individual possesses the mental capacity to give informed consent (Hembree et al., 2017). Specific aspects concerning the assessment of adolescents and the involvement of their caregivers and a multidisciplinary team are described in more detail in Chapter 6—Adolescents.

If possible, TGD adolescents should have access to experts in pediatric transgender health from multiple disciplines including primary care, endocrinology, fertility, mental health, voice, social work, spiritual support, and surgery (Chen, Hidalgo et al., 2016; Eisenberg et al., 2020; Keo-Meier & Ehrensaft, 2018). Individual providers are encouraged to form collaborative working relationships with providers from other disciplines to facilitate referrals as needed for the individual youth and their family (Tishelman et al., 2015). However, the lack of available

experts and resources should not constitute a barrier to care (Rider, McMorris et al., 2019). Helpful support for adolescents includes access to accurate, culturally informed information related to gender and sexual identities, transition options, the impact of family support, and connections to others with similar experiences and with TGD adults through online and in person support groups for adolescents and their family members (Rider, McMorris et al., 2019).

Many TGD adolescents have been found to experience mental health disparities and initial mental health screening (e.g., PHQ-2, GAD) can be employed as indicated (Rider, McMorris et al., 2019). Providers should keep in mind being transgender or questioning one's gender does not constitute pathology or a disorder. Therefore, individuals should not be referred for mental health treatment exclusively on the basis of a transgender identity. HCPs and MHPs who treat these youths and make referrals should, at a minimum, be familiar with the impact of trauma, gender dysphoria, and gender minority stressors on any potential mental health symptomatology, such as disordered eating, suicidal ideation, social anxiety. These health care providers should also be knowledgeable about the level of readiness of inpatient mental health services in their region to provide competent, gender-affirming care to TGD youth (Barrow & Apostle, 2018; Kuper, Wright et al., 2018; Kuper, Mathews et al., 2019; Tishelman & Neumann-Mascis, 2018). Statements 6.3, 6.4, and 6.12d in Chapter 6—Adolescents address this in more detail. Because parents of these youth commonly experience high levels of anxiety immediately after learning their youth is TGD, and their response to their child predicts that child's long-term physical and mental health outcomes, appropriate referrals for mental health support of the parents can be of great utility (Coolhart et al., 2017; Pullen Sansfaçon et al., 2015; Taliaferro et al., 2019).

Statement 12.9

We recommend health care professionals organize regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until a stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.

Sex steroid hormone therapy is associated with a broad array of physical and psychological changes (Irwig, 2017; Tangpricha & den Heijer, 2017) (see Appendix C—Table 1). After sex steroid hormone therapy has been initiated, the HCP should regularly assess the progress and response of the individual to the treatment (also see Chapter 6—Adolescents). This evaluation should assess the presence of any physical changes as well as the impact of treatment on gender dysphoria (if present) and psychological well-being (see Appendix C—Table 1). Clinical visits provide important opportunities for HCPs to educate patients about the typical time course required for physical changes to manifest and encourage realistic expectations. During the first year of hormone therapy, sex steroid hormone doses are often increased. A major factor guiding the dose is the serum level of the corresponding sex steroid hormone. In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017).

In addition to assessing the positive changes associated with sex steroid hormone therapy, the HCP should regularly assess whether the treatment has caused any adverse effects (see Appendix C—Table 2**).** Examples of adverse signs and symptoms include androgenic acne or bothersome sexual dysfunction (Braun et al., 2021; Kerckhof et al., 2019). GAHT also has the potential to adversely influence several laboratory tests. For example, spironolactone may cause hyperkalemia, although it is an uncommon and transient phenomenon (Millington et al., 2019). Testosterone increases the red blood cell count (hematocrit), which may occasionally cause erythrocytosis (Antun et al., 2020) (see Statement 12.17) (Hembree et al., 2017). Both estrogen and testosterone can alter lipid parameters, such as high-density protein lipoprotein (HDL) cholesterol and triglycerides (Maraka et al., 2017). See Appendix C—Tables 3 and 4.

The frequency of clinical evaluations should be individualized and guided by the individual's response to treatment. We suggest clinical assessments be performed approximately every 3 months during the first year of hormone therapy in patients who are stable and are not experiencing significant adverse effects (Appendix C—Table 5). We suggest rather than recommend testing be carried out every 3 months in the first year to allow some flexibility on the timing of these tests as there is no strong evidence or evidence from published studies supporting specific testing intervals. If an individual does experience an adverse effect, more frequent laboratory testing and/or clinical visits are often needed. Given the potential harm associated with sex hormone levels that exceed expected ranges in humans, we strongly recommend regular testing be performed as a standard practice when initiating GAHT in TGD individuals. Once a person has reached a stable adult dose of sex steroid hormone with no significant adverse effects, the frequency of clinic visits can be reduced to one to two per year (Hembree et al., 2017).

Statement 12.10

We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about options for fertility preservation prior to initiating puberty suppression and prior to administering hormone therapy.

Pubertal suppression and hormone treatment with sex steroid hormones may have potential adverse effects on a person's future fertility (Cheng et al., 2019) (see also Chapter 6—Adolescents and Chapter 16—Reproductive Health). Although some TGD people may not have given much thought to their future reproductive potential at the time of their initial assessment to begin medical therapy, the potential implications of the treatment and fertility preservation options should be reviewed by the hormone prescriber and discussed with the person seeking these therapies (Ethics Committee of the American Society for Reproductive Medicine et al., 2015; De Roo et al., 2016).

Individuals with testes should be advised prolonged treatment with estrogen often causes testicular atrophy and a reduction in sperm count and other semen parameters (Adeleye et al., 2018). Nonetheless, there are major gaps in knowledge, and findings regarding the fertility of trans feminine people who take estrogen and antiandrogens are inconsistent (Cheng et al., 2019). In one study, heterogeneity in testicular histology was evident whether patients discontinued or continued therapy prior to orchiectomies (Schneider et al., 2015). For example, the discontinuation of estrogen and antiandrogens for six weeks resulted in complete spermatogenesis in 45% of individuals with the remainder showing meiotic arrest or spermatogonial arrest (Schneider et al., 2015). However, serum testosterone levels confirmed to be within female reference ranges leads to complete suppression of spermatogenesis in most transgender women (Vereecke et al., 2020). The principal fertility preservation option for patients with functioning testes is sperm cryopreservation, also known as sperm banking (Mattawanon et al., 2018). For prepubertal patients, suppression of puberty with GnRHs pauses the maturation of sperm (Finlayson et al., 2016).

Individuals with functioning ovaries should be advised testosterone therapy usually results in the cessation of menses and ovulation, often within a few months of initiation (Taub et al., 2020). There are also major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility of TGD patients (Eisenberg et al., 2020; Stuyver et al., 2020). One study found testosterone treatment may be associated with polycystic ovarian morphology, whereas other studies reported no metabolic (Chan et al., 2018) or histologic (De Roo et al., 2017; Grynberg et al., 2010) evidence of polycystic ovary syndrome (PCOS) following treatment with testosterone, and some studies have found a pre-existing higher prevalence of PCOS in transgender patients with ovaries (Baba, 2007; Gezer et al., 2021). TGD patients with an intact uterus and ovaries often regain their fertility potential if testosterone therapy is discontinued (Light et al., 2014). Indeed, a live birth after assisted reproductive technology has been reported following hormone-stimulated egg retrieval from a TGD

individual who did not discontinue testosterone therapy (Greenwald et al., 2021; Safer and Tangpricha, 2019). Other fertility preservation options for TGD patients with ovaries are oocyte cryopreservation and embryo cryopreservation with sperm from a partner or donor. The above options require hormonal stimulation for egg retrieval and the use of assisted reproductive technology.

For early pubertal transgender youth, suppression of puberty with GnRHa's pauses the maturation of germ cells, although a recent report noted ovarian stimulation of a TGD adolescent treated with a GnRHa's in early puberty (and continued during ovarian stimulation) resulted in a small number of mature oocytes that were cryopreserved (Rothenberg et al., 2019). Treating an TGD adolescent with functioning testes in the early stages of puberty with a GnRHa not only pauses maturation of germ cells but will also maintains the penis in a prepubertal size. This will likely impact surgical considerations if that person eventually undergoes a penile-inversion vaginoplasty as there will be less penile tissue to work with. In these cases, there is an increased likelihood a vaginoplasty will require a more complex surgical procedure, e.g., intestinal vaginoplasty (Dy et al., 2021; van de Grift et al., 2020). Such considerations should be included in any discussions with patients and families considering use of pubertal blockers in early pubertal adolescents with functioning testes.

Statement 12.11

We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment in transgender and gender diverse people.

TGD people seeking masculinization must be informed about the possibilities, consequences, limitations, and risks associated with testosterone treatment. Testosterone therapy is contraindicated during pregnancy or while attempting to become pregnant given its potential iatrogenic effects on the fetus. Relative contraindications to testosterone therapy include severe hypertension, sleep apnea, and polycythemia since these conditions can be exacerbated by testosterone. Monitoring blood pressure and lipid profiles should be performed before and after the onset of testosterone therapy. The increase in blood pressure typically occurs within 2 to 4 months following the initiation of testosterone therapy (Banks et al., 2021). Patients who develop hypercholesterolemia and/or hypertriglyceridemia may require treatment with dietary modifications, medication, or both.

TGD people seeking feminizing treatment with a history of thromboembolic events, such as deep vein thrombosis and pulmonary embolism, should undergo evaluation and treatment prior to the initiation of hormone therapy. This is because estrogen therapy is strongly associated with an increased risk of thromboembolism, a potentially life-threatening complication. In addition, risk factors that can increase the risk of thromboembolic conditions, such as smoking, obesity, and sedentary lifestyle, should be modified. In patients with nonmodifiable risk factors, such as a known history of thrombophilia, a past history of thrombosis, or a strong family history of thromboembolism, treatment with transdermal estrogen concomitant with anticoagulants may decrease the risk of thromboembolism. However, there are limited data to guide treatment decisions. The presence of a disease at baseline such as a hormone sensitive cancer, coronary artery disease, cerebrovascular disease, hyperprolactinemia, hypertriglyceridemia, and cholelithiasis should be evaluated prior to the initiation of gender-affirming hormone therapy as relative risks may be shifted in association with exogenous hormone treatment (Hembree et al., 2017).

Statement 12.12

We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of physical changes induced by sex hormone treatment.

The effects of testosterone treatment are multiple and may include the appearance of increased body and facial hair, male pattern baldness, increased muscle mass and strength, decreased fat mass, deepening of the voice, interruption of

menses (if still present), increased prevalence and severity of acne, clitoral enlargement, and increased sexual desire (Defreyne, Elaut et al., 2020; Fisher, Castellini et al., 2016; Giltay & Gooren, 2000; T'Sjoen et al., 2019; Yeung et al., 2020). Other testosterone-associated changes include increased lean body mass, skin oiliness, (de Blok et al., 2020; Hembree et al., 2017; Kuper, Mathews et al., 2019; Taliaferro et al., 2019; Tishelman & Neumann-Mascis, 2018) (see Appendix C—Table 1).

Estrogen treatment induces breast development. However, fewer than 20% of individuals reach Tanner breast stages 4–5 after 2 years of treatment (de Blok et al., 2021). Additional changes include decreases in testicular volume, lean body mass, skin oiliness, sexual desire, spontaneous erections, facial hair, and body hair along with increased subcutaneous body fat) (see Appendix C—Table 1). In adult patients, estrogen does not alter a person's voice or height (Iwamoto, Defreyne et al., 2019; Wiepjes et al., 2019).

The time course and extent of physical changes vary among individuals and are related to factors such as genetics, age of initiation, and overall state of health (Deutsch, Bhakri et al., 2015; van Dijk et al., 2019). Knowledge of the extent and timing of sex hormone–induced changes, if available, may prevent the potential harm and expense of unnecessary treatment changes, dosage increases, and premature surgical procedures (Dekker et al., 2016).

Statement 12.13

We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment. For supporting text, see Statement 12.15.

Statement 12.14

We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age >45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended. For supporting text, see Statement 12.15).

Statement 12.15

We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as part of a gender- affirming hormonal treatment.

Determining the safest and most efficacious estrogen compound and route of administration for TGD people is an important topic. The recommended estrogen-based regimens are presented in Appendix C—Table 4. The Amsterdam Medical Center (AMC) first reported 45 events of VTE occurring in 816 transgender women, notably an expected incidence ratio of VTE 20-fold higher than that reported in a reference population (van Kesteren et al., 1997). Following this report, the AMC clinic recommended the use of transdermal estradiol for transgender women older than 40 years of age, which subsequently lowered the incidence of VTE (Nota et al., 2019; Toorians et al., 2003). Other studies suggested ethinyl estradiol is associated with a higher risk of blood clotting due to an increased resistance to the anticoagulating effects of activated protein C (APC) and elevated concentrations of the clotting factors protein C and protein S (Toorians et al., 2013). Other studies published within the past 15 years from other clinics reported transgender women taking other forms of estrogen had lower rates of VTE than transgender women taking ethinyl estradiol (Asscheman et al., 2013). Furthermore, a 2019 systematic review concluded ethinyl estradiol administration was associated with the highest risk of VTE in transgender women, while an association between progesterone use and VTE was also identified (Goldstein et al., 2019).

The 2017 Endocrine Society guidelines did not recommend conjugated equine estrogens (CEEs) as a treatment option because blood levels of conjugated estrogens cannot be measured in transgender women making it difficult to prevent supraphysiologic dosing of estrogen and thereby increasing the potential risk of VTE (Hembree et al., 2017). A retrospective study from the UK examined the risks of oral CEE versus oral estradiol valerate versus oral ethinyl estradiol and found up to a 7-fold increase in the percentage of transgender women in the oral CEE group

who developed VTE compared with transgender women using other forms of estrogen (Seal et al., 2012). In a nested, case-control study, over 80,000 cisgender women aged 40–79 who developed a VTE were matched to approximately 390,000 cisgender women without VTE; the results showed oral estradiol use had a lower risk of VTE than conjugated estrogens, and transdermal estrogen was not associated with an increased risk of VTE (Vinogradova et al., 2019).

A systematic review evaluated several formulations of estrogen and identified a retrospective and a cross-sectional study that made head-to-head comparisons of the risks associated with different formulations (Wierckx, Mueller et al., 2012; Wierckx et al., 2013). No identified studies evaluating the risk of different formulations of estrogen employed a prospective interventional design. The retrospective study examined 214 transgender women taking transdermal estradiol (17β-estradiol gel 1.5 mg/d or estradiol patch 50 mcg/d) or a daily intake of oral estrogens (estradiol 2 mg/d, estriol 2 mg/d, ethinyl estradiol 50 mcg/day, or ethinyl estradiol 30–50 mcg in an oral contraceptive) (Wierckx et al., 2013). Within a 10-year observation period, 5% of the cohort developed a VTE, 1.4% (3 of 214) experienced a myocardial infarction (MI), and 2.3% (5 of 214) a transient ischemic attack or cerebrovascular accident (TIA/CVA). The prevalence of VTE, MI and TIA/CVA was increased following the initiation of estrogen therapy. However, the authors did not report differences between regimens of estrogen in terms of these endpoints.

The same group of investigators conducted a cross-sectional study that examined 50 transgender women (mean age 43 ± 10) taking oral estrogen (estradiol valerate 2 mg/d, estriol 2 mg/d or ethinyl estradiol 50–120 mcg/day) or using transdermal estradiol (17β-estradiol 1.5 mg/day or estradiol 50 mcg/day) over a follow-up duration of 9.2 years (Wierckx, Mueller et al., 2012). Twelve percent (n = 6) developed either a VTE, MI, or a TIA/CVA. Two of the participants were taking conjugated estrogen 0.625 mg/d (one person in combination with cyproterone acetate), 2 participants were taking ethinyl estradiol 20–50 mcg/d, 1 was taking cyproterone acetate 50 mg/d, while the estrogen regimen used by the sixth participant was not defined. None of the subjects taking oral estradiol or transdermal estradiol developed a VTE, MI, or TIA/CVA.

One prospective study examined the route of estrogen administration in 53 transgender women in a multicenter study carried out throughout Europe. Transgender women younger than 45 years of age (n = 40) received estradiol valerate 4 mg/d in combination with cyproterone acetate (CPA) 50 mg/d and transgender women older than 45 years of age (n = 13) received transdermal 17β-estradiol, also with CPA. No VTE, MI, or TIA/CVA was reported after a 1-year follow-up in either the oral or transdermal estrogen group. An additional retrospective study from Vienna found no occurrences of VTE among 162 transgender women using transdermal estradiol who were followed for a mean of 5 years (Ott et al., 2010).

We are strongly confident in our recommendation against the use of ethinyl estradiol based on historical data from the Amsterdam clinic demonstrating a reduction in the incidence of VTE after discontinuing the use of ethinyl estradiol and the recent systematic review demonstrating an increased risk of VTE in transgender women taking ethinyl estradiol (Weinand & Safer, 2015). We are confident in our recommendation against the use of CEE based on the 2012 study by Seal et al. demonstrating an increased risk of VTE in transgender women taking CEE compared with other formulations of estrogen and with data from cisgender women on hormone replacement therapy (Canonico et al., 2007; Seal et al., 2012). Prospective and retrospective studies in transgender women have reported occurrences of VTE/MI/CVA only in those taking CEE or ethinyl estradiol. Since estradiol is inexpensive, more widely available, and appears safer than CEE in limited studies, the committee recommends against using CEE when estradiol is an available treatment option. The quality of studies may be limited to prospective, cohort or cross-sectional study designs; however, the stronger level of recommendation is based on the consistent evidence supporting the association between the use of ethinyl estradiol and CEE and a greater risk of VTE/MI/CVA in transgender women.

We are also confident in our recommendation for the administration of transdermal preparations of estrogen in older transgender women

(age > 45 years) or those with a previous history of VTE. The confidence in our recommendation is based on the decreased incidence of VTE reported from the Amsterdam clinic when transgender women are switched to using transdermal preparations after age 40 (van Kesteren et al., 1997). Furthermore, the prospective, multicenter cohort study ENIGI found no incidence of VTE/MI/CVA in transgender women who are routinely switched to transdermal estrogen at age 45 (Dekker et al., 2016). In addition, a study by Ott et al. demonstrated no incidence of VTE in 162 transgender women treated with estradiol patches (Ott et al., 2010).

With the exception of cyproterone acetate (note this is not approved for use in the US because of concerns of potential hepatotoxicity), the use of progestins in hormone therapy regimens remains controversial. To date, there have been no quality studies evaluating the role of progesterones in hormone therapy for transgender patients.

We are aware some practitioners who prescribe progestins, including micronized progesterone, are under the impression there may be improvements in breast and/or areolar development, mood, libido, and overall shape for those seeking it along with other benefits yet to be demonstrated (Deutsch, 2016a; Wierckx, van Caenegem et al., 2014). However, these improvements remain anecdotal, and there are no quality data to support such progestin use. An attempted systematic review we commissioned for this version of the SOC failed to identify enough data to make a recommendation in favor of any progestins. Instead, existing data suggest harm is associated with extended progestin exposure (Safer, 2021).

For cisgender women who have a uterus, progestins in combination with estrogens are necessary to avoid the endometrial cancer risk associated with the administration of unopposed estrogen. For cisgender women who do not have a uterus, progestins are not used. The best data for the concerns related to progestin use come from comparisons between the above two cisgender populations, which we acknowledge is not necessarily generalizable to this population. Although not definitive of a class effect for all progestins, medroxyprogesterone added to combined equine estrogens is associated with greater breast cancer and cardiac risks (Chlebowski 2020; Manson, 2013). It is important to note data from the Women's Health Initiative (WHI) studies may not be generalizable to transgender populations. Compared with the cisgender women in the studies, transgender populations seeking hormone therapy tend to be younger, do not use equine estrogen, and hormone therapy in these cases address current mental health and quality of life and not solely risk prevention (Deutsch, 2016a).

Potential adverse effects of progestins include weight gain, depression, and lipid changes. Micronized progesterone may be better tolerated and may have a more favorable impact on the lipid profile than medroxyprogesterone (Fitzpatrick et al., 2000). When paired with estrogens for transgender women, the progestin cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas—none of which are seen when estrogens are paired with GnRH agonists or spironolactone (Bisson, 2018; Borghei-Razavi, 2014; Defreyne, Nota et al., 2017; Sofer et al., 2020).

Thus, data to date do not include quality evidence supporting a benefit of progestin therapy for transgender women. However, the literature does suggest a potential harm of some progestins, at least in the setting of multi-year exposure. If, after a discussion of the risks and benefits of progesterone treatment, there is a collaborative decision to begin a trial of progesterone therapy, the prescriber should evaluate the patient within a year to review the patient's response to this treatment.

Statement 12.16

We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gendered diverse people with testes taking estrogen as part of a hormonal treatment plan if their individual goal is to approximate levels of circulating sex hormone in cisgender women.

Most gender clinics in the US and Europe prescribe estrogen combined with a testosterone-lowering medication (Mamoojee et al., 2017) (see Appendix C—Table 5). In the

US, spironolactone is the most commonly prescribed testosterone-lowering medication, while GnRHas are commonly used in the UK, and cyproterone acetate are most often prescribed in the rest of Europe (Angus et al., 2021; Kuijpers et al., 2021). The rationale for adding a testosterone-lowering medication is two-fold 1) to lower testosterone levels to within the reference range of cisgender women; and 2) to reduce the amount of estrogen needed to achieve adequate physical effects. Each testosterone-lowering medication has a different side effect profile. Spironolactone is an antihypertensive and potassium-sparing diuretic, and thus may lead to hyperkalemia, increased frequency of urination, and a reduction in blood pressure (Lin et al., 2021). Cyproterone acetate has been associated with the development of meningioma and hyperprolactinemia (Nota et al., 2018). GnRHa's, while very effective in lowering testosterone levels, can result in osteoporosis if doses of estrogen given concurrently are insufficient (Klink, Caris et al., 2015).

One systematic review identified one study that reported findings from a head-to-head comparison of the testosterone-lowering medications cyproterone acetate and leuprolide (Gava et al., 2016). Two studies compared a group of transgender women taking estrogen plus testosterone-lowering medications with a group who received only estrogen. The systematic review did not provide sufficient evidence to suggest any of the three testosterone-lowering medications had a better safety profile in terms of improved outcomes in bone health, testosterone levels, potassium levels, or in the incidence of hyperprolactinemia or meningiomas (Wilson et al., 2020). Therefore, no recommendation can be given. The review did report spironolactone-based regimens were associated with a 45% increase in prolactin levels, whereas cyproterone-based regimens increased prolactin levels by more than 100%. However, the clinical significance of elevated prolactin levels is not clear because the rates of prolactinomas were not significantly elevated in either the spironolactone- or CPA-treated groups (Wilson et al., 2020). One retrospective, cohort study from a single center in the US reported no clinically significant increases in prolactin levels in 100 transgender women treated with estrogen plus spironolactone (Bisson et al., 2018). A retrospective study from the Netherlands of 2,555 transgender women taking primarily CPA with various formulations of estrogen reported an increased standardized incidence ratio of meningiomas in patients who used cyproterone acetate after gonadectomy for many years when compared with the general Dutch population (Nota et al., 2018). Furthermore, in a shorter study in Belgium, 107 transgender women had transient elevations in prolactin levels following treatment with cyproterone acetate, which declined to normal after discontinuation (Defreyne, Nota et al., 2017). A recent publication, not included in the systematic review, examined 126 transgender women taking spironolactone, GnRHas, or cyproterone and concluded cyproterone was associated with higher prolactin levels and a worse lipid profile than spironolactone or GnRHas (Sofer et al., 2020). After balancing the costs and accessibility of measuring prolactin levels against the clinical significance of an elevated level, a decision was made not to make a recommendation for or against monitoring prolactin levels at this time. HCPs should therefore make individualized clinical decisions about the necessity to measure prolactin levels based on the type of hormone regimen and/or the presence of symptoms of hyperprolactinemia or a pituitary tumor (e.g., galactorrhea, visual field changes).

Cyproterone has also been linked to meningiomas. Nine cases of meningioma have been reported in the literature among transgender women primarily taking cyproterone acetate (Mancini et al., 2018). This increased risk has also been identified in cisgender populations. In 2020, the European Medicines Agency published a report recommending cyproterone products with daily doses of 10 mg or more should be restricted because of the risk of developing meningioma (European Medicines Agency, 2020). Most likely this association is a specific effect of cyproterone acetate and has not been extrapolated to include other testosterone-lowering drugs. In the US, where cyproterone acetate is not available, the North American Association of Central Cancer Registries (NAACCRs) database did not identify an increased risk of brain tumors (not specific to

meningiomas) among transgender women (Nash et al., 2018). Furthermore, there was not an increase in the hazard ratio of brain tumors in the Kaiser cohort of 2,791 transgender women compared with cisgender controls (Silverberg et al., 2017). No long-term studies have reported on the risk of meningiomas and prolactinomas in transgender women taking GnRHas.

Our strong recommendation for the use of testosterone-lowering medications as part of a hormone regimen for transgender individuals with testes is based on the global practice of using these medications in addition to estrogen therapies as well as the relatively minimal risk associated with these therapies. However, we are not able to make a recommendation favoring one testosterone-lowering medication over another at this time. The published data thus far raises some concerns about the risk of meningiomas with the prolonged use (>2 years) and higher doses (>10mg daily) of cyproterone acetate (Nota et al., 2018; Ter Wengel et al., 2016; Weill et al., 2021).

Bicalutamide is an antiandrogen that has been used in the treatment of prostate cancer. It competitively binds to the androgen receptor to block the binding of androgens. Data on the use of bicalutamide in trans feminine populations is very sparse and safety data is lacking. One small study looked at the use of bicalutamide 50 mg daily as a puberty blocker in 23 trans feminine adolescents who could not obtain treatment with a GnRH analogue (Neyman et al., 2019). All adolescents experienced breast development which is also commonly seen in men with prostate cancer who are treated with bicalutamide. Although rare, fulminant hepatotoxicity resulting in death has been described with bicalutamide (O'Bryant et al., 2008). Given that bicalutamide has not been adequately studied in trans feminine populations, we do not recommend its routine use.

The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The Food & Drug Administration (FDA) approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. Data on the use of 5α-reductase inhibitors in trans feminine populations is very sparse (Irwig, 2021). It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We therefore do not recommend their routine use in trans feminine populations. Finasteride may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. Nonetheless, treatment with a 5α-reductase inhibitor may impair clitoral growth and the development of facial and body hair in trans masculine individuals. Studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in transgender populations.

Statement 12.17

We recommend health care professionals monitor hematocrit (or hemoglobin) levels in transgender and gender diverse people treated with testosterone.

There are good quality data suggesting a rise in hematocrit (or hemoglobin) is associated with TGD persons treated with testosterone (Defreyne et al., 2018). The testosterone regimens in the systematic review included testosterone esters ranging from the equivalent of 25–250 mg SC/IM weekly, testosterone undecanoate 1000 mg every 12 weeks, or testosterone gel 50 mg applied daily to the skin (Defreyne et al., 2018; Gava et al., 2018; Giltay et al., 2000; Meriggiola et al., 2008; Pelusi et al., 2014; T'Sjoen et al., 2005; Wierckx, van Caenegem et al., 2014; Wierckx, van de Peer et al., 2014). The expected rise should be consistent with reference ranges in cisgender males.

Statement 12.18

We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery. For supporting text, see Statement 12.19.

Statement 12.19

We suggest health care professionals counsel eligible* transgender and gender diverse people about the various options for gender-affirmation surgery unless surgery is either not indicated or is medically contraindicated.

Despite the absence of evidence, perioperative clinical standards for gender-affirmation surgeries have included cessation of hormone therapy for 1–4 weeks before and after surgery, most commonly genital surgeries (Hembree et al., 2009). Such practice was meant to mitigate the risk of VTE associated with exogenous estrogen administration (Hembree et al., 2009). Estrogen and testosterone could then be resumed at some point postoperatively.

After careful examination, investigators have found no perioperative increase in the rate of VTE among transgender individuals undergoing surgery, while being maintained on sex steroid treatment throughout when compared with that among patients whose sex steroid treatment was discontinued preoperatively (Gaither et al., 2018; Hembree et al., 2009; Kozato et al., 2021; Prince & Safer, 2020). Sex steroid treatment is especially important after gonadectomy to avoid the sequelae of hypogonadism, the risk of developing osteoporosis, and for the maintenance of mental health and quality of life (Fisher, Castellini et al., 2016; Rosen et al., 2019). Thus, hormone providers and surgeons should educate patients about the necessity for continuous exogenous hormone therapy after gonadectomy.

To be able to educate patients and serve as clinical advocates, HCPs should be knowledgeable about the risks and benefits of gender-affirmation surgeries and should also be cognizant of the performance measures and surgical outcomes of the surgeons to whom they might refer patients (Beek, Kreukels et al., 2015; Colebunders et al., 2017; Wiepjes et al., 2018). In general, most medically necessary surgeries can be thought of as involving three regions: the face, chest/breasts, and genitalia (internal and external). Additional medically necessary procedures include body contouring and voice surgery. See medical necessity statement in Chapter 2—Global Applicability, Statement 2.1).

Multiple procedures are available for facial gender-affirming surgeries including, but not limited to chondrolanryngoplasty, rhinoplasty, contouring or augmentation of the jaw, chin, and forehead, facelift, hair removal and hair transplantation (see Chapter 13—Surgery and Postoperative Care). Procedures available for chest/breast surgery include breast augmentation, double mastectomy with nipple grafts, periareolar mastectomy, and liposuction. The most common gender-affirmation surgery for TGD individuals with endogenous breast development is masculinizing chest surgery (mastectomy) (Horbach et al., 2015; Kailas et al., 2017).

Internal genital surgery procedures include but are not limited to orchiectomy, hysterectomy, salpingo-oophorectomy, vaginoplasty, and colpectomy/vaginectomy (Horbach et al., 2015; Jiang et al., 2018). The inner lining in vaginoplasty is typically constructed from penile skin, skin grafts, a combination of both, or a bowel segment. Removal of the uterus/ovaries can be performed individually or all at once (hysterectomy, salpingo-oophorectomy, and colpectomy). If colpectomy is performed, a hysterectomy must also be performed. The ovaries may remain in situ, upon patient request. A potential benefit of leaving one or both ovaries is fertility preservation, while the downside is the potential for the development of ovarian pathology, including cancer (De Roo et al., 2017).

External genital surgery procedures include but are not limited to vulvoplasty, metoidioplasty, and phalloplasty (Djordjevic et al., 2008; Frey et al., 2016). Hair removal is generally necessary before performing external genital procedures (Marks et al., 2019). Vulvoplasty can include the creation of the mons, labia, clitoris, and urethral opening. Urethral lengthening is an option for both metoidioplasty and phalloplasty, but is associated with a greatly increased complication rate (Schechter & Safa, 2018). Wound care and physical therapy are necessary for managing wounds resulting from the donor sites for phalloplasty (van Caenegem, Verhaeghe et al., 2013). Pelvic physical therapy can also be an important adjunct intervention after surgery for managing voiding and sexual function (Jiang et al., 2019). Dialogue, mutual understanding, and clear communication in a common language between patients, HCPs, and surgeons will contribute to well-considered decisions about the available surgical procedures.

Statement 12.20

We recommend health care professionals initiate and continue gender-affirming hormone

therapy for eligible* transgender and gender diverse people who wish this treatment due to demonstrated improvement in psychosocial functioning and quality of life. For supporting text, see Statement 12.21.

Statement 12.21

We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

Several mental health disparities have been documented in the transgender population including depression, suicidality, anxiety, decreased self-esteem, and post-traumatic stress disorder (Arcelus et al., 2016; Becerra-Culqui et al, 2018; Bouman et al., 2017; Eisenberg et al., 2017; Heylens, Elaut et al., 2014; Witcomb et al., 2018). The gender minority stress model provides evidence of several mediators and moderators of these disparities (Hendricks & Testa, 2012; Meyer, 2003). Mediators and moderators of mental health disparities unique to transgender people include experiences of discrimination, victimization, misgendering, family rejection, and internalized transphobia (Hendricks & Testa, 2012). Factors that have a positive effect on mental health include family acceptance, supportive social and romantic relationships, transgender community connectedness, protection by affirming and inclusive policies, policies of affirmation and inclusion, possession of updated legal name/gender documentation, and achievement of physical gender transition based on individualized embodiment goals (Bauer et al., 2015; Bockting et al., 2013; Bouman et al., 2016; Davey et al., 2014; de Vries et al., 2014; Du Bois et al., 2018; Gower, Rider, Brown et al., 2018; Hendricks & Testa, 2012; Keo-Meier et al., 2015; Meier et al., 2013; Pflum et al., 2015; Ryan et al., 2010; Smith et al., 2018).

Hormone therapy has been found to positively impact the mental health and quality of life of TGD youth and adults who embark on this treatment (Aldridge et al., 2020; Allen et al., 2019; Bauer et al., 2015; Nobili et al., 2018; Russell et al., 2018; Ryan, 2009). In many cases, hormone therapy is considered a lifesaving intervention (Allen et al., 2019; Grossman & D'Augelli, 2006; Moody et al., 2015). Several studies have found associations between the initiation of hormone therapy and improved mental health in youth and adults (Aldridge et al., 2020; Costa et al., 2016; de Vries et al., 2014; Kuper et al., 2020; Nguyen et al., 2018; White Hughto & Reisner, 2016), including improvements in quality of life (Gorin-Lazard et al., 2012; Gorin-Lazard et al., 2013; Murad et al., 2010; Newfield et al., 2006; Nobili et al., 2018; White Hughto & Reisner, 2016), a reduction in anxiety and depression (Aldridge et al., 2020; Colizzi et al., 2014; Davis & Meier, 2014; de Vries, Steensma et al., 2011; Gómez-Gil et al., 2012; Rowniak et al., 2019), decreased stress, and decreased paranoia (Keo-Meier & Fitzgerald, 2017). A prospective, controlled trial using the Minnesota Multiphasic Personality Inventory-2 (MMPI-2) demonstrated significant improvement in multiple domains of psychological functioning in transgender men after only 3 months of testosterone treatment (Keo-Meier et al., 2015). Although there are higher rates of autism symptoms in the transgender population, these symptoms have not been found to increase after the initiation of hormone therapy (Nobili et al., 2020).

As a reduction in depressive symptoms may correlate with a decrease in the risk of suicide, withholding hormone therapy based on the presence of depression or suicidality may cause harm (Keo-Meier et al., 2015; Levy et al., 2003). Turban, King et al. (2020) found a decrease in the odds of lifetime suicidal ideation in adolescents who required pubertal suppression and had access to this treatment compared with those with a similar desire with no such access (Turban, King et al., 2020). A recent systematic review found pubertal suppression in TGD adolescents was associated with an improved social life, decreased suicidality in adulthood, improved psychological functioning and quality of life (Rew et al., 2020). Because evidence suggests hormone therapy is directly linked to decreased symptoms of depression and anxiety, the practice of withholding hormone therapy until these symptoms are treated with traditional psychiatry is considered to have iatrogenic effects

(Keo-Meier et al., 2015). If psychiatric treatment is indicated, it can be started or adjusted concurrently without discontinuing hormone therapy.

**For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents as well as Appendix D.*

CHAPTER 13 Surgery and Postoperative Care

Medically necessary gender-affirmation surgery (GAS) refers to a constellation of procedures designed to align a person's body with their gender identity (see Chapter 2—Global Applicability for medical necessity, Statement 2.1). This chapter describes surgery and postoperative care recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to surgery for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Recognizing the diverse and heterogeneous community of individuals who identify as transgender and gender diverse (TGD), gender-affirming surgical interventions may be categorized along a spectrum of procedures for individuals assigned male at birth (AMAB) and assigned female at birth (AFAB).

In appropriately selected TGD individuals, the current literature supports the benefits of GAS. While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis (Canner et al., 2018; Gaither et al., 2018; Morrison et al., 2016). In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective (Agarwal et al., 2018; Frederick et al., 2017; Top & Balta, 2017; van de Grift, Elaut et al., 2017; van de Grift et al., 2016), retrospective (Bertrand et al., 2017; Claes et al., 2018; Esmonde et al., 2019; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Poudrier et al., 2019; Wolter et al., 2015; Wolter et al., 2018), and cross-sectional cohort studies (Olson-Kennedy, Warus et al., 2018; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; van de Grift, Elfering et al., 2018). The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective (Weigert et al., 2013; Zavlin et al., 2018), 1 retrospective cohort (Fakin et al., 2019), and 3 cross-sectional cohort studies (Kanhai et al., 2000; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018). All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective (Buncamper et al., 2017; Cardoso da Silva et al., 2016; Kanhai, 2016; Manero Vazquez et al., 2018; Papadopulos, Zavlin et al., 2017; Tavakkoli Tabassi et al., 2015; Wei et al., 2018; Zavlin et al., 2018), 15 retrospective cohort (Bouman, van der Sluis et al., 2016; Buncamper et al., 2015; Hess et al., 2016; Jiang et al., 2018; LeBreton et al., 2017; Manrique et al., 2018; Massie et al., 2018; Morrison et al., 2015; Papadopulos, Lelle et al., 2017; Raigosa et al., 2015; Salgado et al., 2018; Seyed-Forootan et al., 2018; Sigurjonsson et al., 2017; Simonsen et al., 2016; Thalaivirithan et al., 2018), and 3 cross-sectional cohort studies have recently been reported (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018).

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident

Statements of Recommendations

13.1- We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:
13.1.a- Training and documented supervision in gender-affirming procedures;
13.1.b- Maintenance of an active practice in gender-affirming surgical procedures;
13.1.c- Knowledge about gender diverse identities and expressions;
13.1.d- Continuing education in the field of gender-affirmation surgery
13.1.e- Tracking of surgical outcomes.
13.2- We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.
13.3- We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.
13.4- We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.
13.5- We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity).
13.6- We suggest health care professionals consider gender-affirming genital procedures for eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).
13.7- We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.
13.8- We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.
13.9- We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.
13.10- We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.
13.11- We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

** For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescents chapters and Appendix D.*

when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort (Garaffa et al., 2010; Stojanovic et al., 2017; Vukadinovic et al., 2014), 6 retrospective cohort (Cohanzad, 2016; Garcia et al., 2014; Simonsen et al., 2016; van de Grift, Pigot et al., 2017; van der Sluis et al., 2017; Zhang et al., 2015), and 4 cross-sectional studies (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; Wierckx, Van Caenegem et al., 2011), which reviewed the risks and benefits of these procedures.

In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort (Morrison et al., 2020), 5 retrospective cohort (Bellinga et al., 2017; Capitán et al., 2014; Noureai et al., 2007; Raffaini et al., 2016; Simon et al., 2022), and 2 cross-sectional studies (Ainsworth & Spiegel, 2010; van de Grift, Elaut

et al., 2018). All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial GAS significantly improves both mid- and long-term quality of life (Morrison et al., 2020). The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended.

Additional procedures and/or interventions such as hair removal (prior to facial and/or genital surgery) may be required as part of the preoperative process. See Chapter 15—Primary Care. Furthermore, consultation with pelvic floor physical therapy may be important (or required) both before and after surgery.

Representative surgical interventions include (for complete list, see appendix E and the end of this chapter):

AMAB: facial feminization surgery (including chondrolaryngoplasty/vocal cord surgery), gender-affirming breast surgery, body contouring procedures, orchiectomy, vagino/vulvoplasty (with/without depth), aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

AFAB: facial masculinization surgery, gender-affirming chest surgery, hysterectomy/oophorectomy, metoidioplasty (including placement of testicular prosthesis), phalloplasty (including placement of testicular/penile prostheses), body contouring procedures, aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

It is important surgeons understand the indication(s) and the timing for GAS. This is especially important when caring for adolescents (see Chapter 6—Adolescents).

It is important the surgeon and the patient participate in a shared decision-making approach that includes 1) a multidisciplinary approach; 2) an understanding of the patient's goals and expectations; 3) a discussion regarding the surgical options and associated risks and benefits; and 4) an informed plan for aftercare (see Chapter 5—Assessment for Adults). These recommendations are designed to facilitate an individualized approach to care.

Appropriate aftercare is essential for optimizing outcomes (Buncamper et al., 2015; Lawrence, 2003), and it is important patients are informed about postoperative needs (including local wound care, activity restrictions, time off from work or school, etc.). In addition, it is important the surgeon is available to provide and facilitate postoperative care, refer to specialty services, or both as needed. This may include the need for ongoing support (i.e., both from the caregiver as well as the primary care provider, mental health professionals (MHPs), or both), as well as the need for routine primary care (i.e., breast/chest cancer screening, urologic/gynecologic care, etc.).

With the increase both in public interest and in the number of gender-affirming surgical procedures (Canner et al., 2018; Ross, 2017; Shen et al., 2019), additional training, tracking of outcomes, and continuing medical education for surgeons are necessary (Schechter et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 13.1

We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:

a. **Training and documented supervision in gender-affirming procedures;**
b. **Maintenance of an active practice in gender-affirming surgical procedures;**
c. **Knowledge about gender diverse identities and expressions;**
d. **Continuing education in the field of gender-affirmation surgery;**
e. **Tracking of surgical outcomes.**

Surgeons offering GAS may have a variety of surgical specialty training and backgrounds. The most common surgical specialties include plastic surgery, urology, gynecology, otolaryngology and oro-maxillofacial surgery (Jazayeri et al., 2021). Consistent with other surgical domains, we recommend only surgeons who are certified or eligible to be certified by their respective national professional boards offer GAS. Furthermore, it is recommended surgeons offering care for TGD people have received documented training in gender-affirming procedures and principles of gender-affirming care (Schechter et al., 2017; Schechter & Schechter, 2019). The latter includes, but is not limited, to knowledge about gender diverse identities and expressions, and how those affect patient goals, expectations, and outcomes. It is important surgeons offering GAS be familiar with the available procedures and can provide informed consent. If surgeons do not offer a requested procedure, they may offer a referral for a second opinion. Surgeons offering GAS are expected to participate in continuing education activities in the field of GAS (i.e., meetings, conferences, seminars, etc.) to maintain current knowledge. We further recommend surgical outcomes be tracked and communicated to the patients as part of the informed consent (Schechter et al., 2017).

In addition, hospitals, institutions, and physician offices that offer GAS need to be knowledgeable regarding cultural competencies (i.e., language, terminology, etc.). This may require ongoing and regular staff education.

Statement 13.2

We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.

Prior to breast augmentation or mastectomy, individuals need to be informed about and assessed for breast cancer risk factors, including genetic mutations (i.e., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery (Brown, Lourenco et al., 2021; Brown & Jones, 2015; Colebunders et al., 2014; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Breast cancer screening balances the identification of cancer with the selection of appropriate imaging, tests, and procedures. Currently, evidence-based screening guidelines specific for TGD individuals do not exist (Salibian et al., 2021), however, recent guidelines have been proposed by the American College of Radiology (Brown, Lourenco et al., 2021). Because the risk of cancer in individuals seeking gender-affirming breast augmentation or mastectomy is similar to that in the general population (even in the setting of hormone use), existing cancer screening guidelines need to be followed (Brown & Jones, 2015; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Professionals need to be familiar with updates to these guidelines as they are subject to change. Individuals who undergo gender-affirming surgery of the chest should have ongoing breast cancer surveillance, which should be overseen by their primary care providers.

Statement 13.3

We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.

Details about the timing, technique, and duration of the aftercare requirements are shared with patients in the preoperative period such that appropriate planning may be undertaken. This includes a discussion regarding the anticipated staging of surgical procedures (and associated travel requirements). Given the small number of surgeons who specialize in GAS, it is common for patients to travel for their procedures. Prior to surgery, surgeons should provide patients with a postoperative follow-up schedule. The surgeon should discuss the duration of the patient's travel dates, the anticipated inpatient versus outpatient stay, and the potential need for flexibility in travel arrangements (especially if complications occur). Given the complexity and cost of travel and lodging, changes in the care plan should be shared with the patient as early as possible. Surgeons should facilitate continuity of care with a local provider upon returning home.

Aftercare and postsurgical follow-up are important. Gender-affirming surgical procedures

often have specific aftercare requirements, such as postsurgery resources (stable, safe housing; resources for travel and follow-up care), instructions in health-positive habits (e.g., personal hygiene, healthy living, prevention of urinary tract infections (UTIs) and sexually-transmitted infections (STIs) (Wierckx, Van Caenegem et al., 2011)), postsurgery precautions or limitations on activities of daily life (e.g., bathing, physical activity, exercise, nutritional guidance, resumption of sexual activity) (Capitán et al., 2020), postsurgery resumption of medications (i.e., anticoagulants, hormones, etc.), and detailed postsurgery self-care activities (e.g., postvaginoplasty dilation and douching regimens, activation of a penile prosthesis, strategies to optimize postphalloplasty urination, recommendations for hair transplant care) (Capitán et al., 2017; Falcone et al., 2018; Garcia, 2018; Hoebeke et al., 2005). Some aspects of postsurgery self-care activities may be introduced prior to surgery and are reinforced after surgery (Falcone et al., 2018). As issues such as wound disruptions, difficulty with dilation, and UTIs may occur (Dy et al., 2019), the follow-up period provides an opportunity to intervene, mitigate, and prevent complications (Buncamper et al., 2016; Garcia, 2021).

Statement 13.4

We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.

Infertility is often a consequence of both gender-affirming hormone therapy (temporary) and GAS (permanent), and fertility preservation is discussed prior to medical interventions, surgical interventions, or both (Defreyne, van Schuylenbergh et al., 2020; Jahromi et al., 2021; Jones et al., 2021). Surgical interventions that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these interventions and on an ongoing basis thereafter (Hembree et al., 2017).

For specific recommendations regarding reproductive options, see Chapter 16—Reproductive Health.

Statement 13.5

We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity). For supporting text, see Statement 13.6.

Statement 13.6

We suggest health care professionals consider gender-affirming genital procedures in eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result unless hormone therapy is either not desired or is medically contraindicated).

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). Depending upon the surgical result required, a period of hormone treatment may be required (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty) or preferred for psychological reasons, anatomical reasons, or both (breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of this on the proposed surgery.

For individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Statement 13.7

We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.

Substantial evidence (i.e., observational studies (Monstrey et al., 2001; Stojanovic et al., 2017), literature reviews and expert opinions (Esteva de Antonio et al., 2013; Frey et al., 2017; Hadj-Moussa et al., 2019; Pan & Honig, 2018), established guidelines (Byne et al., 2018; Chen, Fuqua et al., 2016; Hembree et al., 2017; Karasic & Fraser, 2018; Klein, Paradise et al., 2018; Weissler et al., 2018), and a thematic content analysis (Gerritse et al., 2018), support the importance of a multidisciplinary (i.e., medical, mental health, and surgery) approach to transgender health care.

A multidisciplinary approach is especially important in managing mental health issues if these are experienced by a TGD person undergoing GAS (de Freitas et al., 2020; Dhejne et al., 2016; van der Miesen et al., 2016). In addition, primary care providers and medical specialists can help support decisions regarding the timing of surgery, surgical outcomes and expectations, perioperative hormone management, and optimization of medical conditions (Elamin et al., 2010; Hembree et al., 2017).

For specific recommendations regarding presurgical assessment in adolescents, see Chapter 6—Adolescents.

Statement 13.8

We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.

Gender identities may present along a spectrum, and the expression of a person's identity may vary quite widely amongst individuals (Beek et al., 2015; Koehler et al., 2018). While the overall goal of a particular procedure usually includes reduction of gender dysphoria (van de Grift, Elaut et al., 2017) or achieving gender congruence, gender diverse presentations may lead to individually customized surgical requests some may consider "non-standard" (Beek et al., 2015; Bizic et al., 2018). Individually customized surgical requests can be defined as 1) a procedure that alters an individual's gender expression without necessarily aiming to express an alternative, binary gender; 2) the "non-standard" combination of well-established procedures; or 3) both.

This is designed to help counsel and inform the patient as well as to ensure their goals can be achieved. The patient and their surgeon need to work together to ensure the patient's expectations are realistic and achievable, and the proposed interventions are safe and technically feasible. The patient and their surgical team need to engage in a shared decision-making process (Cavanaugh et al., 2016). This informed consent process needs to address the irreversibility of some procedures, the newer nature of some procedures, and the limited information available about the long-term outcomes of some procedures.

Statement 13.9

We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.

Postoperative complications following metoidioplasty/phalloplasty comprise the urinary tract and sexual function (Kang et al., 2019; Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019). Reported urethral complications (related to urethral lengthening) include urethral strictures 35–58%, urethral fistulae 15–70% (Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019), diverticulae, mucocele due to vaginal remnant, and hair growth within the neourethra (Berli et al., 2021; Veerman et al., 2020). Complications related to sexual function include limited to absent tactile and/or erogenous sensation, difficulties with orgasm function, and complications with penile prosthetics (Kang et al., 2019; Santucci, 2018). Penile prosthesis-related complications are estimated to involve infection (incidence 8–12%),

malfunction, urethral erosion, skin extrusion, and dislocation of its bone fixation (Falcone et al., 2018; Kang et al., 2019; Morrison et al., 2016). Although most urethral and prosthetic complications occur in the immediate and intermediate postoperative period, complications can occur at any time. Early detection may reduce morbidity (e.g., urethral strictures resulting in fistulae, pending erosion of a penile prosthetic leading to infection and requiring total explant) (Blecher et al., 2019).

Routine follow-up to assess for early evidence of urethral stricture (or other urinary issues) includes bladder ultrasound measurement of postvoid residual volume (to screen for and stage neourethral stricture), fluoroscopic urethrography (to identify and stage neourethral strictures, fistulae, and diverticulae), and cystourethroscopy to examine the urethra and bladder. TGD men may also have routine urologic issues that need not be related to gender transition (urinary calculi, hematuria, and genitourinary malignancies; fertility preservation) (Sterling & Garcia, 2020a, 2020b).

Statement 13.10

We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.

Vaginoplasty is a safe procedure (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). While complications may occur, most are self-limited or can be treated with minor interventions (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). Minor complications include issues such as the formation of granulation tissue, intravaginal hair growth, delayed wound healing or wound disruption (or both), aesthetic concerns, and introital stenosis (Ferrando, 2020; Kloer et al., 2021). While these complications are usually self-limited, they may impact patient well-being after surgery. Additionally, these issues may go either undiagnosed or may be misdiagnosed if patients are not able to access care provided by professionals with expertise in the field of transgender health. We recommend patients be followed by their primary surgeon in person and at regular intervals—for example at two weeks, three months, six months, and one year after surgery—although more follow-up may be indicated for some individuals.

Additional gynecologic care is conducted throughout the TGD person's lifetime and can be managed in many settings. A speculum exam to check for granulation tissue, hair, and lesions can be performed by the primary care provider, gynecologist, or GAS surgeon and may be necessary outside of the immediate postoperative period (Grimstad, McLaren et al., 2021; Suchak et al., 2015; van der Sluis et al., 2020). After confirmation by laboratory testing, UTIs, STIs, and other fluctuations in the vaginal microbiome may be treated following relevant guidelines formulated for cisgender populations (Hooton, 2012; Sherrard et al., 2018). Manual prostate checks are performed based on relevant guidelines formulated for cisgender populations via the vaginal canal, as the prostate is located on the anterior wall of the vagina (Carter et al., 2013).

Other complications include issues such as stenosis of the neovaginal canal, rectovaginal fistulae, and inflammation (intestinal vaginoplasty) (Bustos et al., 2021). These require a combination of nonsurgical and surgical treatment with consultation and possible referral back to the primary surgeon with other surgical consultants (i.e., colorectal surgeon), if required. In addition, as pelvic floor dysfunction may affect 30–40% of patients both prior to and following vaginoplasty, the availability of pelvic floor physical therapists is an important adjunct in the postoperative period (Jiang et al., 2019).

Statement 13.11

We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

The percentage of individuals who regret their GAS is very low (between 0.3% and 3.8%) (De Cuypere & Vercruysse, 2009; Defreyne, Motmans et al., 2017; Hadj-Moussa et al., 2019; Hadj-Moussa, Agarwal et al., 2018; Hadj-Moussa, Ohl et al., 2018; Landén et al., 1998; Narayan et al., 2021; van de Grift, Elaut et al., 2018; Wiepjes et al., 2018). The highest incidence of

regret was reported at a time when surgical techniques were less refined, the role of multidisciplinary care was less established, and the *Standards of Care* did not exist or were not widely known (Landén et al., 1998). Regret can be temporarily or permanent and may be classified as (Narayan et al., 2021) social regret (caused by difficulties in familial, religious, social, or professional life), medical regret (due to long-term medical complications, disappointment in surgical results or inadequate preoperative decision-making), and true gender-related regret (mostly based on patient experienced misdiagnosis, insufficient exploration of gender identity, or both). This classification is in accordance with previously discussed positive and negative predictive factors (De Cuypere & Vercruysse, 2009; Gils & Brewaeys, 2007; Pfäfflin & Junge, 1998).

A multidisciplinary team can help identify the etiology of regret as well as the temporal stability of the surgical request (Narayan et al., 2021). Following this evaluation and in consideration of the individual's circumstances, medical and/or surgical interventions with the intent of either continuing transition or performing surgical procedures to return anatomy to that of the sex assigned at birth may be indicated. For further information see Chapter 5—Assessment of Adults.

**For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescent chapters and Appendix D*

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GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

CHAPTER 14 Voice and Communication

Human beings engage in communication practices not only to exchange ideas about the outside world, but also to present themselves as sociocultural beings and to negotiate forms of address, referral and treatment by others that allow them to feel safe and respected (Azul et al., 2022). The human voice is widely regarded as one of the key modalities that contributes to the communication of gender as one of the dimensions of human diversity. However, other aspects and ways of communicating (e.g., articulation, word choice, gesture, listener perceptions and attributions) need to be considered as well (Azul, 2015; Azul & Hancock, 2020). Throughout this chapter "voice and communication" is used as a phrase encompassing the meaning-making practices in which each of the participants of a social encounter engage according to their own needs, wishes, identifications, and capacities.

While a binary understanding of gender has dominated the research literature in this area, the approach recommended in this chapter implies a broadly inclusive view of gender identification (e.g., trans feminine, trans masculine, gender fluid, nonbinary, genderqueer, agender) and the understanding that gender does not exist in isolation, but intersects with other aspects of human diversity (e.g., First Nation status, ethnicity/race, sexuality, dis/ability, faith/religion/spirituality). The recommendations in this chapter apply to all transgender and gender diverse (TGD) people who are seeking professional voice and communication support, including children, adolescents, younger and older adults, and people who wish to transition or detransition, irrespective of their intervention choices.

Not every TGD person experiences challenges with or wants professional support for their voice and communication, but those who do often encounter barriers in accessing care. Although the percentages vary by country and TGD subpopulation, the statistics support the concern TGD people are not able to access voice and communication services when and how they desire (Eyssel et al., 2017; James et al., 2016; Oğuz et al., 2021; Södersten et al., 2015; Veale et al., 2019). In these studies, the percentage of TGD people wishing to receive voice and communication training or voice surgery is generally higher than the percentage of people who have undergone these interventions. With few exceptions, access to voice training is usually greater than access to voice surgery. Groups of TGD people who are further marginalized in their societies, such as TGD people of marginalized race/ethnicity, experience discrimination and limited access to care at even greater rates (James et al., 2016; Xavier et al., 2005).

Cost, not knowing where to access services, and services not being available are amongst the most common barriers cited by research participants. According to studies in the US (Hancock & Downs, 2021; Kennedy & Thibeault, 2020), Turkey (Oğuz et al., 2021), and Aotearoa/New Zealand (Veale et al., 2019), lack of accurate information about options for voice and communication services among TGD people is a significant and ubiquitous barrier to care. Notably, in Sweden, all TGD people are offered support for their voice and communication when a diagnosis of gender incongruence is made (Södersten et al., 2015). Additionally, cultural responsiveness of providers is only slowly improving (Hancock & Haskin, 2015; Jakomin et al., 2020; Matthews et al., 2020; Sawyer et al., 2014). Hancock and Downs (2021) have conducted preliminary work to identify specific barriers to voice and communication services and develop effective means for eliminating them.

This chapter is intended to provide guidance for health care professionals (HCPs) to support and foster well-being in all TGD people who are experiencing challenges or distress regarding their own voice and communication practices and/or regarding responses and attributions they receive from others (Azul et al., 2022).

A number of different approaches TGD people can use to modify their voice and communication, either individually or in combination include self-initiated change, which may be supported by resources TGD people use to guide their voice use and communication practice; behavioral change supported by voice and communication specialists (hereafter referred to as "voice and communication training"); and change as a result of androgen hormonal treatment and/or laryngeal surgery. The currently existing research evidence

does not include self-initiated change, but is focused on the latter three approaches.

A "voice and communication specialist" is someone who has knowledge regarding the ongoing and dynamic agency of speaker and listener practices, relevant professional interventions including behavioral, hormonal, and surgical, and relevant processes related to biophysiology, sociocultural meaning-making, and external material forces (Azul & Hancock, 2020). This specialist is capable of conducting appropriate assessments to inform the TGD person's choice and support the exploration of goals and intervention options by providing guidance in a culturally responsive, person-centered approach. This specialist has knowledge and skills in behavioral voice and communication intervention approaches.

Practices amenable to behavioral change include: speaking and singing voice, mindfulness, relaxation, respiration, pitch and pitch range, voice quality, resonance/timbre, loudness, projection, facial expression, gesture, posture, movement, introducing self to others, describing identifications and requesting culturally responsive treatment and forms of address by others, assertive and resilient responses to misattributions, practicing implementation of voice use and communication practices with different people and in different everyday settings (e.g., Hancock & Siegfriedt, 2020; Mills & Stoneham, 2017).

Voice and communication services are offered as part of a complete and coordinated approach to health, including support for medical, psychological, and social needs (Södersten et al., 2015); however, there are no prerequisites (e.g., hormone use, pursuit of surgeries, or duration living in a gender role). The overall purposes of voice and communication support for TGD people are:

- To educate clients about the factors that influence functional voice and communication practices and the communication of the speaker's identity (speaker, listener, professional practices, external material, biophysiological, and sociocultural factors);
- To enable clients to communicate their sense of sociocultural belonging (e.g., in terms of gender) in everyday encounters in a manner that matches the client's desired self-presentation and to develop, maintain and habituate voices, vocal qualities, and communication practices that support the clients' goals in a manner that does not harm the voice production mechanism;
- To provide training in functional voice production for clients who present with restrictions of voice function (e.g., as a result of overextending their voice production mechanism);
- To support clients with developing the capacity to assertively negotiate desired forms of address and referral from others (e.g., names, pronouns, titles) and to respond to misattributions in a skillful manner that contributes to increasing and maintaining the client's well-being;
- To support clients to develop the problem-solving skills needed to manage anxiety, stress, and dysphoria in collaboration with mental health providers; and to navigate barriers to practice or real-life use of one's preferred voice and communication.
- To provide, or refer clients to, supportive resources that facilitate developing voice and communication skills, vocal awareness, and well-being.
- To refer clients to, or collaborate with, other specialists such as mental health practitioners, laryngeal surgeons, and endocrinologists, who may be more equipped to meet the specific needs of that client. This may be especially relevant in cases where clients face unique challenges due to multiple barriers to their health and well-being or when the client wishes to pursue laryngeal surgery or hormone therapy.

Two types of laryngeal surgeries are relevant for TGD populations: those for raising voice pitch (e.g., glottoplasty with retro-displacement of the anterior commissure, cricothyroid approximation (CTA), feminization laryngoplasty, laser-assisted voice adjustment (LAVA)) (Anderson, 2007; Anderson, 2014; Brown, 2000; Casado, 2017; Geneid, 2015; Gross, 1999; Kelly et al., 2018; Kanagalingam, 2005; Kim, 2017; Kim, 2020; Kocak, 2010; Kunachak, 2000; Mastronikolis, 2013; Mastronikolis et al., 2013; Matai, 2003; Meister,

Statements of Recommendations

14.1- We recommend voice and communication specialists assess current and desired vocal and communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.
14.2- We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.
14.3- We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.
14.4- We recommend health care professionals consider working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.
14.5- We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

2017; Mora, 2018; Neumann, 2004; Nuyen et al., 2022; Orloff, 2006; Pickuth, 2000; Remacle, 2011; Thomas & MacMillan, 2013; Tschan, 2016; Van Borsel, 2008; Wagner, 2003; Wendler, 1990; Yang, 2002) and for lowering voice pitch (e.g., thyroplasty type III, vocal fold injection augmentation) (Bultynck et al, 2020; Isshiki et al., 1983; Kojima, et al. 2008; Webb et al., 2021). Reported acoustic benefits of pitch-raising surgery include increased voice pitch (average frequency (f_o)) and increased Min f_o(the lowest frequency in physiological voice range). TGD people's self-rating ratings show general satisfaction with voice postsurgery, although individuals who are interested in more comprehensive changes to vocal self-presentation may need to engage in behavioral interventions with a voice and communication specialist in addition to laryngeal surgery (Brown, Chang et al. 2021; Kelly et al., 2018; Nuyen et al., 2022). Potential harms of pitch-raising surgery can be assessed and addressed in voice training by a voice and communication specialist. Reported harms of pitch-raising surgery include voice problems such as dysphonia, weak voice, restricted speaking voice range especially upper range (lowered Max f_o, in the physiological voice range), hoarseness, vocal instability, and lowering of frequency values over time (Kelly et al., 2018; Song & Jiang, 2017), although the rate of these outcomes is inconsistent.

Research on pitch-lowering surgeries is limited. However, studies including eight TGD people who elected to undergo thyroplasty type III after continued dissatisfaction with hormonal treatment (Bultynck et al., 2020) and one person who received injection augmentation after testosterone therapy and voice training (Webb et al., 2020), reported statistically significant lowering of fundamental frequency, perceived as pitch.

Estrogen treatment in TGD people has not been associated with measurable voice changes (Mészáros et al., 2005), while testosterone treatment in TGD people has been found to result in both desired and undesired changes in gender- and function-related aspects of voice production (Azul, 2015; Azul et al., 2017, 2018, 2020; Azul & Neuschaefer-Rube, 2019; Cosyns et al., 2014; Damrose, 2008; Deuster, Di Vicenzo et al., 2016; Deuster, Matulat et al. 2016; Hancock et al., 2017; Irwig et al., 2017; Nygren et al., 2016; Van Borsel et al., 2000; Yanagi et al., 2015; Ziegler et al., 2018). Desired changes associated with testosterone treatment include lowered voice pitch, increased male attributions to voice, and increased satisfaction with voice. Reported dissatisfaction with testosterone treatment include lack of or insufficient lowering of voice pitch, dysphonia, weak voice, restricted singing pitch range, and vocal instability. These areas can be assessed and addressed in voice training by a voice and communication specialist.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 14.1.

We recommend voice and communication specialists assess current and desired vocal and

communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.

Voice and communication specialists may assess satisfaction with the presentation of sociocultural positionings in communicative encounters, including gender and other intersecting identifications, taking into consideration that these may or may not be static over time; attributions received from others, and how these relate to the individual's identifications, wishes, and well-being; ratings of voice and speech naturalness; and voice and communication function in relation to vocal demands. Assessments may vary in nature (e.g., client-reported outcome measures, perceptual, acoustic, aerodynamic, endoscopic) according to their purpose (Davies et al., 2015; Leyns et al., 2021; Oates & Dacakis, 1983). For example, laryngeal visualization is used when individuals present with a concomitant voice problem, (e.g., muscle tension dysphonia) (Palmer et al., 2011) or experience voice difficulties, which may or may not be secondary to medical gender-affirming interventions of androgen therapy or laryngeal surgery (Azul et al., 2017).

Voice and communication specialists inform intervention-seeking TGD people who are dissatisfied with their voice and communication about available interventions that support TGD people with their voice, communication, and well-being. The nature of each option, including potential outcomes and permanence, is presented objectively to provide the TGD person respect and autonomy in decision-making. Appropriate intervention plans are individualized and feasible and should be inclusive of any professional services available. Goals may evolve over the course of the support period as the TGD person explores modifications to voice and communication, assesses their satisfaction with achieved change and refines their goals.

Statement 14.2.

We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.

Academic and licensing credentials of voice and communication specialists (e.g., speech-language pathologists, speech therapists, singing voice teachers, voice coaches) vary by location but typically do not specify criteria for working with specific populations. Standard curricula in formal education for these professions often do not include specific or adequate training for working with TGD populations (Jakomin et al., 2020; Matthews et al., 2020). General knowledge and skills related to the vocal mechanism and interpersonal communication are foundational but insufficient for conducting culturally responsive, person-centered care for TGD people that is effective, efficient, inclusive, and accessible (Hancock, 2017; Russell & Abrams, 2019).

Professionals in this area should receive comprehensive education that invites them to develop self-awareness, cultural humility, and cultural responsiveness in order to be respectful of and attentive to gender diversity and other aspects of a client's identifications that can take a variety of forms and imply a range of different support needs (Azul, 2015; Azul et al., 2022). Client preferences for use of names, formal forms of address, gender entry, and pronouns need to be respected in all communication with and about the client (including medical records, reports, emails). Education also needs to inform the setting up of a training space or clinic and administrative practices that are designed to be welcoming to TGD people and allow TGD people to feel safe and respected when raising concerns or issues with the voice and communication support team.

Voice and communication specialists working with TGD people will need working knowledge of applicable intervention principles, mechanisms, and effectiveness, competence in teaching and modeling voice and communication modification skills, and a basic understanding of transgender health, including hormonal and surgical treatments and trans-specific psychosocial issues. Education needs to include methodologies and practices that have been developed within TGD communities and shown to be effective and should ideally be presented by or in collaboration with TGD people with lived experience of voice and communication support.

Statement 14.3.

We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.

A voice and communication specialist is well positioned to provide information and guidance to the TGD person expressing dissatisfaction with their voice or communication when available. There is evidence voice and communication specialists provide support in such a way that a client's satisfaction with voice and communication can be achieved, thereby reducing gender dysphoria and improving communication-related quality of life (Azul, 2016; Block, 2017; Deuster, Di Vincenzo et al., 2016; Hancock, 2017; Hancock et al., 2011; Hardy et al., 2013; Kelly et al., 2018; McNamara, 2007; McNeill et al., 2008; Owen & Hancock, 2010; Pasricha et al., 2008; Söderpalm et al., 2004; Watt et al., 2018).

There is empirical evidence that behavioral voice support for TGD AMAB people is effective with regard to achieving the targeted voice changes (Oates, 2019). Seven studies prior to 2020 provide empirical evidence for the effectiveness of voice training, although it is somewhat weak (Carew et al., 2007; Dacakis, 2000; Gelfer & Tice, 2013; Hancock et al., 2011;Hancock & Garabedian, 2013; McNeill et al., 2008; Mészáros et al., 2005). Voice training methods across these seven studies were similar and indicated voice training can be effective at increasing average fundamental frequency (average pitch), fundamental frequency range (pitch range), satisfaction with voice, self-perception and listener perception of vocal femininity, voice-related quality of life, and social and vocational participation. Weaknesses of the identified studies include lack of randomized controlled trials evaluating voice training, small sample sizes, inadequate long-term follow-up, and lack of control of confounding variables. In 2021, another systematic review of the effects of behavioral speech training for AMAB people reached similar conclusions (Leyns et al., 2021).

Until recently, there was almost no research exploring the effectiveness of voice training with TGD AFAB people. There is, however, some promising, although weak evidence of effectiveness from a case study (Buckley et al., 2020) and one uncontrolled prospective study of group voice training (Mills et al., 2019).

Statement 14.4.

We recommend health care professionals working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.

This statement does not intend to require TGD people receive presurgical voice training. Rather, it is recommended that every available support be offered to provide individualized informational counseling critical to person-centered care. The recommendation is for the TGD person's consideration to be informed as necessary by individualized informational counseling based on voice assessment, trial voice training, and discussion of expected voice outcomes and risks of surgery with a voice and communication specialist.

For most types of laryngeal surgery, voice training is recommended both prior to surgery to ensure preparation of the vocal mechanism for the surgical intervention and postsurgery to ensure a return to functional voice production (Branski et al., 2006; Park et al., 2021). For pitch-raising surgery in particular, another reason a trial of voice training is recommended is because there are indications certain measures improve with training but not with pitch-raising surgery (e.g., factors relevant to intonation and naturalness, such as maximum *f0* pitch in speech range; Kelly et al., 2018).

The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient, particularly with regard to comparing outcomes with and without other interventions (i.e., testosterone) (Bultynck et al., 2020). There are more techniques and studies of pitch-raising surgeries, but the quality of the evidence is still low. Outcomes from pitch-raising surgeries have been compared to outcomes from having no surgery (Anderson, 2007, 2014; Brown et al., 2000;

Geneid et al., 2015; Gross, 1999; Kim, 2017; Kocak et al., 2010; Kunachak et al., 2000; Matai et al., 2003; Meister et al., 2017; Neumann & Welzel, 2004; Orloff et al., 2006; Pickuth et al., 2000; Remacle et al., 2011; Thomas & Macmillan, 2013; Tschan et al., 2016; Van Borsel et al., 2008; Yang et al., 2002), another type of surgical technique (Mora, 2018), voice training alone (Kanagalingam, 2005; Mastronikolis, 2013; Wagner, 2003) and surgery in conjunction with voice training (Casado, 2017; Kelly et al., 2018).

In the 11 studies reporting whether participants had voice training prior to pitch-raising surgery, most participants had prior voice training, but remained dissatisfied with voice and sought surgical intervention. Thus, most studies of surgical outcomes reflect the combined effects of voice training and surgical intervention. Attributes predicting which clients will pursue surgery after training are unknown.

Statement 14.5.

We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

The research on the effects of androgen treatment on voice and communication of TGD people points to diverse and unpredictable effects on individual clients. While a number of studies have revealed effects on voice that matched TGD people's expectations and wishes, there is high quality evidence demonstrating TGD people are not always satisfied with the vocal outcomes of testosterone therapy, and many experience difficulties such as inadequate pitch lowering, compromised voice quality, vocal loudness, vocal endurance, pitch range, and flexibility (Azul, 2015, 2016, 2017, 2018; Cosyns et al., 2014; Nygren et al., 2016; Ziegler et al., 2018). A recent meta-analysis of 19 studies examining the effects of at least 1 year of testosterone therapy estimated 21% of participants did not achieve cisgender male normative frequencies, 21% of participants reported incomplete voice-gender congruence and voice problems, and 16% were not completely satisfied with their voice (Ziegler, 2018).

For people who wish to be treated with androgens, accurate informational counseling prior to commencing treatment should enable the development of realistic expectations to avoid disappointment regarding the permanent impact of hormone treatment on voice and communication. In addition, TGD people who do not have access to or do not wish to be treated with testosterone, but want to change their voice and those who are dissatisfied with the outcomes of testosterone treatment can be advised by a voice and communication specialist of alternative and additional support options (e.g., behavioral voice and communication training; pitch-lowering surgery).

CHAPTER 15 Primary Care

Primary care is the broadest of health care disciplines and is defined as the "provision of integrated, accessible health care services by health care professionals who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community." (Institute of Medicine, 1996).

Primary care providers (PCPs) encompass a wide range of health care professionals (HCPs) who deliver this care, including general and family medical practitioners, nurse practitioners, advanced practice nurses, physician associates/assistants, and internists. PCPs are represented by a variety of educational backgrounds, training, and specialties. Given the type of degree and the nature of the specialty, the scope of practice varies, and not all providers may be trained or qualified to directly provide the full breadth of transgender health care, such as mental health, genital/pelvic care, or postoperative care, following gender-affirming procedures. Physicians and other providers receive little education in transgender and gender-diverse (TGD) health at any time during their training (Dubin et al., 2018), and thus most skills are currently acquired in practice, either informally or through brief continuing education opportunities, see also Chapter 4—Education. However, if providers are competent to deliver similar care for cisgender patients, they should develop competency in caring for TGD patients. The competencies outlined below are all to be understood as being within the provider's scope of licensure and practice. However, all PCPs should be able to manage the comprehensive health of TGD patients either directly or by appropriate referral to other HCPs, including other specialists, for evaluation and treatment. There is no evidence competency in caring for TGD patients can only be achieved through a formal or certification process. In explicitly stating recommended competencies, however, PCP's and TGD persons across all settings can share a standard set of expectations of the knowledge, skills, and cultural competence required for the care of TGD persons.

Due to the unique medical, surgical, and social conditions faced by TGD people, PCPs need distinct competencies in the care of TGD persons, apart from what is expected of all PCP's who may otherwise care for a diverse population that includes ethnic, racial, or sexual minorities. Professional bodies from a range of generalist disciplines have issued position statements and guidelines specific to the care of TGD people (American College of Obstetricians and Gynecology, 2021; Italian Society of Gender, Identity and Health (SIGIS); the Italian Society of Andrology and Sexual Medicine (SIAMS); the Italian Society of Endocrinology (SIE), 2021; Polish Sexological Society, 2021; the Southern African HIV Clinicians' Society, 2021). Wylie et al. (2016) state "For the most part, the general health and well-being of transgender people should be attended to within the primary care setting, without differentiation from services offered to cisgender (non-transgender) people for physical, psychological, and sexual health issues. Specific care for gender transition is also possible in primary care." There are many examples of these services being provided safely and effectively outside of specialist care in diverse cities such as Toronto and Vancouver in Canada, New York and Boston in the US, and in Sydney, Australia, (Radix & Eisfeld, 2014; Reisner, Radix et al., 2016; Spanos et al., 2021).

Hormone therapy

Whether TGD patients receive medically necessary gender-affirming hormone therapy (GAHT) from a specialist, e.g., an endocrinologist, or a PCP may depend on the availability of knowledgeable and welcoming providers and country-level factors, such as health care regulations and health services funding (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). In much of the world, specialty services for TGD people are partly or wholly unavailable, which reinforces the need for all health providers to undertake

training in the provision of gender-affirming care. In some countries, PCPs may be required to refer TGD patients to specialist services (e.g., gender identity clinics) resulting in unacceptable delays to access GAHT (Royal College of General Practitioners, 2019).

Hormone-related therapy encompasses a range of interventions, such as puberty suppression and hormone initiation or hormone maintenance. With training, gender-affirming hormone therapy can be managed by most PCPs. Regardless of whether they serve as the primary hormone prescriber, all PCPs should be familiar with the medications, suggested monitoring, and potential side effects associated with GAHT (see Chapter 12—Hormone Therapy). PCPs should be able to make appropriate referrals to appropriate providers for all transition-related services they do not themselves provide.

This chapter supports the argument GAHT can be prescribed by PCPs or other non-specialists—"Considering barriers to health care access and the importance of GAHT to this population, it is imperative that PCPs are able and willing to provide GAHT for TGD patients." (Shires, 2017).

PCPs are commonly called upon to provide care for a broad range of conditions and needs, including those with which they may have had limited or no prior experience. Often this involves accessing commonly used and readily available reference sources, such as professional society guidelines or obtaining a subscription to online knowledge bases. PCPs are advised to use a similar approach when asked to provide basic GAHT care by using the Standards of Care as well as other readily accessed resources (Cheung et al., 2019; Hembree et al., 2017; Oliphant et al., 2018; T'Sjoen et al., 2020). It should be noted most of the commonly used medications in gender-affirming regimens are familiar to everyday primary care practice, including, but not limited to, testosterone, estradiol, progesterone and other progestagens, and spironolactone.

Mental health

PCPs should be able and willing to assess and provide mental health support for TGD people and GAHT that can alleviate gender dysphoria and allow gender expression. At the very least, they should be aware of these needs and consult additional specialty support if needed.

Preventive care

General practitioners are versed to provide comprehensive primary and secondary cancer prevention as a part of routine primary care. Evidence-based cancer prevention guidelines vary globally due to differences in national guidelines and levels of access to screening modalities at the local level. To date, research on the long-term impact of GAHT on cancer risk is limited (Blondeel et al., 2016; Braun et al., 2017). We have insufficient evidence to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018). However, cancer screening should commence, in general, according to local guidelines. Several modifications are discussed in detail, below, depending on the type and duration of hormone use, surgical intervention, or both. In caring for transgender patients, the PCP should maintain an updated record of which organs are present in TGD patients so that appropriate, routine screening can be offered.

This organ inventory should be updated based on the surgical history or any development that has occurred due to taking gender-affirming hormones. Not all PCP's provide care across the lifespan. However, if providers routinely care for children, adolescents, or elder cisgender persons, they should develop competency in transgender care that is applicable to these age groups. If they are unable to do so, then PCPs should be able to make appropriate referrals to other HCPs who care for these populations.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

15.1- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines.
15.2- We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods.
15.3- We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.
15.4- We recommend health care professionals counsel transgender and gender diverse people about their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.
15.5- We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.
15.6- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration the length of time of hormone use, dosing, current age, and the age at which hormones were initiated.
15.7- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.
15.8- We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.
15.9- We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.
15.10- We recommend health care professionals offer cervical cancer screening to transgender and gender diverse people who currently have or previously had a cervix following local guidelines for cisgender women.
15.11- We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.
15.12- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors to assess the optimal age and necessity for osteoporosis screening.
15.13- We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.
15.14- We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Statement 15.1

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people, that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines. For supporting text, see Statement 15.3.

Statement 15.2

We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods. For supporting text, see Statement 15.3.

Statement 15.3

We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.

Cardiovascular disease (CVD) and stroke are the leading causes of mortality worldwide (World Health Organization, 2018). Extensive data among racial, ethnic, and sexual minorities in multiple settings demonstrate significant disparities in the prevalence of CVD and its risk factors as well as in the outcomes to medical interventions. Structural factors such as access to care, socioeconomic status, and allostatic load related to minority stress contribute to these disparities (Flentje et al., 2020; Havranek et al., 2015; Streed et al., 2021). TGD people often experience social, economic, and discriminatory conditions similar to other minority populations with known increased cardiovascular risk (Carpenter et al., 2020; James et al., 2016; Reisner, Radix et al., 2016). TGD persons of racial, ethnic, and sexual

minorities have been shown to experience increased impact related to intersectional stress. Conversely, access to gender-affirming care, including GAHT, may buffer against the elevation of CVD risk due to the improvement in quality of life and reduction in gender dysphoria and incongruence (Defreyne et al., 2019; Martinez et al., 2018). PCPs can significantly improve TGD health through screening and prevention of CVD and its associated risk conditions—such as tobacco use, diabetes mellitus, hypertension, dyslipidemia, and obesity.

The few, primarily US based, studies evaluating the prevalence of CVD, stroke, or CVD risk in TGD persons independent of GAHT indicate an elevated CV risk, including high rates of undiagnosed and untreated CV risk factors with inadequate CV prevention when compared with cisgender populations (Denby et al., 2021; Malhotra et al., 2022; Nokoff et al., 2018). In one population-based study, TGD people had greater odds of discrimination, psychological distress, and adverse childhood experience, and these were associated with increased odds of having a cardiovascular condition (Poteat et al., 2021).

In US studies that are based on data from the Behavioral Risk Factor Surveillance System, both transgender men and transgender women show a higher prevalence of myocardial infarction (MI), stroke, or any CVD compared with cisgender men, cisgender women or both. Results vary based on the adjustment of data for additional variables, including race, income, or cardiovascular risk factors (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Gender nonbinary persons also have higher odds of CVD (Downing & Przedworski, 2018). Data on hormone use was not collected in these studies, which are also limited by the use of self-reported health histories. In the US, TGD individuals presenting for GAHT may have higher rates of undiagnosed and untreated CVD risk factors compared with the cisgender population (Denby et al., 2021), although this may not be applicable globally.

A large 2018 case control study from several US centers that used 10:1 cisgender matched controls found no statistically significant difference in rates of MI or stroke between transgender women and cisgender men, and no difference in rates of MI, stroke, or venous thromboembolism (VTE) between transgender men and cisgender men or women. There was a statistically significant hazard ratio of 1.9 for VTE among transgender women when compared with cisgender men. A subcohort of transgender women who initiated GAHT during (versus prior to) the 6-year study window did show an increased risk of stroke. Increases in rates of VTE in the overall cohort of transgender women and in rates of stroke in the initiation subcohort of transgender women demonstrated calculated numbers-needed-to-harm (not reported in the paper) between 71-123 (Getahun et al., 2018). Other studies have demonstrated no increase in CV events or stroke among transgender men undergoing testosterone therapy, although studies are limited by their small sample size, relatively short follow-up, and the younger age of the sample population (Martinez et al., 2020; Nota et al., 2019).

European and US studies in transgender women who have accessed feminizing GAHT increasingly indicate a higher risk of CVD, stroke, or both, compared with cisgender women and, in some studies, cisgender men (Getahun et al., 2018; Nota et al., 2019; Wierckx et al., 2013). Many of these studies had significant limitations, such as variably adjusting for CV-related risk factors, small sample sizes—especially involving older transgender women—and variable duration and types of GAHT (Connelly et al., 2019; Defreyne et al., 2019, Martinez et al., 2020). Furthermore, the overall increased risk was small. In many of these studies, the majority of transgender women who experienced cardiac events or stroke were over 50 years old, had one or more CVD risk factors, and were taking a variety of hormone regimens, including, but not limited, to ethinyl estradiol, a synthetic estrogen that confers significant elevations in thrombotic risk and is not recommended for use in feminizing regimens (Gooren et al., 2014; Martinez et al., 2020). Current limited evidence suggests estrogen-based GAHT is associated with an increased risk of myocardial infarction and stroke, but whether this small risk is a result of GAHT or an effect of pre-existing CV risk is unclear. There are no known studies that specifically address CVD and

related conditions in nonbinary individuals, individuals who use subphysiologic doses of gender-affirming hormones, or in adults previously treated with puberty suppression.

PCPs can best address CVD risk during GAHT by assessing TGD people for CVD and modifiable CVD risk factors, such as diabetes mellitus, hypertension, hyperlipidemia, obesity, and smoking, as well as by addressing the impact of minority stress on cardiovascular risk (Streed et al., 2021). In addition, PCPs can mitigate transgender cardiovascular health disparities by providing a timely diagnosis and treatment of risk conditions and by tailoring their management in a way that supports ongoing gender-affirming interventions.

Risk assessment guidelines vary based on the national or international context and scientific affiliation of guideline developers. CVD prevention guidelines also vary in terms of the nature and frequency of the risk assessment for otherwise healthy adults under age 40 (Arnett et al., 2019; Piepoli et al., 2020; Précoma et al., 2019; Streed et al., 2021; WHO, 2007). Over age 40, when cardiovascular risk increases, guidelines clearly recommend scheduled risk assessments using a calculated prediction of ten-year total CVD risk based on risk prediction equations from large population samples. Examples of risk calculators include SCORE (recommended by the European Guidelines on CVD Prevention), Pooled Cohort Studies Equations (2013 AHA ACC Guideline on the Assessment of CVD risk), Framingham Risk scores, and the World Health Organization (WHO) Risk Prediction Charts. The WHO charts were developed based on information from the countries in each WHO subregion. In many low resource settings, facilities are not available to measure cholesterol or serum glucose, and alternative predication charts are available without these measures.

Of note, all current cardiovascular risk calculators are gendered, using sex as a significant risk variable. There is currently insufficient data on cardiovascular risk interventions across the lifespan in TGD persons with medical and surgical interventions to adjust these predictive equations. Nonetheless, it is clear both sex assigned at birth and medical transition can affect the parameters used to calculate cardiovascular risk (Connelly et al., 2019; Defreyne et al., 2019; Maraka et al., 2017; Martinez et al., 2020). Providers can take a variety of approaches to using cardiovascular risk calculators in TGD persons, including employing the risk calculator for the sex assigned at birth, affirmed gender, or a weighted average of the two, taking into consideration total lifetime exposure to GAHT. Although data are lacking, using the affirmed gender for transgender adults with a history of pubertal-age GAHT initiations is likely to be most appropriate. Patients with a history of submaximal GAHT use or prolonged periods of time postgonadectomy without hormone replacement before roughly age 50 may require an even more nuanced approach. Providers should be aware of the characteristics and limitations of the risk calculator in use and should engage patients in shared decision-making regarding these specific considerations.

There are currently no studies comparing the prevalence of dyslipidemia between transgender and cisgender samples, while controlling for hormone use. As noted previously, data in other populations demonstrate the presence of psychosocial stress during childhood and remote adulthood favor adiposity and abnormal lipid metabolism. Both testosterone- and estrogen-based GAHT affect lipid metabolism, although evidence is limited by the variety of hormone regimens and additional variables (Connelly et al., 2019; Defreyne et al., 2019; Deutsch, Glidden et al., 2015; Maraka et al., 2017; Martinez et al., 2020;). On balance, estrogen tends to increase high-density lipoprotein (HDL) cholesterol and triglycerides with variable effects on low density lipoprotein (LDL) cholesterol, while testosterone variably affects triglycerides, decreases HDL cholesterol and increases LDL cholesterol. The method of administration may also affect this pattern, particularly in relation to oral versus transdermal estrogen and their impact on triglycerides (Maraka et al., 2017). In general, the effect sizes of these differences are minimal, and the overall impact on cardio- and cerebrovascular outcomes is unclear. There are no studies examining hormone effects in TGD people with pre-existing dyslipidemia with hormone use starting over age 50, or investigating effects beyond 2-5 years of therapy.

Studies comparing the prevalence of hypertension between TGD and cisgender samples that controlled for hormone use are lacking. Data in other populations demonstrate chronic and acute psychosocial stress, including experiences of discrimination can mediate hypertension (Din-Dzietham et al., 2004; Spruill, 2010). In US studies that were based on the Behavioral Risk Factor Surveillance System, a large national US health survey, there were no differences in reported hypertension between transgender men or women compared with cisgender samples (Alzahrani et al., 2019; Nokoff et al., 2018).

Studies of testosterone—and estrogen-based GAHT have shown inconsistent effects on systolic and diastolic blood pressure. A retrospective study of the effects of estrogen- and testosterone-based GAHT regimens on blood pressure found a slight reduction in systolic blood pressure with the initiation of estrogen-based regimens; while there was a slight elevation (4 mm Hg) in mean systolic blood pressure on long term follow-up of testosterone-based regimens, this difference was at the margin of statistical significance and of limited clinical relevance (Banks et al., 2021). A systematic review concluded, given the limited quality of the studies, there is insufficient data to reach conclusions on the effects of gender-affirming hormone therapy on blood pressure (Connelly et al., 2021). Spironolactone, often used as an androgen blocker in feminizing GAHT, is a potassium sparing diuretic and may increase potassium when used in conjunction with ACE inhibitors or angiotensin receptor blocker medications, as well as salt substitutes. There are no studies examining hormone effects in TGD people with pre-existing hypertension with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. Transgender persons receiving GAHT should undergo any additional blood pressure screening or monitoring indicated by WPATH guidelines for GAHT.

There are limited data comparing the prevalence of diabetes mellitus between TGD and cisgender samples independent of hormone use. Recent data from the STRONG cohort study (Islam et al., 2021) found the prevalence and incidence of type 2 diabetes was more common in the trans feminine cohort compared with cisgender females but not cisgender male controls. No significant differences in the prevalence or incidence of type 2 diabetes were observed in the trans masculine cohort and in TGD persons overall after starting hormone therapy. However, the mean follow-up for both cohorts was 2.8 and 3.1 years, respectively (Islam et al., 2021). Data in other populations, including sexual minorities, indicates chronic and acute psychosocial stress can mediate the development and control of type 2 diabetes (Beach et al., 2018; Kelly & Mubarak, 2015).

US studies based on the Behavioral Risk Factor Surveillance System found no differences in reported diabetes between transgender men, transgender women and nonbinary persons compared with cisgender persons (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Several small studies have shown a higher-than-expected prevalence of polycystic ovarian syndrome or hyperandrogenemia among transgender men (Feldman et al., 2016), conditions associated with insulin resistance and diabetes risk. While studies of both testosterone- and estrogen-based GAHT show varying effects on weight/body fat, glucose metabolism, and insulin resistance (Defreyne et al., 2019), most do not demonstrate any increase in prediabetes or diabetes (Chan et al., 2018; Connelly et al., 2019). There are no studies examining hormone effects in TGD people with pre-existing diabetes, with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. There are currently no studies specifically addressing diabetes in adults previously treated with puberty suppression.

While intermediate-outcome studies of the effects of GAHT on blood pressure and lipids are helpful for hypothesis generation and for studying etiology, future studies should focus on cardiovascular outcomes of interest, with a specific focus on individual predictors such as age, route and dose of hormones used, and total lifetime exposure to GAHT. Interpretation of data should always consider whether cisgender controls were of the same natal sex or identified gender.

Statement 15.4

We recommend health care professionals counsel transgender and gender diverse people about

their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.

Tobacco use is a leading contributor to cardiovascular disease, pulmonary disease, and cancer worldwide (World Health Organization, 2020). TGD persons have a higher prevalence of tobacco use compared with cisgender individuals, which varies across the gender spectrum (Azagba et al., 2019; Buchting et al., 2017). This pattern is consistent with other populations experiencing minority stress (Gordon et al., 2021). PCPs can promote protective factors against tobacco use, including reducing exposure to personal or structural discrimination, having gender-affirming identification, and having health insurance (Kidd et al., 2018; Shires & Jafee, 2016).

The health risks of tobacco use affect TGD persons disproportionately, primarily due to decreased access to culturally competent, affordable screening, and treatment of tobacco-related diseases (Shires & Jafee, 2016). Smoking may further increase cardiovascular and VTE risk for TGD individuals taking feminizing GAHT (Hontscharuk, Alba, Manno et al., 2021). Smoking also doubles or triples the risk of general surgery complications, such as wound healing, scarring, and infection (Yoong et al., 2020) and increases these risks for those accessing gender-affirming surgeries. Data in cisgender populations show quitting smoking prior to surgery and maintaining abstinence for six weeks postoperatively significantly reduces complications (Yoong et al., 2020).

There are currently few studies of smoking cessation programs specifically focused on TGD persons (Berger & Mooney-Somers, 2017). However, limited evidence suggests PCPs can enhance smoking cessation efforts by addressing the effects of minority stress (Gamarel et al., 2015) and incorporating gender-affirming interventions, such as GAHT (Myers & Safer, 2016).

HCPs should take into consideration the significant barriers people habituated to nicotine encounter when attempting cessation. Nicotine replacement therapy and/or other cessation adjuncts should be made available, with an emphasis on individual preferences and a recognition of underlying behavioral health factors that contribute to continued nicotine use. Decision-making regarding approaches to GAHT or surgery should include consideration of the "first do no harm" principle of medical practice, with the realities of an individual patient's abilities and needs.

Statement 15.5

We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.

Aging presents specific social, physical, and mental health challenges for TGD persons. While the literature on aging and transgender elders is limited, many older TGD adults have experienced a lifetime of stigma, discrimination, and repression of identified gender (Fabbre & Gaveras, 2020; Witten, 2017). This experience affects TGD elders' interactions with health care systems (Fredriksen-Goldsen et al., 2014; Kattari & Hasche, 2016; Walker et al., 2017). Transgender elders are more likely than cisgender LGB peers to report poor physical health, even when controlling for socio-demographic factors (Fredriksen-Goldsen 2011; Fredriksen-Goldsen et al., 2014). Reduced access to culturally competent care and the sequelae of minority stress often result in delayed care, potentially exacerbating chronic conditions common with aging (Bakko & Kattari, 2021; Fredriksen-Goldsen et al., 2014).

Although there are few studies on gender-affirming medical interventions among TGD elders, evidence suggests older adults experience a significantly higher quality of life with medical transition even when compared with younger TGD adults (Cai et al., 2019). Although age itself is not an absolute contraindication or limitation to gender-affirming medical or surgical interventions, TGD elders may not be aware of the current range of social, medical or surgical options available that can help them meet their individual needs (Hardacker et al., 2019; Houlberg, 2019).

While studies on mental health among TGD elders are limited, those over age fifty experience significantly higher rates of depressive symptoms and perceived stress compared with cisgender LGB and heterosexual older adults (Fredriksen-Goldsen 2011, Fredriksen-

Goldsen et al., 2014). Risk factors specific to TGD elders include gender- and age-related discrimination, general stress, identity concealment, victimization, and internalized stigma, while social support and community belonging appear protective (Fredriksen-Goldsen et al., 2014; Hoy-Ellis & Fredriksen-Goldsen, 2017; White Hughto & Reisner, 2018). PCPs can assist patients by encouraging spirituality, self-acceptance and self-advocacy, and an active healthy lifestyle, all of which are associated with resilience and successful aging (McFadden et al., 2013; Witten, 2014).

TGD elders often face social isolation, loss of support systems, and disconnection from close friends and children (Fredriksen-Goldsen 2011; Witten, 2017). The most common aging concerns among TGD persons are losing the ability to care for themselves followed by having to go into a nursing home or assisted living facility (Henry et al., 2020). While long-term care settings offer the helpful needed assistance, they also have the potential for physical or emotional abuse, for denial of GAHT and routine care, for being "outed," and being prevented from living and dressing according to one's affirmed gender (Auldridge et al., 2012; Pang et al., 2019; Porter et al., 2016). TGD elders identify senior housing, transportation, social events, support groups as being the most needed services (Auldridge et al., 2012; Witten, 2014).

Despite barriers, most TGD persons engage in successful aging strengthened by self-acceptance, caring relationships, and advocacy (Fredriksen-Goldsen 2011; Witten, 2014). PCPs should address core health issues facing TGD elders, including mental health, gender-affirming medical interventions, social support, and end of life/long-term care.

Beyond the independent impact of factors such as minority stress and social determinants of health in later years, data are lacking on specific health issues facing transgender people who use GAHT later in life, individuals who began GAHT at a younger age, and those seeking to continue or begin GAHT in their sixth, seventh, eighth, or later decades. With an increasing proportion of transgender people beginning GAHT at younger ages, including some who begin at the time of puberty, studies to examine the impact of decades of such treatment on long-term health are ever more important.

Statement 15.6

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration length of time of hormone use, dosing, current age, and the age at which hormones were initiated.

TGD individuals taking estrogen-based GAHT will develop breasts, and therefore warrant consideration for breast cancer screening. Exogenous estrogen may be one of multiple factors that contribute to breast cancer risk in cisgender people. Two cohort studies have been published evaluating breast cancer prevalence among transgender women in the Netherlands (Gooren et al., 2013) and the US (Brown & Jones, 2015). Both were retrospective cohorts of clinical samples using a diagnosis of breast cancer as the outcome of interest and cisgender controls as a comparison group. Neither study involved prospective screening for breast cancer, and both had significant methodological limitations. Numerous guidelines have been published (Deutsch, 2016a) recommending some combination of "age plus length of estrogen exposure" as the determinant of need to commence screening. These recommendations are based on expert consensus only and are evidentiarily weak.

BRCA1 and 2 mutations increase the risk of breast cancer, however the role sex hormone exposure plays, if any, in this increased risk is unclear (Rebbeck et al., 2005) The degree of increase in risk, if any, from gender-affirming estrogen therapy is unknown. Patients with a known BRCA1 mutation should be counseled about the unknowns and shared decision-making with informed consent should occur between the patient and provider, recognizing the numerous benefits of GAHT.

Breast cancer screening among transgender women should also take into consideration the likelihood that a transgender woman's breasts may be denser on mammography. Dense breasts, a history of injecting breasts with fillers such as silicone, and breast implants may complicate the interpretation of mammographic findings (Sonnenblick et al., 2018). Therefore, special

techniques should be used accordingly. People who have injected particles such as silicone or other fillers for breast augmentation may also develop complications, such as sclerosing lipogranulomas, which obscure normal tissue on mammography or ultrasound.

Statement 15.7

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.

For TGD people assigned female at birth and who developed breasts via natal puberty, there are theoretical concerns about whether direct exposure to testosterone and exposure to aromatized estrogen resulting from testosterone therapy are risk factors for the development of breast cancer. Limited retrospective data has not demonstrated increased risk for breast cancer among transgender men (Gooren et al., 2013; Grynberg et al., 2010), however prospective and comparison data are lacking. Most people in this group will have some breast tissue remaining, and therefore it is important for providers to be aware breast cancer risk is not zero in this population. The timing and approach to breast cancer screening in this group who have had chest surgery is currently not established, and, similar to cisgender men with significant family history or BRCA gene mutation, screening via MRI or ultrasound may be appropriate. Because the utility and performance of these approaches have not been studied and because self- and HCP-led chest/breast screening exams are not recommended in cisgender women due to potential harms of both false-positive results and over-detection (detection of a cancer which would have regressed on its own with no need for intervention), any approach to screening in this group should occur in the context of shared decision-making between patients and providers regarding the potential harms, benefits, and unknowns of these approaches.

Statement 15.8

We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.

Current consensus guidelines do not recommend routine ovarian cancer screening for cisgender women. Case reports of ovarian cancer among transgender men have been reported (Dizon et al., 2006; Hage et al., 2000). There is currently no evidence testosterone therapy leads to an increased risk of ovarian cancer, although long-term prospective studies are lacking (Joint et al., 2018).

Statement 15.9

We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.

TGD people with ovaries who are taking testosterone-based GAHT are often in an oligo- or anovulatory state, or otherwise experience shifts in luteal phase function and progesterone production. This condition combined with the possible increased estrogen exposure from aromatization of exogenous testosterone raises the concern for excessive or unopposed endometrial estrogen exposure, although the clinical significance is unknown. Histologic studies of the endometrium in TGD people taking testosterone have found atrophy rather than hyperplasia (Grimstad et al., 2018; Grynberg et al., 2010; Perrone et al., 2009). In a large cohort of trans masculine people who underwent a hysterectomy with oophorectomy, benign ovarian histopathology was noted in all cases (n = 85) (Grimstad et al., 2020). While prospective outcome data are lacking, there is insufficient evidence at this time to support a recommendation transgender men undergo routine hysterectomy or oophorectomy solely to prevent endometrial or ovarian cancer. Certainly, unexplained signs/symptoms of endometrial or ovarian cancer should be evaluated appropriately.

Statement 15.10

We recommend health care professionals offer cervical cancer screening to transgender and

gender diverse people who currently have or previously had a cervix, following local guidelines for cisgender women.

Individuals with a cervix should undergo routine cervical cancer screening and prevention according to age-based regional practices and guidelines. This includes vaccination against the human papilloma virus (HPV) and screening according to local guidelines, including cytologic, high-HPV co-testing if available. It is important HCPs be mindful of performing pelvic speculum examinations in a manner that minimizes pain and distress for transgender masculine people.

TGD people with a cervix are less likely to have had conventional cervical cancer screening, either because the exam can cause worsening of dysphoria and/or because general practitioners and patients are misinformed about the need for this screening (Agenor et al., 2016; Potter et al., 2015). In addition, testosterone therapy can result in atrophic changes of the genital tract, and the duration of testosterone use has been associated with a greater likelihood of obtaining an inadequate sample for cytologic screening of cervical cancer (Peitzmeier et al., 2014). Alternatives to speculum exams and cervical cytology, such as provider- or self-collected high-risk HPV swabs, may be of particular benefit for screening people with a cervix. Research underway in the US is investigating the use of self-collected vaginal high-risk HPV testing among transgender masculine populations. HPV swabs were found to be highly acceptable among transgender men with a sensitivity to high-risk HPV of 71.4% (negative predictive value of 94.7%) and a specificity of 98.2% (Reisner et al., 2018). Further study is needed to evaluate the harms of HPV primary screening in transgender men in terms of the potential increased harms associated with invasive examinations and colposcopies.

Statement 15.11

We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.

Human immunodeficiency virus (HIV) prevalence is disproportionately high in TGD populations. A recent large metanalysis found a global odds ratio for HIV infection of sixty-six for trans feminine individuals and 6.8 for trans masculine individuals (Stutterheim et al., 2021). PCPs have unique opportunities to provide crucial education and implement prevention strategies, especially related to decreasing HIV burden among TGD people. Mistrust of health care providers due to past experiences of discrimination and transphobia impacts HIV prevention and disrupts the linkage to care efforts (Sevelius et al., 2016). Stigma, lack of adequate training, and innate power hierarchies within medical establishments, all contribute to ambivalence and uncertainty among HCPs when caring for TGD people (Poteat et al., 2013). Finally, a lack of inclusiveness and gender-affirming practices in the health care setting may lead to TGD people feeling unsafe discussing sensitive topics, such as HIV diagnosis and avoiding care out of fear (Bauer et al., 2014; Gibson et al., 2016; Seelman et al., 2017).

HCPs should be aware of this broader context within which many TGD people are seeking care for either gender-affirming hormones, HIV pre-exposure chemoprophylaxis/treatment (PrEP), or both. There may be various misconceptions about the safety of taking gender-affirming hormones concurrently with antiretroviral therapy for HIV chemoprophylaxis or treatment.

Direct study of antiretroviral/gender-affirming hormone therapy (ART/GAHT) interactions has been limited. A subanalysis of transgender women and trans feminine persons in the multinational iPrEx trial found poor effectiveness in this group in the intention-to-treat analysis, although effectiveness was similar to that in cisgender gay men among those transgender participants who adhered to the medication as prescribed, suggesting that uptake and adherence to PrEP remain challenging in this population. Two studies of the effects of GAHT on tenofovir diphosphate (Grant et al., 2021) and tenofovir diphosphate and emtricitabine (Shieh et al., 2019) found the significantly lowered ART drug levels were unlikely to be of clinical significance. Overall, data on the interactions between hormonal contraceptives and antiretrovirals are reassuring in terms of the impact of hormones on ART (Nanda

et al., 2017). Because estradiol is partially metabolized by cytochrome P450 (CYP) 3A4 and 1A2 enzymes, potential drug interactions with other medications that induce or inhibit these pathways, such as non-nucleoside reverse transcriptase inhibitors (NNRTIs, e.g., efavirenz (EFV) and nevirapine (NVP)), may exist (Badowski et al., 2021). However, the preferred first-line ART regimens in most countries include integrase inhibitors, which have minimal to no drug interactions with gender-affirming hormones and can be used safely (Badowski, 2021; Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021). If concerns exist about potential interactions, HCPs should monitor blood hormone levels as needed. Therefore, TGD people living with HIV and taking antiretroviral medications should be counseled that taking antiretrovirals alongside GAHT is safe.

Statement 15.12

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors, to assess the optimal age and necessity for osteoporosis screening. For supporting text, see Statement 15.13.

Statement 15.13

We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.

Estrogen and testosterone both support bone formation and turnover. Decreased sex hormone levels are associated with a greater risk of osteoporosis in older age (Almeida et al., 2017). TGD individuals may receive medical and/or surgical interventions that have the potential to influence bone health, such as sex hormone treatment, androgen blockade, and gonadectomy. Therefore, a detailed medical history, including past and present use of hormones along with gonadal surgeries, is necessary to establish the need for osteoporosis screening.

Several observational studies have compared bone mineral density (BMD) of TGD adults before and after gender-affirming hormone therapy along with in TGD individuals compared with sex-at-birth matched cisgender controls.

Low BMD may exist before the initiation of hormones. One study showed a lower mean areal BMD at the femoral neck, total hip, and spine in transgender women than in age-matched cisgender male controls (Van Caenegem, Taes et al., 2013). Another study revealed a high prevalence of low BMD scores among TGD youth before starting puberty blockers (Lee, Finlayson et al., 2020). The authors of both studies concluded low rates of physical activity may be an important contributor to these findings.

Acceleration of bone loss can occur after gonadectomy if hormones are stopped or if hormones levels are suboptimal. In one study, thirty percent of transgender women who had undergone gonadectomy had low bone mass, and this correlated with lower 17-ß estradiol levels and adherence to GAHT (Motta et al., 2020).

Investigation of the effects of GAHT on BMD have revealed TGD women receiving estrogen therapy show improvements in BMD. A systematic review and meta-analysis on the impact of sex hormones on bone health of transgender individuals included 9 eligible studies in transgender women (n = 392) and 8 eligible studies in transgender men (n = 247) published between 2008 and 2015. The meta-analysis revealed transgender women showed a statistically significant increase in lumbar spine BMD (but not femoral neck BMD) compared with baseline measures. Among transgender men, there were no statistically significant changes in the lumbar spine, femoral neck, and total hip BMD at 12 and 24 months after starting testosterone compared with baseline measures (Singh-Ospina et al., 2017). Since the publication of this study, the European Network for Investigation of Gender Incongruence (ENIGI) study, a multicenter prospective observational study (Belgium, Norway, Italy, and the Netherlands) published results on BMD outcomes for 231 transgender women and 199 transgender men one year after initiating GAH (Wiepjes et al., 2017). Transgender women had an increase in BMD of the lumbar spine, total hip and

femoral neck, and increased BMD of the total hip occurred in transgender men. One study reported no fractures in transgender individuals at 12 months following initiation of hormones in 53 transgender men and 53 transgender women (Wierckx, van Caenegem et al., 2014). No studies suggest GAHT should be an indication for enhanced osteoporosis screening. Rather, gaps in GAHT in those who have undergone prior gonadectomy would be a consideration for such screening.

Clinical practice guidelines include recommendations for osteoporosis screening in TGD individuals (Deutsch, 2016a; Hembree et al., 2017; Rosen et al., 2019). For TGD people, both the International Society for Clinical Densitometry and the Endocrine Society suggest consideration of baseline BMD screening before initiation of hormones. Further recommendations for BMD screening are based on several factors including sex reported at birth and age along with the presence of traditional risk factors for osteoporosis, such as prior fracture, high risk medication use, conditions associated with bone loss, and low body weight (Rosen et al., 2019). Specifically, the ISCD guidelines state BMD testing is indicated for TGD individuals if they have a history of gonadectomy or therapy that lowers endogenous gonadal steroid levels prior to the initiation of GAHT, hypogonadism with no plan to take GAHT or known indications for BMD testing (Rosen et al., 2019). However, the evidentiary basis for these recommendations is weak.

The recommended screening modality for osteoporosis is dual energy x-ray absorptiometry (DXA) of the lumbar spine, total hip, and femoral neck (Kanis, 1994). However in many low- and middle-income countries, BMD tests using DXA are not available, and routine DXA-based screening is conducted in few countries, the US being an exception.

PCPs should discuss ways to optimize bone health with TGD people. In addition, PCPs should provide information about the importance of nutrition and exercise on maintaining bone health. TGD individuals with (or at risk) for osteoporosis should be informed about the benefits of weight bearing exercise along with strength and resistance exercises in limiting bone loss (Benedetti et al., 2018). Nutrition is integral to bone health. Nutritional deficiencies, including insufficient calcium intake and low vitamin D, can result in low bone mineralization. Vitamin D and calcium supplementation have been shown to reduce hip as well as total fracture incidence (Weaver et al., 2016). Although relevant to all populations, this discussion is pertinent as a high prevalence of hypovitaminosis D has been observed in TGD populations (Motta et al., 2020; Van Caenegem, Taes et al., 2013).

Statement 15.14

We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Hair removal is necessary both for the elimination of facial hair (Marks et al., 2019) as well as in preparation for certain gender-affirming surgeries (GAS) such as vaginoplasty, phalloplasty, and metoidioplasty (Zhang et al., 2016). Preoperative permanent hair removal is required for any skin area that will either be brought into contact with urine (e.g., used to construct a neourethra) or be moved to reside within a partially closed cavity within the body (e.g., used to line the neovagina) (Zhang et al., 2016). Hair removal techniques used in gender-affirming care are electrolysis hair removal (EHR) and laser hair removal (LHR) (Fernandez et al., 2013). EHR is currently the only US Food and Drug Administration–approved method of permanent hair removal, whereas LHR is approved for permanent hair reduction (Thoreson et al., 2020).

EHR involves the use of an electric current with a very fine probe that is manually inserted sequentially into individual hair follicles (Martin et al., 2018). Since this method uses direct mechanical destruction of the blood supply to the hair, it can be used on all hair colors and skin types (Martin et al., 2018). EHR is time consuming and costly as it requires each hair follicle to be treated individually, but is effective for permanent hair removal. For genital permanent hair removal prior to GAS, this treatment needs to be performed by a practitioner competent in genital hair removal as this method differs

from that of the face and body. EHR is more painful than LHR, with possible side effects of erythema, crusting, and swelling (Harris et al., 2014). Postinflammatory hyperpigmentation is a risk for dark-skinned individuals (Richards & Meharg, 1995). Pain can be controlled with topical local anesthetic and cooling techniques, and tolerance to EHR does develop to some degree with many persons able to tolerate longer sessions (Richards & Meharg, 1995).

LHR uses laser energy to target hair follicles. It is beneficial for larger surface areas. The mechanism is photo-thermolysis, whereby light from a laser selectively targets melanin in the hair shaft (Gao et al., 2018). This energy is converted to heat, which damages the follicles within the skin that produce hairs and results in the destruction of hair growth. Further treatments are needed to achieve best results and are typically spaced six weeks apart to allow for hair cycling (Zhang et al., 2016). Because LHR targets melanin, results may be limited for those with grey, blonde, or red hair.

There are specific considerations for using LHR in dark-skinned individuals (Fitzpatrick skin types IV to VI) (Fayne et al., 2018)). The higher melanin content of the epidermis can compete with the target chromophore of the light or laser, which is the melanin in the hair shaft of the hair follicle. For selective thermolysis to occur, heat diffuses from the hair shaft to the follicular stem cells to cause damage. In darker skin types, rather than reaching the target melanin in the hair shaft, light is absorbed in the epidermis where it is then converted to heat. This may result in poorer clinical outcomes and a higher rate of thermally induced adverse effects, such as hypo- or hyperpigmentation, blistering, and crust formation (Fayne et al., 2018). The selection of laser wavelength is critical in reducing this risk, with longer wavelength recommended to minimize the absorption of light in epidermal melanin and thus maximize efficacy and minimize adverse effects in patients with dark skin (Zhang et al., 2016). Side effects from LHR can include the feeling of sunburnt after treatment, as well as inflammation, redness, hyperpigmentation, and swelling. Flashing lights have been known to induce seizures in susceptible patients, so patients should be screened for this risk. Pain and discomfort during the procedure can also represent a significant barrier, and PCPs should be prepared to prescribe topical or systemic analgesics, such as a eutectic mixture of local anesthetics (EMLA) or a low dose systemic opioid. For genital GAS, some have recommended a 3-month wait after the last planned hair removal treatment before proceeding with surgery to confirm that no further hair regrowth will occur (Zhang et al., 2016).

CHAPTER 16 Reproductive Health

All humans, including transgender individuals, have the reproductive right to decide whether or not to have children (United Nations Population Fund, 2014). Medically necessary gender-affirming hormonal treatments (GAHTs) and surgical interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1) that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Hembree et al., 2017; Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these treatments and to continue these conversations on an ongoing basis thereafter (Hembree et al., 2017). Established FP options, such as embryo, oocyte, and sperm cryopreservation, may be available for postpubertal transgender individuals (Nahata et al., 2019). Research protocols for ovarian and testicular tissue cryopreservation have also been developed and studied (Borgström et al., 2020; Nahata et al., 2019; Rodriguez-Wallberg, et al., 2019). Whereas the use of embryos, mature oocytes, and sperm have all proven to be efficacious when employed within clinical treatments, cryopreserved gonadal tissues would require either future retransplantation aimed at obtaining fully functional gametes or the application of laboratory methods for culture, which are still under development in basic science research settings. Of note, recent American Society for Reproductive Medicine guidelines have lifted the experimental label on ovarian tissue cryopreservation, but evidence remains limited in prepubertal children (Practice Committee of the American Society for Reproductive Medicine, 2019).

Individualized care should be provided in the context of each person's parenthood goals. Some research suggests transgender and gender diverse (TGD) people may be less likely to desire genetically related children or children at all when compared with cisgender peers (Defreyne, van Schuvlenbergh et al., 2020; Russell et al., 2016; von Doussa et al., 2015). Yet, several other studies have shown many TGD individuals 1) desire genetically related children; 2) regret missed opportunities for FP; and 3) are willing to delay or interrupt hormone therapy to preserve fertility and/or conceive (Armuand, Dhejne et al., 2017; Auer et al., 2018; De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Tornello & Bos, 2017).

Many barriers to FP have been reported, such as cost (which is exacerbated when insurance coverage is lacking), urgency to start treatment, inability to make future-oriented decisions, inadequate provider knowledge/provider biases that affect offering FP, and difficulties accessing FP (Baram et al., 2019; Defreyne, van Schuylenbergh et al., 2020). Additionally, transgender individuals may have worsening dysphoria due to various steps in the FP process that are inseparably connected with the gender assigned at birth (Armuand, Dhejne, et al., 2017; Baram et al., 2019). When available, a multidisciplinary team approach, where both medical and mental health providers collaborate with gender-affirming fertility specialists, can help overcome some of these barriers (Tishelman et al., 2019). TGD individuals should be educated about the distinction between fertility (utilizing one's own gametes/reproductive tissues) and pregnancy. In addition to fertility considerations, efforts to ensure equitable high-quality care for all forms of family planning and building throughout the full reproductive continuum must be maintained. This includes procreative options such as perinatal care, pregnancy, delivery, and postpartum care, as well as family planning and contraceptive options to prevent unplanned pregnancies, and pregnancy termination if sanctioned (Bonnington et al., 2020; Cipres et al., 2017; Krempasky et al., 2020; Light et al., 2018; Moseson, Fix et al., 2020). TGD people who wish to carry a pregnancy should undergo standard of care preconception care and prenatal counseling and should receive counseling about breast/chest feeding in environments supportive of people with diverse gender identities and experiences (MacDonald et al., 2016; Obedin-Maliver & Makadon, 2016).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and

Statements of Recommendations

16.1- We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:
16.1.a- Known effects of hormone therapies/surgery on future fertility;
16.1.b- Potential effects of therapies that are not well studied and are of unknown reversibility;
16.1.c- Fertility preservation (FP) options (both established and experimental);
16.1.d- Psychosocial implications of infertility.
16.2- We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.
16.3- We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.
16.4- We recommend health care professionals counsel pre- or early-pubertal transgender and gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.
16.5- We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care, prenatal counseling regarding use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.
16.6. We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.
16.7. We recommend providers who offer pregnancy termination services ensure procedural options are gender-affirming and serve transgender people and those of diverse genders.

harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 16.1

We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:

a. **Known effects of hormone therapies/surgeries on future fertility;**
b. **Potential effects of therapies that are not well studied and are of unknown reversibility;**
c. **Fertility preservation (FP) options (both established and experimental;**
d. **Psychosocial implications of infertility.**

TGD individuals assigned female at birth

GAHT may negatively impact future reproductive capacity (Hembree et al., 2017). Based on current evidence in transgender men and gender diverse people assigned female at birth, these risks are as follows:

Gonadotropin-releasing hormone agonists (GnRHas) may be used for pubertal suppression to prevent further pubertal progression until adolescents are ready for masculinizing treatment. GnRHas may also be used for menstrual suppression. GnRHas impact the maturation of gametes but do not cause permanent damage to gonadal function. Thus, if GnRHas are discontinued, oocyte maturation would be expected to resume.

There are few studies detailing the effects of testosterone therapy on reproductive function in transgender men (Moravek et al., 2020). Restoration of normal ovarian function with oocyte maturation after testosterone interruption has been demonstrated in transgender men who have achieved natural conception. A retrospective study on oocyte cryopreservation showed no differences in the total number of oocytes retrieved or in the number of mature oocytes between transgender men and age- and BMI-matched cisgender women (Adeleye et al., 2018, 2019). The first results have recently been published evaluating live birth rates after controlled ovarian stimulation in transgender men compared with cisgender women (Leung et al., 2019). Testosterone was discontinued prior to ovarian stimulation. Overall, the results concerning the influence of testosterone on reproductive organs and their function appear to be reassuring. However, there have been no prospective studies to date evaluating the effect of long-term hormone therapy on fertility (i.e., started in adolescence) or in those treated with GnRHas in early puberty followed by testosterone therapy. It is important to take into consideration that required medications and procedures for cryopreserving oocytes (a

pelvic examination, vaginal ultrasound monitoring, and oocyte retrievals) may lead to increasing gender dysphoria in transgender men (Armuand, Dhejne et al., 2017).

Surgical interventions among transgender men will have obvious implications for reproductive capacity. If patients desire a hysterectomy, the option should be offered of preserving the ovaries to retain the possibility of having a genetically related child. Alternatively, if the ovaries are removed either separately or concurrently with the hysterectomy, egg freezing should be offered prior to surgery and/or ovarian tissue cryopreservation can be done at the time of oophorectomy. Although this procedure is no longer considered experimental, many transgender men may desire *in vitro* maturation of primordial follicles, which is still investigational. Studies evaluating oocyte function have shown oocytes isolated from transgender men with testosterone exposure at the time of oophorectomy can be matured *in vitro* to develop normal metaphase II meiotic spindle structure (De Roo et al., 2017; Lierman et al., 2017).

TGD individuals assigned male at birth

Based on current evidence in transgender women and gender diverse people assigned male at birth (AMAB), the influence of medical treatment is as follows:

GnRHas inhibit spermatogenesis. Data suggest discontinuation of treatment results in a re-initiation of spermatogenesis, although this may take at least 3 months and most likely longer (Bertelloni et al., 2000). Furthermore, the psychological burden of re-exposure to testosterone should be considered.

Anti-androgens and estrogens result in an impaired sperm production (de Nie et al., 2020; Jindarak et al., 2018; Kent et al., 2018). Spermatogenesis might resume after discontinuation of prolonged treatment with anti-androgens and estrogens, but data are limited (Adeleye et al., 2019; Alford et al., 2020; Schneider et al., 2017). Testicular volumes diminish under the influence of gender-affirming hormone treatment (Matoso et al., 2018). Semen quality in transgender women may also be negatively affected by specific life-style factors, such as a low frequency of masturbation, wearing the genitals tight against the body (e.g., with use of tight undergarments for tucking) (Jung & Schuppe, 2007; Mieusset et al., 1985, 1987; Rodriguez-Wallberg, Häljestig et al., 2021).

Statement 16.2

We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.

Research shows many transgender adults desire biological children (De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Wierckx, Van Caenegem et al., 2012), yet FP rates remain widely variable, particularly in youth (< 5%–40%) (Brik et al., 2019; Chen et al., 2017; Chiniara et al., 2019; Nahata et al., 2017; Segev-Becker et al., 2020). In a recent survey, many youth acknowledged their feelings about having a biological child might change in the future (Strang, Jarin et al., 2018). Non-elective sterilization is a violation of human rights (Ethics Committee of the American Society for Reproductive Medicine, 2015; Equality and Human Rights Commission, 2021; Meyer III et al., 2001) and due to advances in social attitudes, fertility medicine, and affirmative transgender health care, opportunities for biological parenthood during transition should be supported for transgender people. Due to the influence clinical opinion may have on transgender or nonbinary people's FP and on parenting decisions, FP options should be explored by health care providers alongside options such as fostering, adoption, coparenting, and other parenting alternatives (Bartholomaeus & Riggs, 2019). Transgender patients who have been offered this type of discussion and have been given the choice to undergo procedures for FP have reported the experience to be an overall positive one (Armuand, Dhejne et al., 2017; De Sutter et al., 2002; James-Abra et al., 2015).

In other patient populations, fertility referrals and formal fertility programs have been shown to increase FP rates and improve patient satisfaction (Kelvin et al., 2016; Klosky, Anderson et al., 2017; Klosky, Wang et al., 2017;

Shnorhavorian et al., 2012) Physician attitudes have been investigated, and recent studies indicate both an awareness and a desire to provide fertility-related information to children and their families (Armuand et al., 2020). However, barriers have also been identified, including lack of knowledge, comfort, and resources (Armuand, Nilsson et al., 2017; Frederick et al., 2018). Thus, the need for appropriate training of health care providers has been highlighted, with emphasis placed on fertility counseling and offering FP options to all at-risk individuals in an unbiased way (Armuand, Nilsson et al., 2017). Parents' recommendations have also been shown to significantly influence FP rates in adolescent and young adult males with cancer (Klosky, Flynn et al., 2017). While there are clear clinical differences in these populations, these findings can help inform best practices for fertility counseling and FP referrals for transgender individuals.

Statement 16.3

We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.

Cryopreservation of sperm and oocytes are established FP techniques and can be offered to pubertal, late pubertal, and adult birth assigned males and birth assigned females, respectively, preferably prior to the initiation of GAHT (Hembree et al., 2017; Practice Committee of the American Society for Reproductive Medicine, 2019). Cryopreservation of embryos can be offered to adult (post-pubertal) TGD people who wish to have a child and have an available partner. The future use of cryopreserved gametes is also dependent on the gametes and reproductive organs of the future partner (Fischer, 2021; Maxwell et al., 2017)

Although semen parameters have been shown to be compromised when FP is performed after initiation of GAH medication (Adeleye et al., 2019), one small study showed when the treatment was discontinued, semen parameters were comparable to those in TGD patients who had never undergone GAH treatment. With regard to ovarian stimulation, oocyte vitrification yield and subsequent use of the oocytes in in-vitro fertilization (IVF), there is no reason to anticipate a different outcome in assisted reproductive technology (ART) treatments for TGD patients than that obtained in cisgender patients undergoing ART—other than individual confounding factors related to (in)fertility—when gametes are banked prior to any medical treatment (Adeleye et al., 2019). The use of oocytes in ART treatment resulted in similarly successful outcomes in TGD compared with controlled, matched cisgender patients (Adeleye et al., 2019; Leung et al., 2019; Maxwell et al., 2017).

Although these are established options, few pubertal, late pubertal or adult TGD people undergo FP (Nahata et al., 2017), and many experience challenges while undergoing FP interventions. Not only is access and cost of these methods a barrier (particularly in regions without insurance coverage), but these procedures are often physically and emotionally uncomfortable, and many express concerns about postponing the transitioning process (Chen et al., 2017; De Sutter et al., 2002; Nahata et al., 2017; Wierckx, Stuyver et al., 2012). Especially for the birth assigned females, the invasiveness of endovaginal ultrasound follow-up of the ovarian stimulation and oocyte retrieval procedures (and associated psychological distress) have been cited as a barrier (Armuand, Dhejne et al., 2017; Chen et al., 2017). There is also the concern young adults going through transitioning may not have a clear vision of parenting and are therefore likely to decline the opportunity to use FP at that time—while as adults, they may have different opinions about parenthood (Cauffman & Steinberg, 2000). The reduction of gender dysphoria during transitioning could also influence the decision-making process surrounding FP (Nahata et al., 2017). Based on research showing TGD youths' fertility perspectives may change over time (Nahata et al., 2019; Strang, Jarin et al., 2018), FP options should be discussed on an ongoing basis.

Statement 16.4

We recommend health care professionals counsel pre- or early-pubertal transgender and

gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.

For prepubertal and early-pubertal children, FP options are limited to the storage of gonadal tissue. Although this option is available for TGD children in the same way that it is available for cisgender prepubertal and early-pubertal oncological patients, there is no literature describing the utilization of this approach in the transgender population. Ovarian tissue autotransplantation has resulted in over 130 live births in cisgender women. Most of these patients conceived naturally without ART (Donnez & Dolmans, 2015; Jadoul et al., 2017), and the majority stored their ovarian tissue either as adults or during puberty. Although the recent American Society for Reproductive Medicine guideline has lifted the experimental label from ovarian tissue cryopreservation (Practice Committee of the American Society for Reproductive Medicine, 2019), there are very few case reports describing a successful pregnancy in a woman following the transplantation of ovarian tissue cryopreserved before puberty. Demeestere et al. (2015) and Rodriguez-Wallberg, Milenkovic et al. (2021) described cases of successful pregnancies following transplantation of tissue procured at the age of 14, and recently Matthews et al. (2018) described the case of a girl diagnosed with thalassemia who had ovarian tissue stored at the age of 9 and transplantation 14 years late. She subsequently conceived through IVF and delivered a healthy baby.

Currently, the only future clinical application for storing ovarian tissue is autotransplantation, which might be undesirable in a transgender man (due to the potentially undesirable effects of estrogen). A laboratory procedure that would make it possible to mature oocytes *in vitro* starting with ovarian tissue would be the ideal future application of stored ovarian tissue for transgender people, but this technique is currently only being investigated and optimized in basic science research settings (Ladanyi et al., 2017; Oktay et al., 2010).

Prepubertal procurement of testicular tissue has been documented as a low-risk procedure (Borgström et al., 2020; Ming et al., 2018). Some authors have also described this approach as a theoretical option in transgender people (De Roo et al., 2016; Martinez et al., 2017; Nahata, Curci et al., 2018). However, there are no reports in the literature describing the clinical or investigational utilization of this FP option for TGD patients. Moreover, the viability of the clinical application of autotransplantation of testicular tissue remains unknown in humans, and *in vitro* maturation techniques are still in the realm of basic science research. Thus, specialists currently consider this technique experimental (Picton et al., 2015). The possibility of storing gonadal tissue should be discussed prior to any genital surgery that would result in sterilization, although the probability of being able to use this tissue must be clearly addressed.

Statement 16.5

We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care and prenatal counseling regarding the use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.

Most transgender men and gender diverse people (AFAB) retain their uterus and ovaries and thus can conceive and carry a pregnancy even after long-term testosterone use (Light et al., 2014). Many transgender men desire children (Light et al., 2018; Wierckx, van Caenegem et al., 2012) and are willing to carry a pregnancy (Moseson, Fix, Hastings et al., 2021; Moseson, Fix, Ragosta et al., 2021). ART has expanded the opportunity for many transgender men to conceive and fulfill their family planning wishes (De Roo et al., 2017; Ellis et al., 2015; Maxwell et al., 2017). Some transgender men report psychological isolation, dysphoria related to the gravid uterus and chest changes, and depression (Charter, 2018; Ellis et al., 2015; Hoffkling et al., 2017; Obedin-Maliver & Makadon, 2016). Conversely, other studies have reported some positive experiences during pregnancy as well (Fischer, 2021; Light et al., 2014). Mental health providers should be involved to provide support, and counseling should be

provided addressing when to stop and when to resume gender-affirming hormones, what options are available for the mode of delivery and for chest/breast feeding (Hoffkling et al., 2017). Finally, system-level and interpersonal-level interventions should be implemented to ensure person-centered reproductive health care for all people (Hahn et al., 2019; Hoffkling et al., 2017; Moseson, Zazanis et al., 2020; Snowden et al., 2018).

Given the potential harmful effects of testosterone on the developing embryo, discontinuing testosterone or masculinizing hormone therapy prior to conception and during the entire pregnancy is recommended. However, the optimal time for both the discontinuation of testosterone prior to pregnancy and its resumption after pregnancy is unknown. Since stopping gender-affirming hormones may cause distress and exacerbate dysphoria in transgender men, when and how to stop this therapy should be discussed during prenatal counseling (Hahn et al., 2019). Because information about the duration of testosterone exposure and the risk of teratogenicity is lacking, testosterone use should be discontinued prior to attempting pregnancy and before stopping contraception. Moreover, there is limited information regarding health outcomes of infants born to transgender men. Small case series attempting to evaluate this question have revealed no adverse physical or psychosocial differences between infants born to transgender men and infants in the general population (Chiland et al., 2013).

Chest/Breast feeding

In the limited studies evaluating lactation and chest/breast feeding, the majority of transgender men and TGD individuals AFAB who chose to chest/breast feed postpartum were successful, with research suggesting induction of lactation is in part dependent on preconception counseling and experienced lactation nursing support (MacDonald et al., 2016; Wolfe-Roubatis & Spatz, 2015). Specifically, transgender men and TGD people who use testosterone should be informed 1) although quantities are small, testosterone does pass through chest/breast milk; and 2) the impact on the developing neonate/child is unknown, and therefore gender-affirming testosterone use is not recommended during lactation but may be resumed after discontinuation of chest/breast feeding (Glaser et al., 2009). Transgender men and other TGD individuals AFAB should be made aware some patients who carry a pregnancy may experience undesired chest growth and/or lactation even after chest reconstruction and should therefore be supported if they desire to suppress lactation (MacDonald et al., 2016).

There is limited information concerning lactation in transgender women as well as other TGD AMAB but many also express the desire to chest/breast feed. While there is a case report of a transgender woman successfully lactating and chest/breast feeding her infant after hormonal support using a combination of estrogen, progesterone, domperidone, and breast pumping (Reisman & Goldstein, 2018), the nutritional and immunological profile of chest/breast milk under these conditions has not been studied. Therefore, patients need to be informed about the risks and benefits of this approach to child feeding (Reisman & Goldstein, 2018).

Statement 16.6

We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.

Many TGD individuals may retain reproductive capacity, and they (if they retain a uterus, ovaries, and tubes) or their sexual partners (for sperm producing individuals) may experience unplanned pregnancies (James et al., 2016; Light et al., 2014; Moseson, Fix et al., 2020). Therefore, intentional family planning counseling, including contraception and abortion conducted in gender-expansive ways is needed (Klein, Berry-Bibee et al., 2018; Obedin-Maliver, 2015; Stroumsa & Wu, 2018). TGD people AFAB may not use contraception due to an erroneous assumption that testosterone is a reliable form of contraception (Abern & Maguire, 2018; Ingraham et al., 2018; Jones, Wood et al., 2017; Potter et al., 2015). However, based on current understanding, testosterone should not be considered a reliable form of contraception because of its incomplete suppression of the hypothalamic-pituitary-adrenal axis (Krempasky et al., 2020). Furthermore, pregnancies have occurred while individuals are amenorrheic due

to testosterone use, which may outlast active periods of administration (Light et al., 2014). Pregnancy can also occur in TGD people after long-term testosterone use (at least up to 10 years), although the effect on oocytes and baseline fertility is still unknown (Light et al., 2014).

TGD people AFAB may use a variety of contraceptive methods (Abern & Maguire, 2018; Bentsianov et al., 2018; Bonnington et al., 2020; Chrisler et al., 2016; Cipres et al., 2017; Jones, Wood et al., 2017; Krempasky et al., 2020; Light et al., 2018).These methods may be used explicitly for pregnancy prevention, menstrual suppression, abnormal bleeding, or other gynecological needs (Bonnington et al., 2020; Chrisler et al., 2016; Krempasky et al., 2020; Schwartz et al., 2019). Contraceptive research gaps within this population are profound. No studies have examined how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or non-hormonal and barrier contraceptive methods (e.g., internal and external condoms, non-hormonal intrauterine devices, diaphragms, sponges, etc.).

Gender diverse individuals who currently have a penis and testicles may engage in sexual activity with individuals who have a uterus, ovaries, and tubes of any gender. Gender diverse people who have a penis and testicles can produce sperm even while on gender-affirming hormones (i.e., estrogen), and although semen parameters are diminished among those who are currently using or who have previously used gender-affirming hormones, azoospermia is not complete and sperm activity is not totally suppressed (Adeleye et al., 2019; Jindarak et al., 2018; Kent et al., 2018). Therefore, contraception needs to be considered if pregnancy is to be avoided in penis-in-vagina sexual activity between a person with a uterus, ovaries, and tubes and one with a penis and testicles, irrespective of the use of gender-affirming hormones by either partner. Currently, contraceptive methods available for use by the sperm-producing partner are primarily mechanical barriers (i.e., external condoms, internal condoms), permanent sterilization (i.e., vasectomy), and gender-affirming surgery (e.g., orchiectomy, which also results in sterilization). Contraceptive counseling that considers sperm producing, egg producing, and gestating partners (as relevant) is recommended.

Statement 16.7

We recommend providers who offer pregnancy termination services ensure procedural approaches are gender-affirming and serve transgender people and those of diverse genders.

Unplanned pregnancies and abortions have been reported among TGD individuals with a uterus (Abern & Maguire, 2018; Light et al., 2014; Light et al., 2018; Moseson, Fix et al., 2020) and documented through surveys of abortion-providing facilities (Jones et al., 2020). However, the population-based epidemiology of abortion provision and the experiences and preferences of TGD individuals AFAB undergoing abortion still represents a critical gap in research (Fix et al., 2020; Moseson, Fix et al., 2020; Moseson, Lunn et al., 2020). Nonetheless, given that pregnancy capacity exists among many TGD people and pregnancies may not always be planned or desired, access to safe, legal, and gender-affirming pregnancy medical and surgical termination services is necessary.

CHAPTER 17 Sexual Health

Sexual health has a profound impact on physical and psychological well-being, regardless of one's sex, gender, or sexual orientation. However, stigma about sex, gender and sexual orientation influences individual's opportunities to live out their sexuality and to receive appropriate sexual health care. Specifically, in most societies, cisnormativity and heteronormativity lead to the assumption that all people are cisgender and heterosexual (Bauer et al., 2009), and that this combination is superior to all other genders and sexual orientations (Nieder, Güldenring et al., 2020; Rider, Vencill et al., 2019). Hetero-cisnormativity negates the complexity of gender, sexual orientation, and sexuality and disregards diversity and fluidity. This is all the more important since sexual identities, orientations, and practices of transgender and gender diverse (TGD) people are characterized by an enormous diversity (Galupo et al., 2016; Jessen et al., 2021; Thurston & Allan, 2018; T'Sjoen et al., 2020). Likewise, a strong cross-cultural tendency toward allonormativity—the assumption that all people experience sexual attraction or interest in sexual activity—negates the diverse experiences of TGD people, especially those who locate themselves on the asexual spectrum (McInroy et al., 2021; Mollet, 2021; Rothblum et al., 2020).

The World Health Organization (WHO, 2010) emphasizes sexual health depends on respect for the sexual rights of all people, including the right to express diverse sexualities and to be treated respectfully, safely, and with freedom from discrimination and violence. Sexual health discourses have focused on agency and body autonomy, which include consent, sexual pleasure, sexual satisfaction, partnerships, and family life (Cornwall & Jolly, 2006; Lindley et al., 2021). In light of this, the WHO defines sexual health as "a state of physical, emotional, mental, and social well-being in relation to sexuality and not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled" (WHO, 2006, p. 5). This includes individuals on the asexual spectrum, who may not experience sexual attraction to others but may still choose to be sexual at times (e.g., via self-stimulation) and/or experience interest in forming and building romantic relationships (de Oliveira et al., 2021).

Scientific attention to the sexual experiences and behaviors of TGD people has grown in recent years (Gieles et al., 2022; Holmberg et al., 2019; Klein & Gorzalka, 2009; Kloer et al., 2021; Mattawanon et al., 2021; Stephenson et al., 2017; Tirapegui et al., 2020; Thurston & Allan, 2018). This expansion within the literature reflects a sex-positive framework (Harden, 2014), a framework that recognizes both the positive aspects such as sexual pleasure (Laan et al., 2021) and potential risks associated with sexuality (Goldhammer et al., 2022; Mujugira et al., 2021). Studies of TGD people's sexuality, however, often lack validated measures, an appropriate control group, or a prospective design (Holmberg et al., 2019). Additionally, most focus exclusively on sexual functioning (Kennis et al., 2022), and thus neglecting sexual satisfaction and broader operationalizations of sexual pleasure beyond functioning. The effects of current TGD-related medical treatments on sexuality are heterogeneous (Özer et al., 2022; T'Sjoen et al., 2020), and there has been little research on the sexuality of TGD adolescents (Bungener et al., 2017; Maheux et al., 2021; Ristori et al., 2021; Stübler & Becker-Hebly, 2019; Warwick et al., 2022). While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date there is insufficient research on the effectiveness of such interventions. Focusing on the promotion of sexual health, the World Association for Sexual Health (WAS) asserts the importance of sexual pleasure and considers self-determination, consent, safety, privacy, confidence, and the ability to communicate and negotiate sexual relations as major facilitators (Kismödi et al., 2017). WAS asserts sexual pleasure is integral to sexual rights and human rights (Kismödi et al., 2017). To contribute to

Statements of Recommendations

17.1- We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills needed to address sexual health issues (relevant to their care provision).
17.2- We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.
17.3- We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.
17.4- We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.
17.5- We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectations of the transgender and gender diverse individual and assess their level of understanding of possible changes.
17.6.-We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.
17.7- We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.
17.8- We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

the sexual health of TGD people, health care professionals (HCPs) need both transgender-related expertise and sensitivity (Nieder, Güldenring et al., 2020). With the goal of improving sexual health care for TGD people to an ethically-sound, evidence-based and high-quality level, HCPs must provide their health services with the same care (i.e., with transgender-related expertise), respect (i.e., with transgender-related sensitivity), and investment in sexual pleasure and sexual satisfaction as they provide for cisgender people (Holmberg et al., 2019).

In many societies, nonconforming gender expressions can elicit strong (emotional) reactions, including in HCPs. Thus, when initiating a health-related contact or establishing a therapeutic relationship, a nonjudgmental, open and welcoming manner is most likely ensured when HCPs reflect on their emotional, cognitive, and interactional reactions to the person (Nieder, Güldenring et al., 2020). In addition, transgender-related expertise refers to identifying the impact the TGD person's intersectional identities and experiences of marginalization and stigma may have had on their whole self (Rider, Vencill et al., 2019). To adequately address the specific physical, psychological, and social conditions of TGD people, HCPs must be aware these conditions are generally overlooked due to hetero-cis-normativity, lack of knowledge, and lack of skills (Rees et al., 2021). It is also important to consider cultural norms in relation to sexuality. For example, in some African cultures, the idea of sex as taboo restricts the number of acceptable terms to be used when taking a sexual history (Netshandama et al., 2017). Culturally respectful language can facilitate talking openly about one's sexual history and reduce ambiguity or shame (Duby et al., 2016). In addition, HCPs must be sensitive to the history of (mis)use of sexual identity and orientation as a gatekeeping function to exclude transgender people from gender-affirming health care (Nieder & Richter-Appelt, 2011; Richards et al., 2014). The following recommendations aim to improve sexual health care for TGD people.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 17.1

We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills to address sexual health issues (relevant to their care provision).

It is important HCPs addressing the sexual health of TGD people be familiar with commonly used terminology (see Chapter 1—Terminology) and invite those seeking care to explain terms with which the provider may not be familiar. In this context, it is also important HCPs (are

prepared to) take a sexual history and offer treatment (according to their competencies) in a gender-affirming way with a sex-positive approach (Centers for Disease Control, 2020; Tomson et al., 2021). However, HCP's should apply greater importance to the terminology that the TGD person uses for their own body over more traditionally accepted or used medical terminology (Wesp, 2016). When talking about sexual practices, it is advisable to focus on body parts (e.g., "Do you have sex with people with a penis, people with a vagina, or both?"; ACON, 2022) and what role they play in their sexuality (e.g., "During Sex, do any parts of your body enter your partners body, such as their genitals, anus, or mouth?"; ACON, 2022).

Statement 17.2

We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.

To achieve gender-affirming care, it is crucial HCPs providing transition-related medical interventions be sufficiently informed about the possible effects on sexual function, pleasure, and satisfaction (T'Sjoen et al., 2020). Since clinical data indicate that TGD people score significantly lower in sexual pleasure compared to cisgender individuals, this is even more important (Gieles et al., 2022). If the HCP cannot provide information about the effects of their treatment on sexual function, pleasure, and satisfaction, they are at least expected to refer the individual to someone qualified to do so. If the sexuality-related effects of their treatment are unknown, HCPs should inform their patients accordingly. As introduced above, the sexuality of TGD people often challenges heteronormative views. Nevertheless, there is a large amount of literature (e.g., Bauer, 2018; Laube et al., 2020; Hamm & Nieder, 2021; Stephenson et al., 2017) highlighting the spectrum character of sexuality that does not fit into expectations of what male and female sexuality entails (neither cis- nor transgender), let alone that of gender diverse people (e.g., nonbinary, agender, genderqueer). Thus, these aspects should be carefully considered by HCPs as cisnormativity, heteronormativity, and transition-related medical interventions, all have a strong impact on sexual health.

Sexual pleasure has been well documented as a factor in improving sexual, mental, and physical health outcomes (Anderson, 2013). Next to sexual function, HCPs providing sexual health care must address sexual pleasure and satisfaction as a key factor within sexual health. Historically sexual health care has been disease focused, and this is particularly true for research and clinical practice in working with TGD patients. Although competent sexual health care regarding HIV and STIs is necessary, integration of valuing sexual pleasure of TGD patients is also necessary. Calls for integrating sexual pleasure as a focal point in STI prevention education and interventions rest on the understanding that pleasure is a motivator of behavior (Philpott et al., 2006). TGD people are concerned about their sexual pleasure and need HCPs who are knowledgeable about the diversity of sexual practices and anatomical functioning particular to TGD health care.

Statement 17.3

We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.

When appropriate and relevant to clinical concerns, inclusion of a sexual and/or romantic partner(s) in sexual health care decision-making can increase TGD patients' sexual well-being and satisfaction outcomes (Kleinplatz, 2012). TGD people may choose a range of transition-related medical interventions, and these interventions may have mixed results in shifting experiences of anatomical dysphoria (Bauer & Hammond, 2015). When discussing the impact of medical interventions on sexual functioning, pleasure, and satisfaction, inclusion of partner(s) can increase knowledge of potential changes and encourage communication between partners (Dierckx et al., 2019). Because the process of transitioning is often not a completely solitary endeavor, the inclusion of sexual and/or romantic partners in transition-related health care can facilitate the process of "co-transitioning" (Lindley et al., 2020;

Siboni et al., 2022; Theron & Collier, 2013) and can also support sexual growth and adjustment both in the individual as well as in the relationship. Social and psychological barriers to sexual functioning and pleasure, including experiences of gender dysphoria, stigmatization, lack of sexual and relationship role models, and limited skills, can have negative impacts on overall sexual health (Kerckhof et al., 2019). Supportive, gender-affirming sexual communication between partners improves sexual satisfaction outcomes for TGD people (Stephenson et al., 2017; Wierckx, Elaut et al., 2011).

Inclusion of sexual and/or romantic partners offers an additional opportunity to set realistic expectations, disseminate helpful and accurate information, and facilitate gender-affirming positive communication related to sexual health. Ultimately, however, it is important to recognize individual choices related to gender health and transition are the patients to make, not a partner's decision. It is important the inclusion of partners in sexual health-related care occur only when appropriate and as desired by patients. Contraindications might include interpersonal dynamics that are abusive or violent, in which case patient safety overrides partner involvement. Finally, it is critical HCPs treat all people in an affirming and inclusive manner, including sexual and romantic partners. This means, for example, monitoring and addressing assumptions and potential biases about the gender or sexual orientation of a patient's partner(s) or a patient's relationship structure.

Statement 17.4

We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.

The TGD community is disproportionately impacted by stigma, discrimination, and violence (de Vries et al., 2020; European Union Agency for Fundamental Rights, 2020; McLachlan, 2019). These experiences are often traumatic in nature (Burnes et al., 2016; Mizock & Lewis, 2008) and can create barriers to sexual health, functioning, and pleasure (Bauer & Hammond, 2015). For example, stigmatizing narratives about transgender sexualities can increase dysphoria and sexual shame, increasing potential avoidance of the sexual communication needed for safety and optimizing pleasure (Stephenson et al., 2017). Research demonstrates stigma, a history of sexual violence, and body image concerns can negatively impact sexual self-esteem and agency, for example the ability to assert what is pleasurable or to negotiate condom use (Clements-Nolle et al., 2008; Dharma et al., 2019). Additionally, gender dysphoria can be exacerbated by past trauma experiences and ongoing trauma-related symptoms (Giovanardi et al., 2018). It may be difficult for some TGD individuals to engage sexually using the genitals with which they were born, and they may choose to avoid such stimulation altogether, disrupting arousal and/or orgasmic processes (Anzani et al., 2021; Bauer & Hammond, 2015; Iantaffi & Bockting, 2011) or result in complex feelings about orgasm (Chadwick et al., 2019). HCPs providing gender-affirming counseling and interventions must be knowledgeable about the spectrum of sexual orientations and identities (including asexual identities and practices) to avoid assumptions based in heteronormative, cisnormative, allonormative modes of behavior or satisfaction while also affirming the potential impacts of stigma and trauma on sexual health and pleasure (Nieder, Güldenring et al., 2020). Some level of disconnect or dissociation may at times be present, particularly in the case of acute trauma symptoms (Colizzi et al., 2015). It is important HCPs be aware of these potential impacts on sexual health, functioning, pleasure, and satisfaction, so they may refer patients as needed to trauma-informed sexual counselors, mental health providers, or both, who may be of further assistance and may also normalize and validate TGD patients exploring multiple diverse pathways of healing and accessing sexual pleasure.

Statement 17.5

We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectation of the transgender and gender diverse individual, and assess their level of understanding of possible changes.

Transition-related care can affect sexual function, pleasure, and satisfaction, both in positive and negative ways (Holmberg et al., 2018; Kerckhof et al., 2019; Thurston & Allan, 2018; Tirapegui et al., 2020). On the positive side, gender-affirming care can help TGD people improve their sexual functioning and increase their sexual pleasure and satisfaction (Kloer et al., 2021; Özer et al., 2022; T'Sjoen et al., 2020). On the negative side, however, data indicate problematic sexual health outcomes due to hormonal and surgical treatments (Holmberg et al., 2018; Kerckhof et al., 2019, Stephenson et al., 2017; Weyers et al., 2009). Transition-related hormones may affect mood, sexual desire, the ability to have an erection and ejaculation, and genital tissue health, which in turn can impact sexual function, pleasure and sexual self-expression (Defreyne, Elaut et al., 2020; Garcia & Zaliznyak, 2020; Kerckhof et al., 2019; Klein & Gorzalka, 2009; Wierckx, Elaut et al., 2014). TGD people who wish to use their original genital anatomy for penetrative sex may benefit from medications that address sexual health side effects of hormone therapy, such as erectile dysfunction, medications for TGD persons taking estrogen or antiandrogens, and topical estrogen and/or moisturizers for TGD persons experiencing vaginal atrophy or dryness due to testosterone therapy.

Sexual desire, arousal, and function may also be affected by the use of psychotropic drugs (Montejo et al., 2015). As some TGD people are prescribed medication to treat depression (Heylens, Elaut et al., 2014), anxiety (Millet et al., 2017) or other mental health concerns (Dhejne et al., 2016), their potential side effects on sexual health should be considered.

Many gender-affirming surgeries can have significant effects on erogenous sensation, sexual desire and arousal as well as sexual function and pleasure. The impact of these changes for patients may be mixed (Holmberg et al., 2018). Chest surgeries (breast reduction, mastectomy, and breast augmentation) and body contouring surgeries, for example, may offer desired changes in form and appearance thereby reducing psychological distress that can disrupt sexual functioning but may adversely affect erogenous sensation (Bekeny et al., 2020; Claes et al., 2018; Rochlin et al., 2020). Genital surgeries in particular can potentially affect sexual function and pleasure in adverse ways, although they are likely to be experienced positively as the patient's body becomes more aligned with their gender, potentially opening new avenues for sexual pleasure and satisfaction (Hess et al., 2018; Holmberg et al., 2018; Kerckhof et al., 2019).

There are numerous examples of this in the extant literature:

- Surgery may result in a decrease, a total loss, or a possible increase in erogenous stimulation and/or experienced sensation compared with the patient's presurgery anatomy (Garcia, 2018; Sigurjónsson et al., 2017).
- A particular surgical option may be associated with specific limitations to sexual function that may manifest immediately, in the future, or at both timepoints, and which patients should consider before finalizing their choice when considering different surgical options (Frey et al., 2016; Garcia, 2018; Isaacson et al., 2017).
- Postsurgical complications can adversely affect sexual function by either decreasing the quality of sexual function (e.g., discomfort or pain with sexual activity) or by precluding satisfactory intercourse (Kerckhof et al., 2019; Schardein et al., 2019).

In general, satisfaction with any medical treatment is heavily influenced by the patient's expectations (Padilla et al., 2019). Furthermore, when patients have unrealistic expectations before treatment, they are much more likely to be dissatisfied with the outcome, their care, and with their HCP (Padilla et al., 2019). Therefore, it is important to both provide patients with adequate information about their treatment options and to understand and consider what is important to the patient with regard to outcomes (Garcia, 2021). Finally, it is important the HCP ensure patients understand the potential adverse effects of a treatment on their sexual function and pleasure so that a well-informed decision can be made. This is relevant for both meeting the standard of informed consent (i.e.,

discussion and understanding) and for providing an opportunity to offer further clarification to patients and, if desired, to their partners (Glaser et al., 2020).

Statement 17.6

We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.

The WHO (2015) recommends HCPs implement brief sexuality-related communication in primary care for all adolescents and adults. Therefore, TGD persons who are sexually active or considering sexual activity may benefit from sexuality-related communication or counseling for the purpose of HIV/STI prevention. These conversations are particularly important as TGD persons are disproportionately impacted by human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs) relative to cisgender persons (Baral et al., 2013; Becasen et al., 2018; Poteat et al., 2016). However, few data are available for non-HIV STIs, such as chlamydia, gonorrhea, syphilis, viral hepatitis, and herpes simplex virus (Tomson et al., 2021). The United Nations Joint Programme on HIV/AIDS estimates transgender women are 12 times more likely than other adults to be living with HIV (UNAIDS, 2019). A meta-analysis estimated a pooled global HIV prevalence of 19% among transgender women who have sex with men (Baral et al., 2013). HIV/STI risk is concentrated among TGD subgroups at the confluence of multiple biological, psychological, interpersonal, and structural vulnerabilities. In particular, transfeminine persons who have sex with cisgender men, belong to minoritized racial/ethnic groups, live in poverty, and engage in survival sex work are at elevated HIV/STI risk (Becasen et al., 2018; Poteat et al., 2015; Poteat et al., 2016). Less is known about HIV/STI risk among transgender men or gender diverse persons AFAB. Small studies in high-income countries indicate a laboratory-confirmed HIV prevalence of 0-4% among transmasculine people (Becasen et al., 2018; Reisner & Murchison, 2016). Almost no research has been conducted with transmasculine people who have sex with cisgender men in high-HIV-prevalence countries. Despite limited epidemiologic data, transmasculine persons who have sex with cisgender men frequently report HIV/STI risk related to receptive vaginal and/or anal sex (Golub et al., 2019; Reisner et al., 2019; Scheim et al., 2017) and may be more susceptible to HIV acquisition from vaginal intercourse than (pre-menopausal) cisgender women due to hormone-related vaginal atrophy.

HCPs will need to supplement general guidelines by developing the knowledge and skills needed for discussing sexual health issues with TGD people, such as the use of gender-affirming language (see Statement 17.1 in this chapter). It is critical HCPs avoid assumptions about HIV/STI risk based solely on a patient's gender identity or anatomy. For example, many transgender people are not sexually active, and TGD persons may use prosthetics or toys for sex. To provide appropriate prevention counseling, HCPs should inquire about the specific sexual activities TGD people engage in, and the body parts (or prosthetics) involved in those activities (ACON, 2022). Well-prepared HCPs (including, but not limited to mental health providers) may also engage in in-depth counseling with their patients to address the underlying drivers of HIV/STI risk (see Statement 17.3 in this chapter).

In all cases, HCPs should be sensitive to the collective and individual histories of TGD people (e.g., stereotypes and stigma about trans sexualities and gender dysphoria) and should explain to patients the reasons for sexuality-related inquiries and the voluntary nature of such inquiries. In discussing HIV/STI prevention, HCPs should refer to the full range of prevention options including barrier methods, post-exposure prophylaxis, pre-exposure prophylaxis, and HIV treatment to prevent onwards transmission (WHO, 2021). Trans-specific considerations for pre-exposure prophylaxis are addressed in Statement 17.8.

Statement 17.7

We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.

Like cisgender patients, TGD adolescents and adults should be offered screening for HIV/STIs in accordance with existing guidelines and based on their individual risk of HIV/STI acquisition, considering anatomy and behavior rather than gender identity alone. Where local or national guidelines are unavailable, WHO (2019a) offers global recommendations; more frequent screening is recommended for transgender people who have sex with cisgender men as a key population affected by HIV.

Gender-affirming genital surgeries and surgical techniques have implications for STI risks and screening needs, as outlined in recent guidelines from the US Centers for Disease Control (Workowski et al., 2021). For instance, transfeminine persons who have had penile inversion vaginoplasty using only penile and scrotal skin to line the vaginal canal are likely at lower risk of urogenital Chlamydia trachomatis *(C. trachomatis)* and Neisseria gonorrhoeae *(N. gonorrhoeae)*, but newer surgical techniques that employ buccal or urethral mucosa or peritoneum flaps could in theory increase susceptibility to bacterial STIs relative to the use of penile/scrotal skin alone (Van Gerwen et al., 2021). Routine STI screening of the neovagina (if exposed) is recommended for all transfeminine persons who have had vaginoplasty (Workowski et al., 2021). For transmasculine persons who have had metoidioplasty with urethral lengthening, but not vaginectomy, testing for bacterial urogenital STIs should include a cervical swab because infections may not be detected in urine (Workowski et al., 2021).

Further, it is important for HCPs to offer testing at multiple anatomical sites as STIs in transgender patients are often extragenital (Hiransuthikul et al., 2019; Pitasi et al., 2019). Consistent with WHO (2020) recommendations, self-collection of samples for STI testing should be offered as an option, particularly if patients are uncomfortable or unwilling to undergo provider-collected sampling due to gender dysphoria, trauma histories, or both. Where relevant, integration of HIV/STI testing with regular serology used to monitor hormone therapy may better facilitate access to care (Reisner, Radix et al., 2016; Scheim & Travers, 2017).

Statement 17.8

We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

For TGD adolescents and adults at substantial risk of HIV infection (generally defined as an ongoing serodiscordant relationship or condomless sex outside of a mutually monogamous relationship with a known HIV-negative partner; WHO, 2017), pre-exposure prophylaxis (PrEP) is an important HIV prevention option (Golub et al., 2019; Sevelius et al., 2016; WHO, 2021). To encourage uptake of PrEP, in 2021 the US Centers for Disease Control recommended all sexually active adolescents and adults be informed about PrEP and offered it if requested (CDC, 2021). For treatment among people living with HIV, transgender-specific guidelines are available in some settings (e.g., Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019).

For both HIV prevention and treatment, there are antiretroviral dosing and administration considerations specific to TGD persons. For oral PrEP, only daily dosing is currently recommended for TGD persons as studies demonstrating the effectiveness of event-driven PrEP with emtricitabine/tenofovir disoproxil fumarate (TDF) have been limited to cisgender men (WHO, 2019c). In addition, while emtricitabine/tenofovir alafenamide (TAF) is a new oral PrEP option, as of early 2022 it is not recommended for people at risk of HIV acquisition through receptive vaginal sex due to a lack of evidence (CDC, 2021). Finally, long-acting injectable formulations of both PrEP and HIV treatment are increasingly available (e.g., cabotegravir for PrEP), and while they are recommended for all patients who might benefit from injectable options, indicated injection sites (i.e., the gluteal muscle) may be unsuitable for individuals who have used soft tissue fillers (Rael et al., 2020).

There is little evidence supporting the occurrence of drug-drug interactions between gender-affirming hormones and PrEP medications. A few small studies, primarily relying on self-reported PrEP use, have shown reduced PrEP drug concentrations in transgender women undergoing hormone therapy, although

concentrations remained in the protective range (Yager & Anderson, 2020). A subsequent drug-drug interaction study using directly observed PrEP therapy failed to detect an impact of hormone therapy on PrEP drug concentrations in transgender women and found transgender women and men taking hormone therapy achieved high levels of protection against HIV infection (Grant et al., 2020). Most importantly, for many TGD people, no impact of PrEP on hormone concentrations has been detected. With regard to HIV treatment, specific antiretroviral medications may impact hormone concentrations; however, these can be managed by selecting alternative agents, monitoring and adjusting hormone dosing, or both (Cirrincione et al., 2020) as detailed in guidelines from the US Department of Health and Human Services (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019). Nevertheless, concerns about drug-drug interactions, particularly interactions that may limit hormone concentrations, represent a barrier to the implementation and adherence to antiretroviral therapy for HIV prevention or treatment (Radix et al., 2020; Sevelius et al., 2016). Therefore, it is advisable for HCPs to proactively address such concerns with those who are candidates for PrEP or HIV treatment. Integration of PrEP or HIV treatment with hormone therapy may further reduce barriers to implementation and adherence (Reisner, Radix et al., 2016). Integration may be achieved through colocation or through coordination with an HIV specialist if the primary care provider does not have the necessary expertise. Some TGD persons may benefit from standalone PrEP or sexual health services that provide greater privacy and flexibility, and thus differentiated service delivery models are needed (Wilson et al., 2021).

CHAPTER 18 Mental Health

This chapter is intended to provide guidance to health care professionals (HCPs) and mental health professionals (MHPs) who offer mental health care to transgender and gender diverse (TGD) adults. It is not meant to be a substitute for chapters on the assessment or evaluation of people for hormonal or surgical interventions. Many TGD people will not require therapy or other forms of mental health care as part of their transition, while others may benefit from the support of mental health providers and systems (Dhejne et al., 2016).

Some studies have shown a higher prevalence of depression (Witcomb et al., 2018), anxiety (Bouman et al., 2017), and suicidality (Arcelus et al., 2016; Bränström & Pachankis, 2022; Davey et al., 2016; Dhejne, 2011; Herman et al., 2019) among TGD people (Jones et al., 2019; Thorne, Witcomb et al., 2019) than in the general population, particularly in those requiring medically necessary gender-affirming medical treatment (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). However, transgender identity is not a mental illness, and these elevated rates have been linked to complex trauma, societal stigma, violence, and discrimination (Nuttbrock et al., 2014; Peterson et al., 2021). In addition, psychiatric symptoms lessen with appropriate gender-affirming medical and surgical care (Aldridge et al., 2020; Almazan and Keuroghlian; 2021; Bauer et al., 2015; Grannis et al., 2021) and with interventions that lessen discrimination and minority stress (Bauer et al., 2015; Heylens, Verroken et al., 2014; McDowell et al., 2020).

Mental health treatment needs to be provided by staff and implemented through the use of systems that respect patient autonomy and recognize gender diversity. MHPs working with transgender people should use active listening as a method to encourage exploration in individuals who are uncertain about their gender identity. Rather than impose their own narratives or preconceptions, MHPs should assist their clients in determining their own paths. While many transgender people require medical or surgical interventions or seek mental health care, others do not (Margulies et al., 2021). Therefore, findings from research involving clinical populations should not be extrapolated to the entire transgender population.

Addressing mental illness and substance use disorders is important but should not be a barrier to transition-related care. Rather, these interventions to address mental health and substance use disorders can facilitate successful outcomes from

Statements of Recommendations

18.1- We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.
18.2- We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.
18.3- We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact that mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.
18.4- We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender- affirmation surgery.
18.5- We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.
18.6- We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.
18.7- We recommend health care professionals ensure if transgender and gender diverse people need in-patient or residential mental health, substance abuse or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.
18.8- We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.
18.9- We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.
18.10- We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

transition-related care, which can improve quality of life (Nobili et al., 2018).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 18.1

We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.

Because patients generally are assumed to be capable of providing consent for care, whether the presence of cognitive impairment, psychosis, or other mental illness impairs the ability to give informed consent is subject to individual examination (Applebaum, 2007). Informed consent is central to the provision of health care. The health care provider must educate the patient about the risks, benefits, and alternatives to any care that is offered so the patient can make an informed, voluntary choice (Berg et al., 2001). Both the primary care provider or endocrinologist prescribing hormones and the surgeon performing surgery must obtain informed consent. Similarly, MHPs obtain informed consent for mental health treatment and may consult on a patient's capacity to give informed consent when this is in question. Psychiatric illness and substance use disorders, in particular cognitive impairment and psychosis, may impair an individual's ability to understand the risks and benefits of the treatment (Hostiuc et al., 2018). Conversely, a patient may also have significant mental illness, yet still be able to understand the risks and benefits of a particular treatment (Carpenter et al., 2000). Multidisciplinary communication is important in challenging cases, and expert consultation should be utilized as needed (Karasic & Fraser, 2018). For many patients, difficulty understanding the risks and benefits of a particular treatment can be overcome with time and careful explanation. For some patients, treatment of the underlying condition that is interfering with the capacity to give informed consent—for example treating an underlying psychosis—will allow the patient to gain the capacity to consent to the required treatment. However, mental health symptoms such as anxiety or depressive symptoms that do not affect the capacity to give consent should not be a barrier for gender-affirming medical treatment, particularly as this treatment has been found to reduce mental health symptomatology (Aldridge et al., 2020).

Statement 18.2

We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.

The inability to adequately participate in perioperative care due to mental illness or substance use should not be viewed as an obstacle to needed transition care, but should be seen as an indication mental health care and social support be provided (Karasic, 2020). Mental illness and substance use disorders may impair the ability of the patient to participate in perioperative care (Barnhill, 2014). Visits to health care providers, wound care, and other aftercare procedures (e.g., dilation after vaginoplasty) may be necessary for a good outcome. A patient with a substance use disorder might have difficulty keeping necessary appointments to the primary care provider and the surgeon. A patient with psychosis or severe depression might neglect their wound or not be attentive to infection or signs of dehiscence (Lee, Marsh et al., 2016). Active mental illness is associated with a greater need for further acute medical and surgical care after the initial surgery (Wimalawansa et al., 2014).

In these cases, treatment of the mental illness or substance use disorder may assist in achieving successful outcomes. Arranging more support for the patient from family and friends or a home health care worker may help the patient participate sufficiently in perioperative care for surgery to proceed. The benefits of mental health treatments that may delay surgery should be weighed against the risks of delaying surgery and should

include an assessment of the impact on the patients' mental health delays may cause in addressing gender dysphoria (Byne et al., 2018).

Statement 18.3

We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.

Gender-affirming surgical procedures vary in terms of their impact on the patient. Some procedures require a greater ability to follow preoperative planning as well as engage in peri- and postoperative care to achieve the best outcomes (Tollinche et al., 2018). Mental health symptoms can influence a patient's ability to participate in the planning and perioperative care necessary for any surgical procedure (Paredes et al., 2020). The mental health assessment can provide an opportunity to develop strategies to address the potential negative impact mental health symptoms may have on outcomes and to plan support for the patient's ability to participate in the planning and care. Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health (Owen-Smith et al., 2018; van de Grift, Elaut et al., 2017). These benefits are weighed against the risks of each procedure when the patient and provider are deciding whether to proceed with the treatment. HCPs can assist TGD people in reviewing preplanning and perioperative care instructions for each surgical procedure (Karasic, 2020). Provider and patient can collaboratively determine the necessary support or resources needed to assist with keeping appointments for perioperative care, obtaining necessary supplies, addressing financial issues, and handling other preoperative coordination and planning. In addition, issues surrounding appearance-related and functional expectations, including the impact of these various factors on gender dysphoria, can be explored.

Statement 18.4

We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender-affirmation surgery.

Regardless of specialty, all HCPs have a responsibility to support patients in accessing medically necessary care. When HCPs are working with TGD people as they prepare for gender-affirming surgical procedures, they should assess the levels of psychosocial and practical support required (Deutsch, 2016b). Assessment is the first step in recognizing where additional support may be needed and enhancing the ability to work collaboratively with the individual to successfully navigate the pre-, peri-, and postsurgical periods (Tollinche et al., 2018). In the perioperative period, it is important to help patients optimize functioning, secure stable housing, when possible, build social and family supports by assessing their unique situation, plan ways of responding to medical complications, navigate the potential impact on work/income, and overcome additional hurdles some patients may encounter, such as coping with electrolysis and tobacco cessation (Berli et al., 2017). In a complex medical system, not all patients will be able to independently navigate the procedures required to obtain care, and HCPs and peer navigators can support patients through this process (Deutsch, 2016a).

Statement 18.5

We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.

Transgender populations have higher rates of tobacco and nicotine use (Kidd et al., 2018). However, many are unaware of the well-documented smoking-associated health risks (Bryant et al., 2014). Tobacco consumption increases the risk of developing health problems (e.g., thrombosis) in individuals receiving gender-affirming hormone treatment, particularly estrogens (Chipkin & Kim, 2017).

Tobacco use has been associated with worse outcomes in plastic surgery, including overall complications, tissue necrosis, and the need for surgical revision (Coon et al., 2013). Smoking also increases the risk for postoperative infection (Kaoutzanis et al., 2019). Tobacco use has been shown to affect

the healing process following any surgery, including gender-related surgeries (e.g., chest reconstructive surgery, genital surgery) (Pluvy, Garrido et al., 2015). Tobacco users have a higher risk of cutaneous necrosis, delayed wound healing, and scarring disorders due to hypoxia and tissue ischemia (Pluvy, Panouilleres et al., 2015). In view of this, surgeons recommend stopping the use of tobacco/nicotine prior to gender-affirmation surgery and abstaining from smoking up to several weeks postoperatively until the wound has completely healed (Matei & Danino, 2015). Despite the risks, cessation may be difficult. Tobacco smoking and nicotine use is addictive and is also used as a coping mechanism (Matei et al., 2015). HCPs who see patients longitudinally before surgery, including mental health and primary care providers, should address the use of tobacco/nicotine with individuals in their care, and either assist TGD people in accessing smoking cessation programs or provide treatment directly (e.g., varenicline or bupropion).

Statement 18.6

We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.

TGD people entering inpatient psychiatric, substance use treatment, or medical units should be maintained on their current hormone regimens. There is an absence of evidence supporting routine cessation of hormones prior to medical or psychiatric admissions. Rarely, a newly admitted patient may be diagnosed with a medical complication necessitating suspension of hormone treatment, for example an acute venous thromboembolism (Deutsch, 2016a). There is no strong evidence for routinely stopping hormone treatment prior to surgery, and the risks and benefits for each individual patient should be assessed before doing so (Boskey et al., 2018).

Hormone treatment has been shown to improve quality of life and to decrease depression and anxiety (Aldridge et al., 2020; Nguyen et al., 2018; Nobili et al., 2018; Owen-Smith et al., 2018, Rowniak et al., 2019). Access to gender-affirming medical treatment is associated with a substantial reduction in the risk of suicide attempt (Bauer et al., 2015). Halting a patient's regularly prescribed hormones denies the patient of these salutary effects, and therefore may be counter to the goals of hospitalization.

Some providers may be unaware of the low risk of harm and the high potential benefit of continuing transition-related treatment in the inpatient setting. A study of US and Canadian medical schools revealed that students received an average of 5 hours of LGBT-related course content over their entire four years of education (Obedin-Maliver et al., 2011). According to a survey of Emergency Medicine physicians, who are often responsible for making quick decisions about medications as patients are being admitted, while 88% reported caring for transgender patients, only 17.5% had received any formal training about this population (Chisolm-Straker et al., 2018). As education about transgender topics increases, more providers will become aware of the importance of maintaining transgender patients on their hormone regimens during hospitalization.

Statement 18.7

We recommend health care professionals ensure if transgender and gender diverse people need inpatient or residential mental health, substance abuse, or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.

Many TGD patients encounter discrimination in a wide range of health settings, including hospitals, mental health treatment settings, and drug treatment programs (Grant et al., 2011). When health systems fail to accommodate TGD individuals, they reinforce the longstanding societal exclusion many have experienced (Karasic, 2016). Experiences of discrimination in health settings lead to avoidance of needed health care due to anticipated discrimination (Kcomt et al., 2020).

The experience of discrimination experienced by TGD individuals is predictive of suicidal ideation (Rood et al., 2015; Williams et al., 2021). Gender minority stress associated with rejection and nonaffirmation has also been associated with suicidality (Testa et al., 2017). Denial of access to gender appropriate bathrooms has been

associated with increased suicidality (Seelman, 2016). However, the use of chosen names for TGD people has been associated with lower depression and suicidality (Russell et al., 2018). Structural as well as internalized transphobia must be addressed to reduce the incidence of suicide attempts in TGD people (Brumer et al., 2015). To successfully provide care, health settings must minimize the harm done to patients because of transphobia by respecting and accommodating TGD identities.

Statement 18.8

We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.

While minority stress and the direct effects of discriminatory societal discrimination can be harmful to the mental health of TGD people, strong social support can help lessen this harm (Trujillo et al., 2017). TGD children often internalize rejection from family and peers as well as the transphobia that surrounds them (Amodeo et al., 2015). Furthermore, exposure to transphobic abuse may be impactful across a person's lifespan and may be particularly acute during the adolescent years (Nuttbrock et al., 2010).

The development of affirming social support is protective of mental health. Social support can act as a buffer against the adverse mental health consequences of violence, stigma, and discrimination (Bockting et al., 2013), can assist in navigating health systems (Jackson Levin et al., 2020), and can contribute to psychological resilience in TGD people (Bariola et al., 2015; Başar and Öz, 2016). Diverse sources of social support, especially LGBTQ+peers and family, have been found to be associated with better mental health outcomes, well-being, and quality of life (Bariola et al., 2015; Başar et al., 2016; Kuper, Adams et al., 2018; Puckett et al., 2019). Social support has been proposed to facilitate the development of coping mechanisms and lead to positive emotional experiences throughout the transition process (Budge et al., 2013).

HCPs can support patients in developing social support systems that allow them to be recognized and accepted as their authentic identity and help them cope with symptoms of gender dysphoria. Interpersonal problems and lack of social support have been associated with a greater incidence of mental health difficulties in TGD people (Bouman, Davey et al., 2016; Davey et al., 2015) and have been shown to be an outcome predictor of gender-affirming medical treatment (Aldridge et al., 2020). Therefore, HCPs should encourage, support, and empower TGD people to develop and maintain social support systems. These experiences can foster the development of interpersonal skills and help with coping with societal discrimination, potentially reducing suicidality and improving mental health (Pflum et al., 2015).

Statement 18.9

We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.

Psychotherapy has a long history of being used in clinical work with TGD people (Fraser, 2009b). The aims, requirements, methods and principles of psychotherapy have been an evolving component of the Standards of Care from the initial versions (Fraser, 2009a). At present, psychotherapeutic assistance and counseling with adult TGD people may be sought to address common psychological concerns related to coping with gender dysphoria and may also help some individuals with the coming-out process (Hunt, 2014). Psychological interventions, including psychotherapy, offer effective tools and provide context for the individual, such as exploring gender identity and its expression, enhancing self-acceptance and hope, and improving resilience in hostile and disabling environments (Matsuno and Israel, 2018). Psychotherapy is an established alternative therapeutic approach for addressing mental health symptoms that may be revealed during the initial assessment or later during the follow-up for gender-affirming medical interventions. Recent research shows, although mental health symptoms are reduced following gender-affirming medical treatment, levels of anxiety remain high (Aldridge et al., 2020) suggesting psychological therapy can play a role in helping

individuals suffering from anxiety symptoms following gender-affirming treatment.

In recent years, the uses and potential benefits of specific psychotherapeutic modalities have been reported (Austin et al., 2017; Budge, 2013; Budge et al., 2021; Embaye, 2006; Fraser, 2009b; Heck et al., 2015). Specific models of psychotherapy have been proposed for adult transgender and nonbinary individuals (Matsuno & Israel, 2018). However, more empiric data is needed on the comparative benefits of different psychotherapeutic models (Catelan et al., 2017). Psychotherapy can be experienced by transgender persons as a fearful as well as a beneficial experience (Applegarth & Nuttall, 2016) and presents challenges to the therapist and to alliance formation when it is associated with gatekeeping for medical interventions (Budge, 2015).

Experience suggests many transgender and nonbinary individuals decide to undergo gender-affirming medical treatment with little or no use of psychotherapy (Spanos et al., 2021). Although various modalities of psychotherapy may be beneficial for different reasons before, during, and after gender-affirming medical treatments and varying rates of desire for psychotherapy have been reported during different stages of transition (Mayer et al., 2019), a requirement for psychotherapy for initiating gender-affirming medical procedures has not been shown to be beneficial and may be a harmful barrier to care for those who do not need this type of treatment or who lack access to it.

Statement 18.10

We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

The use of "reparative" or "conversion" therapy or gender identity "change" efforts is opposed by many major medical and mental health organizations across the world, including the World Psychiatric Association, Pan American Health Organization, American Psychiatric and American Psychological Associations, Royal College of Psychiatrists, and British Psychological Society. Many states in the US have instituted bans on practicing conversion therapy with minors. Gender identity change efforts refers to interventions by MHPs or others that attempt to change gender identity or expression to be more in line with those typically associated with the person's sex assigned at birth (American Psychological Association, 2021).

Advocates of "conversion therapy" have suggested it could potentially allow a person to fit better into their social world. They also point out some clients specifically ask for help changing their gender identities or expressions and therapists should be allowed to help clients achieve their goals. However, "conversion therapy" has not been shown to be effective (APA, 2009; Przeworski et al., 2020). In addition, there are numerous potential harms. In retrospective studies, a history of having undergone conversion therapy is linked to increased levels of depression, substance abuse, suicidal thoughts, and suicide attempts, as well as lower educational attainment and less weekly income (Ryan et al., 2020; Salway et al., 2020; Turban, Beckwith et al., 2020). In 2021, the American Psychological Association resolutions states that "scientific evidence and clinical experience indicate that GICEs [gender identity change efforts] put individuals at significant risk of harm" (APA, 2021).

While there are barriers to ending gender identity "change" efforts, education about the lack of benefit and the potential harm of these practices may lead to fewer providers offering "conversion therapy" and fewer individuals and families choosing this option.

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Conflict of Interest

Conflict of interests were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential.

Ethical Approval

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Appendix A METHODOLOGY

1. Introduction

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Evidence-based research provides the basis for sound clinical practice guidelines and recommendations but must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

The SOC-8 revision committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers and stakeholders with diverse perspectives and geographic representation. All committee members completed conflict of interest declarations.*

A guideline methodologist assisted with the planning and development of questions, and an independent team undertook systematic reviews that were used to inform some of the statements for recommendations. Additional input to the guidelines was provided by an international advisory committee, legal experts, and feedback received during a public comment period. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus of the final recommendations was attained using a Delphi process that included all members of the Standards of Care Revision committee and required that recommendation statements were approved by 75% of members. Supportive and explanatory text of the evidence for the statements were written by chapter members. Drafts of the chapters were reviewed by the Chair and the Co-Chairs of the SOC Revision Committee to ensure the format was consistent, evidence was properly provided, and recommendations were consistent across chapters. An independent team checked the references used in the SOC-8 before the guidelines were fully edited by a single professional. A detailed overview of the SOC-8 Methodology is described below.

2. Difference between the methodology of the SOC-8 and previous editions

The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are:

- The involvement of a larger group of professionals from around the globe;
- A transparent selection process to develop the guidelines steering committee as well as to select chapter leads and members;
- The inclusion of diverse stakeholders in the development of the SOC-8
- Management of conflicts of interest
- The use of a Delphi process to reach agreement on the recommendations among SOC-8 committee members
- The involvement of an independent body from a reputable university to help develop the methodology and undertake independent systematic literature reviews where possible
- Recommendations were graded as either "recommend" or "suggest" based upon the strength of the recommendations.
- The involvement of an independent group of clinical academics to review citations.
- The involvement of international organizations working with the transgender and gender diverse (TGD) community, members of WPATH and other professional organizations as well as the general public who provided feedback through a public comment period regarding the whole SOC-8.

3. Overview of SOC-8 development Process

The steps for updating the Standards of Care are summarized below:

1. Establishing Guideline Steering Committee including Chair, and Co-Chairs (July 19, 2017)
2. Determining chapters (scope of guidelines)
3. Selecting Chapter Members based upon expertise (March 2018)
4. Selecting the Evidence Review Team: John Hopkins University (May 2018)
5. Refining topics included in the SOC-8 and review questions for systematic reviews
6. Conducting systematic reviews (March 2019)
7. Drafting the recommendation statements
8. Voting on the recommendation statements using a Delphi process (September 2019–February 2022)
9. Grading of the recommendations statements
10. Writing the text supporting the statements
11. Independently validating the references used in the supportive text
12. Finalizing a draft SOC-8 (December 1, 2021)
13. Feedback on the statements by International Advisory Committee
14. Feedback on the entire draft of the SOC-8 during a public comment period (November 2021–January 2022)
15. Revision of Final Draft based on comments (January 2022- May 2022)
16. Approval of final Draft by Chair and Co-Chairs (June 10, 2022)
17. Approval by the WPATH Board of Directors
18. Publication of the SOC-8
19. Dissemination and translation of the SOC-8

3.1. Establishment of Guideline Steering Committee

The WPATH Guideline Steering Committee oversaw the guideline development process for all chapters of the Standards of Care. Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board from WPATH members applying for these positions. Job descriptions were developed for the positions of Co-Chairs, Chapter Leads, Chapter Members and Stakeholder. WPATH members were eligible to apply by completing an application form and submitting their CV. The Board of WPATH voted for the position of co-chair (one member of the board did not participate in view of conflict of interest). The chairs and co-chairs selected the chapter leads and members (as well as stakeholders) based on the application form and CVs.

The Guideline Steering Committee for Standards of Care 8th Version are:

- Eli Coleman, PhD (Chair) Professor, Director and Academic Chair, Institute for Sexual and Gender Health, Department of Family Medicine and Community Health, University of Minnesota Medical School (USA)
- Asa Radix, MD, PhD, MPH (Co-chair) Senior Director, Research and Education Callen-Lorde Community Health Center Clinical Associate Professor of Medicine New York University, USA
- Jon Arcelus, MD, PhD (Co-chair) Professor of Mental Health and Well-being Honorary Consultant in Transgender Health University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

3.2. Determination of topics for chapters

The Guideline Steering Committee determined the chapters for inclusion in the Standards of Care by reviewing the literature and by reviewing the previous edition of the SOC. The chapters in the Standards of Care 8th Version:

1. Terminology
2. Global Applicability
3. Population estimates
4. Education*
5. Assessment of Adults
6. Adolescent
7. Children
8. Nonbinary
9. Eunuch
10. Intersex
11. Institutional environments
12. Hormone Therapy
13. Surgery and Postoperative Care
14. Voice and communication
15. Primary care
16. Reproductive Health
17. Sexual Health
18. Mental Health

* The Education Chapter was originally intended to cover both education and ethics. A decision was made to create a separate committee to write a chapter on ethics. In the course of writing the chapter, it was later determined topic of ethics was best placed external to the SOC8 and required further in-depth examination of ethical considerations relevant to transgender health.

3.3. Selection of chapter members

A call for applications to be part of the SOC-8 review committee (chapter lead or member) was sent to the WPATH membership. The Chairs of the Guideline Steering Committee appointed the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members were required to be WPATH Full Members in good standing and content experts in transgender health, including in at least one chapter topic. Chapter Leads reported to the Guideline Steering Committee and were responsible for coordinating the participation of Chapter Members. Chapter members reported directly to the Chapter Lead.

Each chapter also included stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that included a transgender child, sibling, partner, parent, etc. Stakeholders were not required to be full members of WPATH.

The Chapter Members were expected to:

- Participate in the development refinement of review questions
- Read and provide comments on all materials from the Evidence Review Team
- Critically review draft documents, including the draft evidence report
- Review and assess evidence and draft recommendations
- Participate in the Delphi consensus process
- Develop the text to back up the recommendation statements
- Grade each statement to describe the strength of the recommendation
- Review and address the comments from the Chairs during the whole process
- Develop the content of the chapters
- Review comments from public comments and assist in the development of a revision of guidelines
- Provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members was provided, as needed. Training content included formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation state-

ments, grading the evidence and the recommendations, and information about the guideline development program and process.

A total of 26 chapter-leads were appointed (some chapters required co-leads), 77 chapter members and 16 stakeholders. A total of 127 were selected. During the SOC process, 8 people left, due to personal or work-related issues. Therefore, there were 119 final authors of the SOC-8.

3.4. Selection of the evidence review team

The WPATH Board issued a request for applications to become the Evidence Review Team. For Standards of Care 8th Version the WPATH Board engaged the Evidence Review Team at Johns Hopkins University under the leadership of Karen Robinson.

- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

Dr Robinson also guided the steering committee in the development of the SOC-8 by providing advice and training in the development of PICO questions, statements, and the Delphi process as well as undertaking a very rigorous systematic literature review where direct evidence was available.

Conflict of interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team were asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, are personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

3.5. Refinement of topics and review of questions

The Evidence Review Team abstracted the recommendation statements from the prior version of the Standards of Care. With input from the Evidence Review Team, the Guideline Steering Committee and Chapter Leads determined:

- Recommendation statements that needed to be updated
- New areas requiring recommendation statements

3.6. Conduct the systematic reviews

Chapter Members developed questions to help develop recommendation statements. For the questions eligible for systematic review, the Evidence Review Team drafted review questions, specifying the Population, Interventions, Comparisons, and Outcomes (PICO elements). The Evidence Review Team undertook the systematic reviews. The Evidence Review Team presented evidence tables and other results of the systematic reviews to the members of the relevant chapter for feedback.

Protocol

A separate detailed systematic review protocol was developed for each review question or topic, as appropriate. Each protocol was registered on PROSPERO.

Literature search

The Evidence Review Team developed a search strategy appropriate for each research question including MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team searched additional databases as deemed appropriate for the research question. The search strategy included MeSH and text terms and was not limited by language of publication or date.

The Evidence Review Team hand searched the reference lists of all included articles and recent, relevant systematic reviews. The Evidence Review Team searched ClinicalTrials.gov for any additional relevant studies.

Searches were updated during the peer review process.

The literature included in the systematic review was mostly based on quantitative studies conducted in Europe, the US or Australia. We acknowledge a bias towards perspectives from the global north that does not pay sufficient attention to the diversity of lived experiences and perspectives within transgender and gender diverse (TGD) communities across the world. This imbalance of visibility in the literature points to a research and practice gap that needs to be addressed by researchers and practitioners in the future in order to do justice to the support needs of all TGD people independent of gender identification.

Study selection

The Evidence Review Team, with input from the Chapter Workgroup Leads, defined the eligibility criteria for each research question *a priori*.

Two reviewers from the Evidence Review Team independently screened titles and abstracts and full-text articles for eligibility. To be excluded, both reviewers needed to agree that the study met at least one exclusion criteria. Reviewers resolved differences regarding eligibility through discussion.

Data extraction

The Evidence Review Team used standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer abstracted the data, and a second reviewer confirmed the abstracted data.

Assessment of risk of bias

Two reviewers from the Evidence Review Team independently assessed the risk of bias for each included study. For

randomized controlled trials, the Cochrane Risk of Bias Tool was used. For observational studies, the Risk of Bias in Non-Randomized Studies—of Interventions (ROBINS-I) tool was used. Where deemed appropriate, existing recent systematic reviews were considered and evaluated using ROBIS.

Data synthesis and analysis

The Evidence Review Team created evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups reviewed and provided comments on the evidence tables.

Grading of the evidence

The Evidence Review Team assigned evidence grades using the GRADE methodology. The strength of the evidence was obtained using predefined critical outcomes for each question and by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

3.7. Drafting of the Recommendation Statements

Chapter Leads and Members drafted recommendation statements. The statements were crafted to be feasible, actionable, and measurable.

Evidence-based recommendation statements were based on the results of the systematic, and background literature reviews plus consensus-based expert opinions.

The Chair and Co-Chairs and Chapter Leads reviewed and approved all recommendation statements for clarity and consistency in wording. During this review and throughout the process any overlap between chapters was also addressed.

Many chapters had to work closely together to ensure consistency of their recommendations. For example, as there are now separate chapters for childhood and adolescence, to ensure consistency between both chapters, some authors were part of both chapters. For a similar reason, when applicable, a workgroup collaborated with other Chapter Workgroups on topics shared between the chapters (i.e., Assessment of Children, Assessment of Adults, Hormone Therapy, Surgery and Postoperative Care and Reproductive Health).

3.8. Approval of the recommendations using the Delphi process

Formal consensus for all statements was obtained using the Delphi process (a structured solicitation of expert judgements in three rounds). For a recommendation to be approved, a minimum of 75% of the voters had to approve the statement. A minimum of 65% of the SOC-8 members had to take part in the Delphi process for each statement. People who did not approve the statement had to provide information as to the reasons for their disapproval, so the statement could be modified (or removed) according to this feedback. Once modified, the statement was put through the Delphi process again. If after 3 rounds the statement was not approved, the statement was removed from the SOC. Every member of the SOC voted for each statement. There was a response rate between (74.79% and 94.96%) for the statements.

3.9. Grading criteria for statements

Once the statements passed the Delphi process, chapter members graded each statement using a process adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. This a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations (Guyatt et al., 2011). The statements were graded based on factors such as:

- The balance of potential benefits and harms
- Confidence in that balance or quality of evidence
- Values and preferences of providers and patients
- Resource use and feasibility

The statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
  - the evidence is of high quality
  - estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice)
  - there are few downsides of therapy/intervention/strategy
  - there is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
- Weak recommendations ("we suggest") are for those interventions/therapy/strategies where:
  - there are weaknesses in the evidence base
  - there is a degree of doubt about the size of the effect that can be expected in practice
  - there is a need to balance the potential upsides and downsides of interventions/therapy/strategies
  - there are likely to be varying degrees of acceptance among providers and patients or those for whom the recommendation applies.

3.10. Writing of the text supporting the statements

Following the grading of the statements, the Chapter Workgroups wrote the text providing the rationale or reasoning for the recommendation. This included providing the available evidence, providing details about potential benefits and harms, describing uncertainties, and information about implementation of the recommendation, including expected barriers or challenges among others. References use APA-7 style, to support the information in the text. Links to resources are also provided, as appropriate. The text, including whether a recommendation has been described as strong or weak, was reviewed and approved by the Chair and Co-Chairs.

3.11. External validation of references used to support the statements

A group of independent clinical academics working in the field of transgender health reviewed the references used in every chapter in order to validate that the references were appropriately used to support the text. Any queries regarding the references were sent back to the chapters for review.

3.12. Finalizing a draft SOC-8

A final SOC-8 draft was made available for comments.

3.13. Distribute Standards of Care for review by international advisors

The statements of the recommendations of Standards of Care 8th were circulated among the broader Standards of Care Revision Committee and the WPATH International Advisory Group, which included the Asia Pacific Transgender Network (APTN), the Global Action for Transgender Equality (GATE), the International Lesbian, Gay, Bisexual, Transgender, Intersex Association (ILGA), and Transgender Europe (TGEU).

3.14. Public comment period

The revised draft version of the Standards of Care document was posted online for comment from the public, including WPATH members, on the WPATH website. A 6-week period was allocated for comments. A total of 1,279 people made comments on the draft with a total of 2,688 comments.

3.15. Revision of final draft based on comments

The Chapter Leads and Guideline Steering Committee considered the feedback and made any necessary revisions. All public comments were read and, where appropriate, integrated into the background text.

As part of this process, 3 new Delphi statements were developed and 2 were modified enough to require a new vote by the SOC-8 committee. This meant a new Delphi process was initiated in January 2022. The results of this Delphi process were accepted by the chapters, and the new statements were added or modified accordingly. The new supportive text was added.

All the new versions of the chapters were reviewed again by the Chair and Co-Chairs and changes or modifications were suggested. Finally, once the Chairs and the Chapter Members were satisfied with the draft, the chapter was finalized.

All new references were double checked by an independent member.

3.16. Approval of final draft by Chair and Co-Chairs

Modifications were reviewed by the Chairs and were accepted by them.

3.17. Approval by the WPATH Board of Directors

The final document was presented to the WPATH Board of Directors for approval and it was approved on the 20th of June 2022.

3.18. Publication of the SOC-8 and dissemination of the Standards of Care

The Standards of Care was disseminated in a number of venues and in a number of formats including publication in the International Journal of Transgender Health (the official scientific journal of WPATH).

4. Plan to Update

A new edition of the SOC (SOC-9) will be developed in the future, when new evidence and/or significant changes in the field necessitating a new edition is substantial.

*The development of SOC-8 was a complex process at a time of COVID-19 and political uncertainties in many parts of the world. Members of the SOC-8 worked on the SOC-8 on top of their day-to-day job, and most of the meetings took place out of their working time and during their weekends via Zoom. There were very few face-to-face meetings, most of them linked to WPATH, USPATH or EPATH conferences. Committee members of the SOC-8 were not paid as part of this process.

Appendix B GLOSSARY

CISGENDER refers to people whose current gender identity corresponds to the sex they were assigned at birth.

DETRANSITION is a term sometimes used to describe an individual's retransition to the gender stereotypically associated with their sex assigned at birth.

EUNUCH refers to an individual assigned male at birth whose testicles have been surgically removed or rendered non-functional and who identifies as a eunuch. This differs from the standard medical definition by excluding those who do not identify as eunuch.

EUNUCH-IDENTIFIED: An individual who feels their true self is best expressed by the term eunuch. Eunuch-identified individuals generally desire to have their reproductive organs surgically removed or rendered non-functional.

GENDER: Depending on the context, gender may reference gender identity, gender expression, and/or social gender role, including understandings and expectations culturally tied to people who were assigned male or female at birth. Gender identities other than those of men and women (who can be either cisgender or transgender) include transgender, nonbinary, genderqueer, gender neutral, agender, gender fluid, and "third" gender, among others; many other genders are recognized around the world.

GENDER-AFFIRMATION refers to being recognized or affirmed in a person's gender identity. It is usually conceptualized as having social, psychological, medical, and legal dimensions. Gender affirmation is used as a term in lieu of transition (as in medical gender-affirmation) or can be used as an adjective (as in gender-affirming care).

GENDER-AFFIRMATION SURGERY (GAS) is used to describe surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity.

GENDER BINARY refers to the idea there are two and only two genders, men and women; the expectation that everyone must be one or the other; and that all men are males, and all women are females.

GENDER DIVERSE is a term used to describe people with gender identities and/or expressions that are different from social and cultural expectations attributed to their sex assigned at birth. This may include, among many other culturally diverse identities, people who identify as nonbinary, gender expansive, gender nonconforming, and others who do not identify as cisgender.

GENDER DYSPHORIA describes a state of distress or discomfort that may be experienced because a person's gender identity differs from that which is physically and/or socially attributed to their sex assigned at birth. Gender Dysphoria is also a diagnostic term in the DSM-5 denoting an incongruence between the sex assigned at birth and experienced gender accompanied by distress. Not all transgender and gender diverse people experience gender dysphoria.

GENDER EXPANSIVE is an adjective often used to describe people who identify or express themselves in ways that broaden the socially and culturally defined behaviors or beliefs associated with a particular sex. Gender creative is also sometimes used. The term gender variant was used in the past and is disappearing from professional usage because of negative connotations now associated with it.

GENDER EXPRESSION refers to how a person enacts or expresses their gender in everyday life and within the context of their culture and society. Expression of gender through physical appearance may include dress, hairstyle, accessories, cosmetics, hormonal and surgical interventions as well as mannerisms, speech, behavioral patterns, and names. A person's gender expression may or may not conform to a person's gender identity.

GENDER IDENTITY refers to a person's deeply felt, internal, intrinsic sense of their own gender.

GENDER INCONGRUENCE is a diagnostic term used in the ICD-11 that describes a person's marked and persistent experience of an incompatibility between that person's gender identity and the gender expected of them based on their birth-assigned sex.

INTERSEX refers to people born with sex or reproductive characteristics that do not fit binary definitions of female or male.

MISGENDER/MISGENDERING refers to when language is used that does not correctly reflect the gender with which a person identifies. This may be a pronoun (he/him/his, she/her/hers, they/them/theirs) or a form of address (sir, Mr.).

NONBINARY refers to those with gender identities outside the gender binary. People with nonbinary gender identities may identify as partially a man and partially a woman or identify as sometimes a man and sometimes a woman, or identify as a gender other than a man or a woman, or as not having a gender at all. Nonbinary people may use the pronouns they/them/theirs instead of he/him/his or she/her/hers. Some nonbinary people consider themselves to be transgender or trans; some do not because they consider transgender to be part of the gender binary. The shorthand NB or "enby" is sometimes used as a descriptor for nonbinary. Examples of nonbinary gender identities are genderqueer, gender diverse, genderfluid, demigender, bigender, and agender.

RETRANSITION refers to second or subsequent gender transition whether by social, medical, or legal means. A retransition may be from one binary or nonbinary gender to another binary or nonbinary gender. People may retransition more than once. Retransition may occur for many reasons, including evolving gender identities, health concerns, family/societal concerns, and financial issues.

SEX ASSIGNED AT BIRTH refers to a person's status as male, female, or intersex based on physical characteristics. Sex is usually assigned at birth based on appearance of the external genitalia. AFAB is an abbreviation for "assigned female at birth." AMAB is an abbreviation for "assigned male at birth."

SEXUAL ORIENTATION refers to a person's sexual identity, attractions, and behaviors in relation to people on the basis of their gender(s) and or sex characteristics and those of their partners. Sexual orientation and gender identity are distinct terms.

TRANSGENDER or trans are umbrella terms used to describe people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth. These words should always be used as adjectives (as in "trans people") and never as nouns (as in "transgenders") and never as verbs (as in "transgendered").

TRANSGENDER MEN or **TRANS MEN** or **MEN OF TRANS EXPERIENCE** are people who have gender identities as men and who were assigned female at birth. They may or may not have undergone any transition. FTM or Female-to-Male are older terms that are falling out of use.

TRANSGENDER WOMEN or **TRANS WOMEN** or **WOMEN OF TRANS EXPERIENCE** are people who have gender identities as women and who were assigned male at birth. They may or may not have undergone any transition. MTF or Male-to-Female are older terms that are falling out of use.

TRANSITION refers to the process whereby people usually change from the gender expression associated with their assigned sex at birth to another gender expression that better matches their gender identity. People may transition socially by using methods such as changing their name, pronoun, clothing, hair styles, and/or the ways that they move and speak. Transitioning may or may not involve hormones and/or surgeries to alter the physical body. Transition can be used to describe the process of changing one's gender expression from any gender to a different gender. People may transition more than once in their lifetimes.

TRANSPHOBIA refers to negative attitudes, beliefs, and actions concerning transgender and gender diverse people as a group. Transphobia may be enacted in discriminatory policies and practices on a structural level or in very specific and personal ways. Transphobia can also be internalized, when transgender and gender diverse people accept and reflect such prejudice about themselves or other transgender and gender diverse people. While transphobia sometimes may be a result of unintentional ignorance rather than direct hostility, its effects are never benign. Some people use the term anti-transgender bias in place of transphobia.

Appendix C GENDER-AFFIRMING HORMONAL TREATMENTS

Table 1. Expected time course of physical changes in response to gender-affirming hormone therapy

Testosterone Based Regimen		
Effect	**Onset**	**Maximum**
Skin Oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	6–12 months	>5 years
Scalp hair loss	6–12 months	>5 years
Increased muscle mass/ strength	6–12 months	2–5 years
Fat redistribution	1–6 months	2–5 years
Cessation of menses	1–6 months	1–2 years
Clitoral enlargement	1–6 months	1–2 years
Vaginal atrophy	1–6 months	1–2 years
Deepening of voice	1–6 months	1–2 years
Estrogen and testosterone-lowering based regimens		
Effect	**Onset**	**Maximum**
Redistribution of body fat	3–6 months	2–5 years
Decrease in muscle mass and strength	3–6 months	1–2 years
Softening of skin/ decreased oiliness	3–6 months	Unknown
Decreased sexual desire	1–3 months	Unknown
Decreased spontaneous erections	1–3 months	3–6 months
Decreased sperm production	Unknown	2 years
Breast growth	3–6 months	2–5 years
Decreased testicular volume	3–6 months	Variable
Decreased terminal hair growth	6–12 months	> 3 years
Increased scalp hair	Variable	Variable
Voice changes	None	

Adapted from Hembree et al., 2017.

Table 2. Risks associated with gender affirming hormone therapy (bolded items are clinically significant) (Updated from SOC-7)

RISK LEVEL	Estrogen-based regimens	Testosterone-based regimens
Likely increased risk	**Venous Thromboembolism** **Infertility** Hyperkalemia[S] Hypertrigyceridemia Weight Gain	**Polycythemia** **Infertility** Acne Androgenic Alopecia Hypertension Sleep Apnea Weight Gain Decreased HDL Cholesterol and increased LDL Cholesterol
Likely increased risk with presence of additional risk factors	Cardiovascular Disease Cerebrovascular Disease Meningioma[C] Polyuria/Dehydration[S] Cholelithiasis	Cardiovascular Disease Hypertriglyceridemia
Possible increased risk	Hypertension Erectile Dysfunction	
Possible increased risk with presence of additional risk factors	Type 2 Diabetes Low Bone Mass/ Osteoporosis Hyperprolactinemia	Type 2 Diabetes Cardiovascular Disease
No increased risk or inconclusive	Breast and Prostate Cancer	Low Bone Mass/ Osteoporosis Breast, Cervical, Ovarian, Uterine Cancer

[C]cyproterone-based regimen
[S]spironolactone-based regimen

Table 3. Gender-Affirming Hormone Regimens In Transgender And Gender Diverse Youth (Adapted from the Endocrine Society Guidelines; Hembree et al., 2017)

Induction of female puberty (estrogen-based regimen) with oral 17ß-estradiol

Initiate at 5µg/kg/d and increase every 6 months by 5 µg/kg/d up to 20 µg/kg/d according to estradiol levels

Adult dose = 2-6 mg/day

In postpubertal TGD adolescents, the dose of 17ß-estradiol can be increased more rapidly:

1 mg/d for 6 months followed by 2 mg/d and up according to estradiol levels

Induction of female puberty (estrogen-based regimen) with transdermal 17ß-estradiol

Initial dose 6.25-12.5 µg/24 h (cutting 24 g patch to ¼ then ½)

Titrate up by every 6 months by 12.5 µg/24 h according to estradiol levels

Adult dose = 50-200 µg/24 hours

For alternatives once at adult dose (Table 4)

Induction of male puberty (testosterone-based regimen) with testosterone esters

25 mg/m^2/2 weeks (or alternatively half this dose weekly)

Increase by 25 mg/m^2/2 weeks every 6 months until adult dose and target testosterone levels are achieved. See alternatives for testosterones (Table 4)

Table 4. Hormone regimens in transgender and gender diverse adults*

Estrogen-based regimen (Transfeminine)	
Estrogen	
Oral or sublingual	
Estradiol	2.0-6.0 mg/day
Transdermal	
Estradiol transdermal patch	0.025-0.2 mg/day
Estradiol gel various	‡ daily to skin
Parenteral	
Estradiol valerate or cypionate	5-30 mg IM every 2 weeks 2-10 IM every week
Anti-Androgens	
Spironolactone	100–300 mg/day
Cyproterone acetate	10 mg/day**
GnRH agonist	3.75–7.50 mg SQ/IM monthly
GnRH agonist depot formulation	11.25/22.5 mg SQ/IM 3/6 monthly
‡ Amount applied varies to formulation and strength	
Testosterone-Based Regimen (Transmasculine)	
Transgender males	
Testosterone	
Parenteral	
Testosterone enanthate/ cypionate	50–100 IM/SQ weekly or 100–200 IM every 2 weeks
Testosterone undecanoate	1000 mg IM every 12 weeks or 750 mg IM every 10 weeks
Transdermal testosterone	
Testosterone gel	50-100 mg/day
Testosterone transdermal patch	2.5–7.5 mg/day

Doses are titrated up or down until sex steroid hormone levels are in the therapeutic range. Hormone regimens do not reflect all formulations that are available in all pharmacies throughout the world. Hormone regimens may have to be adapted to what is available in local pharmacies.

**Kuijpers et al (2021).

Table 5. Hormone monitoring of transgender and gender diverse people receiving gender-affirming hormone therapy (Adapted from the Endocrine Society Guidelines)

Transgender male or trans masculine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and 1 to 2 times per year thereafter to monitor for appropriate physical changes in response to testosterone.
2. Measure serum total testosterone every 3 months (with dose changes) until levels are at goal
   a. For parenteral testosterone, the serum total testosterone should be measured midway between injections. The target level is 400-700 ng/dL. Alternatively, measure peak and trough peaks to ensure levels remain in the range of reference men.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before injection. If the level is < 400 ng/dL, adjust the dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 week of daily application (at least 2 hours after application of product).
3. Measure hematocrit or hemoglobin concentrations at baseline and approximately 3 months (with dose changes) for the first year and then one to two times a year.

Transgender Female or trans feminine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and one to two times per year thereafter to monitor for appropriate physical changes in response to estrogen.
   a. Serum testosterone levels should be less than 50 ng/dL.
   b. Serum estradiol should be in the range of 100-200 pg/mL.
2. For individuals receiving spironolactone, serum electrolytes, in particular potassium, and kidney function, in particular creatinine, should be monitored.
3. Follow primary care screening per primary care chapter recommendations

Appendix D SUMMARY CRITERIA FOR HORMONAL AND SURGICAL TREATMENTS FOR ADULTS AND ADOLESCENTS

The SOC-8 guidelines are intended to be flexible in order to meet the diverse health care needs of TGD people globally. While adaptable, they offer consensus-based standards derived from the best available scientific evidence for promoting optimal health care and guiding the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender affirming interventions are clinical guidelines; individual health care professionals and programs, in consultation with the TGD person, may modify them. Clinical departures from the SOC may occur due to a TGD person's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, discussed with the TGD person, and documented. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve. This summary criteria needs to be read in conjunction with the relevant chapters (see Adult Assessment and Adolescent chapters).

SUMMARY CRITERIA FOR ADULTS

Related to the assessment process

- Health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment should liaise with professionals from different disciplines within the field of trans health for consultation and referral, if required*
- If written documentation or a letter is required to recommend gender affirming medical and surgical treatment (GAMST), only one letter of assessment from a health care professional who has competencies in the assessment of transgender and gender diverse people is needed.

Criteria for hormones

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
d. Other possible causes of apparent gender incongruence have been identified and excluded;
e. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
f. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

Criteria for surgery

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
d. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
e. Other possible causes of apparent gender incongruence have been identified and excluded;
f. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
g. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).*

*These were graded as suggested criteria

SUMMARY CRITERIA FOR ADOLESCENTS

Related to the assessment process

- A comprehensive biopsychosocial assessment including relevant mental health and medical professionals;
- Involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible;
- If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical and mental health professionals (MHPs).

Puberty blocking agents

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Hormonal treatments

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Surgery

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. At least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

Appendix E GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

Children's Hospital Los Angeles

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TRANS YOUTH CARE – BLOCKER COHORT

Subject's Name:			
Medical Record Number:		Birth Date:	

1. Dr. Olson is doing a research study about medication that can be used to stop you from going into puberty.

2. We are asking you to take part in this research because we want to learn more about what happens to children who are transgender and use a medicine to stop puberty. We want to see if it changes how your body works and want to know how you and your parents feel about not going into puberty.

3. If you agree to be in this study, you will be asked to:
   - Answer questions at the start of the research and 6 months, 1 year, 1½ years, and 2 years from now.
     - If you have not had your puberty blocker put in within 3 months of taking the first survey, you will be asked to retake the first survey.
     - The questions will take about 2 hours to complete each time and will include:
       - how you feel about your body,
       - if you feel sad or happy,
       - other types of feelings that you are having.
   - Let your doctor and some of the people who work with her look at and write down medical information about you.

4. We will also ask your parent/legal guardian to answer questions about you and about how they feel.

When you are in a research study, sometimes good things and bad things can happen:

Study ID: CHLA-16-00108 Valid From: 3/5/2019 To: 3/4/2020

5. Things that happen to children in research studies that make them feel bad are called "risks." Some of the bad things for this research study could be:
   - You might not like some of the questions we ask you. If you don't like a question, you do not have to answer it or you can tell us you want to stop and don't want to answer any more questions.
   - We are very careful with the answers and information you give us so that people won't see it if they're not supposed to, but sometimes they might accidentally find out something.

   Not all of these things may happen to you. None of them may happen. Or things may happen that the doctors don't know about yet.

6. Things that happen to children in research studies that are good are called "benefits." Some of the good things for this research study could be we could learn more about how this medicine affects children and how best to take care of transgender children in the future.

7. We will do everything possible to keep your information private.

8. Your parent will receive payment for each study visit.

9. You do not have to be in this study if you don't want to. You may stop being in this study at any time. Remember, being in this study is up to you.

10. Please talk with your parents before you decide whether or not to be in this study. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes," **you** can still decide not to do this.

11. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, please write it down to help you remember. You can call me or ask me next time you see me.

323-361-3128

12. Signing your name at the bottom means that you agree to be in this study. Your doctors will still take good care of you whether or not you agree to be in this study.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please put a check to mark your decision

_____Yes _____No

Yes, I agree to be in this research study.

_____ _____
Signature of Subject Date

_____
Print Name of Individual Obtaining Assent

_____ _____
Signature of Individual Obtaining Assent Date

Routing of signed copies of the assent form:
1) Give to the child (copy)
2) Give to the parent/legal guardian (copy)
3) Place in the Investigator's research files (original)

Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care – Blocker Cohort

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

Study ID: CHLA-16-00108 Valid From: 3/5/2019 To: 3/4/2020

You are invited to participate in a research study conducted by Johanna Olson-Kennedy, MD, from the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles (CHLA). This research is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. Participation in this study is completely voluntary.

The purpose of the study is to evaluate how taking a medication called gonadotropin releasing hormone (GnRH) agonists used for blocking puberty affects your body. We will do this by looking at information about your bone health and lab results. The study also wants to understand the effects of preventing puberty on your and your parent's or legal guardian's mental health and psychological well-being. There will be a total of 110 youth participating in this study, along with one parent/legal guardian for each youth, at 4 sites across the United States.

If you volunteer to participate in this study, your participation will last 2 years and involve:

- For you:
  - Taking a survey on a computer at the start of the research and 6 months, 1 year, 1½ years, and 2 years after your puberty blocker is put in. The surveys include questions about your gender identity, how you feel about your body, depression, and other mental health issues. The surveys will take about 2 hours to complete each time.
  - If you have not had your puberty blocker put in within 3 months of taking the first survey, you will be asked to retake the first survey.
  - Allowing the research team to collect information from your medical records such as your height and weight, blood pressure, lab results, bone health, medications you take, and diagnoses.
- For your parent/legal guardian:
  - Completing a computer based survey about your child at the start of the research and 6 months, 1 year, 1½ years, and 2 years after your child's puberty blocker is put in. These surveys include questions about your child's gender identity and quality of life. Additionally you will be asked about your experience as a caregiver of a gender non-conforming child. The surveys will take about 2 hours to complete each time.
  - Participating in an interview or additional questionnaires about your child's behaviors and physical and mental health at the start of the research and 1 year and 2 years after

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

your child's puberty blocker is put in. These interviews will take from 1 hour to 2 hours.

It is possible that some questions in the survey may make you feel uncomfortable. If you do not feel comfortable answering a question, you can choose not to answer that question or you can stop filling out the questionnaire. There is the potential of accidental release of confidential information. To protect against this risk, your name and any other personal identifying information will not be shared with anyone else. We will use a secret code on your surveys and forms, and the list that links your name and the secret code is kept in a password-protected file on the CHLA computer network. There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

You should not expect any direct benefit as a result of participating in this research; however, the information that we learn from this research can help us improve care for transgender youth in the future. The alternative to participation is to not participate.

In consideration for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: $50 for each visit; if you participate in all visits, the total amount is $400.

If the payments are greater than $150 per visit or if there is a possibility that you could receive $600 or more for your participation in any Children's Hospital Los Angeles studies, you will need to provide the name, address, date of birth, and social security number (or taxpayer ID number) of the person (family or friend) you'd like to receive the payments. If payments (for all research and/or clinical programs) in a calendar year equal $600 or more, the income will be reported to the IRS and a 1099 form will be issued. The person you designate to receive the payments can use this form with their income tax return, if appropriate.

In addition to payments, and in consideration of the expenses you may have related to participation in the research, you or a family member or friend you designate will receive reimbursement for parking and/or transportation or be provided transportation, as needed. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

To receive either payments or reimbursements (or both), you will be issued a ClinCard, which is a specially designed debit card for clinical research. When a visit is completed, funds will be approved and loaded onto your card and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, please ask the research coordinator for a replacement ClinCard. If the ClinCard funds are not used within 6 months, a fee will be deducted. You will be provided details about the use of the ClinCard in a separate form.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.

If you don't wish to receive payment or reimbursement (or both), you have other choices. You can decline payment and/or reimbursement or you can choose to donate the funds set aside for your participation to Children's Hospital Los Angeles (a non-profit hospital), to be used in the area of greatest need or for a specific program you can designate.

Please let the research team know how you would like to manage the funds set aside for your participation.

This study includes procedures that are also a part of standard treatment. The cost of these procedures will be billed to your insurance or other third-party payer. Your family may be responsible for any co-pays or deductibles.

Only the research team will know that you are a research subject and have access to the information you provide. You will not be identified in publications of the research results. Authorized representatives of the Department of Health and Human Services and the CHLA Institutional Review Board may review subject records but are bound by rules of confidentiality not to reveal your identity. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at CHLA.

You may be removed from the study by the investigator to protect your health or if other situations arise that make it necessary to do so. If you experience certain side effects such as depression, anxiety, or emotional distress because of your participation, you may have to drop out even if you would like to continue. The investigator, Dr. Olson-Kennedy, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to continue participating in the study, you will be informed and your consent to continue participating in the study may be requested.

If you have questions about the research or wish to report a concern or complaint about the research, the Principal Investigator, Dr. Olson, may be reached at 323-361-3128. You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator; or just want to talk to someone other than the Investigator, you may call the CHLA Human Subjects Protection Program at 323-361-2265.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please provide your **initials** beside your decision.

_____Yes _____No [for subject to complete, if the subject is 14 years or older]

_____Yes _____No [for parent to complete, if subject is a minor]

Children's Hospital LOS ANGELES
We Treat Kids Better

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

_____ _____

Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____

Signature of Parent/Legal Guardian Date

_____ _____

Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____

Print Name of Individual Obtaining Consent

_____ _____

Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Routing of signed copies of the form:

1) Give to the subject if at least 14 years old (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital LOS ANGELES
We Treat Kids Better

Children's Hospital Los Angeles

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Addendum to Consent Form for
The Impact of Early Medical Treatment in Transgender Youth
Trans Youth Care

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You are currently enrolled in a research study at Children's Hospital Los Angeles. When you began the study you were under the age of 18 years and your parent or legal guardian gave their permission for you to participate. Now that you are an adult, you have the legal right to consent for your own continued participation.

The original consent form for the study is attached. A member of the research team will discuss the remaining study activities with you. Participation in this study is completely voluntary. Please read the information provided, and ask questions about anything you do not understand, before deciding whether or not to participate.

SIGNATURE OF RESEARCH SUBJECT

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your participation in this research study; and
- You will be given a signed copy of this.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

Study ID: CHLA-16-00108 Valid From: 3/5/2019 To: 3/4/2020

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and have answered all of his/her questions. I believe that he/she understands all of the information described in this document and freely gives consent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

Children's Hospital LOS ANGELES We Treat Kids Better

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Routing of signed copies of the consent form:
1) Give to the subject (copy)
2) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles

ASSENT TO PARTICIPATE IN A RESEARCH STUDY

TRANS YOUTH CARE –
GENDER-AFFIRMING HORMONE COHORT

Subject's Name:			
Medical Record Number:		Birth Date:	

1. Dr. Olson-Kennedy is doing a research study about how using gender-affirming hormones for gender transition affect children and adolescents.

2. We are asking you to take part in this research because we want to learn more about what happens to children and adolescents who are transgender and use gender-affirming hormones for gender transition. We want to see if it changes how your body works and want to know how you feel about transitioning your body to match your gender.

3. If you agree to be in this study, you will be asked to:
   - Answer questions at the start of the research, and 6 months, 1 year, 1½ years, and 2 years after you start gender-affirming hormones.
     - If you have not started gender-affirming hormones within 3 months of taking the first survey – at the start of the research – you will be asked to retake the first survey.
     - The questions will take about 2 hours to complete each time and will include:
       - how you feel about your body
       - if you feel sad or happy
       - drug and alcohol use
       - your physical activity and types of food you eat
       - other types of feelings that you are having
     - At your last study visit, we will also ask you about how it felt being in the study and what you thought about some of the questions we asked you.

Study ID: CHLA-16-00108 Valid From: 3/5/2019 To: 3/4/2020

- Let your doctor and some of the people who work with them look at and write down medical information about you.

When you are in a research study, sometimes good things and bad things can happen:

4. Things that happen to children in research studies that make them feel bad are called "risks." Some of the bad things for this research study could be:
   - You might not like some of the questions we ask you. If you don't like a question, you do not have to answer it or you can tell us you want to stop and don't want to answer any more questions.
   - We are very careful with the answers and information you give us so that people won't see it if they're not supposed to, but sometimes they might accidentally find out something.

   Not all of these things may happen to you. None of them may happen. Or things may happen that the doctors don't know about yet.

5. Things that happen to children in research studies that are good are called "benefits." Some of the good things for this research study could be we could learn more about how this medicine affects children and how best to take care of transgender children in the future.

6. We will do everything possible to keep your information private.

7. You do not have to be in this study if you don't want to. You may stop being in this study at any time. Remember, being in this study is up to you.

8. Your parent will receive payment for each study visit.

9. Please talk with your parent/legal guardian before you decide whether or not to be in this study. We will also ask your parent/legal guardian to give their permission for you to take part in this study. But even if your parent/legal guardian say "yes," **you** can still decide not to do this.

10. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, please write it down to help you remember. You can call me or ask me next time you see me.

323-361-3128

11. Signing your name at the bottom means that you agree to be in this study. Your doctors will still take good care of you whether or not you agree to be in this study.

Contact for future research

May someone from CHLA contact you to invite you to participate in future research? Please put a check to mark your decision

_____Yes _____No

Yes, I agree to be in this research study.

Children's Hospital Los Angeles
We Treat Kids Better

_____ _____

Signature of Subject Date

_____

Print Name of Individual Obtaining Assent

_____ _____

Signature of Individual Obtaining Assent Date

Routing of signed copies of the assent form:

1) Give to the child (copy)
2) Give to the parent/legal guardian (copy)
3) Place in the Investigator's research files (original)

8hil dern' Co'shtai Ho' Argeie'

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

p8e 9T sant of cadiEy elhmai pdeatTert hr pdar'gerledMoYt8
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- F pawhrg a 'YdNeE or a noT sYted at t8e 'tadt of t8e de'eadn8 arl 6 Tort8'Kl Eead Kl½ Eead'K arl 4 Eead' afted EoY 'tadt gerledLaffhdΓhrg 8odΓore') p8e 'YdNeE' hrmiYle qYe'thor' aSoYt EoYd gerledhlerthtEK EoYd gerledLaffhdΓhrg nadeK EoYd s8E'hmai amthNhtEK 8at tEse' of fool EoY eatK8o. EoY feei aSoYt EoYd SolEKles de''horKldYg arl aino8oi Y'eKarl ot8ed Tertai 8eait8 h''Ye') p8e ia't 'YdNeE. hii hrmiYle qYe'thor' aSoYt 8o. EoY feit aSoYt Sehrg hr t8e 'tYlE arl. 8at EoY t8oYg8t aSoYt 'oTe of t8e qYe'thor' EoY. ede a'wel) p8e 'YdNeE'. hii tawe aSoYt 4 8oYd' to noT siete eam8 thTe)
- F Padtlmhsathrg hr ar hrtedNne. od allhthorai qYe'thorrahde' aSoYt EoYd Se8aNhod' arl s8E'hmai arl Tertai 8eait8 at t8e 'tadt of t8e de'eadn8K1 EeadKarl 4 Eead' afted EoY 'tadt gerledLaffhdΓhrg 8odΓore') p8e'e hrtedNne. ' od qYe'thorrahde'. hii tawe fdoT 1 to 4 8oYd')
- F 9f EoY 8aNe rot 'tadtel gerledLaffhdΓhrg 8odΓore'. ht8hr GTort8' of tawhrg t8e fhd't 'YdNeE u at t8e 'tadt of t8e de'eadn8 u EoY. hii Se a'wel to detawe t8e fhd't 'YdNeE)
- F Aiio. hrg t8e de'eadn8 teaT to noiiemt hr fodΓathor fdoT EoY od EoYd Telhmai demodl' 'Yn8 a' EoYd 8ehg8t arl. ehg8t KSiool sde''YdeKiaSde'Yit'KTelhmathor' EoY tawe Klhagro'e'K arl SolEm8arge' fdoT 'tadthrg gerledLaffhdΓhrg 8odΓore')

[1] p8h' fodΓai'o 'edNe' a' t8e sedΓh'hor fodΓ fodt8e sadert,'(to deal arl 'hgr)9r t8h' ma'eK3MoYx defed' to EoYd m8hil)

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9I RB: # CHALI6I2212-

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9t h' so''hSie t8at 'oT e qYe'thor' hr t8e 'YdNeE T aE T awe EoY feei YrmoT fodtaSie) 9f EoY l o rot feei moT fodtaSie ar'. edhr g a qYe'thor KEoY nar m8oo'e r ot to ar'. ed t8at qYe'thor od EoY nar 'tos fhihr g oYt t8e qYe'thor r ahde) p 8ede h' t8e soter thai of amnhl er tai deiea'e of mor fhl er thai hr fodΓathor) po sdobtemt agahr't t8h' dh'wK EoYd r aT e ar l ar E ot8ed sed'or ai hl er thfEhr g hr fodΓathor. hii r ot Se '8adel. ht8 ar Eor e ei'e) " e. hii Y'e a 'emdet mol e or EoYd 'YdNeE' ar l fodΓ'Kar l t8e ih't t8at ihr w' EoYd r aT e ar l t8e 'emdet mol e h' west hr a sa''. odl Isdobtemtel fhie or t8e # CHA moT s Yted r et. odw) p 8ede T aE Se al l hthor ai dh'w' to sadthmhsathor hr t8h' 'tYl E t8at . e l o r ot wr o. aSoYt ar l t8edefode mar r ot l e'mdhSe)

MoY'8oYil r ot e"semt ar E l hdemt Ser efht a' a de'Yit of sadthmhsathr g hr t8h' de'eadm8; 8o. eNedKt8e hr fodΓathor t8at. e ieadr fdoT t8h' de'eadm8 mar 8eis Y' hT sdoNe made fod tdar 'ger l ed EoYt8 hr t8e fYtYde) p 8e aited r athNe to sadthmhsathor h' to r ot sadthmhsate)

9r mor'hl edathor fod EoYd thΓe sadthmhsathr g hr t8h' de'eadm8Kt8e 'tYl E teaT. oYil ihwe to offed EoY saETer t) p 8e saETer t' fod sadthmhsathor ade a' foiio. ': $W2 fod eam8 Nh'ht; hf EoY sadthmhsate hr aii Nh'ht'Kt8e totai aT oYr t h' $U22)

9f t8e saETer t' ade gdeated t8ar $1W2 sed Nh'ht od hf t8ede h' a so''hShht E t8at EoY moYil demehNe $622 od T ode fod EoYd sadthmhsathor hr ar E # 8hil dern' Co'shtai Ho' Ar geie' 'tYl he'KEoY. hii r eel to sdoNhl e t8e r aT eKal l de''Klate of Shdt8Kar l 'omhai 'emYdtE r YT Sed ,od ta"saEed 9D r YT Sed(of t8e sed'or ,faT hiE od fdher l (EoYnl ihwe to demehNe t8e saETer t') 9f saETer t' ,fod aii de'eadm8 ar l /od mihr hmai sdogdaT'(hr a maier l ad Eead eqYai $622 od T odeKt8e hr moT e. hii Se desodtel to t8e 9I k ar l a 1200 fodΓ. hii Se h'Yel) p 8e sed'or EoY l e'hgr ate to demehNe t8e saETer t' mar Y'e t8h' fodΓ. ht8 t8ehdhr moT e ta" detYdr Khf ass dosdhate)

9r al l hthor to saETer t'Kar l hr mor'hl edathor of t8e e"ser'e' EoY T aE 8aNe deiatel to sadthmhsathor hr t8e de'eadm8KEoY od a faT hiE T eT Sed od fdher l EoY l e'hgr ate. hii demehNe dehΓ SYd'eT er t fod sadwhr g ar l /od tdar'sodathor od Se sdoNhl el tdar'sodathor Ka' r eel el) po demehNe dehΓ SYd'eT er t'KEoY. hii r eel to sdoNhl e a r aT e ar l l ate of Shdt8) 5od eam8 e"ser'eK EoY. hii ai'o r eel to 'YSTht demehst' od 'YSTht a Thieage dehΓ SYd'eT er t fodΓ) I ehΓ SYd'eT er t' ade r ot desodtel to t8e 9I k)

po demehNe eht8ed saETer t' od dehΓ SYd'eT er t' ,od Sot8(KEoY. hii Se h'Yel a # ihr # adl K 8hm8 h' a 'semhaiiE l e'hgr el l eSht nadl fod mihr hmai de'eadm8) " 8er a Nh'ht h' moT sietel KfYr l'. hii Se ass doNel ar l ioal el or to EoYd nadl ar l nar Se Y'el at EoYd l h'mdethor) MoY. hii Se h'Yel or e nadl fod t8e l Ydathor of EoYd sadthmhsathor) 9f EoYd nadl h' io't od 'toier Ksiea'e a'w t8e de'eadm8 moodl hr atod fod a desiameT er t # ihr # adl) 9f t8e # ihr # adl fYr l' ade r ot Y'el. ht8hr 6 T or t8'Ka fee. hii Se l el Ymtel) MoY. hii Se sdoNhl el l etahi' aSoYt t8e Y'e of t8e # ihr # adl hr a 'esadate fodΓ)

Aii sed'or ai hr fodΓathor moiiemtel fod saETer t' od dehΓ SYd'eT er t h' 'todel hr a 'emYde fa'8hor ar l. hii Se west moT sieteiE mor fhl er thai)

9f EoY l or mt. h'8 to demehNe saETer t od dehΓ SYd'eT er t ,od Sot8(KEoY 8aNe ot8ed m8ohme') MoY mar l emihr e saETer t ar l /od dehΓ SYd'eT er t od EoY nar m8oo'e to l or ate t8e fYr l' 'et a'hl e fod EoYd sadthmhsathor to # 8hil dern' Co'shtai Ho' Ar geie' ,a r or Isdofht 8o'shtai(Kto Se Y'el hr t8e adea of gdeate't r eel od fod a 'semhfhmsdogdaT EoY nar l e'hgr ate)

Date: 1/44/4210
9I RB: # CHAL16I2212-

Piea'e iet t8e de'eadn8 teaT wr o. 8o. EoY. oYil ihwe to Tar age t8e fYr l' 'et a'hl e fod EoYd sadthmhsathor)

p8h' 'tYl E hr miYl e' sdomel Yde' t8at ade ai'o a sadt of 'tar l adl tdeatTert) p8e mo't of t8e'e sdomel Yde' . hii Se Shiiel to EoYd hr 'Ydar me od ot8ed t8hdl IsadtE saEed) MoYd faT hiE TaE Se de'sor'hSie fodar E moIsaE' odl el YmtlSie')

J riE t8e de'eadn8 teaT . hii wr o. t8at EoY ade a de'eadn8 'YSbemt ar l 8aNe amme'' to t8e hr fodΓathor EoY sdoNhl e) MoY. hii r ot Se hl erthfhel hr sYSihmathor' of t8e de'eadn8 de'Yit') AYt8odhzel desde'er tathNe' of t8e DesadTert of Ceait8 ar l CYTar kedNme' ar l t8e #CHA 9r'thtYthor ai I eNne. Roadl TaE deNne. 'YSbemt demodl ' SYt ade SoYr l SE dYie' of mor fhl er thailtE r ot to deNeai EoYd hl er thtE) po 8eis Y' sdotemt EoYd sdhNamEK. e 8aNe oStahr el a #edhfhmate of #or fhl er thailtE fdoT t8e j athor ai 9r'thtYte' of Ceait8) " ht8 t8h' #edhfhmateKt8e de'eadn8ed' mar r ot Se fodmel to l h'mio'e hr fodΓathor t8at TaE hl er thfE EoYKeNer SE a moYdt 'YSs oer aKhr ar E fel edaiK'tateKod iomai mhNhiKmdhΓ hr aiKal T hr h'tdathNeKieghiathNeKod ot8ed sdomeel hr g') p8e de'eadn8ed' . hii Y'e t8e #edhfhmate to de'h't ar E l eT ar l ' fodhr fodΓathor t8at . oYil hl er thfE EoYK e"nest a' e"siahr el Seio.) MoY'8oYil Yr l ed'tar l t8at a #edhfhmate of #or fhl er thailtE l oe' r ot sdeNer t EoYod a T eT Sed of EoYd faT hiE fdoT NoiYr tadhiE deiea'hr g hr fodΓathor aSoYt EoYd'eif od EoYd hr NoiNeT er t hr t8h' de'eadn8) 9f ar hr 'YdedKeT sioEedKod ot8ed sed'or oStahr' EoYd. dtter mor'er t to demehNe de'eadn8 hr fodΓathor Kt8er t8e de'eadn8ed' TaE r ot Y'e t8e #edhfhmate to . ht88oil t8at hr fodΓathor) p8e #edhfhmate of #or fhl er thailtE l oe' r ot sdeNer t8e de'eadn8ed' fdoT l h'mio'hr g NoiYr tadhiEK. ht8oYt EoYd mor'er tKhr fodΓathor t8at . oYil hl er thfE EoY a' a sadthmhsar t hr t8e de'eadn8 sdotemt Yr l ed t8e foiio. hr g mhdmYT 'tar me':

L NoiYr tadE l h'mio'Yde SE de'eadn8ed' of hr fodΓathor or 'Ym8 t8hr g' a' n8hil od eil ed aSY'eKdesodtaSie moT T Yr hmaSie l h'ea'e'Kod so''hSie t8deat to 'eif od ot8ed')

A #edhfhmate of #or fhl er thailtE l oe' r ot desde'er t ar er l od'eT er t of t8e de'eadn8 'tYl E SE t8e DesadTert of Ceait8 ar l CYTar kedNme' od t8e j athor ai 9r'thtYte' of Ceait8)

MoYd n8ohme aSoYt . 8et8ed od r ot to sadthmhsate . hii 8aNe r o effemt or EoYd madeK'edNme' od Ser efht' at #8hil dern' Co'shtai Ho' Ar geie') 9f EoY agdee to sadthmhsateKSYt iated l emhl e to . ht8l da. fdoT t8h' 'tYl EKEoY T aE l o 'o. ht8oYt affemthr g EoYd dhg8t' to 8eait8 madeK'edNme' od ot8ed Ser efht' at #CHA)

MoY TaE Se deT oNel fdoT t8e 'tYl E SE t8e hr Ne'thgatod to sdotemt EoYd 8eait8 od hf ot8ed 'htYathor' adh'e t8at Tawe ht r eme''adE to l o 'o) 9f EoY e"sedher me medtahr 'hl e effemt' 'Ym8 a' l es de''hor Kar"hetEKod eT othor ai l h'tde'' SemaY'e of EoYd sadthmhsathor KEoY T aE 8aNe to l dos oYt eNer hf EoY. oYil ihwe to mor thr Ye) p8e hr Ne'thgatodKDd) J i'or IOer r el EK. hii Tawe t8e l emh'hor ar l iet EoY wr o. hf ht h' r ot so''hSie fod EoY to mor thr Ye) p8e l emh'hor T aE Se T al e eht8ed to sdotemt EoYd 8eait8 ar l 'afetEKod SemaY'e ht h' sadt of t8e de'eadn8 siar t8at seosie. 8o l eNeios medtahr mor l hthor' T aE r ot mor thr Ye to sadthmhsate)

9f t8ede h' 'hgr hfhmar t r e. hr fodΓathor foYr l l Ydhr g t8e moYd'e of t8e 'tYl E od t8e de'eadn8 siar h' n8ar gel hr a. aE t8at T hg8t affemt EoYd l emh'hor to mor thr Ye sadthmhsathr g hr t8e 'tYl EKEoY. hii Se hr fodΓel ar l EoYd mor'er t to mor thr Ye sadthmhsathr g hr t8e 'tYl E T aE Se deqYe'tel)

9f EoY 8aNe qYe'thor' aSoYt t8e de'eadm8 od . h'8 to desodt a mor medr od moT siahrt aSoYt t8e de'eadm8Kt8e Pdhr mhsai 9rNe'thgatodKDd) J i'or LOerr el EKTaE Se deam8el at G4GLG61LGl4-) MoY TaE. ht8l da. fdoT t8h' 'tYl E at ar EthTe arl l h'mor thr Ye sadthmhsathor . ht8oYt ser aitE) MoY ade r ot . ahNhr g ar E iegai miahT 'Kdhg8t' od deT el he' SemaY'e of EoYd sadthmhsathor hr t8h' de'eadm8 'tYl E) 9f EoY 8aNe qYe'thor' degadl hr g t8e dhg8t' of de'eadm8 'YSbemt' od hf EoY 8aNe moT siahr t' od mor medr' aSoYt t8e de'eadm8 ar l mar r ot deam8 t8e Pdhr mhsai 9rNe'thgatod, od bY't . ar t to taiw to 'oT eor e ot8ed t8ar t8e 9rNe'thgatodK EoY TaE maii t8e #CHA CYT ar kYSbemt' Pdotemthor Pdogda T at G4GLG61L446W)

Contact for future research

y aE'oT eor e fdoT #CHA mor tamt EoY to hr Nte EoY to sadthmhsate hr fYtYde de'eadm8? Piea'e sdoNhl e EoYdhr hthai' Se'hl e EoYdl emh'hor)

_____Me' _____j o [fod'YSbemt to moT sieteKhf t8e 'YSbemt h' 1UEead' odoil ed]

_____Me' _____j o [fodsader t to moT sieteKhf 'YSbemt h' a T hr od]

SIi NATURE Ol RESEARCH SUGFECT Bf the suJ(ect bs 1j 4ears or oyder)

MoYd'hgr atYde Seio. hr l hmate'

- MoY 8aNe deal t8h' l omYT er t ar l Yr led'tar l ht' T ear hr g;
- MoY 8aNe 8al a m8ar me to a'wqYe'thor' ar l 8aNe 8al t8e'e qYe'thor' ar '. edel to EoYd 'ath'famthor;
- MoY mor 'er t/a''er t to EoYd sadthmhsathor hr t8h' de'eadm8 'tYl E; ar l
- MoY. hii Se ghNer a 'hgr el mos E of t8h')

_____
Pdhr t j aT e of kYSbemt

_____ _____
khgr atYde of kYSbemt Date

SIi NATURE Ol PARENTBS)/LEi AL i UARDIANBS) Hf the suJ(ect bs a mhnor)

MoYd'hgr atYde,'(Seio. hr l hmate'

- MoY 8aNe deal t8h' l omYT er t ar l Yr l ed'tar l ht' T ear hr g;
- MoY 8aNe 8al a n8ar me to a'wqYe'thor ' ar l 8aNe 8al t8e'e qYe'thor ' ar '. edel to EoYd 'ath'famthor ;
- MoY agdee to EoYdm8hil n' sadhmbsathor hr t8h' de'eadn8 'tYl E; ar l
- MoY. hii Se ghNer a 'hgr el mosE of t8h' fodT)

_____ _____

Pdhr t j aT e,'(of Padert,'(/Hegai – Yadl har,'(

_____ _____

khgr atYde of Padert/Hegai – Yadl har Date

_____ _____

khgr atYde of Padert/Hegai – Yadl har Date

SIi NATURE Ol INDIVIDUAL OGTAININi CONSENT

9 8aNe e"siahr el t8e de'eadn8 to t8e 'YSbemt ar l /od t8e 'YSbemtn' sadert,'(/iegai gYadl har,'(ar l 8aNe ar '. edel aii of t8ehd qYe'thor ') 9 SeiheNe t8at t8eE Yr l ed'tar l aii of t8e hr fodT athor l e'mdfSel hr t8h' l omYT er t ar l fdeeiE ghNe mor 'er t/sedT h''hor /a''er t to sadhmbsate)

_____

Pdhr t j aT e of 9r l hNhl Yai J Stahr hr g # or 'er t

_____ _____

khgr atYde of 9r l hNhl Yai J Stahr hr g # or 'er t Date

Date: 1/44/4210
9I RB: # CHAL16I2212-

SIi NATURE Ol WITNESS Bf appyheaJye)

MoYd'hgratYde Seio. hrlhmate':

- 9. a' sde'ert fodt8e erthde mor'ert mor federme;
- p8e hr fodΓathor hr t8e mor'ert lomYTert arl arEot8ed. dtter hr fodΓathor . a' ammYdateiEe"siahrel to t8e 'YSbemtarl/odt8e 'YSbemtn' sadert,'(/iegai gYadlhar,'(;
- p8e 'YSbemtarl/odt8e 'YSbemtn' sadert,'(/iegai gYadlhar,'(8al ar ossodtYrhtE to a'w qYe'thor' arl t8o'e qYe'thor' . ede ar'. edel; arl
- p8e 'YSbemtarl/odt8e 'YSbemtn' sadert,'(/iegai gYadlhar,'(NoiYrtadhiE'hgrel t8e mor'ert/sedΓh'hor/a''ert fodΓ hr TEsde'erme)

_____

Pdrtj aTe of "htre''

_____ _____

khgratYde of "htre'' Date

I oYthrg of 'hgrel mosle' of t8e fodΓ:
1(–hNe to t8e 'YSbemthfatiea't 1UEead' oil ,mosE(
4(–hNe to t8e sadert/iegai gYadlhar hf 'YSbemth' a Throd,mosE(
C(Piame hr t8e Pdrmhsai 9rNe'thgatodn' de'eadn8 fhie ,odhghrai(

Children's Hospital LOS ANGELES
We Treat Kids Better

Children's Hospital Los Angeles

CONSENT/PERMISSION/ASSENT[1] TO PARTICIPATE IN A RESEARCH STUDY

The Impact of Early Medical Treatment in Transgender Youth

Trans Youth Care – Gender-Affirming Hormone Cohort

Addendum: New Information

Subject's Name:	_____		
CHLA#:	_____	Birth Date:	_____

You were previously informed that if there was significant new information found during the course of the study or the research plan was changed in a way that might affect your decision to continue participating in the study, you would be informed and your consent to continue participating in the study could be requested.

The research plan for the study in which you are currently participating at Children's Hospital Los Angeles has changed.

The research study team would like to ask you some questions about how you felt being in the research study and how you felt answering some of the questions in the computer survey.

You have the right to withdraw from this research study at any time and discontinue participation without penalty. Your choice about whether or not to continue participating will have no effect on your care, services or benefits at Children's Hospital Los Angeles.

The original consent form for the study is attached. A member of the research team will discuss the new information with you. Continued participation in this study is completely voluntary. Please read the information provided and ask questions about anything you do not understand, before deciding whether or not to continue participating in the research.

If after receiving this information you agree to continue taking part in this research study, please sign below.

[1] This form also serves as the permission form for the parent(s) to read and sign. In this case, "You" refers to your child.

Study ID: CHLA-16-00108 Valid From: 3/5/2019 To: 3/4/2020

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study; and
- You will be given a signed copy of this form.

_____ _____
Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____
Signature of Parent/Legal Guardian Date

_____ _____
Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

My signature as Witness indicates that the subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed this consent/permission/assent form addendum in my presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INTERPRETER (if applicable)

_____
Print Name of Interpreter

_____ _____
Signature of Interpreter Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information.)

_____

_____

Date:_____

Time:_____ Signature_____

Routing of signed copies of the form:
1) Give to the subject (copy)
2) Give to the parent/legal guardian if subject is a minor (copy)
3) Place in the Principal Investigator's research file (original)

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Feminizing Medications (transfeminine individuals on GnRH analogs)

This form refers to the use of estrogen by persons in the male-to-female spectrum who wish to become feminized to reduce gender dysphoria and facilitate a more feminine gender presentation. While there are risks associated with taking feminizing medications, when appropriately prescribed they can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking feminizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

1. Estrogen is being prescribed to reduce male physical features and feminize the body.

2. The feminizing effects of estrogen can take several months or longer to become noticeable, and that the rate and degree of change can't be predicted.

3. If you are taking estrogen you will probably develop breasts, and:

- Although most breast development occurs over the first two years of starting hormones, they may take several years to develop to their full size.
- Even if estrogen is stopped, the breast tissue that has developed will remain.
- There may be milky nipple discharge (galactorrhea). This can be caused by taking estrogen or by an underlying medical condition. It is advised to check with a doctor to determine the cause.
- Reported cases of breast cancer in transgender women are extraordinarily rare, and only 10 cases have been reported in the literature as of 2016.

4. The following changes are generally not permanent (that is, they will likely reverse if I stop taking feminizing medications):

- Skin may become softer.
- Fat may redistribute to a more feminine pattern (decreased in abdomen, increased on buttocks/hips/thighs – changing from "apple shape" to "pear shape").

5. Taking feminizing medications after or while being on GnRH analogs will likely lead to infertility, particularly when GnRH analogs have been started in early puberty.

- Sperm will not mature, leading to infertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication.
- The amount of fluid ejaculated may be reduced.
- There is typically a decrease in morning and spontaneous erections.
- Erections may not be firm enough for penetrative sex.

• Libido (sex drive) may decrease.

Risks of Feminizing Medications

The medical effects and safety of feminizing medications in youth younger than age 18 are not fully understood, there may be long-term risks that are not yet known. You are strongly advised not to take more medication than prescribed, as this increases health risks. Taking more than prescribed will not make feminization happen more quickly or increase the degree of change. Also, extra estrogen can be converted to testosterone, which may slow or stop feminization.

6. Estrogen minimally increases the risk of blood clots, which can result in:

- pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- stroke, which may cause permanent brain damage or death
- heart attack
- chronic leg vein problems

If you experience any of the following symptoms, you should call 911, or go to the emergency room:

- Unexplained shortness of breath
- Rapid breathing
- Chest pain
- Rapid heart rate
- Light headedness or passing out
- Leg pain or tenderness, especially in the calf
- Leg swelling

The risk of blood clots is worse if you smoke cigarettes. Please be advised that you should stop smoking completely if you start taking estrogen.

7. Estrogen can occasionally result in the following physiologic changes:

- increase deposits of fat around my internal organs, which is associated with increased risk for diabetes and heart disease.
- increased blood pressure
- increased risk of gallstones
- nausea and vomiting, similar to morning sickness in pregnant women
- headaches or migraines

8. In very rare instances, estrogen increases the risk of non-cancerous tumors of the pituitary gland (prolactinoma). Although prolactinomas are typically not life-threatening, it can damage vision and cause headaches. Your prolactin will be checked when you first start taking estrogen.

9. Dangerous side effects from estrogen are greater in those who: smoke, are overweight, have a history of blood clots or high blood pressure.

Feminizing medications will result in changes that will be noticeable by other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Please be advised that referrals can be made for support/counseling if this would be helpful.

Some people experience changes in their mood when taking estrogen. We strongly encourage youth to establish or continue in mental health therapy for support of this change, and other challenges that may arise as a result of physical gender transition.

Preventing Medical Complications

Taking feminizing medications as prescribed and letting your health care provider know if you are not happy with the treatment or are experiencing any problems helps prevent potential complications.

The right dose or type of medication prescribed for you may not be the same as for someone else, so it's best not to compare to others also undergoing physical gender transition.

Physical examinations and blood tests are needed on a regular basis to check for negative side effects of feminizing medications.

Some medical conditions make it dangerous to take estrogen. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.

You can choose to stop taking feminizing medication at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

My signature below confirms that:

- My doctor has talked with me about the benefits and risks of feminizing medication, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- I understand the risks that may be involved.
- I understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- I have had sufficient opportunity to discuss treatment options with my doctor. All of my questions have been answered to my satisfaction.

_____ _____
Patient Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Feminizing Medications

This form refers to the use of estrogen and/or androgen antagonists (sometimes called “anti-androgens” or “testosterone blockers”) by persons in the male-to-female spectrum who wish to become feminized to reduce gender dysphoria and facilitate a more feminine gender presentation. While there are risks associated with taking feminizing medications, when appropriately prescribed they can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking feminizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Feminizing Effects

1. Estrogen, androgen antagonists, or a combination of the two may be prescribed to reduce male physical features and feminize the body.

2. The feminizing effects of estrogen and androgen antagonists can take several months or longer to become noticeable, and that the rate and degree of change can’t be predicted.

3. If you are taking estrogen you will probably develop breasts, and:

- Although most breast development occurs over the first two years of starting hormones, they may take several years to develop to their full size.
- Even if estrogen is stopped, the breast tissue that has developed will remain.
- There may be milky nipple discharge (galactorrhea). This can be caused by taking estrogen or by an underlying medical condition. It is advised to check with a doctor to determine the cause.
- Reported cases of breast cancer in transgender women are extraordinarily rare, and only 10 cases have been reported in the literature as of 2016.

4. The following changes are generally not permanent (that is, they will likely reverse if I stop taking feminizing medications):

- Skin may become softer.
- Muscle mass decreases and there may be a decrease in upper body strength.
- Body hair growth may become less noticeable and grow more slowly, but it will likely not stop completely even after years on medication.
- Male pattern baldness may slow down, but will probably not stop completely, and hair that has already been lost will likely not grow back.
- Fat may redistribute to a more feminine pattern (decreased in abdomen, increased on buttocks/hips/thighs – changing from “apple shape” to “pear shape”).

5. Feminizing medications will make the testicles produce less testosterone, which can affect overall sexual function:

• Sperm may not mature, leading to reduced fertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication. The options for sperm banking have been explained. People taking estrogen may still be able to make someone pregnant.

• Testicles may shrink by 25-50%. Regular testicular examinations are still recommended.

• The amount of fluid ejaculated may be reduced.

• There is typically a decrease in morning and spontaneous erections.

• Erections may not be firm enough for penetrative sex.

• Libido (sex drive) may decrease.

6. Some aspects of body are not significantly changed by feminizing medications:

• Beard/moustache hair may grow more slowly and be less noticeable, but will not go away.

• Voice pitch will not rise and speech patterns will not become more feminine.

• The laryngeal prominence (“Adam’s apple”) will not shrink.

Although feminizing medication does not change these features, there are other treatments that may be helpful. If there are any concerns about these issues, referrals can be provided to help explore treatment options.

Risks of Feminizing Medications

The medical effects and safety of feminizing medications in youth younger than age 18 are not fully understood, and that there may be long-term risks that are not yet known. You are strongly advised not to take more medication than prescribed, as this increases health risks. Taking more than prescribed will not make feminization happen more quickly or increase the degree of change. Also, extra estrogen can be converted to testosterone, which may slow or stop feminization.

7. Estrogen minimally increases the risk of blood clots, which can result in:

- pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- stroke, which may cause permanent brain damage or death
- heart attack
- chronic leg vein problems

If you experience any of the following symptoms, you should call 911, or go to the emergency room:

- Unexplained shortness of breath
- Rapid breathing
- Chest pain
- Rapid heart rate
- Light headedness or passing out
- Leg pain or tenderness, especially in the calf
- Leg swelling

The risk of blood clots is worse if you smoke cigarettes. Please be advised that you should stop smoking completely if you start taking estrogen.

8. Estrogen can occasionally result in the following physiologic changes:

- increase deposits of fat around my internal organs, which is associated with increased risk for diabetes and heart disease.
- increased blood pressure
- increased risk of gallstones
- nausea and vomiting, similar to morning sickness in pregnant women
- headaches or migraines

9. In very rare instances, estrogen increases the risk of non-cancerous tumors of the pituitary gland (prolactinoma). Although prolactinomas are typically not life-threatening, it can damage vision and cause headaches. Your prolactin will be checked when you first start taking estrogen.

10. Dangerous side effects from estrogen are greater in those who: smoke, are overweight, have a history of blood clots or high blood pressure.

Feminizing medications will result in changes that will be noticeable by other people, and that some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Please be advised that referrals can be made for support/counseling if this would be helpful.

Some people experience changes in their mood when taking estrogen. We strongly encourage youth to establish or continue in mental health therapy for support of this change, and other challenges that may arise as a result of physical gender transition.

Risks Associated with Androgen Antagonists

Spironolactone affects the balance of water and salts in the kidneys, and that this may:

- increase the amount of urine produced, making it necessary to urinate more frequently
- reduce blood pressure
- increase thirst
- rarely, cause high levels of potassium in the blood, which can cause changes to heart rhythm that may be life-threatening

Preventing Medical Complications

Taking feminizing medications as prescribed and letting your health care provider know if you are not happy with the treatment or are experiencing any problems helps prevent potential complications.

The right dose or type of medication prescribed for you may not be the same as for someone else, so it’s best not to compare to others also undergoing physical gender transition.

Physical examinations and blood tests are needed on a regular basis to check for negative side effects of feminizing medications.

Some medical conditions make it dangerous to take estrogen. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.

You can choose to stop taking feminizing medication at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

My signature below confirms that:

- My doctor has talked with me about the benefits and risks of feminizing medication, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- I understand the risks that may be involved.
- I understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- I have had sufficient opportunity to discuss treatment options with my doctor. All of my questions have been answered to my satisfaction.

_____ _____
Patient Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Parent/Caretaker Signature Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

PUBERTAL BLOCKERS FOR MINORS IN EARLY ADOLESCENCE

Parent or Guardian Consent

Before initiating a medication for your child to put puberty "on hold", there are several things you need to know. There are possible advantages, disadvantages and risks with pubertal blockers. It's important that you understand all of this information before your child begins the medication.

Please read the following carefully and ask us any questions. We want you to be very comfortable and sure of what pubertal blockers offer your child.

After your questions and concerns are addressed and you have decided to proceed with the pubertal blocker medication for your child, both of you will need to sign this information and consent form.

What are the different medications that can help to stop the physical changes of puberty?

The main way that the physical changes of puberty can be put on hold is by blocking the signal from the brain to the organs that make the hormones of puberty. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

The medications are called Pubertal Blockers. They are also known as a class of medication called GnRH analogues. These medications are given monthly, once every three months, or in the form of an implant that is placed in the upper arm, and stays in for 12-24 months. This medication is effective for both males and females. They can be started just after the early physical changes of puberty.

For transgender girls there are alternative medicines that can block the effect of testosterone. The most common medication of this type is called spironolactone. There is a separate consent form for this medication. Spironolactone is not as effective at blocking puberty in transgender girls, but it is much less expensive.

Every medication has risks, benefits, and side effects that are important to understand before starting. It is also important to know how they work.

Medications for Blocking Puberty

- Puberty Blockers are used to help temporarily suspend or block the physical changes of puberty for your child.

- It can take several months for the medication to be effective. While no one can predict how quickly or slowly your child's body will respond, most youth respond within 3-4 weeks of initiating blockers.

- This medication is not specifically made for the purpose of blocking puberty (they are not FDA approved for this purpose) in transgender youth, however pediatric endocrinologists (children's doctors who work with hormones and puberty), recommend these medications if the physical changes of puberty need to be postponed. They have been in use for this purpose for more than 30 years.

- The medication is not permanent. If your child stops getting the injections, or has the implant removed, in about six months their body will restart the changes of puberty at the developmental stage they were at when they started the hormone blocker.

- By taking these medications, your child's body will not be making the hormones of puberty, testosterone or estrogen.

- Providing these medicines to your child may assist in avoiding the unhappiness and trauma of unwanted puberty, giving your child the opportunity to develop in their affirmed gender, with a better fit between body and psyche. It may also help them avoid the need for surgeries and other treatments (i.e. mastectomies for transmen, tracheal shaving or electrolysis for transwomen) that would be required to try to reverse the effects of puberty.

- If you are interested in getting more information about puberty suppression, we can refer you to an endocrinologist.

- We recommend that your child and family participate in therapy with a therapist experienced in gender issues while your child is taking the hormone blocker.

Risks of Puberty Blockers

- The side effects and the safety of these medicines are not completely understood. There may be long-term risks that are not yet known.

- If your child starts puberty blockers in the earliest stages of puberty, and then goes on to gender affirming hormones, they will not develop sperm or eggs. This means that they will not be able to have biological children. *This is an important aspect of blocking puberty and progressing to hormones that you should understand prior to moving forward with puberty suppression.* If your child discontinues the use of blockers, and does not go on gender affirming hormones, they will continue their pubertal development about 6-12 months after stopping the medication, and fertility would be maintained.

- While on puberty blockers, your child's bone density will go back to developing at a pre-pubertal rate. While the clinical impact of this is not yet known, we will obtain bone density

scans at the beginning of puberty suppression, and each year thereafter to monitor your child's bone density.

- It's possible that your child will get taller while on these medications. This can be problematic for transgender girls to achieve a typical female height. In transgender boys, delaying the onset of puberty may actually make him slightly taller (one of the reasons that girls are usually shorter than boys is because puberty is started earlier).

- These medicines will be stopping the development of puberty for your child and other people may notice. As your child becomes older, this may become more apparent.

- Some transgender people have experienced harassment and discrimination. You can get resources that will support your child and your family. Parents and guardians frequently have to advocate for children to participate safely and free from harassment in schools and other activities. You can ask your child's provider and therapist for help advocating for your child.

Prevention of Medical Complications

- Please take your puberty blocking medication as prescribed. Tell your health care provider if your child has any problems or side effects or is unhappy with the medication.

- Your child needs periodic check-ups to make sure that your child is responding appropriately.

- Using these medicines to block puberty is an off-label use. This means it is not approved by the Food and Drug Administration for this specific use. This medication is recommended for your child based on the judgment and experience of our health care provider and is supported by the Society of Pediatric Endocrinology.

- Your child can choose to stop taking these medications at any time. If your child decides to do that, stop the medications with the help of your health care provider.

Our signatures below confirm that

- Your child's health care provider has talked with you about the benefits and risks of puberty blockers for your child.

- The possible or likely consequences of using puberty blockers and potential alternative treatments.

- You understand the risks that may be involved.

- You know that the information in this form includes the known effects and risks. You also know that there may be unknown long-term effects or risks.

- You have had enough opportunity to discuss treatment options with your child's health care provider.

- All of your questions have been answered to your satisfaction.

- You have enough information to provide informed consent for your child to take, refuse, or postpone using puberty blocking medications.
- Your child is in agreement with this treatment and the signature of your child on this form attests to this agreement.
- Your signature attests to your consent for your child to begin the puberty suppression with GnRH analogs.

Patient Signature	Date
Parent or Guardian signature	Date
Parent or Guardian signature	Date
Prescribing clinician signature	Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Testosterone Therapy

This form refers to the use of testosterone by persons in the female-to-male spectrum who wish to become more masculine to reduce gender dysphoria and facilitate a more masculine gender presentation. While there are risks associated with taking testosterone, when appropriately prescribed it can greatly improve mental health and quality of life.

This form covers the known and unknown benefits, risks, and changes that may occur from taking masculinizing medication. If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Masculinizing Effects

Testosterone is being prescribed to reduce female physical characteristics and masculinize your body. The masculinizing effects of testosterone can take several months or longer to become noticeable, the rate and degree of change can't be predicted, and changes may not be complete for 2-5 years after you start testosterone.

1. The following changes will likely be permanent even if you stopped taking testosterone:
    - Lower voice pitch (i.e., voice becoming deeper).
    - Increased growth of hair, with thicker/coarser hairs, on arms, legs, chest, back, and abdomen.
    - Gradual growth of moustache/beard hair.
    - Hair loss at the temples and crown of the head, with the possibility of becoming completely bald.
    - Genital changes may or may not be permanent if testosterone is stopped early. These include clitoral growth (typically 1-3 cm) and vaginal dryness.

2. The following changes are usually not permanent (that is, they will likely reverse if you stop taking testosterone):
    - Acne, which may be severe and can cause permanent scarring if not treated.
    - Fat may redistribute to a more masculine pattern (decreased on buttocks/hips/thighs, increased in abdomen – changing from "pear shape" to "apple shape").
    - Increased muscle mass and upper body strength.
    - Increased libido (sex drive).
    - Menstrual periods typically stop within 1-6 months of starting testosterone.
3. It is not known what the effects of testosterone are on fertility. Even if you stop taking testosterone it is uncertain if you will be able to get pregnant in the future. Even after testosterone stops your menstrual periods it may still be possible for you to get pregnant, and we advise that you consider birth control options (if applicable). You cannot take testosterone if you are pregnant

4. Your chest tissue may appear slightly smaller due to fat loss, but will not substantially shrink.

Risks of Testosterone

The medical effects and safety of testosterone use in those younger than 18 are not fully understood, and there may be long-term risks that are not yet known.

You are strongly advised not to take more testosterone than prescribed, as this increases health risks. Taking more than prescribed will not make masculinization happen more quickly or increase the degree of change: extra testosterone can be converted to estrogen, which may slow or stop masculinization.

The following are potential medical risks of testosterone:

- Increase your risk of heart disease, including:
    - decreasing good cholesterol (HDL) and increasing bad cholesterol (LDL)
    - increasing blood pressure
    - increasing deposits of fat around your internal organs

  Your risk of heart disease is greater if people in your family have had heart disease, if you are overweight, or if you smoke. Heart health checkups, including monitoring of your weight and cholesterol levels, should be done periodically as long as you are taking testosterone.

- Increase the red blood cells and hemoglobin, and while the increase is usually only to a normal male range (which does not pose health risks), a high increase can cause potentially life-threatening problems such as stroke and heart attack. Your blood should be monitored periodically while you are taking testosterone.

- Increase your risk for diabetes by decreasing your body's response to insulin, causing weight gain, and increasing deposits of fat around your internal organs. Your fasting blood glucose should be monitored periodically while you are taking testosterone.

- Lead to your cervix and the walls of your vagina becoming more fragile, and that this can lead to tears or abrasions that increase the risk of sexually transmitted infections (including HIV) if you have vaginal sex – no matter what the gender of your partner is. Frank discussion with your doctor about your sexual practices can help determine how best to prevent and monitor for sexually transmitted infections.

- Cause headaches or migraines. If you are frequently having headaches or migraines, or the pain is unusually severe, it is recommended that you talk with your health care provider.

- Testosterone can cause emotional changes, including increased irritability, frustration, and anger. We can assist you in finding resources to explore and cope with these changes if necessary.

Testosterone will result in changes that will be noticeable by other people, and some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Your care team can assist in finding advocacy and support resources.

Prevention of Medical Complications

In order to decrease potential medical complications, take testosterone as prescribed and tell your doctor if you are not happy with the treatment or are experiencing any problems.

- The right dose or type of medication prescribed for you may not be the same as for someone else.
- Physical examinations and blood tests are needed on a regular basis to check for negative side effects of testosterone.
- Some medical conditions make it dangerous to take testosterone. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.
- You can choose to stop taking testosterone at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

Your signature below confirms that:

- Your doctor has talked with you about the benefits and risks of testosterone, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- You understand the risks that may be involved.
- You understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- You have had sufficient opportunity to discuss treatment options with your doctor. All of your questions have been answered to your satisfaction.
- You believe you have adequate knowledge on which to base informed consent to the provision of testosterone therapy.

_____ _____
Patient Signature Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Provider Signature Date

Children's Hospital LOS ANGELES
THE CENTER FOR TRANSYOUTH HEALTH AND DEVELOPMENT

Informed Consent Form for Testosterone Therapy (for youth on GnRH analogs)

This form refers to the use of testosterone by persons in the female-to-male spectrum who wish to become more masculine to reduce gender dysphoria and facilitate a more masculine gender presentation. While there are risks associated with taking testosterone, when appropriately prescribed it can greatly improve mental health and quality of life.

If you have any questions or concerns about the information below, please talk with the people involved in your care so you can make fully informed decisions about your treatment. It is your right to seek another opinion if you want additional perspective on any aspect of your care.

Masculinizing Effects

Testosterone is being prescribed to reduce female physical characteristics and masculinize your body. The masculinizing effects of testosterone can take several months or longer to become noticeable, the rate and degree of change can't be predicted, and changes may not be complete for 2-5 years after you start testosterone.

1. The following changes will likely be permanent even if you stopped taking testosterone:
    - Lower voice pitch (i.e., voice becoming deeper).
    - Increased growth of hair, with thicker/coarser hairs, on arms, legs, chest, back, and abdomen.
    - Gradual growth of moustache/beard hair.
    - Hair loss at the temples and crown of the head, with the possibility of becoming completely bald.
    - Genital changes may or may not be permanent if testosterone is stopped. These include clitoral growth (typically 1-3 cm) and vaginal dryness.

2. The following changes are usually not permanent (that is, they will likely reverse if you stop taking testosterone):
    - Acne, which may be severe and can cause permanent scarring if not treated.
    - Fat may redistribute to a more masculine pattern (decreased on buttocks/hips/thighs, increased in abdomen – changing from "pear shape" to "apple shape").
    - Increased muscle mass and upper body strength.
    - Increased libido (sex drive).
    - Menstrual periods typically stop within 1-6 months of starting testosterone.
3. It is not known what the effects of testosterone are on fertility. If you started puberty blockers in the early stages of your puberty, then you will not have mature enough eggs to reproduce. Even if you stop taking testosterone and blockers, and progress through your puberty, it is uncertain if you will be able to get pregnant in the future. While it is unlikely that you could get pregnant while on blockers

and testosterone, we strongly recommend that you use condoms for prevention of pregnancy and transmission of sexually transmitted infections.

4. If you developed chest tissue prior to starting blockers, it may appear slightly smaller when starting testosterone due to fat loss, but will not substantially shrink.

Risks of Testosterone

The medical effects and safety of testosterone use in those younger than 18 are not fully understood, and that there may be long-term risks that are not yet known.

You are strongly advised not to take more testosterone than prescribed, as this increases health risks. Taking more than prescribed will not make masculinization happen more quickly or increase the degree of change: extra testosterone can be converted to estrogen, which may slow or stop masculinization.

The following are potential medical risks of testosterone:

- Increase your risk of heart disease, including:
    - decreasing good cholesterol (HDL) and increasing bad cholesterol (LDL)
    - increasing blood pressure
    - increasing deposits of fat around your internal organs

Your risks of heart disease are greater if people in your family have had heart disease, if you are overweight, or if you smoke. Heart health checkups, including monitoring of your weight and cholesterol levels, should be done periodically as long as you are taking testosterone.

- Cause damage to the liver, possibly leading to liver disease. Monitoring for possible liver damage as long as you are taking testosterone is advised.

- Increase the red blood cells and hemoglobin, and while the increase is usually only to a normal male range (which does not pose health risks), a high increase can cause potentially life-threatening problems such as stroke and heart attack. Your blood should be monitored periodically while you are taking testosterone.

- Increase your risk for diabetes by decreasing your body's response to insulin, causing weight gain, and increasing deposits of fat around your internal organs. Your fasting blood glucose should be monitored periodically while you are taking testosterone.

- Lead to your cervix and the walls of your vagina becoming more fragile, and that this can lead to tears or abrasions that increase the risk of sexually transmitted infections (including HIV) if you have vaginal sex – no matter what the gender of your partner is. Frank discussion with your doctor about your sexual practices can help determine how best to prevent and monitor for sexually transmitted infections.

- Cause headaches or migraines. If you are frequently having headaches or migraines, or the pain is unusually severe, it is recommended that you talk with your health care provider.

- Testosterone can cause emotional changes, including increased irritability, frustration, and anger. I have been advised that your doctor can assist me in finding resources to explore and cope with these changes.

Testosterone will result in changes that will be noticeable by other people, and that some transgender people in similar circumstances have experienced harassment, discrimination, and violence, while others have lost support of loved ones. Your care team can assist in finding advocacy and support resources.

Prevention of Medical Complications

In order to decrease potential medical complications, take testosterone as prescribed and tell your doctor if you are not happy with the treatment or are experiencing any problems.

- The right dose or type of medication prescribed for you may not be the same as for someone else.
- Physical examinations and blood tests are needed on a regular basis to check for negative side effects of testosterone.
- Testosterone can interact with other medication (including other sources of hormones), dietary supplements, herbs, alcohol, and street drugs. Let your healthcare provider know if you are concerned about any of these potential interactions.
- Some medical conditions make it dangerous to take testosterone. If your doctor suspects you might have one of these conditions, they may want to get those issues controlled before you start taking hormones.
- You can choose to stop taking testosterone at any time, it is advised that you do this with the help of your doctor to make sure there are no negative reactions to stopping.

Your signature below confirms that:

- Your doctor has talked with you about the benefits and risks of testosterone, the possible or likely consequences of hormone therapy, and potential alternative treatment options.
- You understand the risks that may be involved.
- You understand that this form covers known effects and risks and that there may be long-term effects or risks that are not yet known.
- You have had sufficient opportunity to discuss treatment options with your doctor. All of your questions have been answered to your satisfaction.
- You believe you have adequate knowledge on which to base informed consent to the provision of testosterone therapy.

_____ _____
Patient Signature Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Parent/Caregiver Signature (for minors) Date

_____ _____
Provider Signature Date

Neutral Citation Number: [2020] EWHC 3274 (Admin)

Case No: CO/60/2020

IN THE HIGH COURT OF JUSTICE
ADMINISTRATIVE COURT
DIVISIONAL COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 01/12/2020

Before :

THE PRESIDENT OF THE QUEEN'S BENCH DIVISION
LORD JUSTICE LEWIS
MRS JUSTICE LIEVEN

- -

Between :

(1) QUINCY BELL
(2) MRS A

Claimants

and

THE TAVISTOCK AND PORTMAN NHS FOUNDATION TRUST

Defendant

NATIONAL HEALTH SERVICE COMMISSIONING BOARD (NHS ENGLAND)

Interested Party

(1) UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
(2) LEEDS TEACHING HOSPITALS NHS TRUST
(3) TRANSGENDER TREND LTD

Interveners

Mr Jeremy Hyam QC and Mr Alasdair Henderson (instructed by **Sinclairslaw**) for the **Claimants**
Ms Fenella Morris QC and Ms Nicola Kohn (instructed by **DAC Beachcroft**) for the **Defendant**
The Interested Party did not appear and was not represented
Mr John McKendrick QC (instructed by **Hempsons**) for the **First and Second Interveners**
Mr Paul Skinner and Mr Aidan Wills (instructed by **Ai Law)** for the **Third Intervener**
Hearing dates: **7 and 8 October 2020**

- -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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THE PRESIDENT OF THE QUEEN'S BENCH DIVISION
LORD JUSTICE LEWIS
MRS JUSTICE LIEVEN

Dame Victoria Sharp P., Lord Justice Lewis, Lieven J.

SECTION A: INTRODUCTION AND BACKGROUND

1. This is the judgment of the court.

2. This is a claim for judicial review of the practice of the defendant, the Tavistock and Portman NHS Foundation Trust, through its Gender Identity Development Service (GIDS) and the first and second Interveners (the Trusts) of prescribing puberty-suppressing drugs to persons under the age of 18 who experience gender dysphoria.

3. Gender dysphoria or GD is a condition where persons experience distress because of a mismatch between their perceived identity and their natal sex, that is, their sex at birth. Such persons have a strong desire to live according to their perceived identity rather than their natal sex.

4. Those with gender dysphoria may be referred to GIDS. GIDS may, in turn, refer them to one of two NHS Trusts (the first and second Interveners) whose clinicians may be prepared to undertake medical interventions in relation to those with gender dysphoria. We are concerned in this case with the administration of gonadotropin-releasing hormone agonists (GnRHa) which are hormone or puberty blocking drugs (also called PBs) to suppress the physical developments that would otherwise occur during puberty.

5. Puberty blocking drugs can in theory be, and have in practice been, prescribed for gender dysphoria through the services provided by the defendant to children as young as 10. It is the practice of the defendant, through GIDS, to require the informed consent of those children and young persons to whom such drugs are prescribed.

6. The issue at the heart of this claim is whether informed consent in the legal sense can be given by such children and young persons.

7. The claimants' case is that children and young persons under 18 are not competent to give consent to the administration of puberty blocking drugs. Further, they contend that the information given to those under 18 by the defendant is misleading and insufficient to ensure such children or young persons are able to give informed consent. They further contend that the absence of procedural safeguards, and the inadequacy of the information provided, results in an infringement of the rights of such children and young persons under Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (the Convention).

8. In our view, it is appropriate to consider first, whether a child under 16, or a young person between 16 and 18, can give the requisite consent; and secondly, if, in principle, they can do so, whether the information provided by the defendant and the Trusts is adequate for achieving informed consent.

9. The court in this case is concerned with the legal requirements of the process of obtaining consent for the carrying out of medical treatment. In considering this issue the court has had to consider evidence on the use of PBs, their impact on the patients, both in the short and long term, and the evidence of the efficacy of their use. The court is not deciding on the benefits or disbenefits of treating children with GD with PBs, whether in the long or short term. The court has been given a great deal of evidence

about the nature of GD and the treatments that may or may not be appropriate. That is not a matter for us. The sole legal issue in the case is the circumstances in which a child or young person may be competent to give valid consent to treatment in law and the process by which consent to the treatment is obtained.

10. We have had placed before us written evidence from a wide variety of those engaged in issues surrounding GD and a number of individuals who have been treated or are still being treated with PBs.

11. On behalf of the defendant and the Trusts there are statements from Dr Polly Carmichael, Director of GIDS, Professor Gary Butler, Consultant in Paediatric Endocrinology at University College Hospital London, and Dr Nurus-Sabah Alvi, Consultant in Paediatric Endocrinology at Leeds General Infirmary and Clinical Lead for Endocrine Liaison Clinics of the GIDS, Leeds. These witnesses describe the process that the children and young people go through at GIDS and at the Trusts. The court has also had a wide range of evidence from a variety of people concerned with the treatment of those under 18 with PBs. We will refer to that evidence and its sources as appropriate below. Our references to a child or children will be to those under the age of 16, and to young person(s) to anyone under the age of 18, save where it is clear from the context that we are referring to anyone under the age of 18.

Gender Dysphoria

12. Gender dysphoria is defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) which provides for one overarching diagnosis of gender dysphoria with separate specific criteria for children and for adolescents and adults:

> "In adolescents and adults gender dysphoria diagnosis involves a difference between one's experienced gender and assigned gender, and significant distress or problems functioning. It lasts at least six months and is shown by at least two of the following:
>
> 1. A marked incongruence between one's experienced / expressed gender and primary and / or secondary sex characteristics
>
> 2. A strong desire to be rid of one's primary and / or secondary sex characteristics
>
> 3. A strong desire for the primary and / or secondary sex characteristics of the other gender
>
> 4. A strong desire to be of the other gender
>
> 5. A strong desire to be treated as the other gender
>
> 6. A strong conviction that one has the typical feelings and reactions of the other gender.
>
> In children, gender dysphoria diagnosis involves at least six of the following and an associated significant distress or impairment in function, lasting at least six months:

1. A strong desire to be of the other gender or an insistence that one is the other gender

2. A strong preference for wearing clothes typical of the other gender

3. A strong preference for cross-gender roles in make-believe play or fantasy play

4. A strong preference for toys, games or activities stereotypically used or engaged in by the other gender

5. A strong preference for playmates of the other gender

6. A strong rejection of toys, games and activities typical of one's assigned gender

7. A strong dislike of one's sexual anatomy

8. A strong desire for the physical sex characteristics that match one's experienced gender."

Gender Identity Development Service (GIDS)

13. The defendant is an NHS Foundation Trust employing specialist staff including child psychologists, psychotherapists, psychiatrists, social workers, family therapists and nurses. Since 1989 it has provided a gender identity development service, a specialised service providing care to patients up to the age of 18 suffering from GD. GIDS is commissioned by the National Health Service Commissioning Board. The statutory mechanism is that under section 3B of the NHS Act 2006, the Secretary of State has the power to require NHS England to arrange services or facilities as may be prescribed by regulations. The Secretary of State has exercised that power (pursuant to Regulation 11 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2296, which concerns specified services for rare and very rare conditions) that NHS England must arrange for the provision of services including, pursuant to para 56 of Schedule 4, a gender identity development service specifically for children and adolescents in addition to gender dysphoria services more generally (para 57).

14. Schedule 2, Part A of the NHS Standard Contract, pursuant to which GIDS is provided, sets out the Service Specification which establishes the context of the service, its aims and objectives and the manner in which it will be delivered. As set out in the Service Specification, the service is commissioned to provide specialist assessment, consultation and care including psychological support and physical treatments. The purpose of the treatment is *"to help reduce the distressing feelings of a mismatch between their natal (assigned) sex and their gender identity."* The service also provides support to family and carers of children and young persons so affected.

15. GIDS recognises three stages of physical intervention that may be appropriate in cases of GD. Stage 1 is the administration of GnRHa (one form of puberty blocker). This is clinically appropriate for children and young people who have reached Tanner Stage 2

of puberty and above. Tanner Stage 2 marks the beginning of the physical development of puberty. In natal girls this is the start of development of the breasts, and in boys the testicles and scrotum begin to get larger. Stage 2 of the treatment is the administration of cross-sex hormones (CSH) which can only be prescribed from around the age of 16. Stage 3 is gender reassignment surgery which is only available via adult services to people aged over 18.

16. GIDS takes referrals from across England and Wales and from a wide range of professionals in the health, social services and education sectors, and the voluntary sectors. When a referral is made, the case will be discussed with the relevant regional team. If the intake is successful, then the child will then progress to the GIDS waiting list.

17. As at November 2019 the waiting time for a first assessment at GIDS was between 22-26 months. When a young person reaches the top of the waiting list, they will be invited to the first of a number of assessment appointments at GIDS. The assessment process laid out in the Service Specification anticipates that the assessment process will typically span three to six sessions over 6 months or longer. Most young people will have more sessions than this, and the younger the age the more sessions are likely.

18. Dr Carmichael said that during assessments young persons will be asked, for example, about: the onset of their gender dysphoria; the consistency of their feelings about their gender; how they identify (cross-gender, non-binary, etc); their relationships with peers and family members; their social functioning in general, thoughts about or experience of puberty; their relationship to their bodies; their attractions or romantic relationships as appropriate based on their age and maturity; and their hopes and expectations for the future.

19. As this case is brought by way of judicial review of the GIDS policy and practice, rather than a challenge to an individual treatment decision, it is not possible to give a detailed analysis of the facts of an individual case and the degree to which all the matters referred to by Dr Carmichael were explored in the particular case. We refer at paras 78 to 89 below to the evidence of the experience of the first claimant and some of the other patients of the GIDS service.

20. Dr Carmichael sets out the broad range of professionals who work within GIDS, their specialism in working with young people with GD and the care that is taken when discussing the young person's expression of their gender identity.

21. At the end of the assessment period the clinicians will agree a care plan with the young person and their family. Where the young person fulfils the criteria in the Service Specification and has reached at least Tanner Stage 2 of puberty, they will be referred by GIDS to the first and second Interveners for consultation and/or physical assessment with endocrinologists with a view to being prescribed PBs. Dr Carmichael explains that before any referral to the Trusts, GIDS clinicians discuss the treatment with the young person, including explaining side effects.

The Age and Patient Group for Puberty Blockers

22. Until 2011 PBs were only available at GIDS for those aged 16 or older. In 2011 PBs started to be prescribed for those aged 12-15 and in mid-puberty. This was first done between 2011-14 at University College London Hospital (UCLH) under an approved research study known as the Early Intervention Study. The Study took an uncontrolled treatment cohort of 12-15 year olds with established and persistent GD in England. The Study recruited children for 3 years, but there was then a period until February 2019 when the last cohort member began the next stage of therapy (cross-sex hormones).

23. One of the issues raised in these proceedings is the non-existent or poor evidence base, as it is said to be, for the efficacy of such treatment for children and young persons with GD.

24. In that context, we note that though this research study was commenced some 9 years ago, at the time of the hearing before us the results of this research had yet to be published. Dr Carmichael says in her witness statement dated 2 February 2020 that a paper is now being finalised for publication. At the hearing we were told that that this paper had been submitted for peer-review but that Professor Viner, one of the authors of it, had yet to respond to issues raised by the reviewers, as he has been otherwise engaged in working on issues relating to the coronavirus pandemic.

25. The court was however provided with a paper entitled *"The Early Intervention Study. An evaluation of early pubertal suppression in a carefully selected group of adolescents with "Gender Identity Disorder". A statement and update on the Early Intervention Study (dated 2020)".* We refer further to this paper at para 73 below.

26. There are now two types of endocrine clinic: a clinic for under 15s, referred to as the early intervention clinic, and a clinic for over 15s. The Service Specification states that the early intervention clinic will continue to follow the 2011 Protocol, save that PBs will now be considered for any children *under the age of 12* if they are in established puberty.

27. The age distribution of those treated with PBs in each year between 2011 and 2020 was not provided to the court. Although the defendant and the Trusts said that such data was available, in the sense that the ages of the children are known, the data has not been collated for each year. However, Ms Ailsa Swarbrick, the Divisional Director of Gender Services at the Trust, has presented evidence in relation to patients referred to endocrinology services in 2019-20 and those treated in earlier years but who were discharged from GIDS in 2019-2020. This work was done in response to recommendations in the GIDS Review Action Plan 2019 (a Review commissioned by the Trust following a report by Dr David Bell) that data would help to inform clinical and service developments and a process of continuous improvement.

28. We note here that we find it surprising that such data was not collated in previous years given the young age of the patient group, the experimental nature of the treatment and the profound impact that it has.

29. As it is, for the year 2019/2020, 161 children were referred by GIDS for puberty blockers (a further 10 were referred for other reasons). Of those 161, the age profile is as follows:

> 3 were 10 or 11 years old at the time of referral;
>
> 13 were 12 years old;
>
> 10 were 13 years old;
>
> 24 were 14 years old;
>
> 45 were 15 years old;
>
> 51 were 16 years old;
>
> 15 were 17 or 18 years old.

For the year 2019/20, therefore, 26 of the 161 children referred were 13 or younger; and 95 of the 161 (well over 50%) were under the age of 16.

30. It follows from the information that the court does have on age distribution that some young people could be on PBs for a number of years, in the most extreme case for 5 years between the age of 10 and when they start CSH at 16.

31. Apart from the age distribution, there are other aspects of the patient group which are relevant to this case. The number of referrals to GIDS has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519.

32. Further, in 2011 the gender split was roughly 50/50 between natal girls and boys. However, in 2019 the split had changed so that 76 per cent of referrals were natal females. That change in the proportion of natal girls to boys is reflected in the statistics from the Netherlands (Brik et al "*Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria"* 2018). The defendant did not put forward any clinical explanation as to why there had been this significant change in the patient group over a relatively short time.

33. It is recorded in the GIDS Service Specification and the wider literature that a significant proportion of those presenting with GD have a diagnosis of Autistic Spectrum Disorder (ASD). The Service Specification says:

> "There seems to be a higher prevalence of autistic spectrum disorder (ASD) conditions in clinically referred, gender dysphoric adolescents than in the general adolescent population. Holt, Skagerberg & Dunsford (2014) found that 13.3% of referrals to the service in 2012 mentioned comorbid ASD (although this is likely to be an underestimate). This compares with 9.4% in the Dutch service; whereas in the Finnish service, 26% of adolescents were diagnosed to be on the autism spectrum (Kaltiala-Heino et al. 2015)."

34. The court asked for statistics on the number or proportion of young people referred by GIDS for PBs who had a diagnosis of ASD. Ms Morris said that such data was not available, although it would have been recorded on individual patient records. We therefore do not know the proportion of those who were found by GIDS to be *Gillick* competent who had ASD, or indeed a mental health diagnosis.

35. Again, we have found this lack of data analysis – and the apparent lack of investigation of this issue - surprising.

The process of taking consent

36. The position taken by GIDS is that they will only refer a young person for PBs if they determine that person is competent to give consent, i.e. is *Gillick* competent within the meaning of competence identified in the decision of the House of Lords in *Gillick v West Norfolk and Wisbech Health Authority* [1986] AC 112.

37. Dr Carmichael explained that GIDS takes consent from the young person to their case being referred to the Trusts for treatment; however the consent for the actual prescription of the PBs is taken separately by the clinicians working for the Trusts. She set out the careful process by which GIDS gives information to the young persons and to their parents in order to seek to ensure that the young person is in a position to give valid consent. The court was taken through the statements of Dr Carmichael and Professor Butler and various documents to show the level of information and dialogue that was involved in achieving lawful consent to the treatment. The Service Specification includes Section 3.2 on "Informed Consent". This states *"The consequences of treatment decisions can be significant and life-changing"* and states:

> "All efforts will be made to ensure that clients are aware of the longer term consequences of the endocrine treatments, including implications for fertility, and the decision of the competence of the client will be jointly made by the endocrine and psychological members of the Service's integrated team.
>
> The current context of treatment decisions about cross sex hormones in adolescence is that there is limited scientific evidence for the long-term benefits versus the potential harms of the intervention. There are also concerns that it is uncertain whether or not a young person will continue to identify as transgender in the future, given that some subsequently identify in a different way."

38. The defendant has recently adopted a Standard Operating Procedure for the taking of consent in GIDS. This has taken 2 years to develop and is dated 31 January 2020. Dr Carmichael says at para 33 of her first statement:

> "In advance of any referral by the Trust of a young person for consideration by an endocrinologist for GnRHa treatment, GIDS clinicians discuss treatment with the young person. This includes, checking that the young person's hopes for treatment are realistic, explaining what the treatment can and cannot do, discussing any potential

> side-effects, discussing fertility and potential impact on genital development for birth registered males. We have developed visual aids to support this process.
>
> UCLH and LTH have collated extensive written information to help young people and their parents further understand the nature of the drugs, their limitations and the possible side effects. These written documents are given to young people at their first endocrine clinic visit. The written documents act as a reference point for patients with questions whilst they contemplate whether they would like to go ahead with the referral, and subsequently with treatment. In particular, informational slides titled "Have you thought about having children in the future?" explains the impact GnRHa treatment can have on fertility in explicit terms. Young people and their families are encouraged to raise any questions with their GIDS clinicians or at their next endocrine clinic visit."

39. Ms Morris emphasised that the process of ensuring that consent could validly be given was a discursive and iterative one that involved multiple discussions and answering any questions the young people or their parents might raise. Dr Carmichael said at para 35: "*The GIDS clinicians make it very clear to children and young people that there are both known and unknown risks associated with GnRHa treatment."* Further, she said at para 41: "*In my experience, those young people we see who are recommended for GnRHa treatment understand the implications and limitations of treatment with GnRHa treatment and are able to consent to this stage of treatment."*

40. Professor Butler described the approach to consent at the Trusts as follows:

> "For those under 15 years of age all the pre-assessment consultations are individual and occur with a consultant or senior clinical fellow on at least two visits. Parental support (or that of their guardian or social services where appropriate) is a pre-requisite for the under 15 year stream. On occasions, a young person is not deemed, on clinical examination, to be at an appropriate stage of puberty so further follow-up visits are arranged thereafter at 6-12 monthly intervals until a person is deemed at an appropriate physical stage for intervention and taking of consent. This also gives the opportunity to judge the level of emotional cognitive and psychosocial maturity, and capacity.
>
> The decisions at UCLH and Leeds do not automatically follow on from those made at the GIDS Tavistock. They are a reassessment of physical maturity and cognitive capacity in their own right. They may be at odds with the Tavistock formulation (an infrequent event) and thus would be returned to the Tavistock MDT for reconsideration."

41. Professor Butler said that in his clinic they are careful to ensure that the force behind the decision to seek treatment comes from the young person themselves and is not a consequence of pressure upon them from others around them. The Trusts work closely

with parents to reach a solution that is satisfactory to all and meets the best interests of the child. His clinic has never sought to apply to the Court under its inherent jurisdiction "against" parental opinions because he is concerned that would cause familial frictions. Equally, he suggested UCLH would not wish to have to apply to the court for consent on behalf of the child because it would delay treatment and put an additional burden on GIDS and the Trusts; and because "*it would also increase the distress suffered by the young people themselves, finding that their right to autonomous decision making had been removed from them.*"

42. Professor Butler said a full written information package is provided to older adolescents. For those under 15 there is an initial individual consultation because of the need for "*individualising the approach for very young people, taking special care to assess their level of knowledge and understanding and they are given the written information package then.*" In relation to impacts on fertility and sexual functioning he says:

> "It is also relevant for the consultation purposes that matters of fertility are discussed and counselling by the team takes place, and the option of meeting a fertility specialist is offered, and often taken up. The options of fertility preservation are discussed with all the young people and it is a requirement of the consent process that they fully understand this at an age appropriate level. This understanding must include that they are unable to have the typical sexual relationship of their identified gender with another person on account of their biological sex organ development, and that other surgical procedures may be necessary later on to achieve this possibility."

43. He then said: "*it is an absolute requirement before starting any treatment that a young person can fully understand this effect on fertility and sexual functioning according to their age and level of maturation.*"

44. The court asked for statistical material on the number, if any, of young people who had been assessed to be suitable for PBs but who were *not* prescribed them because the young person was considered not to be *Gillick* competent to make the decision, whether at GIDS or the Trusts. Ms Morris could not produce any statistics on whether this situation had ever arisen. She suggested that in the main, GIDS would work with the young person to give them further information, discuss the matter further and in some cases wait until they had achieved further maturity. The court gained the strong impression from the evidence and from those submissions that it was extremely unusual for either GIDS or the Trusts to refuse to give PBs on the ground that the young person was not competent to give consent. The approach adopted appears to be to continue giving the child more information and to have more discussions until s/he is considered *Gillick* competent or is discharged.

45. Relevant to the evidence of consent is the evidence of Professor Scott (Director of University College London's Institute of Cognitive Neuroscience). She *"seeks to explain, from a neuroscientific point of view, why I have significant doubts about the ability of young people under the age of 18 years old to adequately weigh and*

appreciate the significant consequences that will result from the decision to accept hormonal treatment for gender dysphoria."

46. She explained the neurological development of adolescents' brains that leads to teenagers making different, more risky decisions than adults. She said further that this is backed up by behavioural studies showing that when decision making is "hot" (i.e. more emotional), under 18 year olds make less rational decisions than when the responses are made in a colder, less emotional context. Her conclusion was that:

> "11. … given the risk of puberty blocking treatment, and the fact that these will have irreversible effects, that have life-long consequences, it is my view that even if the risks are well explained, that in the light of the scientific literature, that it is very possible for an adolescent to be unable to fully grasp the implications of puberty-blocking treatment. All the evidence we have suggests that the complex, emotionally charged decisions required to engage with this treatment are not yet acquired as a skill at this age, both in terms of brain maturation and in terms of behaviour."

Parental consent

47. If a child cannot give consent for treatment because they are not *Gillick* competent then the normal position in law would be that someone with parental responsibility could consent on their behalf. Mr Hyam sought at one point to argue that a decision as to giving PBs would fall outside the scope of parental responsibility because of the nature of the treatment concerned. However, the GIDS practice in relation to acting on parental consent alone is quite clear. In the response to the pre-action protocol letter the defendant said:

> "36. There is a fundamental misunderstanding in your letter, which states that parents can consent to pubertal suspension on behalf of a child who is not capable of doing so. This is not the case for this service, as is clear from the above. Although the general law would permit parent(s) to consent on behalf of their child, GIDS has never administered, nor can it conceive of any situation where it would be appropriate to administer blockers on a patient without their consent. The Service Specification confirms that this is the case."

It follows that is not necessary for us to consider whether parents could consent to the treatment if the child cannot lawfully do so because this is not the policy or practice of the defendant and such a case could not currently arise on the facts.

The effect of Puberty Blockers

48. PBs have been used for many years to stop precocious puberty. This is a condition experienced largely by children aged 7 or under when puberty commences at a very early age. This condition is seen more often in natal girls but sometimes in natal boys. PBs are used to stop this early onset of puberty and the use of them ceases when the child reaches an appropriate age for puberty. As can be seen from the evidence this use of PBs does not interfere with the onset of puberty at a normal biological age and, as such, will not interfere with normal development of puberty through adolescence.

49. The use of PBs in cases of GD is quite different. We have some evidence of the history of this treatment and the meaning of puberty from Professor Hruz (Associate Professor of Paediatrics, Endocrinology and Diabetes at Washington University, St Louis, USA) on behalf of the claimants.

50. In summary, PBs were first used for such treatment at a Dutch gender clinic in the late 1990s. That clinic developed a protocol, often referred to as the Dutch protocol. The Dutch protocol was published in the European Journal of Endocrinology in 2006 and called for puberty suppression to begin at the age of 12 after a diagnosis of GD. Puberty is understood in medicine or biology as a process of physiological change involving the process of maturation of the gonads. Hormones in a part of the brain secrete a gonadotropin-releasing hormone which, in turn, stimulates the pituitary gland to secrete other hormones. These stimulate the growth of the gonads, that is ovaries in females and testes in males. Further hormones are secreted which contribute to the further development of the primary sex characteristics, the uterus in females and the penis and scrotum in males. The hormones contribute to the development of secondary sex characteristics including breasts and wider hips in girls and wider shoulders, deeper voices and increased muscle mass in boys. Further growth hormones are released, which stimulate growth. With regular injection of the PBs there is no progression of puberty and some regression of the first stages of already developed sexual characteristics. This means that in girls *"breast tissue will become weak and may disappear completely"* and in boys *"testicular volume will regress to a lower volume."*

51. Under the Dutch protocol, the introduction of CSH starts at age 16. As Professor Hruz explained:

> "29. Then, starting at age 16, cross-sex hormones are administered while GnRH analogue treatment continues, in order to induce something like the process of puberty that would normally occur for members of the opposite sex. In female-to-male patients, testosterone administration leads to the development of "a low voice, facial and body hair growth, and a more masculine body shape" as well as to clitoral engagement and further atrophying of breast tissue. In patients seeking a male-to-female transition, the administration of estrogens will result in "breast development and a female-appearing body shape." Cross-sex hormone administration for these patients will be prescribed for the rest of their lives."

52. There is some dispute as to the purpose of prescribing PBs. According to Dr Carmichael, the primary purpose of PBs is to give the young person time to think about their gender identity. This is a phrase which is repeated on a number of the GIDS and Trust information documents. The Health Research Authority carried out an investigation into the Early Intervention Study in 2019. Its report was somewhat critical of the description of the purpose and said:

> "The research team described the purpose of pubertal suppression as 'to induce a sex hormone-neutral environment to provide young people with space to decide whether to progress further with gender reassignment treatment as an adult.' This phrase appears to have caused confusion as it has been interpreted by some that the puberty suppression was for use in

> any children presenting to the clinic, that there would be no change in the course of any gender identity dysphoria during this time, and that the child could then choose to progress to cross-sex hormone treatment or to stop treatment with subsequent onset of puberty in the birth gender. It has been noted that the participants in this study and other research involving early puberty suppression have progressed to cross-sex hormones. This has raised concerns that the treatment might be responsible for generating persistence, rather than 'creating space to decide'.
>
> It would have reduced confusion if the purpose of the treatment had been described as being offered specifically to children demonstrating a strong and persistent gender identity dysphoria at an early stage in puberty, such that the suppression of puberty would allow subsequent cross-sex hormone treatment without the need to surgically reverse or otherwise mask the unwanted physical effects of puberty in the birth gender. The present study was not designed to investigate the implications on persistence or desistence of offering puberty suppression to a wider range of patients, it was limited to a group that had already demonstrated persistence and were actively requesting puberty blockers."

53. Professor Butler said that PBs:

> "may have some help or advantage in the support of transgender adolescents in some aspects of mental health functioning, in particular with reducing the risk of reduction of suicidal ideation and actual suicidal actions themselves."

54. See further the reference at para 73 below to the paper presented by Dr Carmichael and Professor Viner in 2014, referring to the Early Intervention Study and the limited evidence of psychological benefit.

55. As is clear from the literature and referred to by the HRA, the other purpose of giving PBs is stopping the development of the physical effects of puberty (something that obviously varies depending on at what age and stage in pubertal development the PBs are commenced) because slowing or preventing the early development of secondary sex characteristics during puberty can make a later transition (both medical and social) to living as the opposite sex easier.

The relationship between Puberty Blockers and Cross-Sex Hormones (CSH)

56. GIDS and the Trust place reliance on the fact that Stage 1 treatment with PBs and Stage 2 treatment (CSH) are separate. Thus, so it is said, it is possible for a young person to come off the PBs at any point and not proceed to taking CSH. On one view, this is correct. However, the evidence that we have on this issue clearly shows that practically all children / young people who start PBs progress on to CSH.

57. No precise numbers are available from GIDS (as to the percentage of patients who proceed from PBs to CSH). There was some evidence based on a random sample of those who in 2019-2020 had been discharged or had what is described as a closing summary from GIDS. However the court did have the evidence of Dr de Vries. Dr de Vries is a founding board member of EPATH (European Professional Association for Transgender Health) and a member of the WPATH (World Professional Association for Transgender Health) Committee on Children and Adolescents and its Chair between 2010 and 2016, and leads the Centre of Expertise on Gender Dysphoria at the Amsterdam University Medical Centre in the Netherlands (CEGD). This is the institution which has led the way in the use of PBs for young people in the Netherlands; and is the sole source of published peer reviewed data (in respect of the treatment we are considering) produced to the court. She says that of the adolescents who started puberty suppression, only 1.9 per cent stopped the treatment and did not proceed to CSH.

58. We were told that the defendant did not have any data recording the proportion of those on puberty blockers who progress to cross-sex hormones. We were told that in part this resulted from the fact that some would have progressed to adult services and would not be recorded by the defendant. Ms Swarbrick had carried out an analysis of a random sample of 312 of 1648 files of patients discharged from GIDS from 1st March 2019 to 4th March 2020. Dr Carmichael summarised this as:

> "…based on a random sample of those referred to GIDS who had been discharged or had a closing summary from GIDS in 19-20 (analysis B) 16% of patients (49 individuals) had accessed the endocrinology service during their time with GIDS. Of those 16%, 55% (27 individuals) were subsequently approved for or accessed cross-sex hormones during their time with GIDS. This number represents 8.7% of all the patients discharged from GIDS that year. We also know that of the 49 patients who were referred to endocrinology for GnRHa whilst at GIDS, two did not commence GnRHa treatment, and a further five were discharged from GIDS without being referred on to another gender service."

59. We find it surprising that GIDS did not obtain full data showing the figures and the proportion of those on puberty blockers who remain within GIDS and move on to cross-sex hormones. Although neither Dr Carmichael nor Professor Butler could give the equivalent figures in the United Kingdom to those from the Netherlands, the language used in their witness statements suggests that a similarly high proportion of children and young people in the United Kingdom move from PBs onto CSH.

The impact of Puberty Blockers and their reversibility

60. Both WPATH and the Endocrine Society in their documentation describe PBs as fully reversible. Professor Butler says that "*we do not know everything about the blocker and as far as we know it is a safe reversible treatment with a well-established history."* Dr Alvi also referred to the history of the use of PBs as showing that they are fully reversible. However, it is important to note that apart from the Amsterdam study, the history of the use of PBs relied upon in this context is *from the treatment of precocious*

puberty which is a different condition from GD, and where PBs are used in a very different way.

61. Dr de Vries was somewhat more nuanced in her evidence. She said:

> "Puberty blocking treatment is fully reversible (see for example section 2.0 of the Endocrine Society's Clinical Practice Guidelines…). By fully reversible I mean that the administration of puberty blockers in young people has no irreversible physical consequences, for example for fertility, voice deepening or breast growth".

62. At para 20 of her evidence she said:

> "Ethical dilemmas continue to exist around … the uncertainty of apparent long-term physical consequences of puberty blocking on bone density, fertility, brain development and surgical options."

63. The GIDS Early Intervention Young Person Information Sheet states:

> "What are the possible benefits of starting on hormone blockers?
>
> We have looked at other countries who have given this treatment **and the results** suggest that:
>
> - Hormone blockers which block the body's natural sex hormones may improve the way you feel about yourself.
> - If you decide to stop the hormone blockers early **your physical development** will return as usual in your natal gender. **As far as we are aware**, the hormone blockers will not harm your physical or psychological development.
> - Hormone blockers will make you feel less worried about growing up in the wrong body and will give you more time and space to think about your gender identity.
>
> What are the possible disadvantages and risks of the hormone blockers?
>
> - Possible side effects from the hormone blockers are hot flushes, headache, nausea and weight gain.
> - A short term effect is that your bone strength is shown not to grow as fast as it usually would whilst you are on hormone blockers. However, this will resume once your body is exposed to hormones again. That is why we have to do a bone scan every year to check the thickness of your bones. **We do not fully know how hormone blockers will affect bone strength, the development of your sexual organs, body shape or your final adult height. There**

> **could be other long-term effects of hormone blockers in early puberty that we don't yet know about.**
>
> - Hormone blockers could affect your memory, your concentration or the way you feel about your gender and how likely you are to change your mind about your gender identity.
>
> - Hormone blockers could affect your ability to have a baby. It could take 6 to 12 months longer after stopping the hormone blockers before natal boys start making sperm again or natal girls start maturing eggs in their ovaries. However, hormone blockers do not work as a contraceptive. If you are sexually active, please ask your doctor for advice about birth control." (emphasis added)

64. A number of aspects of this asserted reversibility are raised by the claimants. PBs stop the physical changes in the body when going through puberty. But in reliance on the evidence of Professor Levine (Clinical Professor of Psychiatry at Western Reserve University, Ohio) and Professor Hruz, the claimants assert that neurological and psychological changes occurring in puberty are less well understood than the physiological changes. Further, the degree to which neurological differences are caused by biological factors like hormones and genes are matters of debate. Professor Levine set out evidence on the degree to which young people mature through adolescence through both social and personal experiences. For young people on PBs that maturing process is stopped or delayed with potential social and psychological impacts which could be described as non-reversible.

65. Thus, the central point made by the claimants is that although most of the physical consequences of taking PBs may be reversible if such treatment is stopped, the child or young person will have missed a period, however long, of normal biological, psychological and social experience through adolescence; and that missed development and experience, during adolescence, can never be truly be recovered or "reversed".

66. It is to be noted that prior to June 2020, the NHS website on PBs said:

> "The effects of treatment with GnRH analogues are considered to be fully reversible, so treatment can usually be stopped at any time."

67. In June 2020 this section was updated to read as follows:

> "**Little is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria.**
>
> Although the Gender Identity Development Service (GIDS) advises that is a physically reversible treatment if stopped, **it is not known what the psychological effects may be.**

> **It's also not known whether hormone blockers affect the development of the teenage brain or children's bones**. Side effects may also include hot flushes, fatigue and mood alterations." (emphasis added)

68. A second key part of the argument about reversibility turns on the relationship between PBs and CSH and the degree to which commencing PBs in practice puts a young person on a virtually inexorable path to taking CSH. CSH are to a very significant degree not reversible. As is set out above at para 57 above, a very high proportion of those who start PBs move on to CSH and thus in statistical terms once a child or young person starts on PBs they are on a very clear clinical pathway to CSH.

Evidence base to support the use of Puberty Blockers for Gender Dysphoria

69. The claimants submit that the treatment of PBs for GD is properly described as (i) experimental (ii) a treatment with a very limited evidence base, and (iii) as a highly controversial treatment. The claimants rely on witness statements from a number of undoubted experts in various relevant fields and from academic institutions in the United Kingdom, the USA, Sweden and Australia who refer to the controversial nature of the treatment and its limited evidential support.

70. It is not however the court's role to judge the weight to be given to various different experts in a judicial review. In our view, more important is the evidence from the defendant and the evidence base *it* relies upon for the use of PBs. In the USA the treatment of GD is not an FDA approved use and as such PBs can only be used "off-label". That does not prevent clinicians, whether in the USA or the United Kingdom, from using PBs for this purpose, as long as their use falls within the clinician's professional expertise. Professor Butler explained that it is very common for paediatric medicines to be used off-label and that this factor does not render the treatment in any sense experimental.

71. However, the lack of a firm evidence base for their use is evident from the very limited published material as to the effectiveness of the treatment, however it is measured.

72. Paul Jenkins, Chief Executive of the defendant said:

> "…it is correct that in recent years, some clinicians [at the Trust] have raised their concerns about the use of GnRHa for young people presenting with gender dysphoria. Indeed, some have called for the Trust to alter its practices and have done so in a variety of ways. We are keenly aware that the subject of gender dysphoria raises complex issues and that many have strong opinions about it."

73. The Evaluation Paper on the Early Intervention Study at GIDS, referred to in para 25 above, gives some (albeit limited) material on the outcome of that study. It summarised a meeting paper presented by Dr Carmichael and Professor Viner in 2014 (but not published in a peer review journal) as follows:

> "The reported qualitative data on early outcomes of 44 young people who received early pubertal suppression. It noted that 100% of young people stated that they wished to continue on GnRHa, that 23 (52%) reported an improvement in mood since starting the blocker but that 27% reported a decrease in mood. **Noted that there was no overall improvement in mood or psychological wellbeing using standardized psychological measures**." (emphasis added)

74. Ms Morris submitted it is not for this court to determine clinical disagreements between experts about the efficacy of a treatment. We agree. That is a matter for the relevant NHS and regulatory bodies to oversee and to decide. However the degree to which the treatment is experimental and has, as yet, an unknown impact, does go to the critical issue of whether a young person can have sufficient understanding of the risks and benefits to be able lawfully to consent to that treatment.

Persistence

75. The claimants submit that there is good evidence that for a significant proportion of young people presenting with GD, the condition resolves itself through adolescence without treatment with PBs. Further, that PBs serve to increase the likelihood of GD, and, as such, can be positively harmful to the child or young person's long-term health. According to DSM5: "*in natal males, persistence of [gender dysphoria] has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%."* These figures need to be treated with some caution because it may be that the cohort whose persistence was being considered in these statistics was at a lower age and with less clearly established GD than the young people being treated at GIDS.

76. The Dutch study argued that adolescents who show established GD rarely identify as their biological sex. Professor Hruz suggested there may be two reasons for this. It may be that the clinicians made sound diagnoses of persistent GD. Alternatively, it may be that the very fact of the diagnosis and the course of treatment which affirmed that diagnosis (that is, both gender affirmative psychotherapy and the use of PBs) solidified the feeling of cross-gender identification and led the young people to commit to sex reassignment more strongly than they would have done if there had been a different diagnosis and treatment.

77. As already indicated, it is not our role to adjudicate on the reasons for persistence or otherwise of GD. However, the nature of this issue highlights the highly complex and unusual nature of this treatment and the great difficulty there is in fully understanding its implications for the individual young person. In short, the treatment may be supporting the persistence of GD in circumstances in which it is at least possible that without that treatment, the GD would resolve itself.

SECTION B: EVIDENCE OF THE CLAIMANTS AND OTHER INDIVIDUALS

78. The first claimant was born a female. In her witness statement in these proceedings she set out her experience of being prescribed PBs and then CSH. It should be noted that some of the details relating to her treatment and the information she was given (at GIDS and the first defendant) is disputed. This case is a judicial review of the GIDS policy,

not a tort action relating to the specific facts surrounding the first claimant's treatment and it is not necessary therefore to resolve any factual dispute. We simply record the first claimant's account. She describes a highly traumatic childhood. From the age of 4 or 5 she displayed gender non-conformity, associating more with male games and clothes. She felt highly alienated at secondary school and took birth control pills to stop her periods. She felt disgusted by her body and became depressed and highly anxious. From the age of 14 she began actively to question her gender identity and started to look at YouTube videos and do research on the internet about gender identity disorder and the transition process. She said: "*I thought I had finally found the answer as to why I felt so masculine, uncomfortable with my female body and why I was so much more similar to a stereotypical boy than to a stereotypical girl in physical expression and interests."*

79. When she was 15, the first claimant was referred to GIDS. When she was at the local Children and Adolescent Mental Health Services clinic she remembered: *"the psychiatrist attempted to talk of the gender spectrum as a way of persuading me to not pursue medical transition. I took this as a challenge to how serious I was about my feelings and what I wanted to do and it made me want to transition more. Now I wish I had listened to her."* She was first seen at GIDS aged 16 and had a number of appointments spread out over 1 year and 9 months. She was referred to UCLH in June 2013 and after three appointments commenced PBs. She was given advice about the impact on her fertility, but her priority was to move on to testosterone. She said that at 16, she was not thinking about children and, in any event, egg storage was not available on the NHS.

80. In April 2014 she was referred to an adult Gender Identity Clinic to discuss surgery. She "*was visualising myself becoming a tall, physically strong young man where there was virtually no difference between me and a biological boy."* After commencing testosterone at 17, changes to her body commenced rapidly: these changes included genital changes, her voice dropping and the growth of facial and body hair. She was on testosterone for 3 years but increasingly began to doubt the process of transition:

> "27. I started to have my first serious doubts about transition. These doubts were brought on by for the first time really noticing how physically different I am to men as a biological female, despite having testosterone running through my body. There were also a lot of experiences I could not relate to when having conversations with men due to being biologically female and socialised in society as a girl. There was an unspoken "code" a lot of the time that I felt I was missing. I remember telling a close male friend at the time about these transition doubts, who responded by telling me that I was being silly and I believed him. This was reinforced by the online forums that I browsed where the consensus was that most transsexual people have doubts and that that is a normal part of transitioning, so the doubts should be ignored. I continued on, pushing the doubts in the far back of my mind and no more doubts creeped in for a while."

81. Despite these doubts, when she was 20, she had a double mastectomy. In the year following this:

> "31. … I started to realise that the vision I had as a teenager of becoming male was strictly a fantasy and that it was not possible. My biological make-up was still female and it showed, no matter how much testosterone was in my system or how much I would go to the gym. I was being perceived as a man by society, but it was not enough. I started to just see a woman with a beard, which is what I was. I felt like a fraud and I began to feel more lost, isolated and confused than I did when I was pre-transition."

82. She described facing the reality of taking a regular dose of drugs for the rest of her life to maintain her male appearance; and the need to have a hysterectomy if she remained a man because of the atrophy of her reproductive organs if she continued to take testosterone.

83. From January 2019 the first claimant stopped taking testosterone. She now wishes to identify as a woman and is seeking to change her legal sex back to that on her original birth certificate. She said:

> "39. … It is only until recently that I have started to think about having children and if that is ever a possibility, I have to live with the fact that I will not be able to breastfeed my children. I still do not believe that I have fully processed the surgical procedure that I had to remove my breasts and how major it really was. I made a brash decision as a teenager, (as a lot of teenagers do) trying to find confidence and happiness, except now the rest of my life will be negatively affected. I cannot reverse any of the physical, mental or legal changes that I went through. Transition was a very temporary, superficial fix for a very complex identity issue."

84. The defendant submits the first claimant was given the fullest possible information after a large number of consultations (at least 10) and that she was *Gillick* competent to make the decision to take PBs. Further, the defendant produced witness statements from a number of children and young people who are strongly supportive of the treatment they have received.

85. J is a 20 year old transgender man who received PBs in 2012 at the age of 12 followed by CSH in 2015. He described how he felt a strong need to become a boy from an early age and how he was bullied at school for his behaviour. He found the onset of female puberty horrifying and unbearable. After a number of sessions at GIDS he was prescribed PBs from the age of 12.

86. According to J he was given the fullest possible information from the clinicians at GIDS as to the benefits and disbenefits of the treatment. The clinicians strongly challenged his desire to transition and why he had chosen to express his gender identity as male. He was advised as to the impact on fertility if he chose to go on to CSH and surgery. He said: "*I made the decision to proceed with pubertal suppression without pursuing egg preservation. It was a difficult decision to make because I did not know whether I would want biological children in adulthood, but I was certain I would never want to*

carry a child and give birth. Ultimately, I made the decision because I had a poor quality of life and without immediate treatment I did not feel I had a future at all." He says: "*We discussed sex and I told them the idea of it disgusted me. I knew I would be unable to consider having a sexual relationship as an adult with my body so wrongly formed."* He ended his witness statement by saying that he is thankful that his pubertal development was halted as it removed the distress caused by continued development, but he wishes that the PBs were started earlier which would have prevented the need for breast surgery later.

87. S is a 13 year old trans boy who is on the waiting list at GIDS. He was told that he would have to wait for approximately 24 months to be seen and with his parents decided to see a private provider, GenderGP, where he has been prescribed PBs. We note at this point that the GP in question was removed from the professional register and now operates from outside the United Kingdom. S in his witness statement said:

> "13. … I haven't really thought about parenthood – I have been asked about it by the gender identity specialist I have mentioned but I just have no idea what me in the future is going to think. I haven't had a romantic relationship and it's just not a thing that is really on my radar at the moment."

88. N, an 18 year old trans woman, who was prescribed PBs when she was 17 years old said:

> "12. The treatment of hormone blockers may very well have saved my life. In the period of my life that I was prescribed them my mental health was spiralling due to my dysphoria and this impacting on my daily life, learning and social interactions. While the first injections of gonapeptyl were slow to take effect they eventually began to alleviate my dysphoria in very real ways. I had to shave less and I didn't have to fear pubertal development anymore. I had the time necessary to think about my situation and decide on further courses of action. This also helped my mental health as it gave me significantly less issues overall allowing me to focus and concentrate on aspects in my life alongside my gender identity rather than my fears of puberty and development overtaking everything else in my life."

89. The second claimant, Mrs A, is the mother of a 15 year old girl who has ASD. The daughter has a history of mental health and behavioural problems. She "*is desperate to run away from all that made her female"* and has been referred to CAMHS (Child and Adolescent Mental Health Services). Mrs A is very concerned that her daughter would be referred to GIDS and prescribed PBs. However the daughter has not currently been referred to GIDS and having regard to the defendant's current practice, would not meet the criteria for PBs because her parents would not support that treatment. Mrs A's interest in this action is therefore largely theoretical.

SECTION C: SUBMISSIONS

90. The claimants' primary case is that children or young persons under the age of 18 are not capable of giving consent to the administration of PBs. Their secondary case is that the information given by the defendant and the Interested Party is misleading and inadequate to form the basis for informed consent to be given. In their statement of issues, the claimants put issue one as the adequacy of the information and issue two whether children and young people are capable of giving consent. In our view, the first issue must be whether *Gillick* competence can be achieved, and the secondary or alternative issue, whether the information being given is adequate. We deal with the arguments in that order.

91. Mr Hyam also raised a third issue (at least in writing). This was a submission that if any young person under the age of 18 is prescribed PBs, their case should be referred to the Court of Protection. In oral argument he accepted that the Court of Protection, being a creature of statute, would have no jurisdiction to consider such referrals. We think that the substance of issue three falls within the terms of issue one.

92. Mr Hyam stressed that the claimants were not calling into question that GD existed. Nor were they questioning that it could cause extreme distress or that PBs should never be given to people under 18 or that it was never in their best interests for it to be prescribed. The central issue was whether those under 18 could give informed consent.

93. Mr Hyam submitted that a child still going through puberty is not capable of properly understanding the nature and effect of PBs and weighing the consequences and side effects properly. He pointed to the evidence of the individuals, including that put forward on behalf of the defendant, to show that children of this age cannot understand the implications of matters such as the loss of the ability to orgasm, the potential need to construct a neo-vagina, or the loss of fertility. He argued that the use of PBs to address GD does not have an adequate evidence base to support it and thus should properly be described as experimental treatment. There is evidence that PBs can have significant side effects and there is strong evidence that once a child commences on PBs they will progress to CSH which will cause irreversible changes to the child's body with lifelong medical, psychological and emotional implications for the child. He relies on the harm potentially caused to these vulnerable young people as evidenced by the witness statement of the first claimant.

94. He submitted that the advice given to the children and young persons is misleading because they are told that the PBs are fully reversible when the current evidence on reversibility or the long term implications of the treatment is limited and unclear. He said further, that the reality is that PBs pave the way for CSH which do have irreversible impacts. Further, the information provided by GIDS fails to tell the child that there are no proven benefits to this treatment in either physical or psychological terms. The information is misleading as to the reversibility of PBs, their purpose and their benefits.

95. In those circumstances he submitted that the court should be guided by the approach of the Court of Protection in its *Practice Guidance (Court of Protection: Serious Medical Treatment)* [2020] 1 WLR 641 which sets out those decisions relating to medical treatment where an application should be made to the Court of Protection.

96. Paras 10 and 11 of that Guidance state:

> "10. In any case which is not about the provision of life-sustaining treatment, but involves the serious interference with the person's rights under the ECHR, it is:
>
> "highly probable that, in most, if not all, professionals faced with a decision whether to take that step will conclude that it is appropriate to apply to the court to facilitate a comprehensive analysis of [capacity and] best interests, with [the person] having the benefit of legal representation and independent expert advice."
>
> This will be so even where there is agreement between all those with an interest in the person's welfare.
>
> 11. Examples of cases which may fall into paragraph 10 above will include, but are not limited to: (a) where a medical procedure or treatment is for the primary purpose of sterilisation; (b) where a medical procedure is proposed to be performed on a person who lacks capacity to consent to it, where the procedure is for the purpose of a donation of an organ, bone marrow, stem cells, tissue or bodily fluid to another person; (c) a procedure for the covert insertion of a contraceptive device or other means of contraception; (d) where it is proposed that an experimental or innovative treatment to be carried out; (e) a case involving a significant ethical question in an untested or controversial area of medicine."

97. The defendant and the first and second Interveners make common cause. Ms Morris argued that the care and treatment provided at GIDS fell within the terms of the Service Specification laid down by NHS England (NHSE) as required in accordance with the international frameworks of WPATH and the Endocrine Society and by the domestic regulatory frameworks of the General Medical Council and the Care Quality Commission. The NHSE is currently undertaking a review of the efficacy of treatment for GD (the Cass Review) which will report in due course, and its findings will be reflected in the Service Specification.

98. She argued that the process at GIDS was "deeply *Montgomery* compliant" (i.e. it met the requirements for informed consent identified by the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] AC 1430) having regard to the frequent consultations, discussions and the provision of detailed, but age appropriate, information. The "vast majority" of the children referred for PBs are 15 or older she said, and the information given is varied depending on the age and maturity of the child or young person. Where the assessment is that the individual is not initially *Gillick* competent, time is taken to see if their understanding develops and competency can be achieved. The information that is given is what is salient for that individual at that age.

99. As to those between the ages of 16-18, if the young person, the parents and the clinicians are agreed then she submitted there is no justiciable issue and the court has no jurisdiction.

100. Mr McKendrick for the first and second Interveners argued that the child or young person did not need to understand the impact of CSH on their fertility because that did

not fall to be decided at the stage of prescribing PBs. The PBs provided the space for the person to think about further stages. In appropriate cases, a natal girl or young person's eggs could be harvested and preserved in order to preserve their fertility. The critical thing for the child was that s/he had GD and that there was no alternative physical treatment to PBs. Once the child or young person had reached the Endocrine Clinic at the Trust, there was no alternative psychological treatment available because that was a matter within the purview of GIDS and GIDS had referred the child for PBs, although ongoing psychological treatment is provided at GIDS alongside treatment with PBs. Therefore, the Trust clinicians were faced with a child in acute distress with no alternative treatment options. The purpose of the treatment was to alleviate distress and that, according to Mr McKendrick, had been achieved.

101. When asked by the court what evidence there was that the PBs did achieve the purpose of alleviating distress, in the light of the lack of published research, Mr McKendrick pointed to the evidence of experienced endocrinologists in both Trusts who could see the real benefits of the treatment.

102. Like Ms Morris, Mr McKendrick said the current practice was not to proceed only on parental consent. However, he did argue that if the child's consent was rendered invalid, the treatment would continue to be lawful if the parents had consented.

103. The third Intervener is Transgender Trend Ltd., an organisation that provides evidence-based information and resources for parents and schools concerning children with GD. Ms Davies-Arai is the director of that organisation and she has filed a witness statement in these proceedings. She set out concerns about the lack of evidence as to the impacts and effectiveness of PBs and in relation to which patients it is most likely to help. Much of her evidence focused on the increase of referrals to GIDS of teenage natal girls and the cultural factors, including material on the internet and social media, which may play a part in this. She said that GIDS does not offer young people with GD a range of ways to interpret their experience, and the GIDS pathway offers a minimal challenge to the beliefs and ideas of the young person.

104. Mr Skinner on behalf of Transgender Trend said the case was particularly important because it concerned the deliberate provision by the State of medical treatment to children and young people which may cause harm. The court should be anxious to ensure that vulnerable children, for example those with ASD, are provided with the full protection of the law.

SECTION D: THE LAW

105. In *Gillick v West Norfolk and Wisbech Health Authority* [1986] AC 112, the House of Lords considered the lawfulness of the Secretary of State's policy on giving contraceptive advice to children without parental consent. The House of Lords held by a majority that a doctor could lawfully give contraceptive advice and treatment to a girl aged under 16 if she had sufficient maturity and intelligence to understand that nature and implications of the proposed treatment and provided that certain conditions were satisfied.

106. Lord Fraser at p. 169B-E said:

> "It seems to me verging on the absurd to suggest that a girl or boy aged 15 could not effectively consent, for example, to have a medical examination of some trivial injury to his body or even to have a broken arm set. Of course the consent of the parents should normally be asked, but they may not be immediately available. Provided the patient, whether the boy or a girl, is capable of understanding what is proposed, and of expressing his or her own wishes, I see no good reason for holding that he or she lacks the capacity to express them validly and effectively and to authorise the medical man to make the examination or give the treatment which he advises. After all, a minor under the age of 16 can, with certain limits, enter into a contract. He or she can also sue and be sued, and can give evidence on oath. …."
>
> Accordingly, I am not disposed to hold now, for the first time, that a girl less than 16 lacks the power to give valid consent to contraceptive advice or treatment, merely on account of her age."

107. Lord Scarman at p. 186A-D said:

> "The law relating to parent and child is concerned with the problems of the growth and maturity of the human personality. If the law should impose upon the process of "growing up" fixed limits where nature knows only a continuous process, the price would be artificiality and a lack of realism in an area where the law must be sensitive to human development and social change. If certainty be thought desirable, it is better that the rigid demarcations necessary to achieve it should be laid down by legislation after a full consideration of all the relevant factors than by the courts confined as they are by the forensic process to the evidenced adduced by the parties and to whatever may properly fall within the judicial notice of judges. Unless and until Parliament should think fit to intervene, the courts should establish a principle flexible enough to enable justice to be achieved by its application to the particular circumstances proved by the evidence placed before them."

And at p.189C-E:

> "When applying these conclusions to contraceptive advice and treatment it has to be borne in mind there is much that has to be understood by a girl under the age of 16 if she is to have legal capacity to consent to such treatment. It is not enough that she should understand the nature of the advice which is being given: she must also have a sufficient maturity to understand what is involved. There are moral and family questions, especially her relationship with her parents; long-term problems associated with the emotional impact of pregnancy and its termination; and there are the risks to health of sexual intercourse at her age, risks which contraception may diminish but cannot eliminate. It follows that a doctor will have to satisfy himself that she is able to appraise these factors

> before he can safely proceed upon the basis that she has at law capacity to consent to contraceptive treatment. And it further follows that ordinarily the proper course will be for him, as the guidance lays down, first to seek to persuade the girl to bring her parents into consultation and, if she refuses, not to prescribe contraceptive treatment unless he is satisfied that her circumstances are such that he ought to proceed without parental knowledge and consent."

And p. 191C-D:

> "The truth may well be that the rights of parents and children in this sensitive area are better protected by the professional standards of the medical profession than by "a priori" legal lines of division between capacity and the lack of capacity to consent since any such general dividing line is sure to produce in some cases injustice, hardship, and injury to health."

108. In *R (Axon) v Secretary of State for Health (Family Planning Association Intervening)* [2006] QB 539 Silber J considered *Gillick* in the context of Article 8 of the Convention, the United Nations Convention on the Rights of the Child (UNCRC) and the increasing emphasis on the autonomy of the child. He held that the principles set out in *Gillick* continued to apply, see para 152.

109. There are two cases dealing with children aged 16 or over who refused medical treatment in circumstances where clinicians considered it was clinically indicated. The issue in each was whether the court could nevertheless, authorise the treatment. *Re W (a Minor) (Medical Treatment: Court's Jurisdiction)* [1993] Fam. 64, concerned the case of a 16 year old girl with anorexia nervosa. The local authority applied under the inherent jurisdiction of the High Court to give medical treatment to W without her consent and against her wishes. W relied on section 8 of the Family Law Reform Act 1969, which states:

> "Section 8 is in these terms:
>
> (1) The consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian. (2) In this section 'surgical, medical or dental treatment' includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure which is ancillary to any treatment as it applies to that treatment. (3) Nothing in this section shall be construed

> as making ineffective any consent which would have been effective if this section had not been enacted."

110. The Court of Appeal held that section 8 did not confer on a minor an absolute right to determine whether or not she received medical treatment but protected the medical practitioner from an action in trespass. Lord Donaldson analysed *Gillick* and said that Lord Scarman would necessarily have considered that the purpose of section 8 was to provide the medical practitioners treating the child with a defence to either criminal assault or a civil claim for trespass, see pages 76G-H and 78D-F. Lord Donaldson described the effect of the section as being a *"legal flak jacket",* whereby the 16-17 year old is conclusively proved to be *Gillick* competent but this did not mean that someone else who has parental responsibility cannot give consent for the treatment.

111. When applying his analysis to the facts of W's case, Lord Donaldson said at p. 80G-81B:

> "I have no doubt that the wishes of a 16 or 17-year-old child or indeed of a younger child who is "Gillick competent" are of the greatest importance both legally and clinically, but I do doubt whether Thorpe J was right to conclude that W was of sufficient understanding to make an informed decision. I do not say this on the basis that I consider her approach irrational. I personally consider that religious or other beliefs which bar any medical treatment or treatment of particular kinds are irrational, but that does not make minors who hold those beliefs any the less "Gillick competent". They may well have sufficient intelligence and understanding fully to appreciate the treatment proposed and the consequences of their refusal to accept that treatment. What distinguishes W from them, and what with all respect I do not think that Thorpe J took sufficiently into account (perhaps because the point did not emerge as clearly before him as it did before us), is that it is a feature of anorexia nervosa that it is capable of destroying the ability to make an informed choice. It creates a compulsion to refuse treatment or only to accept treatment which is likely to be ineffective. This attitude is part and parcel of the disease and the more advanced the illness, the more compelling it may become. Where the wishes of the minor are themselves something which the doctors reasonably consider need to be treated in the minor's own best interests, those wishes clearly have a much reduced significance."

112. Lord Donaldson concluded at p. 84A-B that:

> "No minor of whatever age has power by refusing consent to treatment to override a consent to treatment by someone who has parental responsibility for the minor and a fortiori a consent by the court. Nevertheless such a refusal is a very important consideration in making clinical judgments and for parents and the courts in deciding whether themselves to give consent. Its importance increases with the age and maturity of the minor."

113. Balcombe LJ at p. 87G-H agreed with Lord Donaldson that the parents of a 16 and 17 year old retained the right to consent to treatment even if she did not consent, and that the court could continue to exercise its inherent jurisdiction. Nolan LJ did not express a view as to whether parents could consent to treatment where the child had refused, but considered that the court under its inherent jurisdiction could continue to do so. He said, at p. 94D-E:

> "To take it a stage further, if the child's welfare is threatened by a serious or imminent risk that the child will suffer grave and irreversible mental or physical harm, then once again the court when called upon has a duty to intervene. It makes no difference whether the risk arises from the action or inaction of others, or from the action or inaction of the child. Due weight must be given to the child's wishes, but the court is not bound by them. In the present case, Thorpe J was apparently satisfied on the evidence before him that such a risk existed. In my judgment, he was fully entitled to take this view. By the time the matter came to this court, it was impossible to take any other view. For these reasons, I would dismiss the appeal save to the extent of making the necessary variation of the order of Thorpe J."

114. We were taken to two cases concerning the application of *Gillick* in particularly difficult medical and ethical situations, which are of some assistance in the present case. In *Re L (Medical Treatment: Gillick Competency*) [1998] 2 F.L.R. 810 Sir Stephen Brown P. considered the case of a 14 year old girl with a life threatening condition involving the possibility of a blood transfusion. L was a Jehovah's Witness and would not consent to the blood transfusion. The court ordered that the medical treatment should take place without her consent. The expert clinician appointed by the Official Solicitor is recorded as giving the following evidence:

> "He makes the point that the girl's view as to having no blood transfusion is based on a very sincerely, strongly held religious belief which does not in fact lend itself in her mind to discussion. It is one that has been formed by her in the context of her own family experience and the Jehovah's Witness meetings where they all support this view. He makes the point that there is a distinction between a view of this kind and the constructive formulation of an opinion which occurs with adult experience. That has not happened of course in the case of this young girl."

115. Sir Stephen Brown then concluded at p. 813:

> "It is, therefore, a limited experience of life which she has – inevitably so – but this is in no sense a criticism of her or of her upbringing. It is indeed refreshing to hear of children being brought up with the sensible disciplines of a well-conducted family. But it does necessarily limit her understanding of matters which are as grave as her own present situation. It may be that because of her belief she is willing to say, and to mean it, 'I am willing to accept death rather than to have a blood transfusion', but it is quite clear in this case that she has not been able to be given all the

> details which it would be right and appropriate to have in mind when making such a decision.
>
> I do not think that in this case this young girl is 'Gillick competent'. I base that upon all the evidence that I have heard. She is certainly not 'Gillick competent' in the context of all the necessary details which it would be appropriate for her to be able to form a view about."

116. *Re S (A Child) (Child Parent: Adoption Consent)* [2019] 2 Fam 177 also concerned a child under 16. In that case Cobb J considered the competence of a mother under the age of 16 to consent to her baby being placed for adoption. Cobb J held that it was appropriate and helpful in determining *Gillick* competence to read across and borrow from the relevant concepts and language in the Mental Capacity Act 2005 but cognisant of some fundamental differences, in particular that the assumption of capacity in section 1(2) of that Act did not apply and there was no requirement for any diagnostic characteristic as there is in section 2(1) of the Mental Capacity Act 2005, see paras 15,16 and 60.

117. At paras 34 to 37 Cobb J considered what test he should apply to the information that S needed to understand and then set out the information that would be relevant for the decision in question:

> "34. Macur J in *LBL v RYJ and VJ* [2011] 1 FLR 1279, para 24 held that it would not be necessary for a decision-maker to be able to comprehend "all the peripheral detail" in the assessment of capacity to make the relevant decision; in a case concerning residence and the provision of education, Macur J went on to say, at para 58:
>
> "In [the expert's] view it is unnecessary for his determination of RYJ's capacity that she should understand all the details within the statement of special educational needs. It is unnecessary that she should be able to give weight to every consideration that would otherwise be utilised in formulating a decision objectively in her 'best interests'. I agree with his interpretation of the test in section 3 which is to the effect that the person under review must comprehend and weigh the salient details relevant to the decision to be made. To hold otherwise would place greater demands upon RYJ than others of her chronological age/commensurate maturity and unchallenged capacity."
>
> 35. In the same vein, Baker J remarked in *H v A Local Authority* [2011] EWHC 1704 at [16(xi)]: "[the] courts must guard against imposing too high a test of capacity to decide issues such as residence because to do so would run the risk of discriminating against persons suffering from a mental disability."
>
> 36. Although not cited in argument, I further remind myself of the comments of Chadwick LJ in the Court of Appeal in *Masterman-Lister v Brutton & Co (Nos 1 and 2)* [2003] 1 WLR 1511, para 79: "a person should not be held unable to understand the information relevant to a

decision if he can understand the explanation of that information in broad terms and simple language…" So, says Ms Dolan, it is not necessary for S to understand all the peripheral and non-salient information in the adoption consent form in order to be declared capacitous. Nor does she even need to fully understand the legal distinctions between placement for adoption under a placement order and not under a placement order. Indeed, Ms Dolan herself relies in this regard on *In re A (Adoption: Agreement: Procedure)* [2001] 2 FLR 455, para 43 where Thorpe LJ observes that the differences between freeing and adoption are "complex in their inter-relationship and it is not to be expected that social workers should have a complete grasp of the distinction between the two, or always to signify the distinction in their discussion with the clients" (my emphasis)." If social workers are not expected to understand the complexities of the legislation (or its predecessor) or explain the distinction accurately to the parents with whom they are working asks Ms Dolan, why should a person under the age of 16 be expected to be able to grasp them in order to be able to be declared capacitous?

37. Accordingly, argues the local authority, the salient or "sufficient" information which is required to be understood by the child parent regarding extra-familial adoption is limited to the fundamental legal consequences of the same. The factors discussed at the hearing include: (i) your child will have new legal parents, and will no longer be your son or daughter in law, (ii) adoption is final, and non-reversible; (iii) during the process, other people (including social workers from the adoption agency) will be making decisions for the child, including who can see the child, and with whom the child will live; (iv) you may obtain legal advice if you wish before taking the decision; (v) the child will live with a different family forever; you will (probably) not be able to choose the adopters; (vi) you will have no right to see your child or have contact with your child; it is highly likely that direct contact with your child will cease, and any indirect contact will be limited; (vii) the child may later trace you, but contact will only be re-established if the child wants this; (viii) there are generally two stages to adoption; the child being placed with another family for adoption, and being formally adopted; (ix) for a limited period of time you may change your mind; once placed for adoption, your right to change your mind is limited, and is lost when an adoption order is made."

118. Cobb J's conclusions were these:

"60… It follows that in order to satisfy the Gillick test in this context the child parent should be able to demonstrate "sufficient" understanding of the "salient" facts around adoption; she should understand the essential "nature and quality of the transaction" (per Munby J in *Sheffield City Council v E* [2005] Fam 326, para 19) and should not need to be concerned with the peripheral.

> 61. It will, however, be necessary for the competent child decision-maker to demonstrate a "full understanding" of the essential implications of adoption when exercising her decision-making, for the independent CAFCASS officer to be satisfied that the consent is valid. If consent is offered under section 19 and/or section 20 of the 2002 Act, it will be necessary for a form to be signed, even if not in the precise format of that identified by Practice Direction 5A. I accept that on an issue as significant and life-changing as adoption, there is a greater onus on ensuring that the child understands and is able to weigh the information than if the decision was of a lesser magnitude: see Baker J in *CC v KK and STCC* [2012] COPLR 627, para 69. This view is consistent with the Mental Capacity Act 2005 Code of Practice, which provides, at paragraph 4.19:
>
> "a person might need more detailed information or access to advice, depending on the decision that needs to be made. If a decision could have serious or grave consequences, it is even more important that a person understands the information relevant to that decision.""

119. In determining the level of understanding that the child needs to have to consent to PBs, Mr Hyam attached considerable importance to the decision of the Supreme Court in *Montgomery v Lancashire Health Board*. That case concerned an action in negligence brought by a mother on behalf of her child. The child was disabled as a result of complications during delivery and the mother argued that she should have been advised as to the possibility of delivery by elective caesarean. The central issue for present purposes was the information that the doctor needed to have given the patient in order to establish that she had given informed consent for the treatment.

120. Lord Kerr set out the requirements placed on a doctor in providing information on risks of injury from treatment in the following terms at para 87:

> "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

121. Mr Hyam submitted that in determining whether a child is *Gillick* competent the court should consider what would a *"reasonable person in the patient's position understand",* and in asking that question, he submitted that the "reasonable person" is one with adult knowledge.

122. Ms Morris went to the opposite extreme. She submitted that when deciding what information needs to be given to the patient and understood by them, the test is a reasonable person in that individual's position, i.e. a reasonable 12 year old (or other

age) with GD. She said that the "salient" information that needs to be provided is what that reasonable patient would attach importance to. She said that seeking consent, certainly for treatment with lifelong implications such as sterilisation will always involve some *"act of imagination"*. Many patients facing life changing treatment, such as the loss of fertility in cancer treatment or endometriosis, will not have had experience of what they are foregoing, for example, fertility. She submitted that the court ought not to be pronouncing on hypothetical cases: rather, it should or could consider the facts of one specific case as and when it arises.

123. Mr McKendrick submitted that the correct approach in deciding what information was material was to assume a reasonable child of the individual's age.

124. Mr Skinner pointed out that *Montgomery* concerned an adult and therefore the presumption of capacity in the Mental Capacity Act 2005 applied. That presumption is inapplicable in a case concerning *Gillick* competency where the very issue is whether the child is competent to make the decision. The decision in *Montgomery* was of limited assistance, therefore, in the present case. In determining competence, the child must have sufficient understanding of the factors that are not just relevant to him or her now but which on an objective basis ought to be given weight in the future.

125. In our view, the following principles can be derived from the cases to which we have referred:

126. First, the question as to whether a person under the age of 16 is *Gillick* competent to make the relevant decision will depend on the nature of the treatment proposed as well as that person's individual characteristics. The assessment is necessarily an individual one. Where the decision is significant and life changing then there is a greater onus to ensure that the child understands and is able to weigh the information, see *Re S* at para 60.

127. Secondly, however, that does not mean that it is not possible for the court to draw some lines. The Trusts themselves accept that a 7 year old being treated with PBs for precocious puberty cannot give informed consent and his or her parents must give that consent because of the young age of the child concerned and the nature of the treatment.

128. Thirdly, efforts should be made to allow the child or young person to achieve *Gillick* competency where that is possible. Clinicians should therefore work with the individual to help them understand the treatment proposed and its potential implications in order to help them achieve competence.

129. Fourthly, however, that does not mean that every individual under 16 can achieve *Gillick* competence in relation to the treatment proposed. As we discuss below, where the consequences of the treatment are profound, the benefits unclear and the long-term consequences to a material degree unknown, it may be that *Gillick* competence cannot be achieved, however much information and supportive discussion is undertaken.

130. Fifthly, in order to achieve *Gillick* competence it is important not to set the bar too high. It is not appropriate to equate the matters that a clinician needs to explain, as set out in *Montgomery*, to the matters that a child needs to understand to achieve *Gillick* competence. The consequence of Mr Hyam's approach would be significantly to raise

the bar for competence and capacity, which would be contrary both to the common law and to a child's Article 8 rights and the importance of supporting individual autonomy.

131. We adopt the language of Chadwick LJ in *Masterman-Lister v Brutton and Co (Nos 1 and 2)* [2003] 1 WLR 151: a person should be able to "*understand an explanation of that information in broad terms and simple language"*, see *Re S* at para 36. Although this was said in a case that concerned an adult's capacity, in our judgment the same approach should be applied to a case concerning *Gillick* competence. The child or young person needs to be able to demonstrate sufficient understanding of the salient facts, see *Re S* at para 60.

132. Sixthly, we agree with Mr Skinner, that in deciding what facts are salient and what level of understanding is sufficient, it is necessary to have regard to matters which are those which objectively ought to be given weight in the future although the child might be unconcerned about them now. On the facts of this case there are some obvious examples, including the impact on fertility and on future sexual functioning.

SECTION E: CONCLUSIONS

133. The principal issue before this court is in some ways a narrow one. Can a child or young person under the age of 16 achieve *Gillick* competence in respect of the decision to take PBs for GD? The legal position of 16 and 17 year olds is different, and we deal with that below.

134. The starting point is to consider the nature of the treatment proposed. The administration of PBs to people going through puberty is a very unusual treatment for the following reasons. Firstly, there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment. Secondly, there is a lack of clarity over the purpose of the treatment: in particular, whether it provides a "pause to think" in a "hormone neutral" state or is a treatment to limit the effects of puberty, and thus the need for greater surgical and chemical intervention later, as referred to in the Health Research Authority report. Thirdly, the consequences of the treatment are highly complex and potentially lifelong and life changing in the most fundamental way imaginable. The treatment goes to the heart of an individual's identity, and is thus, quite possibly, unique as a medical treatment.

135. Furthermore, the nature and the purpose of the medical intervention must be considered. The condition being treated, GD, has no direct physical manifestation. In contrast, the treatment provided for that condition has direct physical consequences, as the medication is intended to and does prevent the physical changes that would otherwise occur within the body, in particular by stopping the biological and physical development that would otherwise take place at that age. There is also an issue as to whether GD is properly categorised as a psychological condition, as the DSM-5 appears to do, although we recognise there are those who would not wish to see the condition categorised in that way. Be that as it may, in our judgment for the reasons already identified, the clinical intervention we are concerned with here is different in kind to other treatments or clinical interventions. In other cases, medical treatment is used to remedy, or alleviate the symptoms of, a diagnosed physical or mental condition, and

the effects of that treatment are direct and usually apparent. The position in relation to puberty blockers would not seem to reflect that description.

136. Indeed the consequences which flow from taking PBs for GD and which must be considered in the context of informed consent, fall into two (interlinking) categories. Those that are a direct result of taking the PBs themselves, and those that follow on from progression to Stage 2, that is taking cross-sex hormones. The defendant and the Trusts argue that Stage 1 and 2 are entirely separate; a child can stop taking PBs at any time and that Stage 1 is fully reversible. It is said therefore the child needs only to understand the implications of taking PBs alone to be *Gillick* competent. In our view this does not reflect the reality. The evidence shows that the vast majority of children who take PBs move on to take cross-sex hormones, that Stages 1 and 2 are two stages of one clinical pathway and once on that pathway it is extremely rare for a child to get off it.

137. The defendant argues that PBs give the child "time to think", that is, to decide whether or not to proceed to cross-sex hormones or to revert to development in the natal sex. But the use of puberty blockers is not itself a neutral process by which time stands still for the child on PBs, whether physically or psychologically. PBs prevent the child going through puberty in the normal biological process. As a minimum it seems to us that this means that the child is not undergoing the physical and consequential psychological changes which would contribute to the understanding of a person's identity. There is an argument that for some children at least, this may confirm the child's chosen gender identity at the time they begin the use of puberty blockers and to that extent, confirm their GD and increase the likelihood of some children moving on to cross-sex hormones. Indeed, the statistical correlation between the use of puberty blockers and cross-sex hormones supports the case that it is appropriate to view PBs as a stepping stone to cross-sex hormones.

138. It follows that to achieve *Gillick* competence the child or young person would have to understand not simply the implications of taking PBs but those of progressing to cross-sex hormones. The relevant information therefore that a child would have to understand, retain and weigh up in order to have the requisite competence in relation to PBs, would be as follows: (i) the immediate consequences of the treatment in physical and psychological terms; (ii) the fact that the vast majority of patients taking PBs go on to CSH and therefore that s/he is on a pathway to much greater medical interventions; (iii) the relationship between taking CSH and subsequent surgery, with the implications of such surgery; (iv) the fact that CSH may well lead to a loss of fertility; (v) the impact of CSH on sexual function; (vi) the impact that taking this step on this treatment pathway may have on future and life-long relationships; (vii) the unknown physical consequences of taking PBs; and (viii) the fact that the evidence base for this treatment is as yet highly uncertain.

139. It will obviously be difficult for a child under 16 to understand and weigh up such information. Although a child may understand the concept of the loss of fertility for example, this is not the same as understanding how this will affect their adult life. A child's attitude to having biological children and their understanding of what this really means, is likely to change between childhood and adulthood. For many children, certainly younger children, and some as young as 10 and just entering puberty, it will not be possible to conceptualise what not being able to give birth to children (or conceive children with their own sperm) would mean in adult life. Similarly, the

meaning of sexual fulfilment, and what the implications of treatment may be for this in the future, will be impossible for many children to comprehend.

140. Ms Morris submitted that many decisions about complex and long-lasting medical treatment will involve the patient having, to some degree, to imagine themselves into an uncertain future of which they have no experience. However, for the reasons that we have explained in para 135 above we consider the treatment in this case to be in entirely different territory from the type of medical treatment which is normally being considered.

141. Some of the children and young people who have been treated at GIDS say in their witness statements that the thought of sex disgusted them, or they did not really think about fertility. These normal reactions do not detract from the difficulties surrounding consent and treatment with PBs. That adolescents find it difficult to contemplate or comprehend what their life will be like as adults and that they do not always consider the longer-term consequences of their actions is perhaps a statement of the obvious.

142. These various difficulties are compounded by the particular difficulties prevalent in the cohort of children treated at GIDS. On the defendant's case, they suffer considerable psychological distress by reason of their GD and are highly vulnerable. In those circumstances, the consequences of taking PBs on their fertility for example, or on their sexual life, may be viewed as a relatively small price to pay for what may be perceived as a solution to their immediate and real psychological distress. It would not follow however that their weighing of risks and benefits when they might start taking PBs would prevail in the longer-term.

143. The difficulty of achieving informed consent in these circumstances is further exacerbated by the lack of evidence as to the efficacy of PBs in treating GD and the long-term outcomes of taking it. We entirely accept that the fact that a treatment is experimental, or that the long-term outcomes are not yet known, does not of itself prevent informed consent being given. Otherwise no experimental treatment could ever be consented to. However, the combination here of lifelong and life changing treatment being given to children, with very limited knowledge of the degree to which it will or will not benefit them, is one that gives significant grounds for concern.

144. We do not think that the answer to this case is simply to give the child more, and more detailed, information. The issue in our view is that in many cases, however much information the child is given as to long-term consequences, s/he will not be able to weigh up the implications of the treatment to a sufficient degree. There is no age appropriate way to explain to many of these children what losing their fertility or full sexual function may mean to them in later years.

145. *Gillick* makes clear that any decision is treatment and person specific. However, for the reasons that we have set out above, we think that it is appropriate in this case to give clear guidance as to the application of the *Gillick* tests to the treatment and cohort of children in question. The conclusion we have reached is that it is highly unlikely that a child aged 13 or under would ever be *Gillick* competent to give consent to being treated with PBs. In respect of children aged 14 and 15, we are also very doubtful that a child of this age could understand the long-term risks and consequences of treatment in such a way as to have sufficient understanding to give consent. However, plainly the

increased maturity of the child means that there is more possibility of achieving competence at the older age.

146. In respect of a young person aged 16 or over, the legal position is different. There is a presumption of capacity under section 8 of the Family Law Reform Act 1969. As is explained in *Re W*, that does not mean that a court cannot protect the child under its inherent jurisdiction if it considers the treatment not to be in the child's best interests. However, so long as the young person has mental capacity and the clinicians consider the treatment is in his/her best interests, then absent a possible dispute with the parents, the court generally has no role. We do not consider that the court can somehow adopt an intrusive jurisdiction in relation to one form of clinical intervention for which no clear legal basis has been established.

147. We do however recognise that in the light of the evidence that has emerged, and the terms of this judgment, clinicians may well consider that it is not appropriate to move to treatment, such as PBs or CSH, without the involvement of the court. We consider that it would be appropriate for clinicians to involve the court in any case where there may be any doubt as to whether the long-term best interests of a 16 or 17 year old would be served by the clinical interventions at issue in this case.

148. We express that view for these reasons. First, the clinical interventions involve significant, long-term and, in part, potentially irreversible long-term physical, and psychological consequences for young persons. The treatment involved is truly life changing, going as it does to the very heart of an individual's identity. Secondly, at present, it is right to call the treatment experimental or innovative in the sense that there are currently limited studies/evidence of the efficacy or long-term effects of the treatment.

149. The position of the defendant and the Trusts is that they consider it would be an intrusion into the child or young person's autonomy if a decision about treatment with PBs were to be made by the court not by the patient. They are concerned about the use of NHS and court resources if these decisions have to be made by the court. We do not consider that this is the correct approach. In principle, a young person's autonomy should be protected and supported; however, it is the role of the court to protect children, and particularly a vulnerable child's best interests. The decisions in respect of PBs have lifelong and life-changing consequences for the children. Apart perhaps from life-saving treatment, there will be no more profound medical decisions for children than whether to start on this treatment pathway. In those circumstances we consider that it is appropriate that the court should determine whether it is in the child's best interests to take PBs. There is a real benefit in the court, almost certainly with a child's guardian appointed, having oversight over the decision. In any case, under the inherent jurisdiction concerning medical treatment for those under the age of 18, there is likely to be a conflict between the support of autonomy and the protective role of the court. As we have explained above, we consider this treatment to be one where the protective role of the court is appropriate.

150. The claimants' alternative ground is that the information provided by the defendant and the Trusts is inadequate to form the basis of informed consent. We accept that the defendant and the Trusts have in their written information, to children, young people and their parents and carers, tried hard to explain the potential consequences of PBs, including that of moving on to CSH, and to give full information. They have also

attempted to do this in an age appropriate manner. The problem is not the information given, but the ability of the children and young people, to understand and most importantly weigh up that information. The approach of the defendant appears to have been to work on the assumption that if they give enough information and discuss it sufficiently often with the children, they will be able to achieve *Gillick* competency. As we have explained above, we do not think that this assumption is correct.

OVERALL CONCLUSION

151. A child under 16 may only consent to the use of medication intended to suppress puberty where he or she is competent to understand the nature of the treatment. That includes an understanding of the immediate and long-term consequences of the treatment, the limited evidence available as to its efficacy or purpose, the fact that the vast majority of patients proceed to the use of cross-sex hormones, and its potential life changing consequences for a child. There will be enormous difficulties in a child under 16 understanding and weighing up this information and deciding whether to consent to the use of puberty blocking medication. It is highly unlikely that a child aged 13 or under would be competent to give consent to the administration of puberty blockers. It is doubtful that a child aged 14 or 15 could understand and weigh the long-term risks and consequences of the administration of puberty blockers.

152. In respect of young persons aged 16 and over, the legal position is that there is a presumption that they have the ability to consent to medical treatment. Given the long-term consequences of the clinical interventions at issue in this case, and given that the treatment is as yet innovative and experimental, we recognise that clinicians may well regard these as cases where the authorisation of the court should be sought prior to commencing the clinical treatment.

153. We have granted a declaration to reflect the terms of this judgment.