IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

JANE DOE, et al.,

Plaintiffs,

v. Case No. 4:23-cv-114-RH-MAF

JOSEPH A. LADAPO, et al.,

Defendants.
_____/

THE STATE'S NOTICE OF FILING TRIAL EXHIBITS

Surgeon General Ladapo, The Florida Board of Medicine, The Florida Board of Osteopathic Medicine, and State Attorney Gladson (collectively, "the State") hereby submit this Notice of Filing Trial Exhibits, with copies of the State's exhibits included as individual attachments to this notice.

The designation of an exhibit as "may use" does not necessarily mean that the State concedes that the exhibit is admissible if offered by Plaintiffs. The State may use such exhibits for impeachment only or offer them into evidence as appropriate. The State reserves the right to use additional documents for impeachment. The State reserves the right to offer any exhibit identified by Plaintiffs.

Dated: November 6, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2023, the foregoing was filed using the Court's CM/ECF, which will serve a copy to all counsel of record.

/s/ Mohammad O. Jazil
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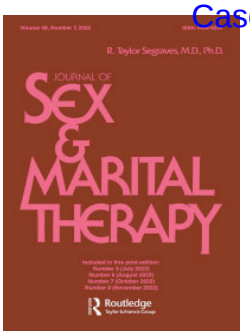
The State's Exhibit List

Trial Exhibit Number	Exhibit Description	Will Use	May Use	Stipulated/Plaintiffs' Objections
Dekker	Any exhibit that was entered into evidence in the *Dekker* trial		X	No Objections
DX1	*Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*		X	Objection: Hearsay; Relevance
DX2	Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent		X	No Objections
DX3	Masculinizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors		X	No Objections
DX4	Puberty Suppression Treatment for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors		X	No Objections
DX5	Surgical Treatment for Adults with Gender Dysphoria, Patient Information and Informed Consent		X	No Objections

DX6	Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Consent		X	No Objections
DX7	Feminizing Medications for Patients with Gender Dysphoria, Patient Information and Informed Parental Consent and Assent for Minors		X	No Objections
DX8	Medical Marijuana Consent Form		X	No Objections
DX9	Dr. Roman's CV	X		No Objections
DX10	Dr. Mortensen's CV	X		No Objections
DX11	Dr. Clemens's CV	X		No Objections
DX12	Dr. Levine's CV	X		No Objections



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Journal of Sex & Marital Therapy

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/usmt20

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To cite this article: Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022) Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, 48:7, 706-727, DOI: 10.1080/0092623X.2022.2046221

To link to this article: https://doi.org/10.1080/0092623X.2022.2046221

Published online: 17 Mar 2022.

JOURNAL OF SEX & MARITAL THERAPY
2022, VOL. 48, NO. 7, 706–727
https://doi.org/10.1080/0092623X.2022.2046221

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REVIEW

Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults

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ABSTRACT

In less than a decade, the western world has witnessed an unprecedented rise in the numbers of children and adolescents seeking gender transition. Despite the precedent of years of gender-affirmative care, the social, medical and surgical interventions are still based on very low-quality evidence. The many risks of these interventions, including medicalizing a temporary adolescent identity, have come into a clearer focus through an awareness of detransitioners. The risks of gender-affirmative care are ethically managed through a properly conducted informed consent process. Its elements—deliberate sharing of the hoped-for benefits, known risks and long-term outcomes, and alternative treatments—must be delivered in a manner that promotes comprehension. The process is limited by: erroneous professional assumptions; poor quality of the initial evaluations; and inaccurate and incomplete information shared with patients and their parents. We discuss data on suicide and present the limitations of the Dutch studies that have been the basis for interventions. Beliefs about gender-affirmative care need to be separated from the established facts. A proper informed consent process can both prepare parents and patients for the difficult choices that they must make and can ease professionals' ethical tensions. Even when properly accomplished, however, some clinical circumstances exist that remain quite uncertain.

KEYWORDS

Informed consent; ethics; gender dysphoria; gender identity; detransition

Introduction

Reconsideration of the meanings, purposes, indications, and processes of informed consent for transgender-identified youth is urgently needed. Parents of gender atypical children are considering social transition as early as preschool or grade school. Parents of preteens and teens are considering supporting their children's wishes to present in a new gender, take puberty blockers and cross-sex hormones, and plan for surgical alterations. College-aged youth are declaring new identities for the first time and obtaining hormones and surgery without their parents' knowledge.

When uncertain parents of children and teens consult their primary care providers, they are usually referred to specialty gender services. Parents and referring clinicians assume that specialists with "gender expertise" will undertake a thorough evaluation. However, the evaluations preceding the recommendation for gender transition are often surprisingly brief (Anderson & Edwards-Leeper, 2021) and typically lead to a recommendation for hormones and surgery, known as *gender-affirmative* treatment.

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This article has been corrected with minor changes. These changes do not impact the academic content of the article.

Despite the widely recognized deficiencies in the evidence supporting gender-affirmative interventions (National Institute for Health & Care Excellence, 2020a; 2020b), the process of obtaining informed consent from patients and their families has no established standard. There is no consensus about the requisite elements of evaluations, nor is there unanimity about how informed consent processes should be conducted (Byne et al., 2012). These two matters are inconsistent from practitioner to practitioner, clinic to clinic, and country to country.

Social transition, hormonal interventions, and surgery have profound implications for the course of the lives of young patients and their families. It is incumbent upon professionals that these consequences be thoroughly, patiently clarified over time prior to undertaking any element of transition. The informed consent process does not preclude transition; it merely educates the family about the state of the science underpinning the decision to transition. Social transition, hormones, and surgeries are unproven in a strict scientific sense, and as such, to be ethical, require a thorough and fully informed consent process.

Ethical Concerns About Inadequate Informed Consent

The concept of informed consent in medicine has roots in both ethical theory and law. The ethical foundation is centered in the principles of beneficence, justice, and respect for autonomy, while the legal issues have to do with questions of malpractice (Katz et al., 2016).

Patients consenting to treatment must meet age-based and decisional capacity requirements (Katz et al., 2016). Minors less than the age of consent participate in decision-making by providing *assent*—an agreement with the intervention. The limited maturational cognitive capacities of minors are the key reason why parents serve as the ethical and legal surrogates for medical decision-making, tasked with signing an informed consent document (Grootens-Wiegers, Hein, van den Broek, & de Vries, 2017).

The informed consent process consists of three main elements: a disclosure of information about the nature of the condition and the proposed treatment and its alternatives; an assessment of patient and caregiver understanding of the information and capacity for medical decision-making; and obtaining the signatures that signify informed consent has been obtained (Katz et al., 2016). The current expectation that clinicians and institutions are required to thoroughly inform their patients about the benefits, risks, and uncertainties of a particular treatment, as well as about alternatives, has a long legal history in the United States (Lynch, Joffe, & Feldman, 2018).

Ethical concerns about inadequate informed consent for trans-identified youth have several potentially problematic sources, including *erroneous assumptions* held by professionals; *poor quality of the evaluation process*; and *incomplete and inaccurate information* that the patients and family members are given.

These concerns are amplified by the *dramatic growth* in demand for youth gender transition witnessed in the last several years that has led to a perfunctory informed consent process. A rushed process does not allow for a proper discussion of not only the benefits, but the profound risks and uncertainties associated with gender transition, especially when gender transition is undertaken before mature adulthood.

a. *Dramatic growth in demand for services threatens true informed consent*

Gender identity variations were thought to be extremely rare a generation ago. While the incidence in youth had not been officially estimated, in adults it was 2-14 per 100,000 (American Psychiatric Association, 2013, p. 454). However, around 2006, the incidence among youth began to rise, with a dramatic increase observed in 2015 (Aitken et al., 2015, de Graaf, Giovanardi, Zitz, & Carmichael, 2018). Currently, 2-9% of U.S. high school students identify as transgender, while in colleges, 3% of males and 5% of females identify as gender-diverse (American College Health Association, 2021; Johns et al., 2019; Kidd et al., 2021).

Whereas previously most of the affected individuals identified as the opposite sex, there is now a growing trend toward identifying as *nonbinary*: neither male nor female or both male and female (Chew et al., 2020). A recent study reported that the majority of transgender-identifying youth (63%) now have a non-binary identity (Green, DeChants, Price, & Davis, 2021). Although the incidence of natal males asserting a trans identity in adolescence has significantly increased, the dramatic increase is driven primarily by the natal females requesting services (Zucker, 2017). Many suffer from significant comorbid mental health disorders, have neurocognitive difficulties such as ADHD or autism or have a history of trauma (Becerra-Culqui et al., 2018; Kozlowska, McClure, et al., 2021).

The increase in rates of transgender identification is reflected in the numbers of youth seeking help from medical professionals. For example, according to data reported by the Tavistock gender clinic in the UK, in 2009, there were 51 requests for services (de Graaf et al., 2018); in 2019-2020, 2728 referrals were recorded—a 53-fold increase in just over a decade (Tavistock & Portman NHS Foundation Trust, 2020). The growing number of urban transgender health centers that have arisen in recent years (HRC, n.d.) reflects the increased demand for gender-related medical care among young people in North America Australia, and Europe.

This unprecedented increase has created pressure on institutions and practitioners to rapidly evaluate these youth and make recommendations about treatment. To respond to growing demand, an innovative *informed consent model of care* has been developed. Under this model, mental health evaluations are not required, and hormones can be provided after just one visit following the collection of a patient's or guardian's consent signature (Schulz, 2018). The provision of transition services under this model of care is available not just to those over 18, but for younger patients as well (Planned Parenthood League of Massachusetts, n.d.).

Although following the informed consent model of care for hormones and surgeries for youth may diminish clinicians' ethical or moral unease (Vrouenraets et al., 2020), we believe this model is the antithesis of true informed consent, as it jeopardizes the ethical foundation of patient autonomy. Autonomy is not respected when patients consenting to the treatment do not have an accurate understanding of the risks, benefits, and alternatives.

b. *Assumptions held by professionals influence the integrity of the informed consent process*

Gender-dysphoric children and teens can intensely occupy the belief that their lives will be immensely improved by transition. Clinicians who have embraced the gender-affirmative model of care operate on the assumption that children and teens know best what they need to be happy and productive (Ehrensaft, 2017). These professionals, responding to the youths' passionate pleas, see their role as validating the young person's fervent wishes for hormones and surgery and clearing the path for gender transition. In doing so, they privilege the ethical principle of respect for patient autonomy (Clark & Virani, 2021) over their obligations for beneficence and non-maleficence.

Many of the gender-affirmative clinicians subscribe to the theory of *minority stress* – the supposition that the frequently co-occurring psychiatric symptoms of gender-dysphoric individuals are a result of prejudice and discrimination brought about by gender non-conformity (Rood et al., 2016; Zucker, 2019), and that gender transition will ameliorate these symptoms. Some even claim that gender-affirmative care will successfully treat not only depression and anxiety but will also resolve neurocognitive deficits frequently present in gender-dysphoric individuals (Turban, 2018; Turban, King, Carswell, & Keuroghlian, 2020; Turban & van Schalkwyk, 2018). These latter assertions have proven controversial even among the proponents of gender-affirmative interventions (Strang et al., 2018; van der Miesen, Cohen-Kettenis, & de Vries, 2018). The minority stress theory as the sole explanatory mechanism for co-occurring mental health illness has also been questioned in light of the evidence that psychiatric symptoms frequently predate the onset of gender dysphoria (Bechard, VanderLaan, Wood, Wasserman, & Zucker, 2017; Kaltiala-Heino, Sumia, Työläjärvi, & Lindberg, 2015; Kozlowska, Chudleigh, McClure, Maguire,

& Ambler, 2021). Other clinicians recognize the limits of gender-affirmative care and are aware that youth with underlying psychiatric issues are likely to continue to struggle post-transition (Kaltiala, Heino, Työläjärvi, & Suomalainen, 2020), but, unaware of alternative approaches such as gender-exploratory psychotherapy or watchful waiting (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019), these well-meaning professionals continue to treat youth with gender-affirmative interventions despite lingering doubts.

It is common for gender-affirmative specialists to erroneously believe that gender-affirmative interventions are a *standard of care* (Malone, D'Angelo, Beck, Mason, & Evans, 2021; Malone, Hruz, Mason, Beck, et al:, 2021). Despite the increasingly widespread professional beliefs in the safety and efficacy of pediatric gender transition, and the endorsement of this treatment pathway by a number of professional medical societies, the best available evidence suggests that the benefits of gender-affirmative interventions are of very low certainty (Clayton et al., 2021; National Institute for Health & Care Excellence, 2020a; 2020b) and must be carefully weighed against the health risks to fertility, bone, and cardiovascular health (Alzahrani et al., 2019; Biggs, 2021; Getahun et al., 2018; Hembree et al., 2017; Nota et al., 2019). Recently, emphasis has also been placed on psychosocial risks and as yet unknown medical risks (Malone, D'Angelo, et al., 2021).

Five scientific observations question and refute the assumption that an individual's experience of incongruence of sex and gender identity is best addressed by supporting the newly assumed gender identity with psychosocial and medical interventions.

1. The most foundational aspect of the diagnoses of "gender dysphoria" (DSM-5) and "gender incongruence" (ICD-11), requisite for the provision of medical treatment, is in flux, as professionals disagree on whether the presence of distress is a key diagnostic criterion, as stated in the DSM-5, or is irrelevant, as is the case according to the latest ICD-11 criteria (American Psychiatric Association, 2013; World Health Organization, 2019). Further, these diagnoses have never been properly field-tested (de Vries et al., 2021).
2. There are no randomized controlled studies demonstrating the superiority of various affirmative interventions compared to alternatives. There isn't even agreement about which outcome measures would be ideal in such studies.
3. There are few long-term follow-up studies of various interventions using predetermined outcome measures at designated intervals. Studies that have been conducted are, at best, inconsistent. Higher quality studies with longer-follow-up fail to demonstrate durable positive impacts on mental health (Bränström & Pachankis, 2020a; 2020b).
4. Rates of post-transition desistance, increased mental suffering, increased incidence of physical illness, educational failure, vocational inconstancy, and social isolation have not been established.
5. Numerous cross-sectional and prospective studies of transgender adults consistently demonstrate a high prevalence of serious mental health and social problems as well as suicide (Asscheman et al., 2011; Dhejne et al., 2011). Controversies about how to deal with trans-identified youth must consider the well described vulnerabilities of transgender adults.

It is equally important to realize that to date, research about alternative approaches, such as psychotherapy or watchful waiting, shares the scientific limitations of the research of more invasive interventions: there are no control groups, nor is there systematic follow-up at predetermined intervals with predetermined means of measurement (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019). Parents and patients need to be informed of this as well.

Perhaps the single most problematic assumption held by some gender clinicians is that the young patients have simply been "born in the wrong body." This assumption seemingly frees clinicians from having to contend with the ethical dilemmas of recommending body-altering

interventions that are based on very low-quality evidence. Despite the principle of development that biology, psychosocial factors, and culture generate behavior, these clinicians may believe that atypical genders are created by biology. This reductionistic approach has been criticized repeatedly (Kendler, 2019).

While the origins of childhood or adolescent onset of gender incongruence have not yet been fully elucidated, brain studies of increasing technical sophistication have yet to demonstrate a distinct structure or pattern that accounts for an atypical gender identity, after statistically controlling for sexual orientation and exposure to exogenous hormones (Frigerio, Ballerini, & Valdés Hernández, 2021). Twin studies also demonstrate that while biology plays a role in one's experience of "gender incongruence," it is far from deterministic (Diamond, 2013).

A growing number of clinicians and researchers are noting that the dramatic rise of teens declaring a trans identity appears to be, at least in part, a result of peer influence (Anderson, 2022; Hutchinson, Midgen, & Spiliadis, 2020; Littman 2018; Littman, 2020; Zucker, 2019). Some have noted yet another influx of trans-identified youth emerging during the COVID lockdowns, and have hypothesized that increased isolation coupled with heavy internet exposure may be responsible (Anderson, 2022). While the research into the phenomenon of social influence as a contributor to trans identification of youth is still in its infancy, the possibility that clinicians are providing treatments with permanent consequences to address what may be transient identities in youth poses a serious ethical dilemma.

c. *Poor evaluations*

There is a growing recognition that rapid evaluations which disregard factors contributing to the development of gender dysphoria in youth are problematic. In November 2021, two-leaders of the World Professional Organization for Transgender Health (WPATH) warned the medical community that the "The mental health establishment is failing trans kids" (Anderson & Edwards-Leeper, 2021). Frequently, evaluations provided by gender clinicians may only ascertain the diagnosis of *gender dysphoria* (DSM-5) or its ICD-11 counterpart *gender incongruence*, and screen for conspicuous mental illness prior to recommending hormones and surgeries. These limited, abbreviated evaluations overlook, and as a result fail to address, the relevant issue of the forces that may have influenced the young person's current gender identity.

Confirming the young person's self-diagnosis of gender dysphoria or gender incongruence is easy. Clarifying the developmental forces that have influenced it and determining an appropriate intervention are not. Contextualizing these forces involves an understanding of child and adolescent developmental processes, childhood adversity, co-existing physical and cognitive disadvantages, unfortunate parental or family circumstances (Levine, 2021), as well as the role of social influence (Anderson, 2022; Anderson & Edwards-Leeper, 2021; Littman, 2018; 2021).

The poor quality of mental health evaluations has been a point of significant discontent for a growing number of parents of gender-dysphoric youth. Increasingly, parents have formed dozens of support groups in North America, Europe, Australia and New Zealand, united in their objections to the idea that the best or the only treatment for their gender-dysphoric children is affirmation (Genspect, 2021). These distressed parents, recognizing that their son or daughter may eventually decide to present to others as a trans person, want a psychotherapeutic investigation to understand what contributed to the development of this identity and an exploration of noninvasive treatment options. Frequently, they cannot find anyone in their community who does not recommend immediate affirmation.

The American Academy of Pediatrics' Committee of Bioethics recognizes that "parents…are better situated than others to understand the unique needs of their children and to make appropriate, caring decisions regarding their children's health care" (Katz et al., 2016). The plight of the families unable to find specialists capable of conducting thorough evaluations draws attention to the widespread acceptance of medical interventions for gender-dysphoric youth as the first line of treatment. The problem is that such care has been established through precedent rather

than through scientific demonstrations of its efficacy. We contend that parents and patients have a right to know this, and that it is the professionals' responsibility and obligation to inform them of the state of knowledge in this arena of care.

d. *Incorrect information shared*

In sharing the information with patients and families, two key areas of uncertainty must be emphasized. The first one is the uncertain permanence of a child's or an adolescent's gender identity (Littman, 2021; Ristori & Steensma, 2016; Singh, Bradley, & Zucker, 2021; Vandenbussche, 2021; Zucker, 2017). The second is the uncertain long-term physical and psychological health outcomes of gender transition (National Institute for Health & Care Excellence, 2020a; 2020b). Unfortunately, gender specialists are frequently unfamiliar with, or discount the significance of, the research in support of these two concepts. As a result, the informed consent process rarely adequately discloses this information to patients and their families.

Problematically, it is common for gender clinicians to emphasize the risk of suicide if a young person's wish to transition gender is not immediately fulfilled. There is a significant amount of misinformation surrounding the question of suicidality of trans-identified youth (Biggs, 2022). Providers of gender-affirmative care should be careful not to unwittingly propagate misinformation regarding suicide to parents and youths. They should also be reminded that any conversations about suicide should be handled with great care, due to its socially contagious nature (Bridge et al., 2020; HHS, 2021).

i. High rate of desistance/natural resolution of gender dysphoria in children is not disclosed

There have been eleven research studies to date indicating a high rate of resolution of gender incongruence in children by late adolescence or young adulthood without medical interventions (Cantor, 2020; Ristori & Steensma, 2016; Singh et al., 2021). An attempt has been made to discount the applicability of this research, suggesting that the studies were based on merely gender non-conforming, rather than truly gender-dysphoric, children (Temple Newhook et al., 2018). However, a reanalysis of the data prompted by this critique confirmed the initial finding: Among children meeting the diagnostic criteria for "Gender Identity Disorder" in DSM-IV (currently "Gender Dysphoria in DSM-5), 67% were no longer gender-dysphoric as adults; the rate of natural resolution for gender dysphoria was 93% for children whose gender dysphoria was significant but subthreshold for the DSM diagnosis (Zucker, et al., 2018). It should be noted that high resolution of childhood-onset gender dysphoria had been recorded before the practice of social transition of young children was endorsed by the American Academy of Pediatrics (Rafferty et al., 2018). It is possible that social transition will predispose a young person to persistence of transgender identity long-term (Zucker, 2020).

The information regarding the resolution of gender dysphoria among those with adolescent-onset gender dysphoria, which is currently the predominant presentation, is less clear. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle, 2020; Littman, 2021; Vandenbussche, 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo, 2018). However, in the last several years since gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

According to a recent study from a UK adult gender clinic, 6.9% of those treated with gender-affirmative interventions detransitioned within only 16 months of starting treatment, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7% of patients disengaged from the clinic without completing

their treatment plan (Hall, Mitchell, & Sachdeva, 2021). While some of these individuals later reengaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for the average 5 years (17 months-10 years) prior to discontinuing.

Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd, Hackett, & Bewley, 2022 p.15). Indeed, given that regret may take up to 8-11 years to materialize (Dhejne, Öberg, Arver, & Landén, 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but two recently published studies examining detransitioner experiences report that detransitioners from the recently-transitioning cohorts feel they had been rushed to medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration (Littman, 2021; Vandenbussche, 2021).

Clinicians should also disclose to patients and parents that there is no test which can accurately predict who will persist in their transgender identification upon reaching mature adulthood (Ristori & Steensma, 2016). Families should be made aware that a period of strong cross-sex identification in childhood is commonly associated with future homosexuality (Korte et al., 2008). Research in desistance confirms that the majority of youth whose gender dysphoria resolves naturally do indeed grow up to be gay, lesbian, or bisexual adults (Cantor, 2020, Appendix; Singh et al., 2021).

ii. Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained

The evidence underlying the practice of pediatric gender transition is widely recognized to be of very low quality (Hembree et al., 2017). In 2020, the most comprehensive systematic review of evidence to date, commissioned by the UK National Health System (NHS) and conducted by the National Institute for Health and Care Excellence (NICE), concluded that the evidence for both puberty blocking and cross-sex hormones is of very low certainty (National Institute for Health & Care Excellence, 2020a; 2020b).

According to the NICE review of evidence for puberty blockers, the studies "are all small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty as assessed using modified GRADE [Grading of Recommendations, Assessment, Development and Evaluations]. All the included studies reported physical and mental health comorbidities and concomitant treatments very poorly" (National Institute for Health & Care Excellence, 2020a, p.13). NICE reached similar conclusions regarding the quality of the evidence for cross-sex hormones (National Institute for Health & Care Excellence, 2020b).

Problematically, the implications of administering a treatment with irreversible, life-changing consequences based on evidence that has an official designation of "very low certainty" according to modified GRADE is rarely discussed with the patients and the families. GRADE is the most widely adopted tool for grading the quality of evidence and for making treatment recommendations worldwide. GRADE has four levels of evidence, also known as certainty in evidence or quality of evidence: very low, low, moderate, and high (BMJ Best Practice, 2021). When evidence is assessed to be "very low certainty," there is a high likelihood that the patients will not experience the effects of the proposed interventions (Balshem et al., 2011).

In the context of providing puberty blockers and cross-sex hormones, the designation of "very low certainty" signals that the body of evidence asserting the benefits of these interventions is

highly unreliable. In contrast, several negative effects are quite certain. For example, puberty blockade followed by cross-sex hormones leads to infertility and sterility (Laidlaw, Van Meter, Hruz, Van Mol, & Malone, 2019). Surgeries to remove breasts or sex organs are irreversible. Other health risks, including risks to bone and cardiovascular health, are not fully understood and are uncertain, but the emerging evidence is alarming (Alzahrani et al., 2019; Biggs, 2021).

iii. The question of suicide is inappropriately handled

Suicide among trans-identified youth is significantly elevated compared to the general population of youth (Biggs, 2022; de Graaf et al., 2020). However, the "transition or die" narrative, whereby parents are told that their only choice is between a "live trans daughter or a dead son" (or vice-versa), is both factually inaccurate and ethically fraught. Disseminating such alarmist messages hurts the majority of trans-identified youth who are not at risk for suicide. It also hurts the minority who are at risk, and who, as a result of such misinformation, may forgo evidence-based suicide prevention interventions in the false hopes that transition will prevent suicide.

The notion that trans-identified youth are at alarmingly high risk of suicide usually stems from biased online samples that rely on self-report (D'Angelo et al., 2020; James et al., 2016; The Trevor Project, 2021), and frequently conflates suicidal thoughts and non-suicidal self-harm with serious suicide attempts and completed suicides. Until recently, little was known about the actual rate of suicide of trans-identified youth. However, a recent analysis of data from the biggest pediatric gender clinic in the world, the UK's Tavistock, found the rate of completed youth suicides to be 0.03% over a 10-year period, which translates into the annual rate of 13 per 100,000 (Biggs, 2022). While this rate is significantly elevated compared to the general population of teens, it is far from the epidemic of trans suicides portrayed by the media.

The "transition or die" narrative regards suicidal risk in trans-identified youth as a different phenomenon than suicidal risk among other youth. Making them an exception falsely promises the parents that immediate transition will remove the risk of suicidal self-harm. Trans patients themselves complain about the so-called "trans broken arm syndrome" – a frustrating pattern whereby physicians "blame" all the problems the patients are experiencing on their trans status, and a result, fail to perceive and respond to other sources of distress (Paine, 2021). Clinicians caring for trans-identified youth should be reminded that suicide risk in all patients is a multi-factorial phenomenon (Mars et al., 2019). To treat trans youths' suicidality as an exception is to deny them evidence-based care.

A recent study of three major youth clinics concluded that suicidality of trans-identifying teens is only somewhat elevated compared to that of youth referred for mental health issues unrelated to gender identity struggles (de Graaf et al., 2020). Another study found that transgender-identifying teens have relatively similar rates of suicidality compared to teens who are gay, lesbian and bisexual (Toomey, Syvertsen, & Shramko, 2018). Depression, eating disorders, autism spectrum conditions, and other mental health conditions commonly found in transgender-identifying youth (Kaltiala-Heino, Bergman, Työläjärvi, & Frisen, 2018; Kozlowska, McClure, et al., 2021; Morandini, Kelly, de Graaf, Carmichael, & Dar-Nimrod, 2021) are all known to independently contribute to the probability of suicide (Biggs, 2022; Simon & VonKorff, 1998; Smith, Zuromski, & Dodd, 2018).

The "transition or suicide" narrative falsely implies that transition will prevent suicides. Clinicians working with trans-identified youth should be aware that although in the short-term, gender-affirmative interventions can lead to improvements in some measures of suicidality (Kaltiala et al., 2020), neither hormones nor surgeries have been shown to reduce suicidality in the long-term (Bränström & Pachankis, 2020a; 2020b). Alarmingly, a longitudinal study from Sweden that covered more than a 30-year span found that adults who underwent surgical transition were 19 times more likely than their age-matched peers to die by suicide overall, with female-to-male participants' risk 40 times the expected rate (Dhejne et al., 2011, Table S1).

Another key longitudinal study from the Netherlands concluded that suicides occur at a similar rate at all stages of transition, from pretreatment assessment to post-transition follow-up (Wiepjes et al., 2020). The data from the Tavistock clinic also did not show a statistically significant difference between completed suicides in the "waitlist" vs. the "treated" groups (Biggs, 2022). Luckily, in both groups, completed suicides were rare events (which may have been responsible for the lack of statistical significance). Thus, we consider the "transition or die" narrative to be misinformed and ethically wrong.

In our experience working with trans-identified youth, an adolescent's suicidality can sometimes arise as a response to parental distress, resistance, skepticism, or wish to investigate the forces shaping the new gender identity before social transition and hormone therapy. When mental health professionals or other healthcare providers fail to recognize the legitimacy of parental concerns, or label the parents as transphobic, this only tends to intensify intrafamilial tension. Clinicians would be well-advised that gender transition is not an appropriate response to suicidal intent or threat, as it ignores the larger mental health and social context of the young patient's life—the entire family is often in crisis. Trans-identified adolescents should be screened for self-harm and suicidality, and if suicidal behaviors are present, an appropriate evidence-based suicide prevention plan should be put in place (de Graaf et al., 2020).

The Dutch Study: the questionable basis for the gender affirmative model of care for youth

Few practitioners of gender-affirmative interventions, and even fewer patients and families, realize that the foundation of the practice of medically transitioning minors stems from a single Dutch proof of concept study, the outcomes of which were documented in two publications (de Vries, Steensma, Doreleijers, Cohen, & Kettenis, 2011; de Vries et al., 2014). The former (de Vries et al., 2011) reported on cases who underwent puberty blockade, while the latter (de Vries et al., 2014) reported on a subset of the cases who completed surgeries.

The Dutch study subjects' high level of psychological functioning at 1.5 years after surgery, which was the study end point, was an impressive feat. However, both of the studies suffer from a high risk of bias due to their study design, which is effectively a non-randomized case series—one of the lowest levels of evidence (Mathes & Pieper, 2017; National Institute for Health & Care Excellence, 2020a). In addition, the studies suffer from limited applicability to the populations of adolescents presenting today (de Vries, 2020). The interventions described in the study are currently being applied to adolescents who were not cross-gender identified prior to puberty, who have significant mental health problems, as well as those who have non-binary identities—all of these presentations were explicitly disqualified from the Dutch protocol. Despite these limitations, the Dutch clinical experiment has become the basis for the practice of medical transition of minors worldwide and serves as the basis for the recommendations outlined in the 2017 Endocrine Society guidelines (Hembree et al., 2017).

We contend that the Dutch studies have been misunderstood and misrepresented as providing evidence of the safety and efficacy of these interventions for all youth. It is important that both the strengths and the weaknesses of these two studies are understood, as to date, the Dutch experience presents the best available evidence behind the practice of pediatric gender transition.

Rationale for pediatric transition

Prior to the 1990s, gender transitions were typically initiated in mature adults (Dhejne et al., 2011). However, it was noted that particularly for natal male patients, hormonal and surgical interventions failed to achieve satisfactory results, and patients had a "never disappearing masculine appearance" (Delemarre-van de Waal & Cohen-Kettenis, 2006). The lack of adequate cosmetic outcomes was thought to contribute to the frequently disappointing outcomes of medical

gender transition, with persistently high rates of mental illness and suicidality post-transition (Delemarre-van de Waal & Cohen-Kettenis, 2006; Dhejne et al., 2011; Ross & Need, 1989).

In the mid 1990s, a team of Dutch researchers hypothesized that by carefully selecting a subset of gender-dysphoric children who would likely be transgender-identified for the rest of their lives, and by medically intervening before puberty left an irreversible mark on their bodies, the cosmetic outcomes would be improved—and as a result, mental health outcomes might be improved (Gooren & Delemarre-van de Waal, 1996).

Mixed study findings

In 2014, the Dutch research team published a key longitudinal study of mental health outcomes of 55 youths who completed medical and surgical transition (de Vries et al., 2014). The 2014 paper (sometimes referred to as the "Dutch study") reported that for youth with severe gender dysphoria that started in early childhood and persisted into mid-adolescence, a sequence of puberty blockers, cross-sex hormones, and breast and genital surgeries (including a mandatory removal of the ovaries, uterus and testes), with ongoing extensive psychological support, was associated with positive mental health and overall function 1.5 years post-surgery.

While the Dutch reported resolution of gender dysphoria post-surgery in study subjects, the reported psychological improvements were quite modest (de Vries et al., 2014). Of the 30 psychological measurements reported, nearly half showed no statistically significant improvements, while the changes in the other half were marginally clinically significant at best (Malone, D'Angelo, et al., 2021). The scores in anxiety, depression, and anger did not improve. The change in the Children's Global Assessment Scale, which measures overall function, was one of the most impressive changes—however it too remained in the same range before and after treatment (de Vries et al., 2014).

Problematic discordance between reduced gender dysphoria and lack of meaningful improvements in psychological measures

The discordance between the marked reduction in gender dysphoria, as measured by the UGDS (Utrecht Gender Dysphoria Scale), and the lack of meaningful changes in psychological function using standard measures, warrants further examination. There are three plausible explanations for this lack of agreement. Any one of these three explanations calls into question the widely assumed notion that the medical interventions significantly improve mental health or lessen or eradicate gender dysphoria.

One possible explanation is that gender dysphoria as measured by UGDS, and psychological function as measured by most standard instruments, are not correlated. This contradicts the primary rationale for providing gender-affirmative treatments for youth (which is to improve psychological health and functioning), and if true, ethically threatens these medical interventions. The other plausible explanation stems from the high psychological function of all the subjects at baseline; the subjects were selected because they were free from significant mental health problems (de Vries et al., 2014). As a result, there was little opportunity to meaningfully improve. This explanation highlights a key limitation in applying the study's results to the majority of today's gender-dysphoric youth, who often present with a high burden of mental illness (Becerra-Culqui et al., 2018; Kozlowska, McClure, et al., 2021). The study cannot be used as evidence that these procedures have been proven to improve depression, anxiety, and suicidality.

A third possible explanation for the discordance between only minor changes in psychological outcomes but a significant drop in gender dysphoria comes from a close examination of the UGDS scale itself and how it was used by the Dutch researchers. This 12-item scale, designed by the Dutch to assess the severity of gender dysphoria and to identify candidates for hormones

and surgeries, consists of "male" (UGDS-aM) and "female" (UGDS-aF) versions (Iliadis et al., 2020). At baseline and after puberty suppression, biological females were given the "female" scale, while males were given the "male" scale. However, post-surgery, the scales were flipped: biological females were assessed using the "male" scale, while biological males were assessed on the "female" scale (de Vries et al., 2014). We maintain that this handling of the scales may have at best obscured, and at worst, severely compromised the ability to meaningfully track how gender dysphoria was affected throughout the treatment.

Consider this example. At baseline, a gender-dysphoric biological female would rate items from the "female" scale such as: "I prefer to behave like a boy" (item 1); "I feel unhappy because I have to behave like a girl" (item 6) and "I wish I had been born a boy" (item 12). Positive answers to these questions would have contributed to a high baseline gender dysphoria score. After the final surgery, however, this same patient would be asked to rate items from the "male" scale, including the following: "My life would be meaningless if I had to live as a boy" (item 1); "I hate myself because I am a boy" (item 6) and "It would be better not to live than to live as a boy" (item 12). A gender-dysphoric female would not endorse these statements (at any stage of the intervention), which would lead to a lower gender dysphoria score.

Thus, the detected drop in the gender dysphoria scores for biological males and females may have had less to do with the success of the interventions, and more to do with switching the scale from the "female" to the "male" version (and vice-versa) between the baseline and post-surgical period. This, too, may explain why no changes in gender dysphoria were noted between baseline and the puberty blockade phase, and were only recorded after the final surgery, when the scale was switched.

It must be considered that had the researchers administered the "flipped" scale earlier, at the completion of the puberty blocker stage, UGDS scale could have registered a reduction in gender dysphoria. Likewise, however, one must consider the possibility that had *both sets of scales* been administered to the same individual at baseline, a "reduction" in gender dysphoria could have been registered upon switching of the scale, *well before any interventions began*. The question here is whether the diminishment of quantitative measures of gender dysphoria is largely an artifact of what scale was used.

It must be noted that the UGDS measure has been demonstrated only to effectively differentiate between clinically referred gender-dysphoric individuals, non-clinically referred controls, and participants with disorders of sexual development, and was not designed to detect changes in gender dysphoria during treatment (Steensma, McGuire, Kreukels, et al. 2013). The presence of items such as "I dislike having erections" (item 11, UGDS-aM), which would have to be rated by birth-females, and "I hate menstruating because it makes me feel like a girl (item 10, UGDS-aF), which would be presented to birth-males, neither of which could be meaningfully rated by either at any stage of the interventions, further illustrates that UGDS has questionable validity for the purpose of detecting meaningful changes in gender dysphoria as a result of medical and surgical treatment.

The updated UGDS scale (UGDS-GS), developed by the Dutch after the publication of their seminal study, has eliminated the two-sex version of the scale in favor of a single battery of questions applicable to both sexes (McGuire et al., 2020). This change may lead to a more reliable measurement of treatment-associated changes in future research. Other gender dysphoria scales also exist (Hakeem, Črnčec, Asghari-Fard, Harte, & Eapen, 2016; Iliadis et al., 2020) and may or may not be better suited for the purposes of measuring the impact of medical interventions on underlying gender distress. Gender dysphoria, of course, may also prove to be a more complex concept than can be measured by any scale.

Other limitations

The two Dutch studies were conducted without a control group (de Vries et al., 2011; de Vires et al., 2014). Nor could the researchers control for mental health interventions, which all the

subjects received in addition to hormones and surgery. The Dutch only evaluated mental health outcomes and did not assess physical health effects of hormones and surgery. The sample size was small: the final study reported the outcomes of only 55 children, and as few as 32 were evaluated on key measures of psychological outcomes.

It is important to realize that the Dutch sample was carefully selected, which introduced a source of bias, and also challenges the study's applicability. From the 196 adolescents initially referred, 111 were considered eligible to start puberty blockers, and of this group, only the 70 most mature and mentally stable who proceeded to cross-sex hormones were included in the study (de Vries et al., 2011). Of note, 97% of the selected cases were attracted to members of their natal sex at baseline. All were cross-sex identified, with no cases of nonbinary identities. The final study only followed 55, rather than the original 70 cases, further excluding from reporting the outcomes of subjects who had experienced adverse events, including: one death from surgery-related complications and three cases of obesity and diabetes that rendered subjects ineligible for surgery. Three more subjects refused to be contacted or dropped out of care, which may mask adverse outcomes (de Vries et al., 2014).

There is no knowledge of the fate of 126 patients who did not participate in the Dutch study. Longer term outcomes of the subjects who did participate are lacking. We are aware of only one case of long-term follow-up for a female-to-male patient treated by the Dutch team in the 1990s. The case study describing the subject's functioning at the age of 33 found that the patient did not regret gender transition. However, he reported struggling with significant shame related to the appearance of his genitals and to his inability to sexually function; had problems maintaining long-term relationships; and experienced depressive symptoms (Cohen-Kettenis, Schagen, Steensma, de Vries, & Delemarre-van de Waal, 2011). Notably, these problems had not yet emerged when the same patient was assessed at the age of 20, when he reported high levels of satisfaction in general, and was "very satisfied with the results [of the metoidioplasty]" in particular (Cohen-Kettenis & van Goozen, 1998, p.248). Since the last round of psychological outcomes of the individuals in the Dutch study was obtained when the subjects were around 21 years of age (de Vries et al., 2014), it raises questions how they will fare during the decade when new developmental tasks, such as career development, forming long-term intimate relationships and friendships, or starting families come into focus.

As to the unknown outcomes of the patients rejected by the Dutch protocol, one study did report on 14 adolescents who sought gender reassignment in the same clinic, but were disqualified from treatment due to "psychological or environmental problems" (Smith, Van Goozen, & Cohen-Kettenis, 2001, p. 473). The study found that at follow-up 1-7 years after the original application, 11 of the 14 no longer wished to transition, and 2 others only slightly regretted not transitioning (Malone, D'Angelo, et al., 2021; Smith et al., 2001). This further underscores the importance of conducting research utilizing control groups and following the subjects for an extended period.

A recent attempt to replicate the results of the first Dutch study (de Vries et al., 2011) found no demonstrable psychological benefit from puberty blockade, but did find that the treatment adversely affected bone development (Carmichael et al., 2021). The final Dutch study (de Vries et al., 2014) has never been attempted to be replicated with or without a control group.

The scaling of the Dutch Protocol beyond original indications

The medical and surgical sequence of Dutch protocol has been aggressively scaled worldwide without the careful evaluations and vetting practiced by the Dutch. The protocol's original investigators have recently expressed concern that the interventions they described have been widely adopted on four continents without several of the protocol's essential discriminatory features (de Vries, 2020).

The extensive multi-year multidisciplinary evaluations of the children have been abbreviated or simply bypassed. The medical sequence is routinely used for children with post-pubertal onset of transgender identities complicated by mental health comorbidities (Kaltiala-Heino et al., 2018), and not just for those high-functioning adolescents with persistent early life cross-identifications, as was required by the Dutch protocol (de Vries & Cohen-Kettenis, 2012). Further, it has become increasingly common to socially transition children before puberty (Olson, Durwood, DeMeules, & McLaughlin, 2016), even though this was explicitly discouraged by the Dutch protocol at the time (de Vries & Cohen-Kettenis, 2012).

In addition, medical transition is frequently initiated much earlier than recommended by the original protocol (de Vries & Cohen-Kettenis, 2012). The authors of the protocol were aware that most children would have a spontaneous realignment of their gender identity with sex by going through early- to mid-stages of puberty (Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008). The average age of initiating puberty blockade in the Dutch study was around 15. In contrast, currently the age limit has been lowered to the age of Tanner stage II, which can occur as early as 8-9 years (Hembree et al., 2017). Irreversible cross-sex hormones, initiated in the Dutch study at the average age of nearly 17, are currently commonly prescribed to 14-year-olds, and this lower age threshold has been recommended by WPATH Standard of Care 8 draft, the final version of which is due to be released in early 2022. The fact that children are transitioned before their identity is tested against the biological reality and before natural resolution of gender dysphoria has had a chance to occur is a major deviation from the original Dutch protocol. Systematic follow-up, reassessments, and tracking and publishing of outcomes are not performed.

As the lead Dutch researchers have begun to call for more research into the novel presentation of gender dysphoria in youth (de Vries, 2020; Voorzij, 2021) and question the wisdom of applying the hormonal and surgical treatment protocols to the newly presenting cases, many recently educated gender specialists mistakenly believe that the Dutch protocol proved the concept that its sequence helps all gender-dysphoric youth. Although aware of the Dutch study's importance, they seem to be unaware of its agreed upon limitations, and the Dutch clinicians' own discomfort that most new trans-identified adolescents presenting for care today significantly differ from the population the Dutch had originally studied. These facts, of course, underscore the need for a robust informed consent process.

The recommendations for informed consent process for children, adolescents, and young adults

Consent for all stages of gender transition should be explicit, not implied

Noninvasive medical care or care that carries little risk of harm does not require a signed informed consent document; rather, consent is implied through the act of a patient presenting for care. For example, when a parent brings in a child for a skin laceration or abscess, consent for sutures or simple incision and drainage is implied. Similarly, when a child presents with pneumonia and is hospitalized, consent for chest x-ray, IV fluids, and antibiotics is also implied. It is assumed that patients or their guardians agree to the interventions and understand the benefits and risks. When risks are greater, such as prior to surgery, chemotherapy, or another invasive procedure, an informed consent document is signed. Such situations require an explicit, or express informed consent.

In the context of interventions for gender dysphoria or gender incongruence, the uncertainties associated with puberty blocking, cross-sex hormones, and gender-affirmative surgeries are well-recognized (Manrique et al., 2018; National Institute for Health & Care Excellence, 2020a; 2020b; Wilson et al., 2018). In these cases, consent should be explicit rather than implied because of the complexity, uncertainty, and risks involved.

Informed consent for social transition represents a gray area. Evidence suggests that social transition is associated with the persistence of gender dysphoria (Hembree et al.,

2017; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013). This suggests that social gender transition is a form of a psychological intervention with potential lasting effects (Zucker, 2020). While the causality has not been proven, the possibility of iatrogenesis and the resulting exposure to the risks of future medical and surgical gender dysphoria treatments, qualifies social gender transition for explicit, rather than implied, consent.

Full unbiased disclosure of benefits, risks and alternatives is requisite

When mental health professionals are involved in evaluations and recommendations, the informed consent process begins either as part of an extended evaluation or is integrated in a psychotherapeutic process, separately or together, with the parents and patient. When pediatricians, nurse practitioners, or primary care physicians perform the initial evaluation, the informed consent process is more likely to be labeled as such in a briefer series of meetings.

In all settings, the informed consent discussions for gender-affirmative care should include three central ideas:

1. The decision to initiate gender transition may predispose the child to persist in their transgender identity long-term.
2. Many of the physical changes contemplated and undertaken are irreversible.
3. Careful long-term studies have not been done to verify that these interventions enable better physical and mental health or improved social functioning, or that they do not cause harm.

The informed consent process, culminating with a signed document, signifies that parents and patient have been educated about the short- and long-term risks, benefits and uncertainties associated with all relevant stages of the gender-affirmative interventions. The process must also inform the patients and families about the full range of alternative treatments, including the choice of not socially or medically treating the child's or adolescent's current state of gender/body incongruence.

Decisional capacity to consent needs to be assessed and family should be involved

Trans-identified youth typically present themselves as strongly desiring hormones and ultimately, surgery. It should not be assumed that their eagerness is matched with the capacity to carefully consider the consequences of their realized desires. Trans-identified youth younger than the age of consent should be part of the informed consent process, but they may not be mature enough to recognize or admit their concerns about the proposed intervention. For this reason, it is the parents who, after careful consideration, are responsible for signing an informed consent document.

The issue of the exact age at which adolescents are mature enough to consent to gender transition has proven contentious: courts have been asked to decide about competence to consent to gender-affirmative hormones for youth in the United Kingdom and Australia (Ouliaris, 2021). In the United States, the legal age for medical consent for gender-affirmative interventions varies by state.

When patients are age 18 and older, and in some jurisdictions as young as age 15 (Right to medical or dental treatment without parental consent, 2010), they do not legally require parental approval for medical procedures. But because an individual's change of gender has profound implications for parents, siblings, and other family members, it is usually prudent for clinicians to seek their input directly or indirectly during the informed consent process. This is done by requesting a meeting with the parents.

A recent study by a Dutch research team attempted to evaluate the decisional capacity of adolescents embarking on gender transition (Vrouenraets, de Vries, de Vries, van der Miesen, & Hein, 2021). The researchers administered the MacCAT-T tool, comprised of the *understanding*, *appreciating*, *reasoning*, and *expressing a choice* domains, to 74 adolescents who were 14.7 years old on average (with the minimum age of 10). They concluded that the adolescents were competent to consent to starting pubertal suppression, calling for similar research for the <12 group, particularly because "birth-assigned girls … may benefit from puberty suppression as early as 9 years of age" (Vrouenraets et al., 2021 p.7).

This study suffers from two significant limitations involving the MacCAT-T tool. It was never designed for children. Rather, it was designed to assess medical consent capacities of adults suffering from conditions such as dementia, schizophrenia, and other psychiatric disorders. There is a fundamental lack of equivalency between consenting to treatment by adults with cognitive impairments and obtaining consent from healthy children whose age-appropriate cognitive capacities are intact, but who lack the requisite life experiences to consent to profound life-changing medical interventions. We doubt, for example, whether even highly intelligent children who have not had sexual experiences can meaningfully comprehend the loss of future sexual function and reproductive abilities.

In addition, even for adults, the MacCAT-T tool has been criticized for its exclusive focus on cognitive aspects of capacity, failing to account for the non-cognitive aspects such as values, emotions and other biographic and context specific aspects inherent in the complexity of the decision process in real life (Breden & Vollmann, 2004). Children's values and emotions undergo tremendous change during the process of maturation.

The authors' conclusion about their young patients' competence to consent should be compared with what a panel of judges wrote in the challenge to the Tavistock treatment protocol (Bell v Tavistock, 2020):

> …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. [para 135]
>
> …we consider the treatment in this case to be in entirely different territory from the type of medical treatment which is normally being considered. [para 140]
>
> … 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. [para 143]

It seems clear that perceptions of children as young as 10 years of age as medically competent vary by country, state, and the institution where the doctor works, and, by clinicians' beliefs about the long-term benefits of these interventions. We maintain that the claim that children can consent to extremely life-altering intervention is fundamentally a philosophical claim (Clark & Virani, 2021). Our view in this matter is that consent is primarily a parental function.

Informed consent should be viewed as a process rather than an event

Most institutions that care for transgender-identified individuals have devised obligatory consent forms that outline the risks and uncertainties of hormonal and surgical gender-affirmative interventions. However, the requisite signatures are frequently collected in a perfunctory manner (Schulz, 2018), akin to signatures collected ahead of a common surgical procedure. The purpose of such informed consent documents appears to be to protect practitioners from lawsuits, rather than attend to the primary ethical foundation of the process.

Although obtaining the signatures is important, the signed document should signify that the process of informed consent has been undertaken over an extended time period and is not simply quickly completed (Vrouenraets et al., 2021). We believe the latter approach poses an ethical concern (Levine, 2019).

The internal dynamics of the trans-identified young person and their families vary considerably. Parental capacities, their private marital and intrafamilial relationships, their cultural awareness, religious and political sensibilities all influence the amount of time necessary to undertake a thorough informed consent process. It is not prudent to suggest a specific duration for the process of informed consent, other than to emphasize that it requires a slow, patient, thoughtful question and answer period as the parents and patient contemplate the meaning of what is known and unknown and whether to embark on alternative approaches to the management of gender dysphoria before the age of full neurological maturity has been reached, mental health comorbidities have been addressed, and a true informed consent by the patient is more likely.

Final thoughts

Sixty years of experience providing medical and surgical assistance to transgender-identified persons have seen many changes in who is treated, when they are treated, and how they are treated. Today, the emphasis has shifted to the treatment of the unprecedented numbers of youth declaring a trans identity. As adolescents pursue social, medical, and surgical interventions, health care providers may experience unease about patients' cognitive and emotional capacities to make decisions with life-changing and enduring consequences. An unrushed informed consent process helps the provider, the parents, and the patient.

Three issues tend to obscure the salience of informed consent: conspicuous mental health problems, uncertainty about the minor's personal capacity to understand the irreversible nature of the interventions, and parental disagreement. Physical and psychiatric comorbidities can contribute to the formation of a new identity, develop as its consequence, or bear no connection to it. Assessing mental health and the minor's functionality is one of the reasons why rapid affirmative care may be dangerous for patients and their families. For example, when situations involve autism, learning disorders, sexual abuse, attachment problems, trauma, separation anxiety, previous depressed or anxious states, neglect, low IQ, past psychotic illness, eating disorders or parental mental illness, clinicians must choose between ignoring these potentially causative conditions and comorbidities and providing appropriate treatment before affirmative care (D'Angelo et al., 2020).

For youth less than the age of majority, informed consent via parents provides a legal route for treatment but it does not make the decision to socially transition, provide hormones, or surgically remove breasts or testes less fraught with uncertainty. The best that health professionals can do is to ensure that the consent process informs the patient and parents of the current state of science, which is sorely lacking in quality research. It is the professionals' responsibility to ensure that the benefits patients and parents seek, and the risks they are assuming, are clearly appreciated as they prepare to make this often-excruciating decision.

Young people who have reached the age of majority, but who have not reached full maturation of the brain represent a unique challenge. It is well-recognized that brain remodeling proceeds through the third decade of life, with the prefrontal cortex responsible for executive function and impulse control the last to mature (Katz et al., 2016). The growing number of detransitioners who had been old enough to legally consent to transition, but who no longer felt they were transgender upon reaching their mid-20's, raises additional concerns about this vulnerable age group (Littman, 2021; Vandenbussche, 2021).

When the clinician is uncertain whether a young person is competent to comprehend the implications of the desired treatment—that is, when informed consent cannot inform the patient—the clinician may need more time with the patient. When parents or guardians do

not agree about whether to use puberty blockers or cross-sex hormones, clinicians are in an uneasy spot (Levine, 2021). This occurs in both intact and divorced families. Australia has given legal instructions to clinicians facing these uncertainties: the court is to be asked to decide (Ouliaris, 2021). The court system in the UK has been grappling with similar issues in recent years. While it is a rare case that ends up in a courtroom, clinicians devoted to a deliberate informed consent process are still likely to encounter ethical dilemmas that they cannot resolve.

Acknowledgments

The authors wish to thank SEGM staff for their grant and bibliographic support.

Funding

This work was supported by the Society for Evidence-based Gender Medicine.

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Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice**.** Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Patient

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing, at least every 6 months;
4. Annual bone scan (DEXA) once a year for the first 5 years to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal Tearing • Vaginal Bleeding • Vaginal Pain • Vaginal infection • Painful intercourse
	This treatment will not change the individual' s biological sex or chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person may become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change:

	• Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
	It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease • Has a high red blood cell count • Is obese • Smokes cigarettes
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop me from appearing more masculine.
	Taking testosterone can cause changes that increase the risk of heart disease. These changes include:

	• Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
	Taking testosterone can damage the liver and possibly lead to liver disease.
	Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
	Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
	Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
	Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
	Taking testosterone causes or worsens migraines.
	Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Risks of Finasteride

Patient	Statement
	Finasteride may be an appropriate treatment option in individuals experiencing bothersome alopecia resulting from testosterone treatment.
	Finasteride may have side effects which include: • decreased libido • dry skin • acne • Breast swelling and tenderness • headache • irregular menstruation • dizziness • increased body hair
	Finasteride is not approved by the FDA for use in biological women and is forbidden in pregnant women due to birth defects.

Requirements of Treatment with HRT

Patient	Statement
	Compliance with the requirements explained above is a prerequisite to receive treatment with testosterone.
	The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I understand that I may decide to stop treatment at any time.

Prevention of Complications while under Treatment of HRT

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or am unhappy with the treatment in any way, and if I have any concerns that I have worsening signs of depression or anxiety or wants to harm myself or attempt suicide or attempt suicide.
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment.

CONSENT:

My signature below confirms that:

1. My prescribing physician has talked with me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my prescribing physician.

4. All my questions have been answered to my satisfaction by my prescribing physician.

5. I know enough to give informed consent to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with testosterone.

Based on all this information:

_____ I want to begin or continue taking testosterone
_____ I want to begin or continue taking finasteride
_____ I do not wish to begin or continue taking masculinizing medication

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

One option available is psychological therapy with a mental health care provider. This is recommended regardless of whether or not the minor undergoes treatment with hormones or hormone antagonists due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning such as Coumadin and Warfarin • Male pattern baldness • More abdominal fat – redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

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Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone may be prescribed to make a minor appear less like a female and more like a male.
			It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
			The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness • Vaginal tearing • Vaginal bleeding • Vaginal pain • Vaginal infection • Painful intercourse

			This treatment will not change the minor's biological sex or chromosomes.
			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Testosterone **SHOULD NOT** be used by anyone who: • Is pregnant • Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack
			Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has acne • Has a family history of heart disease or breast cancer • Has had a blood clot • Has high levels of cholesterol • Has liver disease

			• Has a high red blood cell count • Is obese • Smokes cigarettes or uses tobacco products
			The medical effects and the safety of minors taking testosterone are not completely known and there may be unknown long-term risks.
			Taking testosterone causes changes that other people will notice.
			Treatment with testosterone will not prevent serious psychiatric events, including suicide.
			The minor must not take more testosterone than prescribed. Taking too much testosterone: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
			Taking testosterone can damage the liver and possibly lead to liver disease.
			Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
			Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
			Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
			Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
			Taking testosterone causes or worsen migraines.

			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with testosterone.
			The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, you and the minor need to be aware of the effects and possible risks associated with the use of these medications. After your questions or concerns are addressed and you have decided to have the minor continue treatment with puberty blockers, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are other options if I do not wish to have the minor continue treatment with puberty blockers?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether the minor undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are different medications that are used to suppress puberty?

The main mechanism by which physical changes of puberty can be put on hold is by using medication to block the signal from the brain to the organs that make hormones. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Pediatric endocrinologists (children's doctors who specialize in hormones and puberty) use these medications frequently to suppress puberty in children with precocious (early) puberty, which is the U.S. Food and Drug Administration (FDA) approved use. None of the medications have been approved by the FDA to be used in minors with gender dysphoria. In other words, using these medications for gender dysphoria is considered "off label" use because they are not being used for their intended purpose.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment for puberty suppression. When used for precocious puberty, Lupron is given as a monthly or every 3-month intramuscular injection. When used for precocious puberty, Histrelin (brand name Supprelin) is an implant that is surgically placed under the skin and needs to be replaced every 1 to 2 years.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera is less effective than Lupron and Histrelin. Depo-Provera injections are approved for the use in females with abnormal bleeding and as birth control.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

What are the requirements to receive puberty suppression for gender dysphoria?

To receive treatment with puberty blockers, there are specific requirements that must be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, treatment with puberty blockers may be discontinued by the prescribing physician.

The specific requirements for a minor to receive and continue treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) no less than once a year;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, as puberty blockers may decrease bone density if given for long periods of time;
12. Annual mental health assessment by a Board-certified Florida-licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors
			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience)

			• Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers. The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery

			• Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea • Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.

			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of treatment with puberty blockers;
   b. the possible or likely consequences of treatment with puberty blockers and puberty suppression; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

_____
Parent/legal guardian's name (optional)

_____ _____
Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's name (required)

_____ _____
Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

_____
Minor's name (required)

_____ _____
Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's signature Date

Surgical Treatment for Adults with Gender Dysphoria

Patient Information and Informed Consent

Before having surgery to treat gender dysphoria, you need to be aware of the effects and possible risks of these procedures. Your surgeon will make a medical decision, in consultation with you, about the procedures that are best for you, keeping in mind your overall health.

Your surgeon will discuss with you all the information relating to the surgery. You are asked to read and understand the following information and to discuss any questions you have with your surgeon. After your questions or concerns are addressed and you have decided to have surgery you must initial the statements below and sign this form in person with your surgeon.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the types of surgery to treat gender dysphoria?

Surgery to treat gender dysphoria may involve procedures on the face, chest, or genitalia. Common surgery options include:

- **Facial reconstructive surgery** to make facial features more masculine or feminine.
- **Chest or "Top" surgery** to remove breast tissue for a more masculine appearance or enhance breast size and shape for a more feminine appearance.
- **Genital or "Bottom" surgery** to transform and reconstruct the genitalia.
  - **Orchiectomy:** A bilateral orchiectomy is a procedure performed by a urologist that involves surgical removal of the testicles through a small scrotal incision. This procedure is done with a particular technique that allows for vaginoplasty later, if desired. Afterward, patients may adjust their dose of estrogens downward and no longer require spironolactone. Recovery takes approximately 2 weeks. Individuals seeking orchiectomy may wish to consider semen banking to preserve future fertility options.

Please initial below to acknowledge your understanding of the information on this page.

Patient

DH5084-MQA (Rev. 06/23)
Rules 64B8ER23-11 and 64B15ER23-12

- **Vaginoplasty**: In addition to an orchiectomy, a person may elect to undergo a vaginoplasty, which is a surgical procedure that involves reconstructing the genitals to create external female genitalia with or without a vaginal cavity. For those patients treated with puberty blockers as a minor, such treatment may lead to insufficient penile tissue that could necessitate the use other tissues, such as the colon, to create a vagina.
- **Phalloplasty:** This surgery involves a multi-staged procedure for the creation of a penis, urinary channel to allow urination, scrotum, and the obliteration of the vaginal cavity with closure. The removal of the female genital organs such as the uterus and ovaries and fallopian tubes are required and usually performed separately and prior to the phalloplasty surgery. The creation of the penis is performed with use of tissue from other parts of the body, which could include, more commonly the radial forearm free flap, or anterolateral thigh flap, and latissimus dorsi (MLD) flap. Prosthetics such as silicone or saline testicles can be placed as well as inflatable penile prosthetics in the final stage.
- **Metoidioplasty:** In this procedure, the surrounding tissue of the clitoris is released to achieve maximal length and a more natural-looking male position. A urethra is also reconstructed using either local skin tissue or a graft from the mouth depending on the amount of tissue present. Construction of a scrotum with testicular prosthetics can also be performed at the same time.
- **Hysterectomy:** Removal of the uterus and cervix via laparoscopic or vaginal techniques.
- **Salpingo-oophorectomy:** Removal of the fallopian tubes and ovaries.
- **Vaginectomy:** Obliteration of the vaginal canal and opening.

Is surgery the only treatment for gender dysphoria?

Surgery is just one option. Not everyone who has gender dysphoria chooses to have surgery. Depending on your age and preferences, you may choose:

- Treatment by a licensed mental health care professional that has experience in treating people with gender dysphoria, which is recommend regardless of whether you undergo surgery due to the high risk of anxiety, depression, self-harm, and suicide.
- Hormone replacement therapy to increase masculine or feminine characteristics.

Other options may be discussed with your prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are some potential complications of surgery to treat gender dysphoria?

Potential complications include:

- Changes in sexual sensation
- Diminishment of bladder function
- Problems with urination
- Bleeding
- Infection
- Nerve damage
- Poor healing
- Scarring that can cause pain, firmness, asymmetry
- Side effects of anesthesia, including death

What happens after surgery to treat gender dysphoria?

Recovery times vary based on what procedures or combination of procedures you have as follows:

- **Cheek and nose surgery:** Swelling lasts for around two to four weeks.
- **Chin and jaw surgery:** Most swelling fades within two weeks but may take up to four months for swelling to completely disappear.
- **Chest surgery:** Swelling and soreness lasts for one to two weeks with physical limitations lasting at least one month.
- **Bottom surgery:** Most people do not resume usual activities until at least six weeks after surgery and weekly follow-up visits with your surgeon for several months will be necessary.

When should I see my surgeon?

After surgery, you should see your surgeon if you experience:

- Bleeding for more than a few days.
- Pain that does not go away after several weeks.
- Signs of infection, such as a wound that changes color or does not heal.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the risks and changes associated with gender dysphoria surgeries.

Patient	Statement
	I understand that my surgeon will discuss with me during the preoperative process the available surgical procedures to treat gender dysphoria, the aftercare needs following surgery, and the importance of postoperative follow-up.
	I understand that these surgeries are permanent.
	I understand that if I have my breasts removed, I must undergo reconstructive surgery if I wish to have breasts in the future. If implants are used, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that if I have my breasts removed that breast feeding will never be possible.
	I understand that if I have breast augmentation surgery, complications may include pain, numbness, infection, bleeding, asymmetry, hardening, rippling, scarring, and the possible need for multiple surgeries.
	I understand that my surgeon will assess me for risk factors associated with breast cancer prior to breast augmentation or mastectomy, including genetic mutations (e.g.., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery.
	I understand that if I undergo metoidioplasty/phalloplasty I will need lifelong urological treatment.
	I understand that complications following metoidioplasty/phalloplasty include: • urinary tract strictures and fistulas • mucoceles due to vaginal remnant • hair growth within the neourethra • compromised sexual function including absent tactile and/or erogenous sensation, difficulties achieving orgasm • complications with penile prosthetics
	I understand that if I undergo vaginoplasty I will need lifelong treatment with my surgeon, primary care physician, and/or gynecologist.
	I understand that if I undergo vaginoplasty, complications can include: • the formation of granulation tissue • intravaginal hair growth • delayed wound healing and/or wound disruption • introital stenosis (closing, narrowing, or closure)

	• painful sex
	I understand that my surgeon may stop further treatment because the risks of treatment outweigh the benefits of treatment.
	I understand that this treatment will not prevent serious psychiatric events, including suicide.
	I agree to tell my surgeon if I have any problems or side effects or am unhappy with the surgery, including if I have worsening signs of depression or anxiety or want to harm myself or attempt suicide.
	I understand that my surgeon may be required to refer me to one or more specialists for surgery-related complications, and I agree to go to those specialists as recommended.
	I acknowledge that surgery to treat gender dysphoria is only part of my overall health and that a range of preventative health activities are recommended including: • cervical/prostrate screening tests at appropriate intervals as recommended by my doctor • regularly checking my breasts for lumps, even if I have had a mastectomy • regular mammograms from an appropriate age in consultation with my doctor • quitting smoking • immunizations • regular STI screening, depending on my level of risk • HIV prevention, depending on my level of risk • regular physical activity, including resistance exercise for bone health • healthy eating

CONSENT:

My signature below confirms that:

1. My surgeon has talked with me about:
    a. the benefits and risks of surgery to treat gender dysphoria;
    b. the possible or likely consequences of surgery to treat gender dysphoria;
    c. potential alternative treatments.

2. The information provided to me in this form and by the surgeon includes the known effects and risks of surgery to treat gender dysphoria. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my surgeon.

4. All my questions have been answered to my satisfaction by my surgeon.

5. I know enough to give informed consent to have, refuse, or postpone surgery to treat gender dysphoria.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your surgeon.

7. My signature below attests to my consent to surgery to treat gender dysphoria.

My signature below confirms the following:

_____ _____

Patient's signature (required) Date

_____ _____

Patient's signature (required) Date

SURGEON:

My signature below attests to my compliance with 456.52, Florida Statutes.

_____

Surgeon's printed name (required)

_____ _____

Surgeon's signature (required) Date

WITNESS:

_____

Witness' printed name (required)

_____ _____

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____

Interpreter's printed name

_____ _____

Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

Please initial below to acknowledge your understanding of the information on this page.

Patient

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Patient

The specific requirements for you to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
4. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Has psychological and social support during treatment;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery; and
7. Understands the effect of hormone treatment on reproduction and they have explored reproductive options;

The following may also be recommended by your prescribing physician:

1. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician every 3 months for the initial year and at least annually thereafter;
2. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months for the initial year and at least annually thereafter;
3. Undergoes relevant laboratory testing at least every 6 months;
4. Annual bone density scan (DEXA) once a year for the first 5 years to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
5. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
6. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Patient

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my biological sex or chromosomes.
	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink

	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Patient	Statement
	Estrogen **SHOULD NOT** be used by anyone who has: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist
	Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease

	• Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness

	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:
	• Changes in heart rhythms that may be life threatening
	• Low blood pressure, which can cause:
	  ○ Fatigue
	  ○ Lightheadedness
	  ○ Tingling feelings
	  ○ Muscle weakness
	  ○ Shortness of breath
	• Your need for regular blood tests to monitor risks while on the medication

	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite

	• Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.

	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____

Patient's printed name (required)

_____ _____

Patient's signature (required) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments.

What are the medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are my other options if I do not wish to start or continue my minor's treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health. This is recommended regardless of whether or not the minor undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Other options may be discussed with your prescribing physician.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Before beginning or continuing HRT, a minor must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Has met the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an in-person evaluation by the prescribing physician or their designated covering physician at least every 6 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Annual bone density scan (DEXA) which will allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial below to acknowledge your understanding of the information on this page.

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with treating a minor with feminizing medications.

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less masculine and more feminine
			It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
			This treatment will not change the minor's biological sex or chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this

			purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Estrogen **SHOULD NOT** be used by anyone who has a history of: • Any estrogen-dependent cancer • Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

			Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who: • Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present • Has a family history of heart disease • Has diabetes • Has chronic hepatitis or other liver disease • Has high levels of cholesterol • Has migraines or seizures • Is obese • Smokes cigarettes or uses tobacco products
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage the

			minor's vision and cause headaches if not treated properly. Any changes in the minor's vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness

			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in:
			• Changes in heart rhythms that may be life threatening
			• Low blood pressure, which can cause:
			  ○ Fatigue
			  ○ Lightheadedness
			  ○ Tingling feelings
			  ○ Muscle weakness
			  ○ Shortness of breath

			• The minor's need for regular blood tests to monitor risks while on the medication
			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach

			• Loss of appetite • Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with feminizing medications.
			The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor (required)	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned

			parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks which may be irreversible.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with feminizing medications.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluent in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's signature Date

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient, or the patient's parent or legal guardian if the patient is a minor, must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

This consent form contains three parts. Part A must be completed by all patients. Part B is only required for patients under the age of 18 with a diagnosed terminal condition who receive a certification for medical marijuana in a smokable form. Part C is the signature block and must be completed by all patients.

Part A: Must be completed for all medical marijuana patients

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

_____ The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (I) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.

_____ When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

_____ Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. The potential for addiction.

_____ Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr._____(name of qualified physician).

d. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

_____ The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be
quickly and I should not participate in activities that may be dangerous

understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

e. The potential side effects of medical marijuana use.

_____ Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

There is substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is associated with large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease.

_____ I understand that using marijuana while consuming alcohol is not recommended. Additional side effects may become present when using both alcohol and marijuana.

_____ I agree to contact Dr. _____ if I experience any of the side effects listed above, or if I become depressed or psychotic, have suicidal thoughts, or experience crying spells. I will also contact Dr._____if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends.

f. **The risks, benefits, and drug interactions of marijuana**.

_____ Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.

_____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. _____ immediately or go to the nearest emergency room.

_____ Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr._____regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

_____ Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I agree to contact Dr. _____ immediately or go to the nearest emergency room if these symptoms occur.

_____ I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr._____if I become pregnant, try to get pregnant, or will be breastfeeding.

g. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

___ Cancer

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

  There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.

- There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting.

  There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa.

___ Epilepsy

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.

  Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.

___ Glaucoma

- There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

  Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids, suggesting the potential for therapeutic benefit. A good-quality systemic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reductions in intraocular

pressure. To date, those studies showing positive effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.

___ Positive status for human immunodeficiency virus

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Acquired immune deficiency syndrome

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Post-traumatic stress disorder

- There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder

  A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

___ Amyotrophic lateral sclerosis

- There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

  Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

___ Crohn's disease

- There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

  Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

___ Parkinson's disease

- There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopainduced dyskinesia.

Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

___ Multiple sclerosis

- There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

___ Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's parent or legal guardian a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum_____.

___ Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum_____.

___ Chronic nonmalignant pain

- There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United
States. and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by well controlled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

_____ The Department of Health submits a data set to the Consortium for Medical Marijuana Clinical Outcomes Research for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition.

____ Initial here if you are not a patient under 18 with a diagnosed terminal condition who will be receiving medical marijuana in a smokable form. After initialing here, complete part C.

If the patient is under 18, has a diagnosed terminal condition, and will be receiving medical marijuana in a smokable form, please review and initial the remainder of Part B before completing Part C.

Respiratory Health

____ Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term cannabis smoking leads to similar deleterious effects of respiratory health, and some investigators ague that cannabis smoking may be even more harmful that of tobacco smoking. Data collected from 15 volunteers suggest that smoking one cannabis joint can lead to four times the exposure to carbon monoxide and three to five times more tar deposition than smoking a single cigarette.

Cognitive and Psychosocial Development

____ Researchers are still studying the long-term health effects of marijuana. Most people agree that marijuana use hurts adolescents more than adults. It is during the period of adolescence and young adulthood that the neural substrates that underlie the development of cognition are most active. Adolescence marks one of the most impressive stretches of neural and behavioral change with substantial a protracted development in terms of both brain structure and function. As a result, cannabis and other substance use during this period may incur relatively greater interference in neural, social, and academic functioning compared to late developmental periods.

- There is moderate evidence of a statistical association between acute cannabis use and impairment in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between sustain abstinence form cannabis use and impairments in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between cannabis use and impaired academic achievement and education outcomes.

- There is limited evidence of a statistical association between cannabis use and increased rates of unemployment and/or low income.

- There is limited evidence of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles.

Addiction

Marijuana, like some other brain-altering substances, can be addictive. Nearly one in 10 marijuana users will become addicted. Starting to use marijuana at a younger age can lead to a greater risk of developing a substance use disorder later in life. Adolescents who begin using marijuana before age 18 are four to seven times more likely than adults to develop a marijuana use disorder.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

____ **Acknowledgement of contaminant risks.**

Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminates can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.

____ **Respiratory Health.**

Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators ague that marijuana smoking may be even more harmful that of tobacco smoking.

_____ **Information regarding health risks of 2nd and 3rd hand smoke to other household members.**

You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.

____ **Dangers of smoking marijuana in households where oxygen is in use.**

If you use oxygen or have others in your household who use oxygen you should not smoke marijuana or any other combustible material in the vicinity of where the oxygen is in use due to the risk of fire and explosion.

____ **Self-dosing, if permitted.**

I have been given instructions or discussed guidance on self- dosing with my qualified physician if permitted to do so.

Part D: Must be completed for all medical marijuana patients

_____ I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr._____has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr._____also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. _____informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits. Dr. _____ has explained the information in this consent form about the medical use of marijuana.

Patient (print name) _____

Patient signature or signature of the parent or legal guardian if the patient is a minor:

_____ Date _____

I have explained the information in this consent form about the medical use of marijuana to _____ (Print patient name).

Qualified physician signature:

_____ Date _____

Witness:

_____ Date_____

64B8-9.018, F.A.C.
64815-14.013, F.A.C.
DH-MQA-5026 (Rev. 03/21)

Sven Román Curriculum Vitae

Work experience

2015 03 -
Specialist doctor, sometimes also senior doctor.
Work as a senior physician and psychiatrist consultant at BUP's outpatient care via a staffing agency:
March 2015 - June 2018, BUP Mora
August 2018 - June 2019, BUP Västervik
July - September 2019, BUP Skövde
Nov - Dec 2019, BUP Östersund
Nov - Dec 2018 and May - June 2019, PR Vård, paediatric clinic in Stockholm. Feb - June 2020, BUP Örebro
June - Dec 2020, BUP Umeå
Jan 2021, BUP Avesta
Feb - June 2021, BUP Falun
Aug - Oct 2021, BUP Motala
Nov - Dec 2021, BUP Mora
Jan 2022, BUP Avesta
Feb - Sep 2022, BUP Mjölby (of which a few weeks Motala)
Oct - Dec 2022, BUP Umeå
Jan - Feb 2023 BUP Malmö, Psykiatripartners
April - June 2023, BUP Umeå
August - December 2023, BUP Halden (Norway)

2012 12 - 2015 02
Senior physician
BUP clinic in Stockholm County Council, Unit for young people with psychosis/bipolar disorder.
Consultations based on referrals from primarily outpatient care (carried out more than 100 complete assessments) and usual outpatient work with patients enrolled in a county-wide specialized clinic.

2010 09 - 2012 10
Senior physician
BUP clinic in Stockholm County Council, Unit North
Usual duties as senior physician in BUP's inpatient care.

2010 05 - 2010 08
Acting chief physician
BUP clinic in Stockholm County Council, Unit for young people with psychosis/bipolar disorder and consultant psychiatrist Lövsta school home (locked institutional accommodation for children based on a decision by social services) och Högantorps skolhem
Usual duties as chief physician at the BUP clinic and consultant psychiatrist at two SiS institutions.

2006 11 - 2012 11
Trade union representative
BUP in Stockholm County
Trade union representative in SLSO's (Stockholm County Healthcare Services)doctors' association Nov 2006 - autumn 2012
SACO (the Swedish Confederation of Professional Associations representative in Samverkan at the BUP division during the same period and at the BUP clinic from Aug 2010 - autumn 2012.

2004 03 - 2010 09
Resident doctor in child and adolescent psychiatry
Usual duties as a resident doctor in the above-mentioned speciality.

2002 09 - 2004 03
Internship doctor
S:t Görans Hospital, Stockholm
Normal duties as an intern physician.

2002 01 - 2002 08
Junior doctor with medical degree but without internship service Children's Hospital, Huddinge Hospital
Normal junior doctor duties at a paediatric clinic.

2000 06 - 2001 07
Junior doctor at the end of his/her medical training, without a medical degree Dalens Hospital, Stockholm
Ordinary junior doctors work in a geriatric ward during the summers of 2000 and 2001.

1997 06 - 1999 07
Assistant nurse
Danderyd Hospital
Ordinary assistant nurse work during summers and weekends 1997 - 1999

1984 06 - 1985 01
Health care assistant
Huddinge hospital and Danderyd hospital
Ordinary work as a health care assistant in the dialysis department and internal medicine department

Education and training

2010 -
Specialist training: participation in BUP congresses, pharmacological training, international congresses (e.g. I was at AACAP, the world congress of the American Association of Child Psychiatrists, in San Diego in October 2014), etc. Every year I participate in several congresses and "training courses", trying to have at least 10 such days/year.

2006 01 - 2008 09
Basic training in psychotherapy
BUP, Region Stockholm

2004 03 - 2010 09
Specialist degree, child and adolescent psychiatry
BUP, Region Stockholm

2002 09 - 2004 04
Medical licence
Internship, S:t Göran's Hospital, Stockholm

2002 09 - 2002 09
Supervisor for leadership training
Karolinska Institutet, Solna

1996 09 - 2002 01
Medical degree
Karolinska Institutet, Solna

1989 01 - 1990 06
Music programme, folk high school (classical singing)
S:t Sigfrid, Växjö

1987 09 - 1988 12
Music programme, folk high school (classical singing)
Kapellsberg Folk High School, Härnösand

1986 09 - 1987 06
Musicology
Stockholm university town

1981 08 - 1984 06
Natural science upper secondary school
Södra Latins gymnasium, Stockholm

Articles

1. G. Berglund, G., Sturm, H., Raita, J. & Román, S. (2009) Förslag om en kvalitetssäkrad BUP-vård (Proposal on quality assurance in child and adolescent psychiatry.) Läkartidningen, 2009-06-04. Title in English: https://lakartidningen.se/debatt-och-brev/2009/06/forslag-om-en-kvalitetssakrad-bup-vard/
2. Kritik mot barnpsykiatrin missar målet (Criticism of child psychiatry misses the mark.) Dagens Medicin. June 30, 2010. https://www.dagensmedicin.se/opinion/debatt/kritik-mot-barnpsykiatrin-missar-malet/
3. Román, S. Tvångsåtgärder vanligare hos flickor och unga kvinnor (Coercive measures more common in girls and young women.) (2016). Läkartidningen. 2016/113:DYUH.https://lakartidningen.se/opinion/debatt/2016/04/tvangsatgarder-vanligare
4. Dags att lägga ned de krisande landstingen? (Time to close down the struggling county councils?) Dagens Samhälle. Feb 22, 2017. https://www.dagenssamhalle.se/samhalle-och-valfard/sjukvard/dags-att-lagga-ned-de-krisande-landstingen/
5. One of two main authors of an article with a total of 19 signatures. Många med psykisk ohälsa får inte rätt behandling (Many people with mental

illness do not get the right treatment.) Svenska Dagbladet. June 21, 2017. https://www.svd.se/a/rqPgm/manga-med-

6. Undermåliga adhd-utredningar hos barn- och ungdomspsykiatrin (Substandard adhd investigations in child and adolescent psychiatry.) Dagens Samhälle. October 27, 2017. Link to the article: https://www.dagenssamhalle.se/samhalle-och-valfard/sjukvard/undermaliga-

7. One of 34 signatures. Nätläkare orsakar ohejdbar kostnadsökning (Online doctors cause unprecedented cost increases.) Svenska Dagbladet. Feb 21, 2018. https://www.svd.se/a/ngv7Gn/natlakare-orsakar-ohejdbar-kostnadsokning

8. One of 30 signatures. Risk att suicidala ges dödshjälp med ny modell (Suicidal people at risk of euthanasia under new model.) Svenska Dagbladet. Feb 22, 2018. https://www.svd.se/a/kaQ0Ev/risk-att-suicidala-ges-dodshjalp-med-ny-modell

9. Stora problem med dödshjälp – men de rapporteras inte (Major problems with euthanasia - but not reported.) Dagens Samhälle. Feb 21, 2018. https://www.dagenssamhalle.se/samhalle-och-

10. Exemplet Nederländerna visar att dödshjälp innebär att vi hamnar på ett sluttande plan (The example of the Netherlands shows that euthanasia is a slippery slope.) Dagens Nyheter. June 17, 2018. https://www.dn.se/asikt/exemplet-nederlanderna-visar-att-dodshjalp-innebar-att-vi-hamnar-pa-ett-sluttande-plan/

11. Införande av dödshjälp vore att gå i skandalläkaren Macchiarinis fotspår (Introducing euthanasia would follow in the footsteps of scandalous doctor Macchiarini.) Dagens Nyheter. Aug 14, 2018. https://www.dn.se/asikt/inforande-av-dodshjalp-vore-att-ga-i-skandallakaren-macchiarinis-fotspar/

12. Skolan bär ett tungt ansvar för adhd-diagnoserna (Schools bear a heavy responsibility for ADHD diagnoses.) Dagens Samhälle. April 1, 2019. https://www.dagenssamhalle.se/opinion/debatt/skolan-bar-ett-tungt-ansvar-for-adhd-diagnoserna/

13. Aktiv dödshjälp kan aldrig bli säker (Active euthanasia can never be safe.) Dagens Nyheter. April 8, 2019. https://www.dn.se/asikt/aktiv-dodshjalp-kan-aldrig-bli-saker/

14. Förbättrad vård viktigare än dödshjälp (Improved care more important than euthanasia.) Dagens Nyheter. April 9, 2019. https://www.dn.se/asikt/forbattrad-vard-viktigare-an-dodshjalp/

15. Together with a co-author. Rätten till sin död blir lätt en plikt att dö (The right to die easily becomes a duty to die.) Dagens Medicin. Juli 25, 2019. https://www.dagensmedicin.se/opinion/debatt/ratten-till-sin-dod-blir-latt-en-plikt-att-do/

16. Together with a co-author. Dödshjälp prioriteras framför andra alternativ (Euthanasia prioritized over other options.) Dagens Medicin. Aug 7, 2019. https://www.dagensmedicin.se/opinion/debatt/dodshjalp-prioriteras-framfor-andra-alternativ/

17. Together with a co-author. Dödshjälp har aldrig kunnat begränsas (Euthanasia has never been restricted.) Dagens Medicin. Aug 13, 2019. https://www.dagensmedicin.se/opinion/debatt/dodshjalp-har-aldrig-kunnat-begransas/

18. One of 8 signatures. Erfarenhet och forskning talar emot dödshjälp (Experience and research against euthanasia.) Dagens Medicin. Aug 14, 2019. https://www.dagensmedicin.se/opinion/debatt/erfarenhet-och-forskning-talar-emot-dodshjalp/

19. Könsdysfori sprids som en epidemi på nätet (Gender dysphoria spreads like an epidemic online.) Dagens Nyheter. Sep,13, 2019. https://www.dn.se/asikt/konsdysfori-sprids-som-en-epidemi-pa-natet/ Link to an English version of the article: https://www.ihmistenkirjo.net/blog/psychiatrist-gender-dysphoria-spreads-like-an-epidemic-online

20. Stoppa omedelbart all behandling av könsdysfori för barn och unga vuxna (Immediately stop all treatment of gender dysphoria for children and young adults.) Dagens Medicin. Oct 8, 2019. https://www.dagensmedicin.se/opinion/debatt/stoppa-omedelbart-all-behandling-av-konsdysfori-for-barn-och-unga-vuxna/

21. Svens, K. & Román, S. (2019). Off label-förskrivning av hormoner vid könsdysfori bör utredas (Off-label prescribing of hormones for gender dysphoria should be investigated.) Läkartidningen. 2019,116:FTYW. https://lakartidningen.se/opinion/debatt/2019/10/allvarliga-risker-med-langvarig-konskontrar-hormonbehandling/ Link to an English version of the article: https://www.ihmistenkirjo.net/blog/lkartidningen-off-label-prescribing-of-hormones-in-gender-dysphoria-should-be-investigated

22. One of 8 signatures. Utredare förvanskar om könsdysfori (Investigator misrepresents gender dysphoria.) Svenska Dagbladet. Oct 22, 2019. https://www.svd.se/a/K3kxR7/utredare-forvanskar-om-konsdysfori

23. One of 8 signatures. Allvarliga invändningar förblir obesvarade (Serious concerns remain unanswered.) Svenska Dagbladet. Oct 22, 2019. https://www.svd.se/a/3J7Wzv/allvarliga-invandningar-forblir-obesvarade

24. One of 19 signatures. Även vuxna har rätt till säker vård vid könsdysfori (Adults also have the right to safe treatment for gender dysphoria.) Svenska Dagbladet. Nov 12, 2019. Link to the article: https://www.svd.se/a/AdBM7x/aven-vuxna-har-ratt-till-saker-vard-vid-konsdysfori

25. One of two main authors of an article with a total of 16 signatures. Dödshjälp är det ultimata sättet att spara resurser (Euthanasia is the ultimate way to save resources.) Dagens Samhälle. Nov 27, 2019. https://www.dagenssamhalle.se/opinion/debatt/dodshjalp-ar-det-ultimata-sattet-att-spara-resurser/

26. Du vill kväsa debatten om antidepressiva (You want to stifle the debate on antidepressants.) Aftonbladet. Jan 29, 2020. https://www.aftonbladet.se/debatt/a/LAgB14/du-vill-kvasa-debatten-om-antidepressiva

27. Staten måste utreda hur skandalen med de apatiska barnen kunde ske (State must investigate how the apathetic children scandal happened.) Götebrogs-Posten. Feb 13, 2020. Link to the article: https://www.gp.se/debatt/staten-m%C3%A5ste-utreda-hur-skandalen-med-de-apatiska-barnen-kunde-ske-1.23849279

28. One of 10 signatures. Forsvarlig behandlingstilbud til barn og unge med kjønnsdysfori? (Appropriate treatment for children and young people with gender dysphoria?) Dagens Medisin, Norway. Feb 19, 2020. https://www.dagensmedisin.no/debatt-og-kronikk/forsvarlig-behandlingstilbud-til-barn-og-unge-med-kjonnsdysfori/361774

29. Min slutsats om de apatiska barnen står på stadig grund (My conclusion on apathetic children is firmly grounded.) Göteborgs-Posten, Feb 28, 2020. https://www.gp.se/debatt/min-slutsats-om-de-apatiska-barnen-st%C3%A5r-p%C3%A5-stadig-grund-1.24657443

30. Malone, W & Román, S. (2020). Letters to the Editor. Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress. The American Journal of Psychiatry. 177(8), 766-767. https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.19111149

31. One of 26 signatures. Avgörande kunskap saknas kring dödshjälp (Crucial knowledge missing on euthanasia.) Svenska Dagbladet. Oct 31, 2020. https://www.svd.se/a/6zzWk8/avgorande-kunskap-saknas-kring-dodshjalp

32. One of 19 signatures. Frågor om dödshjälp lämnas obesvarade (Questions on euthanasia left unanswered.) Svenska Dagbladet. Nov 9, 2020. https://www.svd.se/a/1BBlxq/fragor-om-dodshjalp-lamnas-obesvarade

33. The lead author of an article with ten co-authors, all doctors, three of whom are also professors: ”Sänk inte åldersgräns för juridiskt könsbyte” ("Do not lower the age limit for legal gender reassignment"). Svenska Dagbladet, June 1, 2023: https://www.svd.se/a/zEXKG1/debattorer-sank-inte-aldersgransen-for-juridiskt-konsbyte

34. One of 21 doctors and scientists from 9 countries who signed an article in the Wall Street Journal: Youth Gender Transition Is Pushed Without Evidence. July 13, 2023: https://www.wsj.com/articles/trans-gender-affirming-care-transition-hormone-surgery-evidence-c1961e27 and https://archive.is/dG06b

Lectures and hearings for Members of Parliament in the Parliament building

1. Könsdysfori ur ett psykiatriskt och medicinskt perspektiv. Sveriges största medicinska skandal i modern tid? (Gender dysphoria from a psychiatric and medical perspective. Sweden's biggest medical scandal in modern times?) October 16, 2019.
2. Varför dödshjälp inte bör tillåtas (Why euthanasia should not be allowed.) November 28, 2019.
3. Presentation av Oregonmodellen och kapitlet "Psykiatri och dödshjälp" av Sven Román i den nordiska antologin "Dødshjelp i Norden? Etikk, klinikk och politikk" (Presentation of the Oregon Model and the chapter "Psychiatry and Euthanasia" authored by Sven Román from the Nordic anthology "Euthanasia in the Nordics? Ethical, clinical and political".) November 18, 2020.
4. Irreversibel skada eller evidensbaserad behandling (Irreversible damage or evidence-based treatment? On the treatment of gender dysphoria for children and young adults.) September 16, 2021.
5. Livshjälp (Life support (about euthanasia). December 7, 2022.
6. Hearing with MEPs on the treatment of children and young adults with gender dysphoria and in particular on the proposed law to change legal gender from the age of 16. March 7, 2023.
7. Another hearing with MEPs on the treatment of children and young adults with gender dysphoria, in particular on the proposed law on legal gender reassignment from the age of 16. May 23, 2023.

Other media appearances

1. Swedish public television, local news for Stockholm: 50 läkare saknas inom barnpsykiatrin (50 doctors are missing in child psychiatry). April 2, 2008.
2. Swedish public television, the documentary program Dokument Inifrån (Documents from Within): Vem kan hjälpa mitt barn? (Who can help my child?) November 12, 2015.

3. Special Nest online magazine: Överläkare fördjupar kritik mot BUP:s metoder (Consultant psychiatrist deepens criticism of child and adolescent psychiatry methods). December 14, 2015. https://www.specialnest.se/landsting/overlakare-fordjupar-kritik-mot-bups-metoder

4. Swedish public service radio, Kropp & själ (Body & Soul): Hur mår psykiatrin? (How is psychiatry doing.) Nov 1, 2016. https://sverigesradio.se/avsnitt/800449

5. Evening newspaper Aftonbladet: Hemliga läkare fick 13 miljoner av läkemedelsindustrin (Secret doctors received 13 million from the pharmaceutical industry). March 22, 2017. https://www.aftonbladet.se/nyheter/a/vJn5m/hemliga-lakare-fick-13miljoner-av-lakemedelsindustrin

6. Daily newspaper Dagens Nyheter: Psykiater larmar om felaktiga diagnoser på barn (Psychiatrist raises alarm over misdiagnosis of children). Oct 21, 2017. https://www.dn.se/nyheter/sverige/psykiater-larmar-om-felaktiga-diagnoser-pa-barn/

7. Focus magazine: Få tillförlitliga studier som visar på effekten av medicinerna (Few reliable studies on the effectiveness of drugs (on ADHD drugs)). Oct 30, 2017. https://www.fokus.se/inrikes/fa-tillforlitliga-studier-som-visar-pa-effekten-av-medicinerna/

8. Swedish public service radio: Barnpsykiater: För många får diagnoser (Child psychiatrist: Too many people get diagnosed). June 7, 2018. https://sverigesradio.se/artikel/6967615

9. The daily Newspaper Sydsvenskan and Norra Skåne: Ledare: Vem bestämmer över din död? (Editorial: Who decides on your death?). April 10, 2019. https://www.nsk.se/ledare/vem-bestammer-over-din-dod/

10. The medical trade union magazine Sjukhusläkaren (The hospital doctor): Dödshjälp: Den känsliga frågan (Euthanasia: The sensitive issue). June 3, 2019. https://www.sjukhuslakaren.se/dodshjalp-den-kansliga-fragan/

11. Ledare: Farligt rättighetstänkande bakom tonåringars ”könskorrigeringar” (Editorial: Dangerous rights-based thinking behind teenagers' 'gender reassignment'). Aug 27, 2019. https://www.dn.se/ledare/hanne-kjoller-farligt-rattighetstankande-bakom-tonaringars-konskorrigeringar/

12. Filter magazine: Ohörda rop (Unheard cries, on so-called apathetic children seeking asylum). Sep 23, 2019. https://magasinetfilter.se/granskning/apatiska-barn-ohorda-rop/

13. Swedish public service radio, Studio Ett (Studio One): “Jag var så himla rädd” ("I was so scared"). Sep 25, 2019. https://sverigesradio.se/artikel/7306372

14. TV channel TV4, Malou efter tio (Malor after ten): Vi i vården har bidragit till grav barnmisshandel i 15 års tid (We in healthcare have contributed to

serious child abuse for 15 years). Oct 1, 2019. https://www.tv4.se/klipp/va/12502429/vi-i-varden-har-bidragit-till-grav-barnmisshandel-under-15-ars-tid

15. News in TT that all media forwarded, including Läkartidningen(Medical Journal): Läkare vill att råd om apatiska barn ses över (Doctors want advice on apathetic children to be reviewed). Oct 7, 2019. https://lakartidningen.se/aktuellt/nyheter/2019/10/lakare-vill-att-rad-om-apatiska-barn-ses-over/

16. Daily newspaper Svenska Dagbladet editorial podcast: Könsdysfori och undflyende politiker (Gender dysphoria and elusive politicians?) Oct 9, 2019. https://www.svd.se/a/kJ1mkX/konsdysfori-och-undflyende-politiker

17. Article and feature in web TV for the Christian newspaper Dagen: Överläkare Sven Román: Behandlingar av könsdysfori är en epidemi (Consultant Sven Román: Treatment of gender dysphoria is an epidemic). Oct 18, 2019. https://www.dagen.se/nyheter/2019/10/18/overlakare-sven-roman-behandlingar-av-konsdysfori-ar-en-epidemi/

18. Political podcast God Ton (Good Tone): Överläkare Sven Román om könsdysfori och apatiska flyktingbarn (Consultant Sven Román on gender dysphoria and apathetic refugee children). Oct 25, 2019. https://poddtoppen.se/podcast/1372019059/god-ton/60-overlakare-sven-roman-om-konsbyten-och-apatiska-flyktingbarn

19. Swedish public service radio, educational radio, “Ministry of Education”: Skolan och adhd-diagnoserna (Schools and ADHD diagnoses). Nov 8, 2019. https://urplay.se/program/212743-skolministeriet-skolan-och-adhd-diagnoserna

20. Danish public service TV DR1 on the so-called apathetic asylum-seeking children, the program “21 Sunday”. Nov 24, 2019.

21. Finnish public service broadcaster YLE: Slaget efter tolv - dagens debatt: Unga med könsdysfori (The battle after twelve - today's debate: Young people with gender dysphoria). Dec 9, 2019. https://arenan.yle.fi/poddar/1-50351504

22. Daily newspaper Svenska Dagbladet editorial podcast: "Life Overtakes Me" – apatiska flyktingbarn på bio ("Life Overtakes Me" - apathetic refugee children at the cinema). Feb 6, 2020. https://www.svd.se/a/g7O5Jk/life-overtakes-me-apatiska-flyktingbarn-pa-bio

23. Swedish public service radio: Barnpsykiatriker: “De har utrett på löpande band" (Child psychiatrist: "They have been investigating on an assembly line"). Feb 19, 2020. https://sverigesradio.se/artikel/barnpsykiatriker-de-har-utrett-pa-lopande-band

24. Swedish public service radio, the investigative program Kaliber (Calibre): Barnen och diagnoserna (The children and the diagnoses). May 11, 2020. https://sverigesradio.se/avsnitt/1495660

25. Report in the French newspaper Le Figaro: Face à la vague des transgenres, la Suède commence à douter (Faced with the transgender wave, Sweden is beginning to have doubts). June 14, 2021. https://www.lefigaro.fr/international/face-a-la-vague-des-transgenres-la-suede-commence-a-douter-20210614

26. A documentary by the French TV channel M6 on children and young adults with gender dysphoria, including a clip from Sven Román's lecture at the Swedish Parliament on September 16, 2021. May 21, 2023.

27. One of the interviewees in the National Catholic Register article European Countries' Restrictions on Gender Treatment for Minors Contrast Sharply With US Push. July 20, 2023: https://www.ncregister.com/news/european-countries-restrictions-on-gender-treatment-for-minors-contrasts-sharply-with-us-push

28. News in TT forwarded by many media outlets: Miljonflöden från läkemedelsbolag till läkare (Million-dollar flows from pharmaceutical companies to doctors). August 4, 2023: https://www.svd.se/a/xgWQw8/miljonfloden-fran-lakemedelsbolag-till-lakare

Medical involvement

1. Since 2018 member of the Network against inappropriate governance of health care.
2. Since 2018 member of Nordic network against euthanasia.
3. Founded 2019 a Nordic network critical of the treatment of children and young adults with gender dysphoria.
4. Since 2019 member of a network that aims to help patients reduce or stop taking psychotropic drugs.
5. Since 2020, I belong to the Advisory Board of SEGM, Society for Evidence Based Gender Medicine.
6. Since 2020, I have been a board member of GENID, Gender Identity Challenge Sweden, a network of parents, relatives and healthcare professionals who work to ensure that the care of children and young people with gender dysphoria is based on openness, caution and science.

Curriculum Vitae and Bibliography
Monica Mortensen, DO

. PERSONAL INFORMATION

Place of Birth – Chicago, IL

Citizenship: - United States

2. PRESENT ACADEMIC RANK AND POSITION

University of Florida Jacksonville — 2018 - Present
Clinical Assistant Professor, Department of Pediatrics

Nemours Children's Clinic — 2015 - Present
807 Children's Way
Jacksonville, FL 32207
Associate Director of Clinical Service for Endocrinology, Jacksonville
Pediatric Endocrinology

3. EDUCATION

Loyola University- Chicago, IL B.S. in Biological Science — 1989 - 1994

Midwestern University/Chicago College of Osteopathic Medicine — 1996 - 2001
Downers Grove, IL Doctor of Osteopathic Medicine

Bi-County/Henry Ford Hospital- Detroit, MI — 2001 - 2002
Pediatric Internship

Lutheran General Children's Hospital- Park Ridge, IL — 2002 - 2004
Pediatric Residency

University of Chicago Children's Hospital- Chicago, IL
Pediatric Endocrinology Fellow — 2004 - 2007
Chief Pediatric Endocrinology Fellow — 2005 - 2007

Nemours Children's Clinic- Jacksonville, FL — 2014 - 2015
Advanced Pediatric Endocrinology Fellow

4. BOARD CERTIFICATION(S)

American Board of Pediatrics

General Pediatrics	2009-Present

American Board of Pediatrics

Pediatric Endocrinology	2015-Present

5. LICENSURE

Illinois	Lic# 036111969	1997-2020
Florida	Lic# OS10132	2007-Present

6. HONORS/AWARDS

LWPES Travel Grant	2005
LWPES Travel Grant	2007
Nordotropin Grant for Fellow Symposium in Sweden	2007

7. PREVIOUS PROFESSIONAL POSITIONS AND MAJOR APPOINTMENTS

Project Health, Inc, Thomas Langley Medical Center Sumterville, FL	
Pediatrics and Pediatric Endocrinology	2008 – 2012
Director of Pediatrics	2008 – 2012
Lab Director	2010 – 2012
Chief Medical Officer	2011 – 2012
Central Florida Family Health Centers Sanford, FL	2013 – 2014
Pediatrics and Pediatric Endocrinology	
Nova Southeastern University College of Osteopathic Medicine	
Clinical Assistant Professor, Department of Pediatrics	2012 – 2014

8. PROFESSIONAL & COMMUNITY MEMBERSHIPS, SOCIETIES AND SERVICES

American Academy of Pediatrics	2001 – Present
American Academy of Osteopathic Pediatricians	2001 – Present
Florida Osteopathic Medical Association	2001 – Present
The Endocrine Society	2004 – Present
Pediatric Endocrine Society	2004 – Present
Florida Pediatric Medical Association	2008 – Present
International Society for Clinical Densitometry (ISCD)	2019 - Present

9. EDUCATIONAL ACTIVITIES

A. Curriculum/Course Development

Member of curriculum committee for Pediatric Endocrinology Fellowship; In process of enhancing and teaching pediatric endocrinology across the three years of fellowship for the University of Florida College of Medicine Pediatric Endocrine Fellows.	2015 - Present

Member of curriculum committee for Pediatric Endocrinology Rotation for Pediatric residents; In process of enhancing and teaching pediatric endocrinology for the mandatory and elective rotations in endocrine for the University of Florida College of Medicine Pediatric Residents	2015 - Present

B. Teaching

Clinic Preceptor for Mayo Clinic Medical Student and Adult Endocrinology Fellows	2014 - Present
Clinic Preceptor for University of Florida College of Medicine Pediatric Residents and Pediatric Endocrine Fellows.	2014 - Present
Hospital Inpatient Education Wolfson's Children's Hospital	2015 - Present

C. Mentorship

Individual and Position	Timeframe & Description	Outcomes	Current Status
Delia Perez, MD (2nd, 3rd year Ped Endo fellow)	7/2019-6/2020. QI project titled " Monitoring Vitamin D in the use of Zoledronic acid infusions"." This QI project aimed to improve the recognition and management of vitamin D deficiency in patients undergoing zoledronic acid infusion to prevent side effects.	Re-education of providers occurred during the study period, resulting significant improvement in assessment and treatment of vitamin D deficiency in this study population.	Pediatric endocrinologist in Pennsylvania
Dr. Leopold Maldonado, MD (3rd year Ped Endo fellow)	1/2022-current. QI project titled " CGM in T2DM." This QI project aimed to improve the management of T2DM by prescribing and using a CGM in pts with T2DM	This QI project is ongoing.	Current 3rd year fellow
Dr. Kelly Hildebrandt (2nd year fellow)	7/2019-current. QI project titled "Increased screening of Urine microalbumin pts with T1DM. The goal of this QI project is to improve screening, recognition and management of urine microalbuminuria in patients with T1DM.	This QI project is ongoing.	Current 2nd year fellow (2020-2021)

Fellows Mentored	Timeframe	Current Status
Reham Hasan, MD	2014-2017	Pediatric endocrinologist, Nemours Health System, Jacksonville, FL

Dania Al-Hamad, MD	2015-2016	Pediatric endocrinologist, University of Utah
Hussein Elmufti, MD	2016-2018	Pediatric endocrinologist, Virginia
Delia Perez, MD	2016-2019	Pediatric endocrinologist, Pennsylvania
Ashish Malpani, MD	2017-2020	Pediatric endocrinologist, Dubai
Lurah Welch, MD	2019-2022	Pediatric endocrinologist, Texas
Leopoldo Maldonando, MD	2020-2023	Current 3rd year fellow
Kelly Hildebradt, MD	2021-2024	Current 2nd year fellow

D. Academic Career Development

Quality Champions Program 05/2022
Quality and Safety and Education teams, Nemours Children Health Jacksonville, Orlando, FL, and Delaware
Program to train associates and faculty on quality and safety principles such as: quality improvement methodology, patient safety principles, the triple aim for populations, patient and family centered care concepts, teamwork, and leadership principles.

10. INSTITUTIONAL/DEPARTMENTAL ADMINISTRATIVE RESPONSIBILITIES, COMMITTEE MEMBERSHIPS AND OTHER ACTIVITIES

Osteopathic Board of Medicine 2022-Present
Board Member

Northeastern Florida Pediatric Diabetes Center 2022- Present
Assistant Medical Director

Jacksonville Diabetes Camp 2022- Present
Member – Support Assessment, development, implementation and evaluation of education and safety of campers and medical staff

Nemours Quality and Patient Safety Committee 2022 – Present
Member- Development, implementation, and evaluation of QI/QA projects for Nemours Jacksonville, outpatient

Women at Work Committee 2022 – Present
Member- resource and support group working women

Wellness Committee 2021 – Present
Member- Promote physical and mental well being for staff

Associate Director of Clinical Service for Endocrinology, Jacksonville 2018 - Present

Pediatric Endocrinology

Needs Assessment Committee 2018 – 2022
Member- Evaluation & Review of proposed clinical positions

Nemours Pediatric Endocrinology Curriculum Committee 2015 - Present
Member- Development, implementation and evaluation of education
For Pediatric Endocrinology Fellows

Nemours Pediatric Endocrinology QI Committee 2015 – Present
Member- Development, implementation and evaluation
of QI/QA projects for Pediatric Endocrinology Fellows

ADA- Camp JADA Camp Committee
Member – Support Assessment, development, implementation and evaluation of education and safety of campers and medical staff 2015 - 2021

ADA- Triangle D Diabetes Camp Committee 2004 - 2019
Member – Support Assessment, development, implementation and evaluation of education and safety of campers and medical staff

11. PRESENTATIONS

International/

LWPES/ESPR Lyon France: "Precocious Puberty in Turners Syndrome" Monica Mortensen, Donald Zimmerman, Elizabeth Baumann. 08/2005

Endocrine Society Toronto Canada: "The Functional Significance of the Various Types of Ovarian Morphologies of Polycystic Ovary Syndrome" Monica Mortensen, David Ehrmann, Elizabeth Littlejohn, Robert L. Rosenfield. 06/2007

National
OMED 23 Osteopathic Conference
Pediatric Section
"Thyroid disorders in Children"
"Vit D and its Related disorders in Children"
10/2023

12. CLINICAL PRACTICE, INTERESTS, AND ACCOMPLISHMENTS

General Pediatric Endocrinology, PCOS and menstrual disorders, Precocious Puberty and Pubertal Disorders, Adrenal Disorders, Pediatric calcium and bone disorders, as well as T1DM & T2DM

Completed Quality Improvement Program through Nemours and IHI 2022. Currently involved as mentor to fellows QI projects, endocrine QI projects and a member of the Quality and Patient Safety Committee.

Certified Clinical Densitometrist 2022

13. RESEARCH INTERESTS

Use of technology to improve diabetes control, Precocious Puberty, PCOS, Metabolic Effects of Human Growth Hormone. Bone disorders in Pediatrics.

14. Educational Practice, Interests, and Accomplishments

University of Florida College of Medicine Jacksonville, FL USA Assistant Professor of Pediatrics	2018 - Present
Nova Southeastern University College of Osteopathic Medicine Clinical Assistant Professor, Department of Pediatrics	2012 - 2014
Preceptor of visiting medical students (pediatric clerkship): University of Central Florida/ School of Medicine	2013 - 2014
Preceptor of visiting medical students (pediatric clerkship): Nova Southeastern University College of Osteopathic Medicine	2008 - 2014

15. BIBLIOGRAPHY

1. Robert L Rosenfield. K. Wroblewski, V. Padmanabhan , Elizabeth Littlejohn, Monia Mortensen, David Ehrmann. Antimüllerian hormone levels are independently related to ovarian hyperandrogenism and polycystic ovaries. Fertil Steril. 2012 Apr 26.

2. Robert L Rosenfield, Monica Mortensen, K. Wroblewski, Elizabeth Littlejohn, David Ehrmann. Determination of the source of androgen excess in functionally atypical polycystic ovary syndrome by a short dexamethasone androgen-suppression test and a low-dose ACTH test. Hum Reprod. 2011 Nov;26(11):3138-46.

3. Monica Mortensen, David Ehrmann, Elizabeth Littlejohn, Robert L. Rosenfield. Asymptomatic Volunteers with a Polycystic Ovary Are a Functionally Distinct but Heterogeneous Population. J Clin Endocrinol Metab 2009 May; 94 (5):1579-1586.

4. Jennifer Hirshfield-Cytron, Randall B. Barnes, David Ehrmann, Anthony Caruso, Monica Mortensen and Robert L. Rosenfield. Characterization of Functionally Typical and Atypical Types of Polycystic Ovary Syndrome. J Clin Endocrinol Metab 2009 May; 94 (5):1587-1594.

5. Monica Mortensen, Robert L Rosenfield, and Elizabeth Littlejohn. The Functional Significance of Polycystic-Size Ovaries (PSO) during Puberty. J Clin Endocrinol Metab 2006 Oct; 91 (10):3786-90.

Jonathan P. Clemens, DMSc, PA-C

PO Box 5430, Lacey, WA 98509-5430 | (253) 219 – 4181 | jclemens@jclemens.org

Education

Liberty University, Lynchburg VA
Doctor of Philosophy in Health Sciences, Trauma Informed Care — *6/2026*

A.T. Still University, Arizona School of Health Sciences, Mesa AZ
Doctor of Medical Science, Clinical Leadership — 6/2023

Western Seminary, Portland OR
Master of Theology, high honors — 8/2021

Pierce College, Puyallup WA
Undergraduate coursework (20 quarter hours), Fire Command Administration — 2017—19

Pacific University, Forest Grove OR
Master of Science, Physician Assistant Studies — 8/2012

South Puget Sound Community College, Olympia WA
Associate of General Studies, highest honors (pre-PA leveling) — 12/2009

Santa Fe Institute, Santa Fe NM
Complex Systems Summer School — 7/2004

Pepperdine University, Malibu CA
Master of Divinity — 9/1996
Master of Science, Ministry — 12/1994

Excelsior College (then USNY Regents' College), Albany NY
Bachelor of Science, Computer Information Systems — 1/1992
Associate of Science, Computer Software — 9/1991

University of Alaska Southeast, Juneau AK
Associate of Arts (completed prior to high school graduation) — 5/1989

Employment History

Principal/Physician Assistant, ErgoCare Clinic PLLC, Olympia WA — 9/2021—
Leading a PA-owned small-scale occupational and family medicine clinic.

Teaching Assistant, Western Seminary, Portland OR — 1/2021—
Facilitation and instructional support for online seminary courses. Part time.

Physician Assistant, The Emily Program, Lacey WA — 6/2019—
Medical clearance and monitoring for eating disorders clinic. Part time/contract.

Adjunct Clinical Instructor, Pacific University School of Physician Assistant Studies — 1/2016—
Precept PA students in clinical rotations, guest lecture. Part time/intermittent.

EMS Instructor/Evaluator, Thurston County Medic One, Olympia WA — 12/2007—
Provide initial and ongoing training for EMTs. Standardized patient 2007—2009. Instructor 2010—present. Evaluator 2014—present. Part time/intermittent.

Chaplain/Chief EMS Officer, South Bay Fire Department, Olympia WA — 8/2006—
Volunteer/stipend positions. Primary Fire/BLS response for outlying area. Captain 2013—2018. Assistant Medical Services Officer 2015—2017. Acting Battalion Chief 2016—2018. Chief Emergency Medical Services Officer 2018—present.

Physician Assistant, Atlas Sleep Center, Olympia WA — 9/2019—9/21
Sleep Medicine PA. Grew practice from single day clinic in sublet office space to AASM accredited 2 bed sleep center, without onsite physician. Part time. — 1/2017—11/18

Physician Assistant, Anesis Spine and Pain, Lacey WA — 10/2020—8/21
Medical assessment, Opioid management, interventional pain procedures, including joint injections under ultrasound guidance. Part time.

Employment History, Continued

Physician Assistant, Littlerock Family Medicine, Tumwater WA	10/2018—10/20
Primary care, seeing family medicine (scheduled and walk-in/urgent care) patients and occupational medicine cases.	3/2015—5/17
Physician Assistant, Cross Road Health Ministries, Glennallen AK	1/2019—9/20
Provide family and emergency medical care in Glennallen, Delta Junction, and Tok, Alaska for up to 2 weeks at a time. Full time/intermittent.	
Physician Assistant, KB Family Practice, Olympia WA	4/2017—8/19
Family and occupational medicine, coverage for retiring solo physician. Part time.	
Physician Assistant, Group Health Physicians, Olympia WA	9/2012—3/15
Family medicine with specialization in skin biopsies, diabetic foot care, nail surgery, joint injections, and as EPIC electronic medical record "super user."	
Volunteer Firefighter/EMT, Washington County Fire District 2, North Plains OR	9/2010—3/12
Respond to station to staff second unit or cover station for second 911 call.	
Information Security Manager, Intel Corporation, DuPont WA	5/1997—6/10
Extensive career in IT security and risk management, including risk assessment, policy development, penetration testing, investigations, incident response, mergers & acquisitions, and project, program, and people management. Collateral duties included emergency response team command, Christian diversity group leadership.	
Office Systems Analyst, World Vision U.S., Federal Way WA	7/1995—5/97
Team leader of 4 IT help desk analysts serving a large, multilingual nonprofit.	
Ministry Intern, Northwest Church of Christ, Shoreline WA	8/1993—6/95
Emphasis in youth, preaching, chaplaincy, small group ministries.	
Systems Analyst, Unisys Government Systems, Inc., Juneau AK	6/1990—4/93
Systems manager and user training specialist for U.S. Coast Guard.	

Current Professional Certifications	**First earned**
Medical	
Physician Assistant License, Alaska (inactive)	11/2018
Clinical Sleep Educator, Board of Registered Polysomnographic Technologists	2/2017
Fellow of the Academy of Wilderness Medicine, Wilderness Medical Society	8/2016
Registered Medical Examiner, U.S. DOT FMCSE (CDL exams)	5/2015
EMS Evaluator, Washington State	6/2014
Controlled Substances Registration Certificate, Schedules II-V, DEA (WA, Past: AK)	8/2012
Physician Assistant License, Washington State (WA Osteopathic PA 3/2017—4/2021)	8/2012
Physician Assistant, Certified (PA-C), NCCPA	8/2012
EMT Basic (National Registry, Washington. Past: Oregon, WMI Wilderness EMT)	6/2006
Fire/Rescue (prerequisite certificates omitted for brevity)	
Fire Instructor 2, International Fire Service Accreditation Congress (IFSAC)	3/2019
Fire Officer II, IFSAC	12/2017
Master Fire Chaplain, Federation of Fire Chaplains (FFC)	10/2016
Firefighter II, IFSAC	5/2016
Information Risk and Security	
Healthcare Information Security and Privacy Practitioner (HCISPP), ISC^2	12/2014
Certified Information Systems Security Professional (CISSP), ISC^2	7/1999

Selected Publications

Parsons, Marissa and Jonathan Clemens (in press), "Eating Disorders and Bariatric Surgery: The Chicken or the Egg?" *Journal of the American Academy of PAs*

Clemens, Jonathan, “Dear Christian Physicians”, *CMDA Today*, 54:2, Summer 2023.

Kline, Kiki M., Elizabeth A. O’neill, Stephanie Behar, Virginia Ramseyer Winter, and Jonathan P. Clemens. “Weight Stigma: A Potential Barrier to Psychiatric/Mental Health Medication Care.” *Social Work in Mental Health*, March 1, 2023, 1–18. doi:10.1080/15332985.2023.2184191.

Clemens, Jonathan, “Detransitioners in Your Church Doorway?” *Eikon*, 4:2, Fall 2022.

Clemens, Jonathan, “September 12, 2020,” *Health Enhanced by Art,* A.T. Still University, 2022.

Clemens, Jonathan, “Meaningful Use,” *Journal of the American Academy of PAs*, November, 2021. doi:10.1097/01.JAA.0000795044.84373.32.

Clemens, Jonathan, “Addressing Religious Objections to Vaccination,” *Journal of the American Academy of PAs*, February, 2020. doi:10.1097/01.JAA.0000651744.92234.17.

Clemens, Jonathan, “Health Information Security for Wilderness Medical Providers: an Overview,” *Wilderness Medicine Magazine*, 2016. http://wms.org/magazine/1180/Information-Security

Clemens, Jonathan P., "Hyponatremia in Elderly Patients Treated for Depression With Selective Serotonin Reuptake Inhibitors Versus Tricyclic Antidepressants" (2012). *School of Physician Assistant Studies.*

Fellman, Philip V., Jonathan P. Clemens, Roxana Wright, Jonathan Vos Post, and Matthew Dadmun, “Disrupting Terrorist Networks – A Dynamic Fitness Landscape Approach,” in *Conflict and Complexity: Countering Terrorism, Insurgency, Ethnic and Regional Violence*, ed. Philip V. Fellman, Yaneer Bar-Yam, and Ali A. Minai. Cambridge, MA: Springer, 2015.

Clemens, Jonathan and Dennis Morgan, “Choosing the Right Client Model,” *Premier IT Magazine*, Summer, 2007. Framingham, MA: CXO Media.

Clemens, Jonathan, and Lauren O’Neill, “Discovering an Optimum Covert Network”;

Metcalf, Sara S., and Jonathan P. Clemens “Modeling Ourselves: Social Selection and Development in a Substantially Novel Network”;

Schaeffer, Satu Elisa, Jonathan P. Clemens, and Patrick Hamilton, “Decision Making in a Distributed Sensor Network,” all from *Student Papers, 2004 Santa Fe Institute Complex Systems Summer School,* Santa Fe, NM: Santa Fe Institute, 2004.

Selected Public Presentations

Chaplains Association for Public Safety of Thurston County
- “Chaplain Care and First Responder PTSD in Washington State” 2023

AAPA National Convention (Category 1 CME offered)
- “With Great Power Comes Great(er) Responsibility – Reaching Across the Power Differential” (With DEI Commission) 2023
- “Challenges in Communicating Across Cultural Differences” (With DEI Commission) 2022

Conference on Medicine and Religion (Category 1 CME offered)
- “Eunuchs as Biblical Models of Hope for Detransitioners” 2023

Catholic Medical Association, annual educational conference (Category 1 CME offered)
- “Eating Disorders and Social Media: An Exquisitely Distorted Relationship” 2022

Presbyterian College, PA program virtual grand rounds
- “Eating disorders for Non-Specialists” 2022
- “Sleep Medicine” 2022

CMDA Bioethics Perspectives 2021 (Category 1 CME offered)
- “Eating Disorders for Non-Specialists: Awareness and Ethical Considerations at the Intersection of Medical and Mental Healthcare” 2021

Pacific University, PA program lectures
- “Racial Disparities in Maternal Mortality” 2021
- “Eating Disorders” 2020
- “Sleep Medicine” 2017, 19–22

Selected Public Presentations, Continued

Pacific University, PA program lectures, continued
- "Addressing Patient Religious Concerns in a Diverse Society" 2017
- "Occupational Medicine" 2017

LinuxWorld Expo
- "Enterprise Security" 2007

Intel Premier IT Partners,
- "Enterprise Security" 2005, 2007
- "Get Rich or Stay Thin" 2007

Information Systems Audit and Control Association (ISACA) – Mt. Rainier Chapter
- "Using the Incident Command System for Computer Incident Response" 2001

Media appearances

"Eating Disorder Diagnosis and Treatment" *Doctor, Doctor* podcast, 3/31/2023

"Washington's Death with Dignity Act may get an update" Spokane Public Radio, 3/7/2023, https://www.spokanepublicradio.org/regional-news/2023-03-07/washingtons-death-with-dignity-act-may-get-an-update

"What You Need to Know About Eating Disorders" *Doctor, Doctor* podcast, 3/3/2023

"Improving Cross-Cultural Communication Skills With Patients" Medscape, https://www.medscape.com/viewarticle/974645, 5/26/2022.

"Franklin Graham: Americans should 'prayerfully' consider getting the COVID-19 vaccine," Washington Times, https://www.washingtontimes.com/news/2021/may/19/franklin-graham-americans-should-prayerfully-consi/, 5/19/2021.

"Addressing Religious Objections to Vaccination," *CMDA Matters* podcast, https://cmda.org/jonathan-clemens-pa-c-immunizations/, 8/19/2020.

Graduate Level Courses Facilitated as Teaching Assistant, Western Seminary

BL 503 Interpreting Acts through Revelation	Spring 2021
BL 570 Psalms and Ecclesiastes: Ancient Models for Faithful Living	Fall 2022
BT 501 Hermeneutics	Fall 2021
BT 502 Understanding Biblical Theology	Spring 2023
BT 537 Priestly Messiah, Temple and Apocalyptic	Summer 2022
CS 501 Loving God and Others	Summer 2022
ML 506 Ministerial Ethics	Summer 2021, Spring 2022

Medical Coursework	**Attended**
Practical Point of Care Ultrasound 3 day course, Practical POCUS	8/2019
IV Therapy endorsement for EMTs, Mason County Medic One	11/2016
Remote Medicine for Advanced Providers (RMAP), Remote Medical International	9/2013
Wilderness Upgrade for Medical Providers, NOLS/Ready SF	4/2012
The Difficult Airway Course: EMS	9/2011

Expired Medical Certifications	**First Earned**
Advanced Wilderness Life Support, Adventure Med/University of Utah	6/2015
Advanced Life Support in Obstetrics (ALSO), AAFP	9/2014
Fundamental Critical Care Support, SCCM	6/2014
Advanced Trauma Life Support (ATLS), American College of Surgeons	1/2013
Pre-Hospital Trauma Life Support (PHTLS), NAEMT	12/2012
Advanced Burn Life Support (ABLS), American Burn Association	10/2011
Pediatric Advanced Life Support (PALS), American Heart Association (AHA)	5/2011
Advanced Cardiac Life Support (ACLS), AHA	10/2008

Fire/Rescue Coursework

Incident Command System core courses IS-100, -200, -300, -400, -700, -800, FEMA	2006—2015
Blue Card Incident Command Training, (Sim Iab) Fire Command Seminars/Olympia Fire	10/2018
USFA Type 3 Incident Management Team Training, O-305	6/2018
IAFF Fire Ground Survival, Olympia Fire Department	5/2014
Blue Card Incident Command Training Program, (Online) Fire Command Seminars	9/2013
Incident Safety Officer, National Fire Academy (NFA)	2/2010
Strategies and Tactics for Initial Company Operations, NFA	1/2008
Police/Fire Chaplains' Training Academy, WA Criminal Justice Training Commission	10/2007
Volunteer Firefighter Academy, HAZMAT ops Thurston Fire/Rescue Training Consortium	12/2006

Professional Recognition	**Awarded**
Fire Officer of the Year, South Bay Fire Department	2013, 2015
Division Recognition Award for outstanding achievement, Intel Corporation, 6 awards	2002—2008
Patent filings, Intel Corp. PRC patent 101490669, 2012. U.S. Patent 8471904, 2013.	2006—2008
Firefighter of the Year, South Bay Fire Department	2007
Honor Graduate, Thurston County Fire Rescue Training Consortium Academy 06-02	2006

Community Service	**Active**
Fellowship of Christian PAs: Board member, President 2019—20, 2022—23	2017—
Diversity, Equity, and Inclusion commission member, AAPA	2020—23
PAs For Tomorrow, Board Member at Large	2021—23
American Red Cross: Health services volunteer, shelter support, Hurricane Florence	2018
Medical Reserve Corps Volunteer, Thurston County Health Department	2017—
Moderator/Administrator, The Physician Assistant Forum	2012—
Health Talents International: Medical mission team member	2008—
Cub Scouts/Boy Scouts of America: Registered adult leader	2005—2013
Computer Technology Investigators Northwest: Private sector board member-at-large	2000—2006

Professional Memberships	
PAs For Tomorrow	2013—
Christian Medical and Dental Associations/Fellowship of Christian PAs (life member)	2012—
Wilderness Medical Society	2011—
American Academy of Physician Assistants	2010—2013, 2018—
Washington Academy of Physician Assistants	2010—
Federation of Fire Chaplains	2009—
Washington State Firefighters Association	2008—
International Association of Fire Chiefs	2018—2022
Society of Emergency Medicine Physician Assistants	2014—2021

Personal Interests

Games, including card, board, role-playing, and computer. Martial arts. Complex systems studies.

Revision date: June 22, 2023.

Stephen B. Levine, M.D. **Curriculum Vita**
February, 2022

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the author or coauthor of numerous books on topics relating to human sexuality and related relationship and mental health issues. Dr. Levine has been teaching, providing clinical care, and writing since 1973, and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. Dr. Levine has been co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992 to the present. He received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973- Assistant Professor of Psychiatry

1979- Associate Professor

1982- Awarded tenure

1985- Full Professor

1993- Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award-1990 and 2010 (Residency program)

Visiting Professorships

- Stanford University-Pfizer Professorship program (3 days)–1995
- St. Elizabeth's Hospital, Washington, DC –1998
- St. Elizabeth's Hospital, Washington, DC--2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018—Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (Exceling in one's field for at least twenty years)

Professional Societies

1971- American Psychiatric Association; fellow; #19909

2005- American Psychiatric Association, Distinguished Life Fellow

1973- Cleveland Psychiatric Society

1973- Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974-Society for Sex Therapy and Research

- 1987-89-President

1983- International Academy of Sex Research

1983- Harry Benjamin International Gender Dysphoria Association

- 1997-8 Chairman, Standards of Care Committee

1994- 1999 Society for Scientific Study of Sex

Community Boards

1999-2002 Case Western Reserve University Medical Alumni Association

1996-2001 Bellefaire Jewish Children's Bureau

1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

a. Archives of Sexual Behavior
b. Annals of Internal Medicine
c. British Journal of Obstetrics and Gynecology
d. JAMA
e. Diabetes Care
f. American Journal of Psychiatry
g. Maturitas
h. Psychosomatic Medicine
i. Sexuality and Disability
j. Journal of Nervous and Mental Diseases
k. Journal of Neuropsychiatry and Clinical Neurosciences
l. Neurology
m. Journal Sex and Marital Therapy
n. Journal Sex Education and Therapy
o. Social Behavior and Personality: an international journal (New Zealand)
p. International Journal of Psychoanalysis
q. International Journal of Transgenderism
r. Journal of Urology
s. Journal of Sexual Medicine
t. Current Psychiatry
u. International Journal of Impotence Research
v. Postgraduate medical journal
w. Academic Psychiatry

Prospectus Reviewer

a. Guilford

b. Oxford University Press

c. Brunner/Routledge

d. Routledge

Administrative Responsibilities

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Expert testimony at trial or by deposition within the last 4 years

Provided expert testimony for Massachusetts Dept. of Corrections in its defense of a lawsuit brought by prisoner Katheena Soneeya, including by deposition in October 2018, and in-court testimony in 2019.

Provided expert testimony by deposition and at trial in *In the Interests of the Younger Children* (Dallas, TX), 2019.

Testified in an administrative hearing in *In the matter of Rhys & Lynn Crawford* (Washington State), March 2021.

Testified multiple times in juvenile court in *In the matter of Asha Kerwin* (Tucson, Arizona), 2021.

Provided expert testimony by deposition in *Kadel et al v. Folwell et al.* (North Carolina), 2021.

Consultancies

Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010.

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies.

Virginia Department of Corrections –evaluation of an inmate.

New Jersey Department of Corrections—evaluation of an inmate.

Idaho Department of Corrections—workshop 2016.

Grant Support/Research Studies

TAP–studies of Apomorphine sublingual in treatment of erectile dysfunction.

Pfizer–Sertraline for premature ejaculation.

Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction.

NIH- Systemic lupus erythematosis and sexuality in women.

Sihler Mental Health Foundation

a. Program for Professionals
b. Setting up of Center for Marital and Sexual Health
c. Clomipramine and Premature ejaculation
d. Follow-up study of clergy accused of sexual impropriety
e. Establishment of services for women with breast cancer

Alza–controlled study of a novel SSRI for rapid ejaculation.

Pfizer–Viagra and self-esteem.

Pfizer- double-blind placebo control studies of a compound for premature ejaculation.

Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation.

Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement.

Lilly-Icos—study of Cialis for erectile dysfunction.

VIVUS – study for premenopausal women with FSAD.

Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration.

Medtap – interview validation questionnaire studies.

HRA- quantitative debriefing study for Female partners os men with premature ejaculation, Validation of a New Distress Measure for FSD.

Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder.

Biosante- studies of testosterone gel administration for post menopausal women with HSDD.

J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC-Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD.

National registry trial for women with HSDD.

Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women.

Palatin—study of SQ Bremelanotide for HSDD and FSAD.

Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD.

HRA – qualitative and cognitive interview study for men experiencing PE.

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985

2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997

3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992

4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998

5) Editor, Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.

6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003

1. 2006 SSTAR Book Award: Exceptional Merit

7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006

8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals, 2nd edition. Routledge, New York, 2010.

9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.

10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

When his name is not listed in a citation, Dr. Levine is either the solo or the senior author.

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73

2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26

3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2

4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

12) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

13) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the dysfunction? Sexual Medicine Today 1977;1:13

14) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

15) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

16) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977;3:177-186

17) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

18) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978;4:235-258

19) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978;113-958-962

20) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981;6:102-108

21) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

22) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

23) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

24) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983;12:247-61

25) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

26) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982;9:21-28

27) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982;8:316-324

28) Nymphomania. Female Patient 1982;7:47-54

29) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982;16:135-9

30) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

31) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

32) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

33) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984;86:412-418

34) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984;10:176-184

35) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984;13:287-9

36) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

37) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

38) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

39) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI.

External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

40) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

41) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987;13:35-44

42) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

43) Lets talk about sex. National Hemophilia Foundation January, 1988

44) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

45) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

46) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630

47) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. Archives of Sexual Behavior 1991;;20(4):333-43.

48) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19

49) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. Journal of Sex & Marital Therapy 1987**;** 13:155-167

50) Althof SE, Turner LA, Risen CB, Bodner DR, Kursh ED, Resnick MI. Side effects of self-administration of intracavernosal injection of papaverine and phentolamine for treatment of impotence. Journal of Urology 1989;141:54-7

51) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989

52) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989

53) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. Journal of Sex & Marital Therapy

54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? Journal of Sex & Marital Therapy. 1989;15:121-9

55) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. Journal of Sex & Marital Therapy. 1989; 15(3):163-78

56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. Journal of Urology 1990;141(1):79-82

57) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia Journal of Sex & Marital Therapy 1990; 16(2):89-102.

58) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. International Journal of Impotence Research (supplement 2)1990;346-7.

59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. A comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. . International Journal of Impotence Research (supplement 2)1990;289-90

60) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence.International Journal of Impotence Research (supplement 2)1990;340-1.

61) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in Journal of Sex & Marital Therapy 1991; 17(2):101-112

62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dsyfunction in Journal of Sex & Marital Therapy 1991;17(2):81-93

63) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. Urology 1992;39(2):139-44

64) Althof SE, The pathogenesis of psychogenic impotence. J. Sex Education and Therapy. 1991; 17(4):251-66

65) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. Clinical Pediatrics 1991; 30(4):259-260

66) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic

Services), Autumn, 1991

67) Psychological intimacy. Journal of Sex & Marital Therapy 1991; 17(4):259-68

68) Male sexual problems and the general physician, Georgia State Medical Journal 1992; 81(5): 211-6

69) Althof SE, Turner LA, Levine SB, Bodner DB, Kursh E, Resnick MI. Through the eyes of women: The sexual and psychological responses of women to their partner's treatment with self-injection or vacuum constriction devices. Journal of Urology 1992; 147(4):1024-7

70) Curry SL, Levine SB, Jones PK, Kurit DM. Medical and Psychosocial predictors of sexual outcome among women with systemic lupus erythematosis. Arthritis Care and Research 1993; 6:23-30

71) Althof SE, Levine SB. Clinical approach to sexuality of patients with spinal cord injury. Urological Clinics of North America 1993; 20(3):527-34

72) Gender-disturbed males. Journal of Sex & Marital Therapy 19(2):131-141, 1993

73) Curry SL, Levine SB, Jones PK, Kurit DM. The impact of systemic lupus erythematosis on women's sexual functioning. Journal of Rheumatology 1994; 21(12):2254-60

74) Althof SE, Levine SB, Corty E, Risen CB, Stern EB, Kurit D. Clomipramine as a treatment for rapid ejaculation: a double-blind crossover trial of 15 couples. Journal of Clinical Psychiatry 1995;56(9):402-7

75) Risen CB, Althof SE. Professionals who sexually offend: evaluation procedures and preliminary findings. Journal of Sex & Marital Therapy 1994; 20(4):288-302

76) On Love, Journal of Sex & Marital Therapy 1995; 21(3):183-191

77) What is clinical sexuality? Psychiatric Clinics of North America 1995; 18(1):1-6

78) "Love" and the mental health professions: Towards an understanding of adult love. Journal of Sex & Marital Therapy 1996; 22(3)191-202

79) The role of Psychiatry in erectile dysfunction: a cautionary essay on the emerging treatments. Medscape Mental Health 2(8):1997 on the Internet. September, 1997.

80) Discussion of Dr. Derek Polonsky's SSTAR presentation on Countertransference. Journal of Sex Education and Therapy 1998; 22(3):13-17

81) Understanding the sexual consequences of the menopause. Women's Health in Primary Care, 1998

82) Fones CSL, Levine SB. Psychological aspects at the interface of diabetes and erectile dysfunction. Diabetes Reviews 1998; 6(1):1-8

83) Guay AT, Levine SB, Montague DK. New treatments for erectile dysfunction. Patient Care March 15, 1998

84) Extramarital Affairs. Journal of Sex & Marital Therapy 1998; 24(3):207-216

85) Levine SB (chairman), Brown G, Cohen-Kettenis P, Coleman E, Hage JJ, Petersen M, Pfäfflin F, Shaeffer L, van Masdam J, Standards of Care of the Harry Benjamin International Gender Dysphoria Association, 5th revision, 1998. International Journal of Transgenderism at http://www.symposion.com/ijt

- Reprinted by the Harry Benjamin International Gender Dysphoria Association, Minneapolis, Minnesota

86) Althof SE, Corty E, Levine SB, Levine F, Burnett A, McVary K, Stecher V, Seftel. The EDITS: the development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology 1999;53:793-799

87) Fones CSL, Levine SB, Althof SE, Risen CB. The sexual struggles of 23 clergymen: a follow-up study. Journal of Sex & Marital Therapy 1999

88) The Newly Devised Standards of Care for Gender Identity Disorders. Journal of Sex Education and Therapy 24(3):1-11,1999

89) Levine, S. B. (1999). The newly revised standards of care for gender identity disorders. Journal of Sex Education & Therapy, 24, 117-127.

90) Melman A, Levine SB, Sachs B, Segraves RT, Van Driel MF. Psychological Issues in Diagnosis of Treatment (committee 11) in Erectile Dysfunction (A. Jarden, G. Wagner, S. Khoury, F. Guiliano, H. Padma-nathan, R. Rosen, eds.) Plymbridge Distributors Limited, London, 2000

91) Pallas J, Levine SB, Althof SE, Risen CB. A study using Viagra in a mental health practice. J Sex&Marital Therapy.26(1):41-50, 2000

92) Levine SB, Stagno S. Informed Consent for Case Reports: the ethical dilemma between right to privacy and pedagogical freedom. Journal of Psychotherapy: Practice and Research, 2001, 10 (3): 193-201.

93) Alloggiamento T., Zipp C., Raxwal VK, Ashley E, Dey S. Levine SB, Froelicher VF. Sex, the Heart, and Sildenafil. Current Problems in Cardiology 26 June 2001(6):381-416

94) Re-exploring The Nature of Sexual Desire. Journal of Sex and Marital Therapy 28(1):39-51, 2002.

95) Understanding Male Heterosexuality and Its Disorders in Psychiatric Times XIX(2):13-14, February, 2002

96) Erectile Dysfunction: Why drug therapy isn't always enough. (2003)

Cleveland Clinic Journal of Medicine, 70(3): 241-246.

97) The Nature of Sexual Desire: A Clinician's Perspective. Archives of Sexual Behavior 32(3):279-286, 2003 .

98) Laura Davis. What I Did For Love: Temporary Returns to the Male Gender Role. International Journal of Transgenderism, 6(4), 2002 and http://www.symposion.com/ijt

99) Risen C.B., The Crisis in the Church: Dealing with the Many Faces of Cultural Hysteria in The International Journal of Applied Psychoanalytic Studies, 1(4):364-370, 2004

100) Althof SE, Leiblum SR (chairpersons), Chevert-Measson M. Hartman U., Levine SB, McCabe M., Plaut M, Rodrigues O, Wylie K., Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction in World Health Organization Conference Proceedings on Sexual Dysfunctions, Paris, 2003. Published in a book issued in 2004.

101) Commentary on Ejaculatory Restrictions as a Factor in the Treatment of Haredi (Ultra-Orthodox) Jewish Couples: How Does Therapy Work? Archives of Sexual Behavior, 33(3):June 2004

102) What is love anyway? J Sex & Marital Therapy 31(2):143-152,2005.

103) A Slightly Different Idea, Commentary on Y. M. Binik's Should Dyspareunia Be Retained as a Sexual Dysfunction in DSM-V? A Painful Classification Decision. Archives of Sexual Behavior 34(1):38-39, 2005. http://dx.doi.org/10.1007/s10508-005-7469-3

104) Commentary: Pharmacologic Treatment of Erectile Dysfunction: Not always a simple matter. BJM USA; Primary Care Medicine for the American Physician, 4(6):325-326, July 2004

105) Leading Comment: A Clinical Perspective on Infidelity. Journal of Sexual and Relationship Therapy, 20(2):143-153, May 2005.

106) Multiple authors. Efficacy and safety of sildenafil citrate (Viagra) in men with serotonergic antidepressant-associated erectile dysfunction: Results from a randomized, double-blind, placebo-controlled trial. Submitted to Journal of Clinical Psychiatry Feb 2005

107) Althof SE, Leiblum SR, Chevert-Measson M, Hartman U, Levine SB, McCabe M, Plaut M, Rodrigues O, Wylie K. Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction. Journal of Sexual Medicine, 2(6): 793-800, November, 2005

108) Shifren JL, Davis SR, Moreau M, Waldbaum A, Bouchard C., DeRogatis L., Derzko C., Bearnson P., Kakos N., O'Neill S., Levine S., Wekselman K., Buch A., Rodenberg C., Kroll R. Testosterone Patch for the Treatment of Hypoactive Sexual

Desire Disorder in Naturally Menopausal Women: Results for the INTIMATE NM1 Study. Menopause: The Journal of the North American Menopause Society 13(5) 2006.

109) Reintroduction to Clinical Sexuality. Focus: A Journal of Lifelong Learning in Psychiatry Fall 2005. III (4):526-531

110) PDE-5 Inhibitors and Psychiatry in J Psychiatric Practice 12 (1): 46-49, 2006.

111) Sexual Dysfunction: What does love have to do with it? Current Psychiatry 5(7):59-68, 2006.

112) How to take a Sexual History (Without Blushing), Current Psychiatry 5(8): August, 2006.

113) Linking Depression and ED: Impact on sexual function and relationships in Sexual Function and Men's Health Through the Life Cycle under the auspices of the Consortium for Improvement of Erectile Function (CIEF),12-19, November, 2006.

114) The First Principle of Clinical Sexuality. Editorial. Journal of Sexual Medicine,4:853-854, 2007

115) Commentary on David Rowland's editorial, "Will Medical Solutions to Sexual Problems Make Sexological Care and Science Obsolete?" Journal of Sex and Marital Therapy, 33(5), 2007

116) Real-Life Test Experience: Recommendations for Revisions to the Standards of Care of the World Professional Association for Transgender Health International Journal of Transgenderism, Volume 11 Issue 3, 186-193, 2009

117) Sexual Disorders: Psychiatrists and Clinical Sexuality. Psychiatric Times XXIV (9), 42-43, August 2007

118) I am not a sex therapist! Commentary to I. Binik and M. Meana's article Sex Therapy: Is there a future in this outfit? Archives of Sexual Behavior, Volume 38, Issue 6 (2009), 1033-1034

119) Solomon A (2009) Meanings and Political Implications of "Psychopathology" in a Gender Identity Clinic: Report of 10 cases. Journal of Sex and Marital Therapy 35(1): 40-57.

120) Perelman, MA., Levine SB, Fischkoff SA. Randomized, Placebo-Controlled, Crossover Study to Evaluate the Effects of Intranasal Bremelanotide on Perceptions of Desire and Arousal in Postmenopausal Women with Sexual Arousal Disorder submitted to Journal of Sexual Medicine July 2009, rejected

121) What is Sexual Addiction? Journal of Sex and Marital Therapy.2010 May;36(3):261-75

122) David Scott (2010) Sexual Education of Psychiatric Residents. Academic Psychiatry, 34(5) 349-352.

123) Chris G. McMahon, Stanley E. Althof, Joel M. Kaufman, Jacques Buvat, Stephen B. Levine, Joseph W. Aquilina, Fisseha Tesfaye, Margaret Rothman, David A. Rivas, Hartmut Porst. Efficacy and Safety of Dapoxetine for the Treatment of Premature Ejaculation: Integrated Analysis of Results From 5 Phase 3 Trials Journal of Sexual Medicine 2011 Feb;8(2):524-39.

124) Commentary on Consideration of Diagnostic Criteria for Erectile Dysfunction in DSM V. Journal of Sexual Medicine July 2010

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