EXHIBIT 101

The New York Times | https://www.nytimes.com/2024/04/09/health/europe-transgender-youth-hormone-treatments.html

Youth Gender Medications Limited in England, Part of Big Shift in Europe

Five European countries have recently restricted hormone treatments for adolescents with gender distress. They have not banned the care, unlike many U.S. states.

By Azeen Ghorayshi
Azeen Ghorayshi reports on transgender health and visited the world's first youth gender clinic in Amsterdam this fall.

Published April 9, 2024 Updated April 10, 2024, 9:46 a.m. ET

The National Health Service in England started restricting gender treatments for children this month, making it the fifth European country to limit the medications because of a lack of evidence of their benefits and concern about long-term harms.

England's change resulted from a four-year review released Tuesday evening by Dr. Hilary Cass, an independent pediatrician. "For most young people, a medical pathway will not be the best way to manage their gender-related distress," the report concluded. In a related editorial published in a medical journal, Dr. Cass said the evidence that youth gender treatments were beneficial was "built on shaky foundations."

The N.H.S. will no longer offer drugs that block puberty, except for patients enrolled in clinical research. And the report recommended that hormones like testosterone and estrogen, which spur permanent physical changes, be prescribed to minors with "extreme caution." (The guidelines do not apply to doctors in private

practice, who serve a small fraction of the population.)

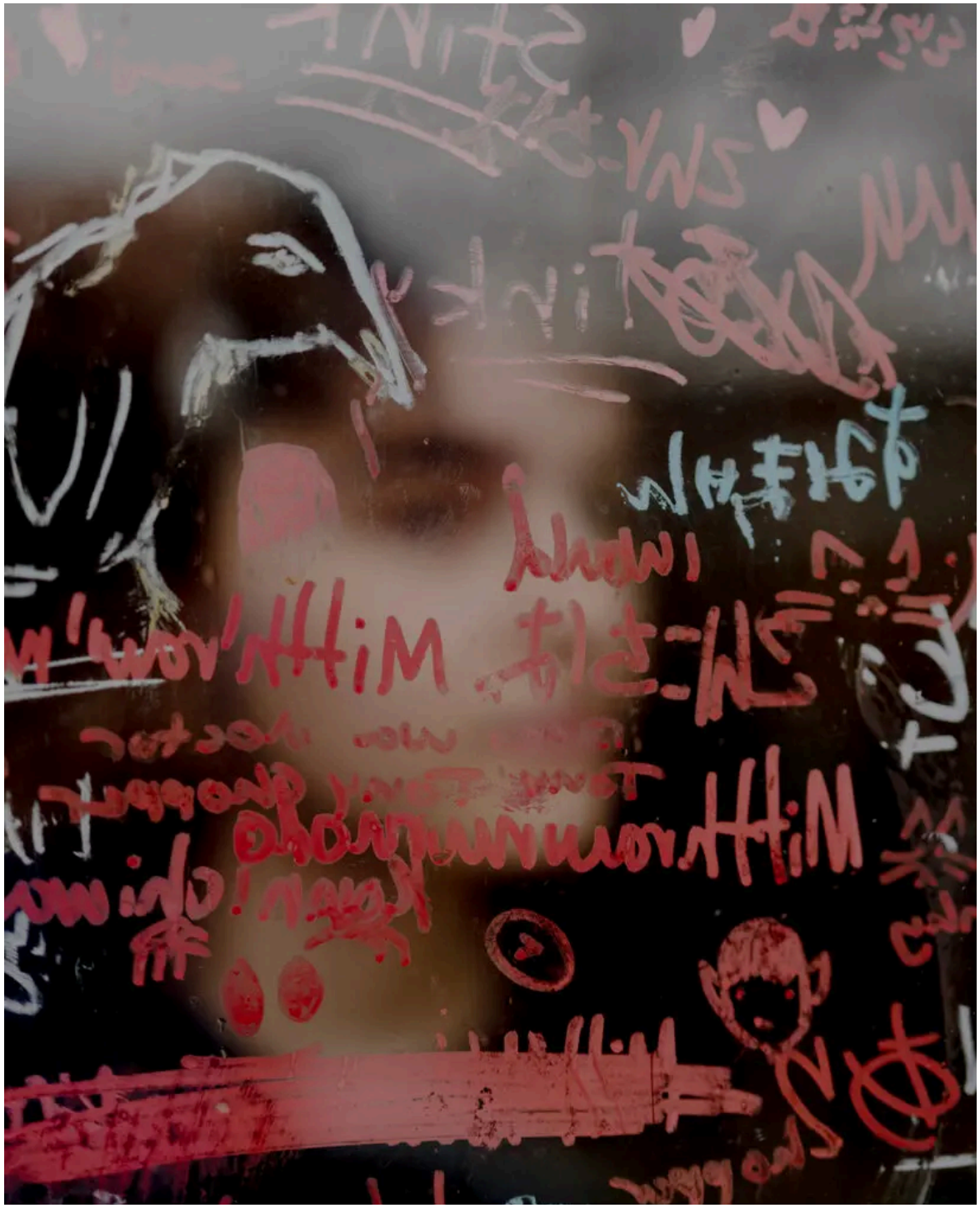
England's move is part of a broader shift in northern Europe, where health officials have been concerned by soaring demand for adolescent gender treatments in recent years. Many patients also have mental health conditions that make it difficult to pinpoint the root cause of their distress, known as dysphoria.

In 2020, Finland's health agency restricted the care by recommending psychotherapy as the primary treatment for adolescents with gender dysphoria. Two years later, Sweden restricted hormone treatments to "exceptional cases."

In December, regional health authorities in Norway designated youth gender medicine as a "treatment under trial," meaning hormones will be prescribed only to adolescents in clinical trials. And in Denmark, new guidelines being finalized this year will limit hormone treatments to transgender adolescents who have experienced dysphoria since early childhood.

Several transgender advocacy groups in Europe have condemned the changes, saying that they infringe on civil rights and exacerbate the problems of overstretched health systems. In England, around 5,800 children were on the waiting list for gender services at the end of 2023, according to the N.H.S.

"The waiting list is known to be hell," said N., a 17-year-old transgender boy in southern England who requested to withhold his full name for privacy. He has been on the waiting list for five years, during which time he was diagnosed with autism and depression. "On top of the trans panic our own government is pushing, we feel forgotten and left behind," he said.



N., a 17-year-old transgender boy in England, has been on the waiting list for the youth gender clinic for five years. He covered windows in his house with Japanese phrases as he was learning the language. Tori Ferenc for The New York Times

In the United States, Republican politicians have cited the pullback in Europe to justify laws against youth gender medicine. But the European policies are notably different from the outright bans for adolescents passed in 22 U.S. states, some of which threaten doctors with prison time or investigate parents for child abuse. The European countries will still allow gender treatments for certain adolescents and are requiring new clinical trials to study and better understand their effects.

“We haven’t banned the treatment,” said Dr. Mette Ewers Haahr, a psychiatrist who leads Denmark’s sole youth gender clinic, in Copenhagen. Effective treatments must consider human rights and patient safety, she said. “You have to weigh both.”

In February, the European Academy of Paediatrics acknowledged the concerns about youth gender medicine. “The fundamental question of whether biomedical treatments (including hormone therapy) for gender dysphoria are effective remains contested,” the group wrote. In contrast, the American Academy of Pediatrics last summer reaffirmed its endorsement of the care, stating that hormonal treatments are essential and should be covered by health insurers, while also commissioning a systematic review of evidence.

Europeans pioneered the use of gender treatments for young people. In the 1990s, a clinic in Amsterdam began giving puberty-suppressing drugs to adolescents who had felt they were a different gender since early childhood.

The Dutch doctors reasoned that puberty blockers could give young patients with gender dysphoria time to explore their identity and decide whether to proceed with hormones to ultimately transition. For patients facing male puberty, the drugs would stave off the physical changes — such as a deeper voice and facial hair

— that could make it more difficult for them to live as women in adulthood. The Dutch team's research, which was first published in 2011 and tracked a carefully selected group of 70 adolescents, found that puberty blockers, in conjunction with therapy, improved psychological functioning.

That study was hugely influential, inspiring clinics around the world to follow the Dutch protocol. Referrals to these clinics began to surge around 2014, though the numbers remain small. At Sweden's clinic, for example, referrals grew to 350 adolescents in 2022 from around 50 in 2014. In England, those numbers grew to 3,600 referrals in 2022 from 470 in 2014.

Clinics worldwide reported that the increase was largely driven by patients raised as girls. And unlike the participants in the original Dutch study, many of the new patients did not experience gender distress until puberty and had other mental health conditions, including depression and autism.

Dr. Annelou de Vries, a psychiatrist who led the original Dutch research. “In a way, if everybody is starting to be concerned, of course, these concerns come also to our country,” she said. Melissa Schriek for The New York Times

Given these changes, some clinicians are questioning the relevance of the original Dutch findings for today’s patients.

“The whole world is giving the treatment, to thousands, tens of thousands of young people, based on one study,” said Dr. Riittakerttu Kaltiala, a psychiatrist who has led the youth gender program in Finland since 2011 and has become a vocal critic of the care.

Dr. Kaltiala’s own research found that about 80 percent of patients at the Finnish clinic were born female and began experiencing gender distress later in adolescence. Many patients also had psychological issues and were not helped by hormonal treatments, she found. In 2020, Finland severely limited use of the drugs.

Around the same time, the Swedish government commissioned a rigorous research review that found “insufficient” evidence for hormone therapies for youth. In 2022, Sweden recommended hormones only for “exceptional cases,” citing in part the uncertainty around how many young people may choose to stop or reverse their medical transitions down the line, known as detransitioning.

Even the original Dutch clinic is facing pressure to limit patients receiving the care. In December, a public documentary series in the Netherlands questioned the basis of the treatments. And in February, months after a far-right political party swept an election in a country long known as socially liberal, the Dutch Parliament passed a resolution to conduct research comparing the current Dutch approach with that of other European countries.

“I would have liked that the Netherlands was an island,” said Dr. Annelou de Vries, a psychiatrist who led the original Dutch research and still heads the Amsterdam clinic. “But of course, we are not — we are also part of the global world. So in a way, if everybody is starting to be concerned, of course, these concerns come also to our country.”

In England, brewing concerns about the surge of new patients reached a boiling point in 2018, when 10 clinicians at the N.H.S.’s sole youth gender clinic, known as the Tavistock Gender Identity Development Service, formally complained that they felt pressure to quickly approve children, including those with serious mental health problems, for puberty blockers.

In 2021, Tavistock clinicians published a study of 44 children who took puberty blockers that showed a different result from the Dutch: The patients given the drugs, on average, saw no impact on psychological function.

Although the drugs did not lessen thoughts of self-harm or the severity of dysphoria, the adolescents were “resoundingly thrilled to be on the blocker,” Dr. Polly Carmichael, the head of the clinic, said at a 2016 conference. And 43 of the 44 study participants later chose to start testosterone or estrogen, raising questions about whether the drug was serving its intended purpose of giving adolescents time to consider whether a medical transition was right for them.

Anna Hutchinson, a former clinical psychologist at the Tavistock center in London. "It's reassuring that we're going to return to a more robust, evidence-based pathway for decisions relating to these children," she said. Tori Ferenc for The New York Times

In 2020, the N.H.S. commissioned Dr. Cass to carry out an independent review of the treatments. She commissioned scientific reviews and considered international guidelines of the care. She also met with young people and their families, trans adults, people who had detransitioned, advocacy groups and clinicians.

The review concluded that the N.H.S.'s standard of care was inadequate, with long waiting lists for access to drug treatments and few routes to address the mental health concerns that may be contributing to gender distress. The N.H.S. shuttered the Tavistock center last month and opened two new youth gender clinics, which Dr. Cass said should have a "holistic" approach, with more support for those with autism, depression and eating disorders, as well as psychotherapy to help adolescents explore their identities.

"Children and young people have just been really poorly served," Dr. Cass said in an interview with the editor of The British Medical Journal, released Tuesday. She added, "I can't think of another area of pediatric care where we give young people potentially irreversible treatments and have no idea what happens to them in adulthood."

The changes enacted by the N.H.S. this month are "an acknowledgment that our concerns were, in fact, valid," said Anna Hutchinson, a clinical psychologist in London who was one of the Tavistock staff members who raised concerns in 2018. "It's reassuring that we're going to return to a more robust, evidence-based pathway for decisions relating to these children."

Some critics said that Europe, like the United States, had also been influenced by a growing backlash against transgender people.

In England, for example, a yearslong fight over a proposed law that would have made it easier for transgender people to change the gender on their identification documents galvanized a political movement to try to exclude transgender women from women's sports, prisons and domestic violence shelters.

"The intention with the Cass review is to be neutral, but I think that neutral has maybe moved," said Laurence Webb, a representative from Mermaids, a trans youth advocacy organization in Britain. "Extremist views have become much more normalized."

Other countries have seen more overt attacks on transgender rights and health care. In 2020, Hungary's Parliament passed a law banning gender identity changes on legal documents. Last year, Russia banned legal gender changes as well as gender-related medical care, with one lawmaker describing gender surgeries as the "path to the degeneration of the nation."

In France this year, a group of conservative legislators introduced a bill to ban doctors from prescribing puberty blockers and hormones, with punishments of two years' imprisonment and a fine of 30,000 euros, or about $32,600. And on Monday, the Vatican condemned gender transitions as threats to human dignity.

Azeen Ghorayshi covers the intersection of sex, gender and science for The Times. More about Azeen Ghorayshi

A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: Britain Limits Gender Drugs For Children

EXHIBIT 102

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Gender identity services in the UK are on pause as evidence comes under scrutiny

Hannah Barnes *investigations producer, BBC Newsnight*

The care provided to young people with gender incongruence or gender related stress by the NHS is in limbo. In July 2022 NHS England announced its intention to close its only specialist youth gender clinic by the spring of 2023 and replace it with two regional services, the first of several. But this timeline looks highly unlikely.

Families under the care of the Gender Identity Development Service (GIDS) at London's Tavistock and Portman NHS Foundation Trust say that clinicians have been leaving the service, making consistency of care difficult. Current GIDS staff said in February that the trust had not received the six month notice of closure from NHS England.

The decision to close GIDS and build a new model of care followed the interim findings of an independent review, chaired by the paediatrician Hilary Cass,[1] and a critical report from England's healthcare regulator the Care Quality Commission, which rated the service "inadequate" in January 2021.[2]

Both of those reports came after GIDS staff had raised concerns about whether the care being provided to young people was always safe. Together with Deborah Cohen, former *BMJ* investigations editor and *BBC Newsnight* colleague, I began reporting on these in 2019. My new book, *Time to Think*,[3] chronicles how numerous GIDS clinicians have voiced their worries consistently and repeatedly over several years. Clinicians such as Anna Hutchinson shared them with the GIDS leadership, members of the Tavistock board, the chief executive and chair, and finally the media.

GIDS was set up initially to provide—for the most part—talking therapies to young people who were questioning their gender identity. In the 1990s the clinic's founder, the psychiatrist Domenico Di Ceglie, said that only a minority of the young people seen at his clinic would transition as adults. For those whose trans identification remained and who were 16 or older, gonadotrophin releasing hormone analogues (GnRHa)—often referred to as puberty blockers—could be prescribed by endocrinologists who were linked to the service.

In 2011 GIDS, together with endocrinologists at University College London Hospitals NHS Foundation Trust, agreed to lower the age at which young people could access GnRHa as part of a research study. Promising data had emerged from the Netherlands showing that for a select group of young people earlier blocking of puberty appeared to be beneficial. But these were early and limited data, so the UK team set out to find out more.

Ahead of the study data being ready, from mid-2014 puberty blockers became available for anyone who was eligible as standard clinical practice at GIDS. The service also moved from an "'age" to a "stage" approach, whereby access to medical interventions would be dictated by a child's stage of puberty, not their age. There were no robust data from the research at that time, and no formal evaluation of the study was presented to NHS England. It allowed the move to go ahead anyway.

Demographic shift

This coincided with a radical shift in referrals—not just in absolute numbers, which increased at a rate of 50% a year from 2009 (and doubled in 2015)[4] but in the underlying demographics of the people being referred: from largely prepubescent boys to mostly adolescent girls, who were often contending with other difficulties.

Some GIDS staff began to worry. The service, they believed, did not adequately consider that the evidence base underpinning the medical treatment of young people—the so called Dutch protocol—not only was limited in and of itself but applied to a different group of young people from those largely seeking the help of GIDS.

GIDS's users were not the young people with lifelong gender congruence and supportive living environments that the protocol was designed for. Rather, they were often teenage girls whose gender related distress had begun in adolescence and who were often experiencing other complex difficulties. They needed more time than the GIDS assessment model could offer them, especially as the number of referrals rocketed.

The Cass review's interim findings,[1] published in February 2022, noted that a single clinic could not provide care to an entire nation's young people. Cass identified that "different subgroups may have quite different needs and outcomes," hormone treatment being just one. She wrote that "there were different views held within the staff group about the appropriate clinical approach" and that the work was not underpinned by a robust evidence base.[5]

Cass's final report is expected later this year, but in the meantime the waiting list for care grows ever longer. In July 2022 it stood at more than 7500 young people, many of them waiting for years to be seen, often without any help in the interim.

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3 Barnes H. *Time to think*. Swift Press, 2023.

4 Di Ceglie D. The use of metaphors in understanding atypical gender identity development and its psychosocial impact. *J Child Psychother* 2018;44:-28. doi: 10.1080/0075417X.2018.1443151.

5 Block J. Gender dysphoria in young people is rising-and so is professional disagreement. *BMJ* 2023;380:. https://www.bmj.com/content/380/bmj.p382. doi: 10.1136/bmj.p382 pmid: 36822640

EXHIBIT 103

Socialstyrelsen
THE NATIONAL BOARD OF HEALTH AND WELFARE

Care of children and adolescents with gender dysphoria

Summary of national guidelines
December 2022

Summary

The National Board of Health and Welfare has been commissioned by the Swedish government to update the national guidelines entitled Good care of children and adolescents with gender dysphoria, published in 2015 [1]. The parts of the guidelines have been updated and published in stages. This is a summary of the final report published in December 2022, which contains the updated guidelines in its entirety, and thus replaces both previous interim reports and the guidelines from 2015.

For decision-makers

For several years, care for people with gender dysphoria has been characterised by accessibility problems and inadequate knowledge about the results of treatments. The National Board of Health and Welfare emphasises the importance of decision-makers in the health regions acting to promote improvement on both issues, and stresses that this needs to happen in the near future.

Young people suffering from gender dysphoria need to be promptly assessed and offered appropriate treatment measures, based on health care needs assessments. Good psychosocial care is essential. The patient group is heterogeneous and psychosocial care needs to clearly include young people with a non-binary gender identity. Gender-affirming treatments need to be offered when these are deemed indicated.

The 2015 guidelines stressed the importance of monitoring and evaluating the treatment interventions offered in the context of clinical work. The quality registry (gender dysphoria registry) that was planned at the time has so far not been able to meet existing needs. It is urgent that the health regions act to ensure that systematic documentation and monitoring of care at national level are realised. Longitudinal data are required to provide a coherent picture of this patient population, from referral to any diagnosis of gender dysphoria and with follow-ups of patients that are offered various treatment interventions.

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) concludes that existing scientific evidence is insufficient for assessing the effects of puberty suppressing and gender-affirming hormone therapy on gender dysphoria, psychosocial health and quality of life of adolescents with gender dysphoria [2]. Knowledge gaps need to be addressed and the National Board of Health and Welfare recommends that these treatments be provided in the context of research. Here too, the health regions have a responsibility to provide support so that relevant research can begin in the near future. Research questions that need to be answered for the healthcare area are listed in the SBU's database of knowledge gaps. Priority needs to be given to studies that can answer the salient questions, as far as possible.

Caution in the use of hormonal and surgical treatment

At group level (i.e. for the group of adolescents with gender dysphoria, as a whole), the National Board of Health and Welfare currently assesses that the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments. The National Board of Health and Welfare therefore gives the following weak, negative recommendations as guidance to the healthcare system:

- Treatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered in exceptional cases.

Care must be provided on the basis of scientific evidence and proven experience and according to the principle of doing good and not harm. In revising its recommendations, the National Board of Health and Welfare has taken account of the fact that the efficacy and safety, benefits and risks of treatments are not proven [2] and that three factors have shifted the balance between benefit and risk in a negative direction:

- The uncertainty resulting from the lack of clarity about the causes, that the number of people diagnosed with gender dysphoria has continued to rise since the publication of the guidelines in 2015, particularly in the 13 to 17 age group and especially among people whose registered sex at birth is female.

- The documented prevalence among young adults of medical detransition, which is the process by which a person discontinues gender-affirming medical treatment for any reason or seeks to reverse the medical effects of completed gender-affirming treatment [3, 4]. According to the SBU, it is not possible to assess how common it is for young people to later change their perception of their gender identity or to discontinue a gender-affirming treatment [2].
- The experience-based knowledge of participating experts is less uniform than it was in 2015.

Decisions on treatment in an individual case

To guide the decision on puberty-suppressing treatment for an adolescent in Tanner Stage 3 and for gender-affirming hormone therapy, the National Board of Health and Welfare recommends the criteria whose use has been documented and monitored within the framework of the "Dutch protocol" [5-7]. The criteria include the existence of the incongruence since childhood, the stability of gender identity over time, clear distress caused by the onset of puberty, and the absence of factors that complicate the diagnostic assessment. According to the participating experts, puberty-suppressing treatment can in some cases be considered to be of great benefit even in Tanner stages 4 and 5, particularly for young people with a registered sex of male at birth whose masculinisation in later puberty makes it very difficult to pass as an adult.

The documented experience with the Dutch protocol includes only adolescents with binary gender identity, and among participating experts there is a lack of clinical experience with puberty-suppressing and gender-affirming hormone therapy for adolescents with non-binary gender identity. The National Board of Health and Welfare notes that there is a lack of knowledge to guide decisions on hormonal treatments for adolescents with non-binary gender identity, but still believes that gender dysphoria rather than gender identity should guide access to care and treatment. Urgent work that remains when updating the guidelines for adults with gender dysphoria [8] is to map the experience of assessment and gen-

der-affirming treatment for patients with non-binary gender identity in adult health care.

Other recommendations

Other recommendations include that health services should:

- Offer psychosocial support for unconditional exploration of gender identity during the diagnostic assessment. As in 2015, the National Board of Health and Welfare emphasises exploration as a prerequisite for good and safe care.
- Systematically search for signs of autism spectrum disorder (ASD) and ADHD/ADD before, or at an early stage of the assessment. In case of signs of ASD, neuropsychiatric assessment should be initiated.

The recommendations of the National Board of Health and Welfare remain as before, that the health care system should offer the following measures to adolescents with gender dysphoria:

- Sexology counselling and treatment
- Fertility preservation
- Voice and communication treatment
- Hair removal

The expected benefit to patients of the measures are considered high and the risks comparatively low. It is important that these measures are also documented for follow-up when they are offered, in order to enable increased and comprehensive knowledge regarding the patient group and care.

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EXHIBIT 104

Gender dysphoria in children and adolescents: an inventory of the literature

A systematic scoping review

SBU POLICY SUPPORT | EVIDENCE ASSESSMENT TO SUPPORT DECISION MAKERS IN SWEDEN

DECEMBER 2019 | WWW.SBU.SE/307E

Executive summary

This report was commissioned by the Swedish government and is a scoping review of the literature on gender dysphoria in children and adolescents. The report can be a basis for further evaluation of risk of bias and evidence.

Conclusions

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.
- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria.
- There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium.
- The scientific activity in the field seems high. A large part of the identified studies are published during 2018 and 2019.
- Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. No relevant randomised controlled trials in children and adolescents were found.
- We have not found any composed national information from Sweden on:
  - the proportion of those who seek health care for gender dysphoria that get a formal diagnosis
  - the proportion starting endocrine treatment to delay puberty
  - the proportion starting gender affirming hormonal treatment
  - the proportion subjected to different gender affirming surgery

Background

The number of persons below age 18 who seeks the health care for gender dysphoria in Sweden has increased during the last decade. There is a debate as to why this happens and how it should be managed.

Aim

To assess the scientific literature for explanations of the increased number of children and adolescents seeking for gender dysphoria and to make an inventory of the literature on management and long-term effects.

Method

The following questions were assessed.

Are there any scientific studies explaining the increase in numbers seeking for gender dysphoria?

Population: Children and adolescents with gender dysphoria up to 18 years of age.
Intervention: Not applicable.
Control: Not applicable.
Outcome: Studies on incidence and prevalence of gender dysphoria and pattern of self-referral or referral.

Are there any scientific studies on long-term effects of treatment for gender dysphoria?

Population: Persons with gender dysphoria.
Intervention: Treatment for gender dysphoria.
Control: Any.
Outcome: Studies reporting long-term effects such as mental health, suicide attempts, suicide, cardiovascular effects, cancer development, bone health and regrets.

What scientific papers on diagnosis and treatment of gender dysphoria has been published after the National Board of Health and Welfare in Sweden issued its national support for managing children and adolescents with gender dysphoria in 2015?

Population: Children and adolescents with gender dysphoria up to 18 years of age.
Intervention: Diagnosis and treatment for gender dysphoria.
Control: Any.
Outcome: Studies on diagnosis and treatment.

This review is limited to peer reviewed papers with primary data and systematic reviews following PRISMA-standards. Case studies, meeting abstracts and editorials where not included. Only studies written in English or Scandinavian languages were eligible.

A structured systematic literature search in the following databases CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE (Embase.com), PsycINFO (EBSCO), PubMed (NLM), Scopus (Elsevier), SocINDEX (EBSCO). The searches were finalised September 19, 2019.

The studies were assessed for their relevance to the questions by two reviewers independently. Assessment of risk of bias, compilation of data or grading of evidence was not done.

Results/discussion

No studies explaining the increase of children and adolescents seeking for gender dysphoria were identified. The literature on management and long-term effects in children and adolescents is sparse, particularly regarding gender affirming surgery. All identified studies are observational, and few are controlled or followed-up over time. Much of the data in the literature are from the University Medical Centre in Amsterdam based on their management tradition. A large part of the literature that was considered relevant was published during 2018 and 2019.

Appendices

For search strategies, excluded articles, references and tables, see www.sbu.se/307e

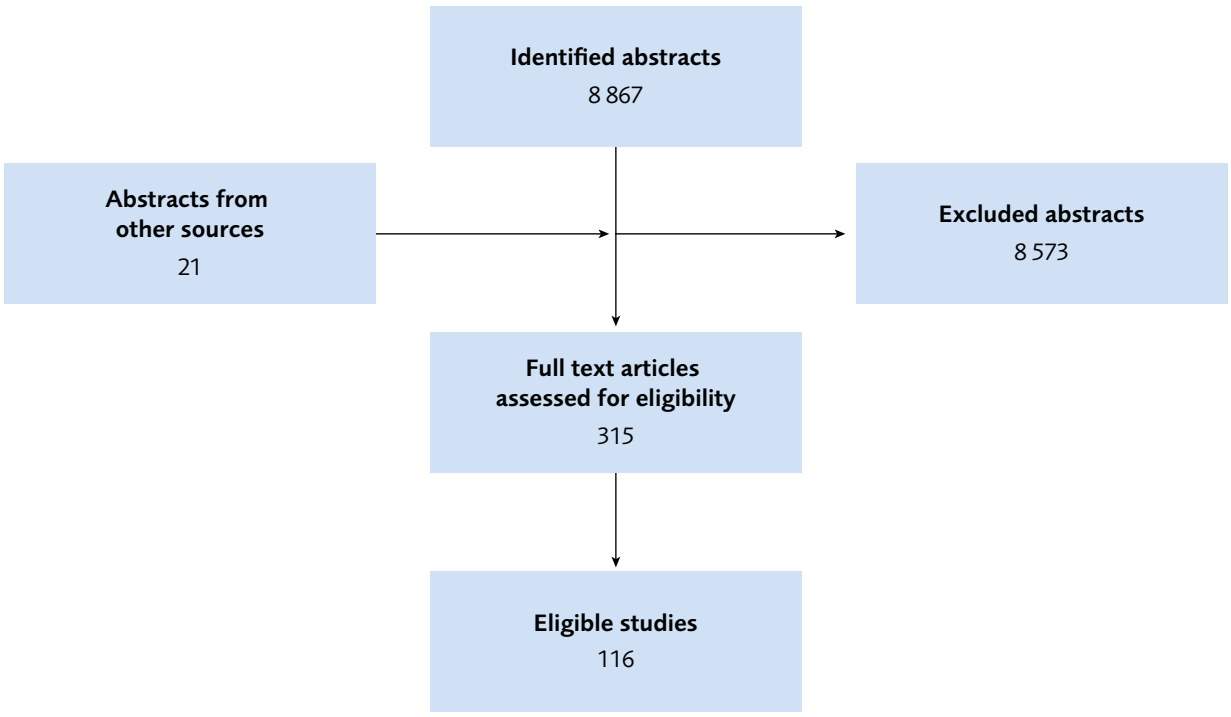

Figure 1 Flow diagram of ingoing studies.

Project group

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Patient representatives were not involved in the work.

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- Lars Sandman, Linköping University
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EXHIBIT 105

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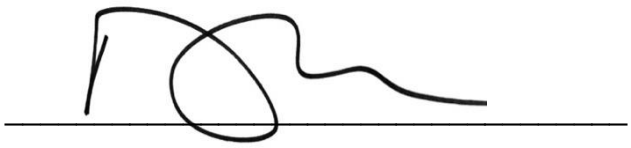
October 12, 2023

CERTIFICATE OF TRANSLATION

Swedish > English > Translation and proofreading of the document titled:

- Care of Children and Adolescents with Gender Dysphoria

I, Diana M. Arbeláez, with the ATA nr. 251348 at Lingua Franca Translations do hereby certify that the translation herein was completed in accordance with the American Translators Association Code of Professional Conduct and Business Practices and that to the best of my knowledge the translation and proofreading into English herein provided is, in fact, a literal and true interpretation of the statements in the original language Swedish. Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.



Diana M. Arbeláez
State of Florida
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This document is an unofficial English translation of a document prepared in Swedish.

Care of children and adolescents with gender dysphoria*[1]

National knowledge support[1] with recommendations for professionals and decision-makers

Socialstyrelsen

* Unofficial translation prepared for purposes of litigation. The Swedish government did not translate this document.

The original document "Vård av barn och ungdomar med könsdysfori : Nationellt kunskapsstöd med rekommendationer tillprofession och beslutsfattare" can be found at: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf

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Foreword

The National Board of Health and Welfare[i] has been commissioned by the Swedish government (S2019/02042/FS, S2019/03899/FS) to update the national guidelines, *Good Care of Children and Adolescents with Gender Dysphoria,*[ii] which were published in 2015.

In order to provide guidance to relevant agencies with the least possible delay, some sections of the guidelines were updated in stages, as the knowledge base and overall assessments became finalized. The sections on support and evaluation were published in March 2021 and the section on hormone therapy in February 2022. This December 2022 report contains the updated guidelines in their entirety.

Appendices to the report include a list of contributors and a glossary of terms.[iii] The knowledge base with methods description is presented in a separate report.[iv]

These guidelines are aimed at professionals working with this patient population and decision-makers responsible for the quality of care. The ongoing gender dysphoria-related initiatives at the National Board of Health and Welfare need to be reflected in the revisions of the information in reports, "For those with gender dysphoria" and "For those who meet people with gender dysphoria in their work." [v] The revised reports will, therefore, be published at a later date.

The updated guidelines contribute to Sweden's efforts to meet the goal of ensuring healthy lives and promoting well-being for people of all ages in Agenda 2030. They also contribute to meeting the goal of the national strategy for sexual and reproductive health and rights; good, equal, and equitable sexual and reproductive health in the entire population. Maria Bodin has been the project manager for the work with the guidelines and Anders Fejer and Anders Berg have been the responsible unit managers.

The National Board of Health and Welfare would like to thank the experts who contributed to the revision of the sections in question, as well as the patient, family and stakeholder organizations and managers who provided comments on the working versions of the documents before publication. The final assessments of the National Board of Health and Welfare on puberty-suppressing and hormonal treatments were not shared by all participating experts.

Olivia Wigzell
Director General

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Summary

The National Board of Health and Welfare has been commissioned by the Swedish government to update the guidelines, *Good Care of Children and Adolescents with Gender Dysphoria*, which was published in 2015 [1]. Sections of the guidelines have been updated and published in stages. This final report contains the updated guidelines in their entirety, and thus supersedes both previous interim reports and the guidelines from 2015.

Key terms are explained in the introductory section and in the appendix.[vi] A separate appendix, *Knowledge Base with Methods Description,* describes how the different sections have been developed.[vii]

For decision-makers

For several years now, care for people with gender dysphoria has been characterized by a lack of access and a lack of knowledge about the outcomes of the care. The National Board of Health and Welfare emphasizes to the decision-makers in healthcare regions that both of these issues need to be improved in the near future.

Young people suffering from gender dysphoria need to be able to promptly begin evaluation and be offered appropriate care, based on needs assessments by the healthcare service. Good psychosocial care is essential. The patient group is heterogeneous and psychosocial care needs to be clearly inclusive of young people with non-binary gender identities. Various gender affirming treatments need to be offered when they have been deemed indicated.

The 2015 guidelines stressed the importance of monitoring and evaluating the healthcare interventions offered in the context of clinical work. The quality registry (gender dysphoria registry) that was planned for at the time has so far been unable to meet the need. It is urgent that the healthcare regions act to ensure that systematic documentation and monitoring of care at a national level is realized.[viii] Longitudinal data are needed to provide a coherent picture of the patient population, from referral to eventual diagnosis of gender dysphoria, with follow-up of patients offered different care interventions.

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) concludes that there is insufficient scientific evidence to assess the effects of puberty suppressing and cross-sex hormone therapy on gender dysphoria, psychosocial health, quality of life for adolescents with gender dysphoria, and other factors [2]. The knowledge gaps need to be addressed and the National Board of Health and Welfare recommends that these treatments be provided within the context of research. Here too, the healthcare regions have a responsibility to provide support

so that relevant research can begin in the near future. The research questions that need to be answered for the field are listed in the SBU's database of knowledge gaps. Priority needs to be given to study designs that can answer the important questions to the greatest extent possible.

Caution with hormonal and surgical treatment

At a population level, i.e., for the population of adolescents with gender dysphoria as a whole, the National Board of Health and Welfare currently assesses that the risks of puberty-suppressing and gender-affirming treatment likely outweigh the expected benefits of these treatments. The National Board of Health and Welfare therefore gives the following weak, negative recommendations as guidance to the health care system:

- that treatment with GnRH analogues, gender-affirming hormones and mastectomy can be provided in exceptional cases.

Care must be provided on the basis of science and proven experience and the principle of doing good and not harm. In revising the recommendations, the National Board of Health and Welfare has taken into account that the efficacy and safety of treatments, benefits, and risks are not proven [2] and that three factors have shifted the balance between benefits and risks in a negative direction:

- the uncertainty resulting from the lack of clarity about the causes to the continued increase in the number of people diagnosed with gender dysphoria, particularly between the ages of 13 and 17 and especially among people whose registered gender at birth was female, since the guidelines were published in 2015
- the documented occurrence of medical detransition among young adults, which refers to the process of discontinuing gender-affirming medical treatment for any reason or seeking to reverse the medical effects of completed gender-affirming treatment [3, 4]. According to SBU, it is not possible to determine how common it is for adolescents to subsequently change their perception of their gender identity or to discontinue gender-affirming treatment [2].
- the experience-based knowledge of participating experts is less uniform than it was in 2015.

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Decisions on treatment for an individual case

For guidance in deciding on puberty-suppressing treatment for an adolescent in Tanner stage 3 and for gender-affirming hormone therapy, the National Board of Health and Welfare recommends using the criteria documented and monitored in the framework of the "Dutch protocol" [5-7]. These criteria include the presence of gender incongruence from childhood, a stability of gender identity over time, clear distress brought upon the onset of puberty, and an absence of factors that complicate the diagnostic assessment. According to the participating experts, puberty-suppressing treatment can, in some cases, be considered to be of great benefit even at Tanner stages 4 and 5, in particular for young people registered as male at birth whose masculinization in later puberty will make it very difficult to pass in adulthood.

The documented experience in the Dutch protocol includes only adolescents with binary gender identity, and the participating experts lack clinical experience with puberty-suppressing and gender-affirming hormonal treatment for adolescents with non-binary gender identity. The National Board of Health and Welfare concludes that there is a lack of knowledge to guide decisions on hormonal treatment for adolescents with non-binary gender identity but continues to consider that gender dysphoria, rather than gender identity, should guide access to care and treatment. An urgent task yet to be performed in connection with updating the guidelines *Good Care of Adults with Gender Dysphoria* [8] is to map the experience of assessment and gender-affirming treatment for non-binary gender identity that is used to care for adults.

Other recommendations

Other recommendations are that healthcare services:

- should offer psychosocial support for an open exploration of gender identity during the diagnostic assessment. As in 2015, the National Board of Health and Welfare emphasizes exploration as a prerequisite for good and safe care.
- should systematically investigate for signs of autism spectrum disorder (ASD) and ADHD/ADD before or at an early stage of the assessment. In the case of signs of ASD, neuropsychiatric assessment should be initiated.

The recommendations of the National Board of Health and Welfare remain as before, that the healthcare system should offer the following measures to adolescents with gender dysphoria:

- sexuality and sexual health counseling and treatment
- fertility preservation
- voice and communication treatment

- hair removal

The expected patient benefit from these measures is considered high and the risks comparatively low. It is important that when offered, these measures are documented for follow-up to enable increased and comprehensive knowledge about this patient population and their care.

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Introduction

This report contains an updated version of the guidelines, *Good Care for Children and Adolescents with Gender Dysphoria,* published in 2015. The update was commissioned by the government and has been carried out in stages. The sections on support and assessment were published in March 2021, the section on hormonal treatment in February 2022, and the remaining sections and the guidelines in their entirety in December 2022. Two new sections have been added: *New recommendations for hormonal treatment - basis and consequences* and *Non-binary gender identity - knowledge and need for clarification*.

Purpose and target group

The aim of the guidelines is to contribute to good and equitable care for children and adolescents with gender incongruence and gender dysphoria. The primary target groups are health professionals in the healthcare sector and decision-makers with responsibility for the respective healthcare activities.

About the recommendations of the National Board of Health and Welfare

The National Board of Health and Welfare's recommendations related to issues such as treatments are based on the state of knowledge at the time the recommendations were developed. The recommendations provide guidance for professionals and decision-makers, i.e., they are not binding statements about appropriate treatment measures for individual patients. It is always the responsibility of the treating health professional to assess the needs of the individual patient on a case-by-case basis to ensure - based on science and proven experience - that the patient receives adequate treatment.

Terms

The meaning of some key terms is explained here, otherwise please refer to appendix 2 *Terms and abbreviations*.[ix] The guidelines apply to children and adolescents, which refers to persons under 18 years of age. Legally, children are defined as any persons under age 18. Wherever there is a reference to legislation, only the term child is used.

In sections related to medicine, children refers to persons under the age of 18 who have not yet entered puberty, while adolescents refers to persons under the age of 18 whose puberty has started. The term youth is sometimes used in [the report] sections to refer to both children and adolescents.

Gender identity refers to a person's self-identified gender, the internal experience of being man/boy, woman/girl, or belonging to no gender or to another gender.

Gender incongruence refers to a perceived mismatch between gender identity and the sex registered at birth. Gender dysphoria refers to distress that may be linked to gender incongruence. People with gender incongruence do not necessarily experience gender dysphoria, but gender dysphoria is common among those who seek care and undergo assessment. To simplify language, the guidelines will mainly use the term gender dysphoria. In the context of clinical diagnosis and statistical classification, the terms gender incongruence and gender dysphoria have more specific meanings.

Clinical diagnosis and statistical classification

Diagnostic assessment

Diagnostic assessment is done according to guidelines and practices, with psychiatry often using the Diagnostic and Statistical Manual of Mental Disorders (the DSM system). The current fifth version (DSM-5) includes a diagnosis for gender dysphoria in children (302.6) and a diagnosis for gender dysphoria in adolescents and adults (302.85). For children, adolescents and adults, the diagnosis is made when:

- A. there is a marked incongruence between the person's perceived/expressed gender and registered sex that has lasted for at least 6 months; and
- B. the condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

For adolescents and adults, the main criterion A is considered present when 2 out of 6 symptom criteria have been met. In order for the main criteria A to be considered present in children, several symptom criteria must be met (6 out of 8), and one of them must be criterion A1, i.e., "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one’s assigned gender)." Symptom criterion A1 can be understood as a requirement that the child has repeatedly expressed a desire to belong, or repeatedly insists on belonging, to the opposite sex (or other gender identity different from the sex registered at birth).

The requirement of symptom criterion A1 means that the diagnosis of gender dysphoria in children is not made solely on the basis of symptom criteria A2-A6 (nonconforming gender role behaviors in relation to dress, play, toys, activities, and playmates), or A7-A8 (dislike of own anatomy, strong desire for sex characteristics consistent with perceived gender identity).

A similar distinction is made in the description of the code HA61 (Gender incongruence of childhood) adopted in 2019 in the latest version of the International Classification of Diseases and Related Health Problems (ICD-11). See further *Gender-variant behavior insufficient for diagnosis and coding* below.

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Coding according to the ICD classification

The International Statistical Classification of Diseases and Related Health Problems (ICD) is the basis for cause-of-death statistics and statistics on diseases and other health problems. The ICD codes are used to provide a uniform way to indicate the diagnosis code when reporting to the National Board of Health's health data registries (e.g., the patient registry). For all inpatient care and some outpatient specialist care visits, the diagnosis or diagnoses that led to the care contact must be reported to the patient registry using ICD codes. Coding is done in accordance with the coding instructions accompanying the classification. When there is no confirmed diagnosis, ICD code for symptoms or other reasons for the health care contact used instead.

The coding of a health condition according to the ICD has no direct link to the care measures deemed justified and appropriate, i.e., the code should be applied once the diagnosis has been made, regardless of the measures that follow. For many conditions, there may be clinical reasons not to provide certain treatment in an individual case, which are made clear in the medical record.

In May 2019, the WHO adopted ICD-11, replacing ICD-10, which was published in 1992. The National Board of Health and Welfare is working on the introduction of a Swedish version of ICD-11.[1] Translation work is underway and is expected to be completed in 2025, after which implementation in the health care system will begin.

New chapter and new codes in the new classification

With ICD-11, the codes related to gender identity in the ICD classification have been moved from the psychiatry section ("Mental, Behavioral and Neurodevelopmental disorders") to a completely new section ("Conditions related to sexual health").

The following ICD-11 codes should be used:

- HA60 (Gender incongruence of adolescence or adulthood)
- HA61 (Gender incongruence of childhood)
- HA6Z (Gender incongruence, unspecified – “unspecified” residual category)

The code "Gender incongruence of adolescence or adulthood" (HA60) will thus replace the three codes related to gender identity in ICD-10-SE: transsexualism (F64.0), other specified gender identity disorders (F64.8), and gender identity disorder unspecified (F64.9) in ICD-10-SE.

The move to a new section and the introduction of the new codes in ICD-11 indicates that trans identity is not a psychiatric condition [9].

[1] See https://www.socialstyrelsen.se/statistik-och-data/klassifikationer-och-koder/icd-11/

The new codes in ICD-11 differ from the F64 codes in ICD-10-SE in several ways. One difference is that the distinction of binary gender identity made by the code Transsexualism (F64.0) in ICD-10-SE will disappear because the HA codes describe gender incongruence without specifying the gender identity. Another difference is that ICD-11 may include the code related to children (HA61).[2]

The English-language code descriptions for ICD-11 are provided below.

Gender incongruence of adolescence or adulthood (HA60)

Description: Gender incongruence of adolescence and adulthood is characterized by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior the onset of puberty. Gender variant behavior and preferences alone are not a basis for assigning the diagnosis.

Gender incongruence of childhood (HA61)

Description: Gender incongruence of childhood is characterized by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years. Gender variant behavior and preferences alone are not a basis for assigning the diagnosis.

Gender incongruence, unspecified (HA6Z)

HA6Z in ICD-11 is an unspecified residual category. During the update process, the question of whether HA6Z will be used as a provisional diagnosis after the first visit was raised.[x] However, HA6Z is intended to be used only if gender mismatch is known but there is not enough information to determine whether HA60 or HA61 should be used. Examples of such situations are if the coder is a different person from the clinician and the information is missing, or if for some reason it would be difficult to determine whether or not the person has entered puberty.

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[2] Several codes in ICD-10-SE were discontinued on 1 January 2009 following a decision by the National Board of Health and Welfare, including "Gender identity disorder in childhood" (F64.2).

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Gender-variant behavior insufficient for diagnosis and coding

The ICD-11 code descriptions for adolescents and adults (HA60) and children (HA61) indicate that variations in gender role behaviors (alone) do not provide a sufficient basis for coding. In addition, the code description for gender incongruence in children is more detailed than that for adolescents and adults and specifies that three signs (relating to the wish, sex characteristics, and activities) must be present for at least two years in order for the code to be used. According to WHO experts, the aim of requiring the presence of all three signs was to avoid the code being used for children who are nonconforming in the sense that they prefer activities that are more often associated with a gender other than the one registered for the child at birth [10].

Corresponding requirements apply to the diagnostic assessment of gender dysphoria in children in the DSM-5, where more symptom criteria must be met for diagnosis in children compared to diagnosis in adolescents and adults, and where criterion A1 must be met (See *Diagnostic assessment* above). Similarly, the purpose of the A1 criterion requirement for children in the DSM-5 has been to avoid overdiagnosis (false positives) of children with gender-variant behavior who do not have a desire to belong to a different gender [11, 12].

Questions about ICD coding in specific situations

Questions about which diagnosis should be coded in some specific situations have been raised during the revision of the guidelines. One is the situation where an endocrinologist cares for a patient who started gender-affirming treatment and who (after age 18) received a legal gender change and no longer meets criteria for the diagnosis of gender dysphoria. Another concerns the code to be used when a person who has undergone gender-affirming treatment later seeks care with a wish to reverse the effects of the gender-affirming treatment and no longer meets the DSM criteria for gender dysphoria. At present, there are no definitive answers to these questions. As a basic principle, when a condition requires treatment, it is coded as that condition, even when the treatment continues over a long period of time. A discussion on coding in situations such as these needs to be conducted jointly by the units authorized to provide national highly specialized care and, if necessary, may involve the National Board of Health and Welfare.

Age limits for gender-affirming treatments

Gender-affirming treatments for gender dysphoria include voice and communication therapy, hormonal and surgical treatments, and hair removal (the latter for people registered male at birth). The aim of the treatments is to change the voice and body to be more in line with gender identity (reduced gender dysphoria) and to make it easier for the person to be perceived by others in accordance with their gender identity (increased quality of life).

Gender-affirming surgery of the genitals and removal of gonads (ovaries and testicles) are regulated by the act (1972:119) on the determination of gender in certain cases ("the Gender Identity Act"). Persons over 18 years of age may apply for these surgical procedures when applying for a change of legal gender under the Gender Identity Act.

Hormone therapy and gender-affirming surgery for secondary sex characteristics (e.g., mastectomy) are not covered by any specific legislation but can be performed under the Health and Medical Services Act (2017:30), HSL. This means that there are no legal age limits for when these treatments may be performed in cases of gender dysphoria.

Prescription of medicines for persons under 18 years of age

The National Board of Health and Welfare has been commissioned by the government to survey the prescription of puberty-suppressing and gender-affirming medicines for persons with gender dysphoria. The survey includes people who were newly diagnosed with gender dysphoria and prescribed the drugs between 2006 and 2018. Among the 1381 people newly diagnosed before age 18, more than half had not received either puberty-suppressing or cross-sex hormone treatment before age 18. Forty percent of those registered female at birth and 53% of those registered male at birth initiated puberty-suppressing treatment within five years of diagnosis. Treatment with cross-sex hormones was started within five years of diagnosis by 66% of those registered female at birth (testosterone) and 59% of those registered male at birth (estrogen) [13].

The child rights perspective

The Convention on the Rights of the Child in Swedish legislation

The UN Convention on the Rights of the Child, known as the CRC, sets forth the rights of children. Since 1 January 2020, the CRC applies as Swedish law.[3]

There are four so-called foundational principles in the CRC. These are the right of the child to non-discrimination (Article 2), the best interests of the child (Article 3), the child's right to life, survival, and development (Article 6) and the child's right to express his or her views and be heard (Article 12). The views of the child shall be given due weight in accordance with the age and maturity of the child. The

[3] See the Act (2018:1197) on the United Nations Convention on the Rights of the Child.

convention also contains other important articles, such as the right of the child to the enjoyment of the highest attainable standard of health and access to health care (Article 24), parental responsibility (Articles 5 and 18), and the right of the child to protection of privacy and personal integrity (Article 16).

The principles of the CRC have been expressed in a number of Swedish statutes, including the Patient Act (2014:821), PL, which contains provisions on the best interests of the child, the right to information and the importance of a child's position in relation to care and treatment.

The best interests of the child must be considered

In the case of health care provided to children, the best interests of the child must be taken into special account.[4] The preparatory work for the Patient Act states that in the difficult decisions that need to be made in healthcare activities, the best interests of the child must be the guiding principle. The assessment of the best interests of the child is a multi-step process. Health professionals must take into account science and proven experience and, depending on the age and maturity of the child, seek a basis for the decision from guardians. The starting point of the best interests of the child is respect for the child's full human value and integrity. What is in the best interests of the child must therefore be determined on a case-by-case basis.

Furthermore, it is stated that the process of arriving at the best interests of the child requires active consideration of each individual case. The life and health of the child must be protected.

However, the child's integrity,[xi] right to express their opinion, and right to influence [matters concerning them] must also be considered when assessing what is in the best interests of the individual child in a particular situation. The child's attitude towards care should be clarified as far as possible and the child's attitude should be given due weight in relation to his or her maturity.[5] The work of caregivers in this area is complex because, depending on the child's age and maturity, they must take into account the child's wishes and desires, interact with the child's guardians and protect the child in vulnerable situations. The preparatory work also states that to the extent possible, both long-term and short-term consequences of decisions such as providing or withholding certain care or treatment from the child should be considered. [6]

[4] Chapter 1, Section 8 of the Patient Act and Chapter 5, Section 6 of the HSL

[5] Chapter 4, Section 3 of the Patient Act

[6] See prop. 2013/14:106 p. 63

Children's right to self-determination and guardians' responsibility

Legal clarifications of children's right to self-determination and the responsibility of guardians are provided in the National Board of Health and Welfare's bulletin *Children seeking healthcare*, number 8/2020.[xii] As a starting point, it is the guardian who has the right and obligation to decide on matters of health care for the child.

However, as the child grows older and more mature, the child's wishes must increasingly be considered. A child may be considered mature enough to decide on his or her own about a particular care or treatment alone if he or she can assimilate the relevant information and understand the consequences of the decision. However, considerable maturity is required for a child to be able to consider more extensive treatments and interventions.[7]

According to the National Board of Health and Welfare's assessment, the support and consent of the guardians is a prerequisite for offering an adolescent with gender dysphoria puberty-suppressing and cross-sex treatment (See *Hormonal treatment for gender dysphoria in adolescents*). Greater emphasis on the child's willingness and maturity to make decisions alone can more often be placed on other types of care, such as psychosocial support. It should be noted that the preamble to the Patient Act emphasizes that even when a child is mature enough to decide on a particular care or treatment, the staff should still endeavor to involve the guardians, unless the child objects, or if doing so cannot be considered to be in the child's best interests.[8] However, it also appears that, for example, in the case of psychiatric care, there are instances where it has been considered acceptable for children under age 15 to seek and receive care without prior consultation with their guardians.

Regardless of the outcome of healthcare providers' assessments of the best interests of the child in relation to various healthcare interventions, all children have a right to their identity and integrity. The fact that children with gender expression and/or gender identity that falls outside the cis-norm are at increased risk of psychological and physical violence and that guardians are sometimes the perpetrators needs to be taken into account [14]. Discomfort with non-cis-heteronormativity may be the basis for guardians to subject their children to "conversion therapy" [15]. If healthcare professionals become aware of, or suspect that, a child is being harmed, they have a duty to immediately report it to social services.[9]

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[7] Cf. prop. 2013/14:106 p. 119

[8] Prop. 2013/14: 106 p 66.

[9] Chapter 14, Section 1 of the SoL.

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Ethical issues in the care of youth with gender dysphoria

A report submitted to the government by the Swedish National Council on Medical Ethics (Smer) in 2020 identified several ethical issues related to the care of children and young people with gender dysphoria [16]. Some of these issues are directly relevant to clinical work and are addressed elsewhere in these guidelines:

- how far youth self-determination should extend
- information that enables informed decision-making
- limitations of the knowledge base
- balancing the expected benefits and risks in the individual case.

Also see the section on hormonal therapy, section *Basic requirements for hormonal therapy*.

In its report, Smer also raises ethical issues at the systemic level, including the importance of care on equal terms, and the [healthcare] prioritization, both within the [patient] group, and in relation to other care needs. A need for care is considered to exist when there is a gap between the individual's current state of health and the state of health that science and evidence suggest can reasonably be achieved with various forms of care [17, 18].

Another issue discussed by the council [16] is whether healthcare today is moving towards more demand-driven care in several areas. Smer concludes that demand-driven care clashes with current priority-setting principles, according to which healthcare providers should prioritize according to need. The Health Care Act does not imply the right of the patient to receive a particular treatment. According to health legislation, care should be based on respect for the patient's autonomy and integrity and should be shaped and carried out to the extent possible in consultation with the patient.[10] In cases where there are several treatment options that are consistent with science and proven experience, the patient should be given the opportunity to choose the option he or she prefers. The patient shall receive the chosen treatment if this appears justified in view of the disease or injury in question and the cost of the treatment.[11] However, the patient cannot dictate which care is to be provided, and the patient's participation can never imply that the requirements for care and treatment provided in accordance with science and proven experience should be lowered (prop. 2013/14:106 p. 72 and 1981/82:97 p. 50). In cases where the care provider and the patient do not agree on the needs assessment, the care provider's interpretation is,

[10] Chapter 5, section 1 of the Health and Medical Care Act [2017:30], HSL, Chapter 4, section 1 and Chapter 5, section 1 of the Patient Act [2014:821], and Chapter 6. Section 1 of the Patient Safety Act [2010:659], PSL

[11] Chapter 7, Section 1 of the Patient Act (2014:821)

according to the preparatory works to the Health and Medical Care Act (HSL), the applicable interpretation.[12]

[12] The preparatory work for the old HSL states that "the patient's right to self-determination and privacy cannot be absolute but must be limited for several reasons. It is not possible to let the patient determine the content and scope of care. Such decisions must always be made by the health care provider and the person who has medical responsibility for the care." (prop. 1981/82:97 p. 118)

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Changing Care Area

The evolution of the diagnosis of gender dysphoria

In a report published by the National Board of Health and Welfare in 2020 [19], the evolution of the diagnosis of gender dysphoria in the population between 1998 and 2018 is presented. In figures 1-4 below, the years 2019 - 2021 are also included. The calculations are based on the number of persons registered in the Patient Registry (PAR) with any of the ICD codes F64.0, F64.8 and F64.9.

It has been noted that coverage in PAR has increased over time and that trends in the prevalence of gender dysphoria may therefore be overestimated [20]. The National Board of Health and Welfare's assessment is that under-coverage may be driving some of the increase in the early part of the time series but that it has little bearing on the increase that occurred in the 2010s.[13]

Figures 1 and 2 show the incidence rate, i.e., the number of new cases of persons with a diagnosis of gender dysphoria per 100,000 broken down by registered sex at birth and by age group. In the 2020 report [19], the National Board of Health and Welfare noted a marked increase in the number of new cases seen between 2013 and 2018. Figure 2 shows that the increase in the number of new cases between 2013 and 2018 was more pronounced among people younger than 30 than among people in the older age groups. The increase was greatest among children aged 13-17, and particularly among children aged 13-17 with a registered gender of female at birth. After 2018, a decrease in the number of new cases is seen for both sexes between 2018 and 2020, followed by a slight increase in 2021 (Figure 1). The decrease in the number of new cases is most pronounced among young people whose registered sex at birth is female. However, for those registered as female at birth in the 13-17 age group, the increase in 2021 brought the incidence rate this year to the same level as in the peak year of 2018 (Figure 2).

Several possible explanations for the decrease in the number of new cases in 2019 and 2020 were submitted in draft comments, including that the clinic in Stockholm, which receives a large proportion of the country's patients, had reduced activity in 2019. Another possible explanation, according to one study, is that media coverage of the care of young people with gender dysphoria led to a reduction in referrals.

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[13] The coverage of the registry is believed to be high, but there is a lack of complete comparative data. Specialist outpatient physician visits began to be collected in 2001, and the coverage rate is assessed to have gradually increased over time, particularly around 2011. Private providers, especially in specialized outpatient care, are estimated to account for most of the non-response.

According to the study, the media coverage that was negatively framed was most intense in 2019 [21].

Figure 1. Incidence of gender dysphoria since 1998

Incidence (new cases) of persons diagnosed with gender dysphoria since 1998. Registered sex at birth.

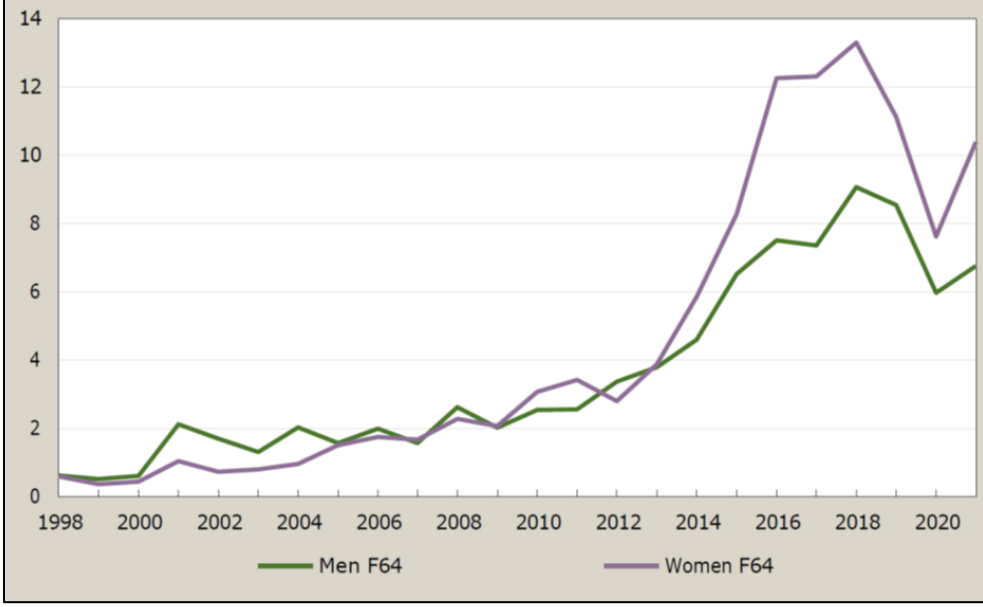

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Figure 2. Incidence of gender dysphoria by age and registered sex

Incidence (new cases) of persons diagnosed with gender dysphoria (F64) since 1998. Registered sex and age at time of diagnosis.

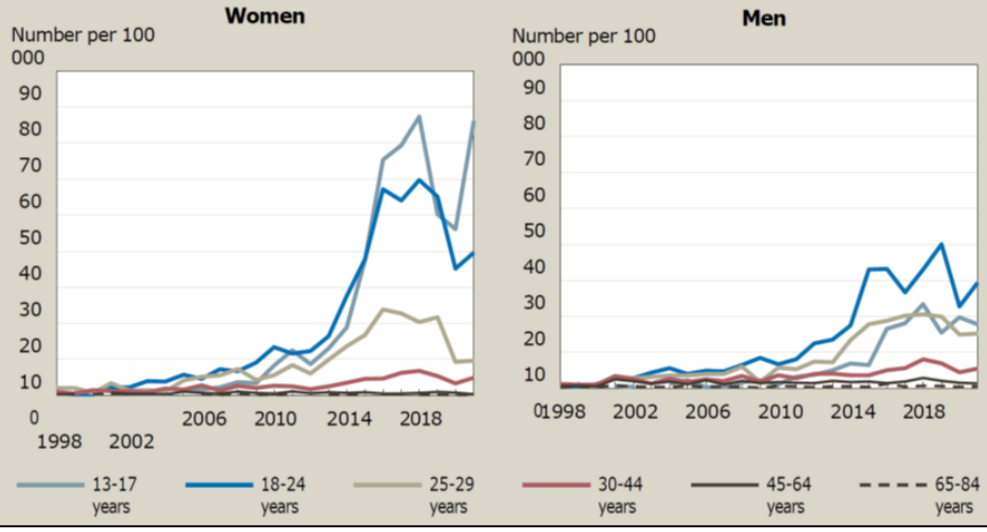


Figure 3 shows that the prevalence of gender dysphoria, i.e., the number of people per 100,000 who had a gender dysphoria diagnosis in a given year, continued to increase after 2018. This is partly explained by the high incidence among young people in the previous year. Figure 4 shows the prevalence over time in different age groups. Until 2018, the prevalence of a gender dysphoria diagnosis increased most among younger persons, both for young people with registered male at birth and those registered female at birth. Between 2018 and 2020, a decrease in prevalence is seen in the13 - 17 years age group, while a continued increase was seen in other age groups. In 2021, however, the incidence of a diagnosis of gender dysphoria was higher than in 2018, even in the 13 to 17 age group.

Figure 3. Prevalence of gender dysphoria since 1998

Prevalence of persons diagnosed with gender dysphoria since 1998 among persons registered in Sweden. Registered sex at birth.

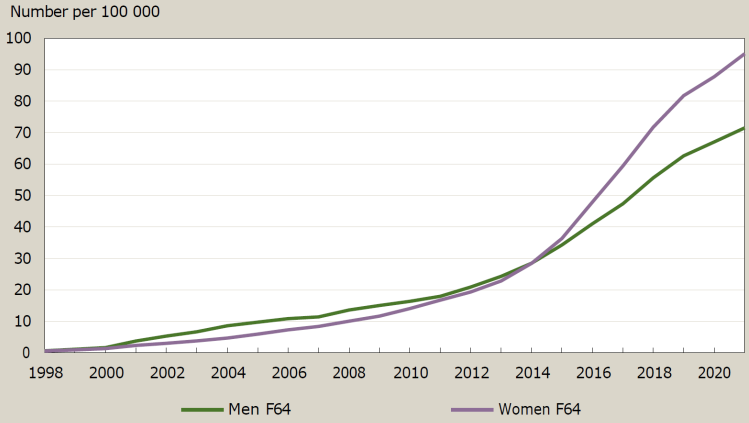
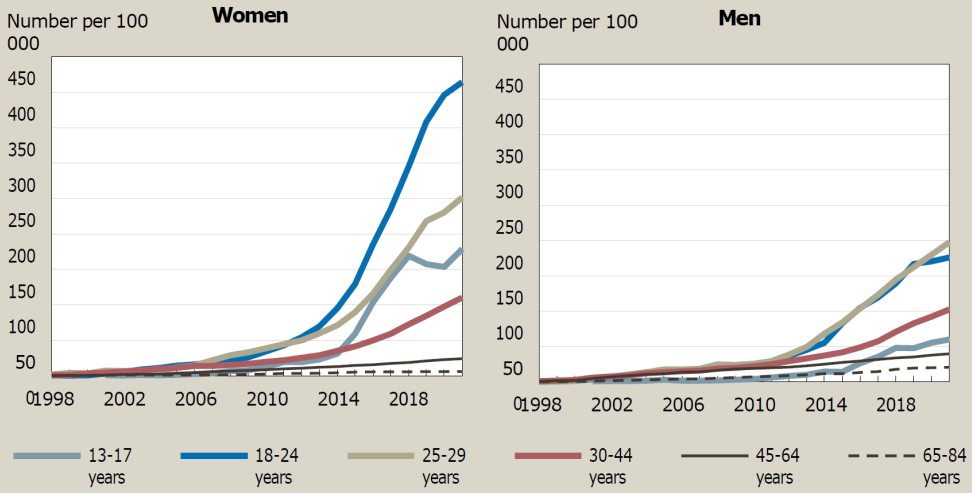


Figure 4. Prevalence of gender dysphoria by age and registered sex

Prevalence of persons diagnosed with gender dysphoria (F64) since 1998 among persons registered in Sweden. Registered sex and age at time of diagnosis.



Transition to national highly specialized care[xiii]

In December 2020, the National Board of Health and Welfare determined [22] that certain gender dysphoria-related care will constitute national highly specialized care and will be provided by three units. Multidisciplinary decisions on gender dysphoria care are to be made under a single operational responsibility within units that are authorized to provide national, highly specialized care.[14]

This 2020 decision means that a national unit will be contacted in cases of suspected gender dysphoria, regardless of the age of the patient. This unit will be responsible for psychiatric and diagnostic evaluation and assessment, as well as decisions about follow-up and further treatment. Endocrinological evaluation, assessment, and treatment initiation shall also be provided by the national units. However, all regions still need to carry out some evaluation and assessment before and after referrals. The allocation of responsibilities and resources will be determined by the national units in dialogue with regional health care providers and decision-makers. Who has the right to refer and what is required for referral needs to be described by the national health units.

[14] At the time of publication of the knowledge-support, no authorization to provide national highly specialized care had been granted to any organization. As granting authorization depends on the preparation process, it is unclear when authorization may be expected to be granted.

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Authorizations to provide national highly specialized care are regulated by law (Section 7, Section 5 of the Health Care Act [2017:30] and Section 2, Section 2 of the Health Care Regulation [2017:80]) and in the National Board of Health and Welfare's regulations (HSLFFS 2018:48) on national highly specialized care. These set out general and specific conditions, including that the units providing national highly specialized care must cooperate with one another and with referring units, and must promote research in the field.

Competence for good care and good treatment[xiv]

Competence of practitioners

Reasons for the decision to designate this care as national highly specialized care [22] include the fact that some care for gender dysphoria is deemed complex and infrequent, requiring a certain volume and multidisciplinary competence. This care requires close collaboration between professionals such as psychiatrists, psychologists, sociologists, endocrinologists, speech therapists, reproductive medicine specialists and plastic surgeons, all with specific competence for the patient group.

Some of the measures mentioned in the guidelines are not included in the definition of national highly specialized care but remain at the regional level (e.g., mastectomy and hair removal). Multidisciplinary assessment and close cooperation between the evaluation team and plastic surgeons in the regions is also required for mastectomy (See *Surgical treatment*).

Competence that enables good treatment is needed in all activities where health professionals meet people with gender dysphoria.

Competence for good treatment

All health care must be provided with respect for the equal value of all people and for the dignity of the individual (Section 3, Section 1, Article 2 of the HSL). It is essential that healthcare professionals who encounter young people with gender dysphoria are familiar with issues relating to gender identity and gender expression and have knowledge of the living conditions, health, and rights of transgender people. Healthcare professionals also need to be aware of cis- and heteronormative assumptions and language and be sensitive and respectful in their contact with the young people and their families.

Once a license to provide national highly specialized care has been granted, the region must cooperate with other regions that provide care in the same licensed care area. Methods of cooperation between national units and the regional level of care

may therefore need to be worked out. Since some evaluation and assessment will continue to be provided at regional level according to the decision, competence-enhancing efforts are important in to enable good care that is fair and equitable and provides good treatment to people with signs of gender dysphoria throughout the entire healthcare pathway. Knowledge building activities and knowledge translation may need to be adapted based on the mission of the regional health services.[15]

When caring for young people with gender dysphoria, it is important for staff to affirm the person's gender identity [15, 23]. One measure that has a significant impact on the individual is for health staff to ask for the person's preferred name and pronouns and then use them, even when they do not match the civil registration data. This applies both in direct contact with the person and in the documentation of the healthcare contact (See appendix 3 for legal clarifications on documentation).

According to participating experts, the fact that the healthcare system affirms the young person's gender identity in this way is also a prerequisite for being able to create a trusting and functioning relationship with the patient during the evaluation.

Many young people with gender dysphoria have a more complicated relationship with their bodies than other young people and may need more time and consideration than is usual for a physical examination. In these situations, it is important that one uses respectful and inclusive language that draws on the terms for naming body parts that the individual prefers, if the person has such preferences. It is also important to provide information about upcoming physical examinations in advance so that the young person has the opportunity to prepare mentally.

[15] Here, regional care refers to care that is not covered by national highly specialized care.

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New Recommendations on Hormonal Treatment – Basis and Consequences

In 2012, the National Board of Health and Welfare was commissioned by the government to produce a guideline for the health care profession, with recommendations on care and treatment of transsexualism and other gender identity disorders. The commission was preceded by a study that had revealed issues such as significant regional differences regarding access to care and the content of care [24]. The guidelines *Good Care of Adults with Gender Dysphoria* and *Good Care of Children and Adolescents with Gender Dysphoria* were published in 2015[1, 8].

When the guidelines for children and adolescents underwent updates in 2020-2022, there were facts, which, according to the National Board of Health and Welfare's overall assessment, have led to the recommendation that puberty-suppressing treatment with GnRH analogues and gender-affirming hormone therapy for adolescents need to be restricted.

The basis of the recommendations

In the context of research

According to the assessment of the National Board of Health and Welfare, there is a need to start generating knowledge about puberty-suppressing and gender-affirming hormone therapy for adolescents with gender dysphoria in the near future. The importance of follow-up and evaluation of the care interventions offered as part of clinical work is emphasized in the 2015 guidelines [1]. At the time, the healthcare system was planning the introduction of a quality registry (the Gender Dysphoria Registry), which has not yet been able to respond to the needs. Longitudinal data are needed to provide a coherent picture of the patient population, from referral to possible diagnosis of gender dysphoria and with follow-up of patients offered different treatment options. The National Board of Health and Welfare urges decision-makers in the relevant healthcare regions to facilitate the registry so that it can reach full functionality as soon as possible.

Eventually, data from the gender dysphoria register could be used for registry studies, but this will take time. The knowledge gaps identified by the SBU, for instance, the impact of treatments on gender dysphoria, mental health, and quality of life [2], also need to be addressed by initiating clinical trials that can answer these research questions to the extent possible given conditions in the field. Here too, healthcare

regions have a responsibility to facilitate the initiation of relevant research in the near future.

Given the uncertainties described in the sections below, clinical trials will also ensure that all relevant information is conveyed to caregivers and young people and that consent is obtained before treatment is initiated.

From "should" to "may in exceptional cases"

The SBU literature review from February 2022 [2] states that for adolescents with gender dysphoria, there is insufficient evidence to assess the effects of puberty-suppressing and cross-sex hormone therapy on most patient-oriented outcome measures (gender dysphoria, psychosocial health, and quality of life). It is also not possible to assess the effects of the treatments on cognitive function, body measurements, body composition, or metabolism.[16] SBU finds some support at the population level that adolescents who have received puberty-suppressing hormone treatment recover bone density during subsequent cross-sex hormone treatment with estrogen or testosterone (low certainty), but that it is not possible to determine whether bone density will eventually fully recover to a level comparable to adolescents in the general population. For details of the study, see the SBU report [2].

Although the state of research has remained largely unchanged since the guidelines were developed in 2015, the previously strong, positive recommendations on puberty-suppressing and gender-affirming treatment have been revised to weak, negative recommendations.

The new assessments are based on the continuing uncertainty of knowledge and the three factors described below (See also *The National Board of Health and Welfare's overall assessment*). Comprehensive descriptions of the expected benefits and risks of the treatments are provided in the section *Hormonal treatment for gender dysphoria in adolescents*.

The patient population has changed

The 2015 guidelines [1] already noted that the number of people with diagnosis codes related to gender identity was increasing. A continued increase in the number of care-seekers and young people with these diagnostic codes has subsequently been seen both nationally and internationally, particularly among young people and especially among young people registered female at birth [19, 25, 26]. Between 2008 and 2018, the number of new cases of diagnosed gender dysphoria among persons aged 13-17 years registered female and male at birth multiplied, from 4 to 77 per 100,000 and

[16] The SBU uses the term "cross-sex", which in the knowledge support corresponds to the term "gender confirmation".

from 2 to 23 per 100,000, respectively [19]. Subsequently, the number of new cases of diagnosed gender dysphoria in the 13-17 age group decreased in 2019 and 2020 and increased again in 2021 (also see *Introduction*).

The SBU noted in 2019 that it is unclear how prevalent gender dysphoria is in the population and whether it has changed over time [25]. Factors that have been discussed as contributors to the increase include increased access to care and awareness of gender identity issues in society, reduced stigma, and social influencing factors [26].[17] Furthermore, the experience of the evaluation teams in recent years is that the patient population is also more heterogeneous than before. Young people whose gender incongruence emerges in childhood and for whom the onset of puberty causes marked distress are described as a smaller proportion of the young people they encounter. Until there is more clarity of the extent to which factors such as social influence play a contributing role, these changes represent an uncertainty that affects the assessment of the benefit-risk balance of the hormonal treatments.

Medical detransition documented among young adults

According to SBU [2], the scientific evidence is not sufficient to determine how often young people change their perception of their gender identity later or discontinue an initiated puberty-suppressing and/or gender-affirming treatment.[18] In recent years, cases of young adults who detransition after undergoing gender affirming treatment have been documented [3, 4].

The concept of detransition is multifaceted and can refer to medical, social, and legal aspects of a gender-affirming process. In some of the scientific publications that have addressed the topic so far, medical detransition is defined as the process by which a person discontinues a gender-affirming medical treatment, such as treatment with sex hormones, or seeks to reverse the medical effects of undergoing gender-affirming hormonal or surgical treatment [4, 27].

Studies that have investigated the reasons for medical detransition have found that some people find it easier to identify with their natal sex for various reasons and that this is the primary reason for the decision to detransition. In an American study, 60% of respondents reported that a change in their own definitions of male and female had made them more comfortable seeing themselves as their natal sex [3]. Others choose medical detransition despite still identifying as transgender. In these cases, the decision may be primarily related to factors that make it difficult to continue treatment and/or difficult to live in accordance with their gender identity, such as

[17] See for example, https://www.umo.se/jag/sexuell-laggning-och-konsidentitet/konskorrigering/

[18] In this context, it should be noted that discontinuation of puberty-suppressing treatment with GnRH analogues during the evaluation is not considered a problem but rather a valid outcome of the evaluation.

medical side effects, societal pressure, discrimination, or dissatisfaction with the results of treatment [28, 29].

Psychological and medical care needs that may arise in the context of medical detransition include the need for support to manage emotions that may arise during the process, support with tapering hormonal treatment, and assessment of the possibility of seeking to reverse the effects of surgical procedures [4]. It is important that healthcare services are prepared to respond to any needs for care that arise. Depending on the primary reason for the decision, individuals' needs for care related to medical detransition may vary [29].

Less consistent experience-based knowledge

The recommendations and treatment criteria in the 2015 guidelines were largely based on recommendations published by The World Professional Association for Transgender Health (WPATH): Standards of Care, version 7 (SoC-7) [30], and on the experience of the experts who participated at the time. The experience of participating experts in the review work of the National Board of Health and Welfare is less uniform than it was in 2015, in that there are also questions and concerns about hormonal treatments and the conditions under which they are provided. It is the National Board of Health and Welfare's determination that the updated treatment criteria should be more clearly tied to the treatment criteria that were evaluated in the Dutch protocol. Key criteria in the Dutch protocol for puberty-suppressing treatment with GnRH analogues and for (possible) subsequent gender-affirming treatment, is that a clear cross-sex identification with the opposite sex has existed since childhood and persisted over time, and that the onset of puberty has caused clear distress. In view of the fact that in the vast majority of cases gender incongruence observed in childhood disappears over time [31], the importance of applying caution when treating with GnRH analogues was stressed in early descriptions of the Dutch protocol [5, 6].

The studies reporting longitudinal treatment outcomes using these criteria [5, 6] cannot answer questions about the efficacy and safety of treatments, but (still) represent the most robust source of experience-based knowledge about the conditions under which treatments can produce good outcomes.

The Consequences of the Recommendations

Desired, intended consequences

The intended consequence of the recommendation to offer puberty-suppressing and gender-affirming treatment in the context of research is

- increased knowledge for appropriate and safe care.

The intended consequence of the recommendation to offer hormonal therapy in exceptional cases, in accordance with the criteria set out in the evidence base, until such time as a study with ethics board approved inclusion and treatment criteria is in place, is

- safe treatment in a more uncertain state of knowledge, in particular minimizing the risk that an adolescent will wish to have the treatment undone later in life.

Possible negative consequences

Risks and possible negative consequences that may result from the two recommendations have been partly identified and taken into account during the course of the work in dialogue with participating experts, and most importantly by patients, relatives and interest groups (in draft comments and at a stakeholder meeting in April 2022). The recommendations are based on existing knowledge and ethical considerations (See also *The National Board of Health and Welfare's overall assessment*). On the part of the National Board of Health and Welfare, the study of negative consequences has been aimed at gathering information that is important to convey to decision-makers in the healthcare regions responsible for the healthcare activities in question.

The recommendation on research

Two risks and possible negative consequences of the recommendation that puberty-suppressing and gender-affirming treatment should be given in the context of research have been pointed out:

- even longer waiting times to get to an evaluation
- compulsion to participate in research in order to receive treatment.

The risks/consequences expressed and, in some cases, related clarifications are described below.

Even longer waiting times for evaluation

In its 2022 report, the Swedish Agency for Youth and Civil Society (MUCF) states that access to gender-affirming care is not working satisfactorily in terms of waiting times [15]. In the case of people under the age of 18, the Swedish National Council on Medical Ethics 2020 [16] describes that waiting times of up to two years to start an evaluation are not uncommon and notes the seriousness of the fact that this is a vulnerable group of young people whose needs for care need to be investigated. Patients, relatives and interest groups have pointed out that waiting times risk being

further extended if resources continue to be needed for the implementation of research as well.

The National Board of Health and Welfare stresses the importance of the timely allocation of resources that enable good and accessible care and facilitate the conduct of relevant research.

Compulsion to participate in research in order to receive treatment

Another consequence that has been pointed out is that patients may feel forced to participate in research in order to access the treatment they feel they need. However, it is common that patients with serious health conditions can only receive a certain treatment, the benefits and risks of which are not yet clear, by participating in research studies. The patient always has the right to opt out. If a patient does not wish to participate in a research study, the healthcare system has a responsibility to offer the patient a treatment other than the one provided in the study to meet the need for care, if such treatment is available.

Recommendation on treatment in exceptional cases

Until a research study with ethics board approved inclusion and treatment criteria is in place, the National Board of Health and Welfare's assessment is that puberty-suppressing and gender-affirming hormone treatment can be given in exceptional cases, in accordance with the criteria in the updated guidelines. The following risks and possible negative consequences of the recommendation have been pointed out:

- continued dysphoria and increased distress due to endogenous puberty
- increased risk of suicide due to gender dysphoria and endogenous puberty
- increased need for future surgery due to undergoing endogenous puberty
- increased self-medication
- manipulated patient histories[xv]
- reduced trust in healthcare and reduced propensity to seek help
- upholding the two-gender norm when non-binary people are excluded.

The risks/consequences expressed and, in some cases, related clarifications are described below. The knowledge base on the risks of not offering the treatments (but providing psychosocial care) is insufficient. However, the risks of increased suffering, suicide, and self-medication need to be taken seriously by the healthcare system and are important to address and prevent (See *For decision-makers* for further information).

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Continued dysphoria, increased suffering, and suicide risk

One risk that has been expressed is that adolescents who feel a strong need for puberty-suppressing and/or gender-affirming treatment but are not offered it, may be at increased risk of mental health problems.

It is important that the healthcare system provide adequate psychosocial care for these young people. See *For decision-makers* for further information below.

Increased need for future surgery and reduced quality of life

One consequence of not offering puberty-suppressing treatment to an adolescent with gender dysphoria is that the effects of natal puberty will persist for the rest of his or her life. Any gender-affirming surgical interventions will not be able to fully compensate for this and the person will find it more difficult to be perceived by others in accordance with their gender identity in adulthood. For the individual whose gender dysphoria persists over time, this will have a lifelong and significant negative impact on quality of life.

Increased self-medication and use of international online services

Another possible negative consequence is an increase in self-medication with sex hormones that adolescents buy themselves or through others on the Internet. More general risks of buying medicines online include the presence of counterfeit medicines and the negative consequences that can occur when taking them.[19] Self-medication among adolescents with gender dysphoria has been described previously [23, 32] and it is unclear how commonly it occurs. In addition to the risk of increased self-medication, the use of international online services that are not subject to Swedish laws may also increase in cases where guardians believe that the child needs puberty-suppressing or gender-affirming hormone treatment but is not offered it.

The section on self-medication in the 2015 guidelines [1] has been deleted in the 2022 update. According to the experience of the current experts, the previous wording on harm reduction and the need for rapid contact with an evaluation team, combined with the long waiting times for treatment, has in some cases led to adolescents starting self-medication.

It is important that adolescents and their guardians are informed about the medical risks of self-medication and how the healthcare provider views the possible

[19] See 1177 on the risks of buying medicines online.

assumption of [responsibility for] medical treatment already started. According to Section 3, Section 2 of the PSL, the healthcare provider must take the measures necessary to prevent patients from suffering harm. When care is to be provided to an adolescent who is self-medicating or where medications have been prescribed by international online services with the involvement of a guardian, the healthcare provider may need to consider the risk of harm, in assessing the need for care. If the healthcare provider deems that the treatment needs to be indicated by a medical professional, and that the healthcare provider cannot assume responsibility for the treatment, it is important that the adolescent and the guardians are informed about this eventuality.

Furthermore, the healthcare service always has a responsibility to report concerns to social services if it considers that there is a risk of harm to the child.[20] Whether self-medication constitutes a basis for a report of concern may vary, according to the experts involved, depending on the circumstances of the individual case. If the healthcare provider deems that self-medication is always a reason for concern, this policy may be applicable and needs to be communicated to the adolescents and guardians.

Decreased trust and propensity to seek help in healthcare

Another possible consequence is that the proportion of young people with gender dysphoria who avoid contacting healthcare services despite feeling the need for care increases. Several government reports [15, 33] indicate that trust in society is low among young LGBTQI people, and especially among young trans people. Powers and authorities are perceived not to act to ensure the rights of trans people, but sometimes to directly oppose them [15]. To the extent that patients perceive that the fundamental right to live in accordance with their gender identity also includes a right to gender-affirming treatment, the revised recommendations may reinforce this lack of trust.

Perceived need for treatment may complicate care assessments

From both professional and patient perspectives, it has been suggested that some adolescents who do not meet the revised treatment criteria may feel compelled to adjust their narrative during the assessment in order to access the care they feel they need. The perception that transgender care is based on a template that one must fit into in order to receive (gender-affirming) care has been described previously [32]. There are also descriptions in government reports and scientific articles that the evaluation team has the role of "gatekeeper" [24, 34, 35], deciding whether patients

[20] Chapter 14, Section 1 of the SoL

should receive further treatment, and that this often contributes to limiting the transparency between the evaluation team and the patients. Patients, relatives and interest groups point to a risk that such "gatekeeping" will increase as a result of the updated recommendations.

The fact that healthcare decisions about gender-affirming treatments can sometimes be based on incorrect information can be viewed as a patient safety issue in principle, which is also relevant for the care of adults. In the evaluation of young people with gender incongruence, the involvement of caregivers means that the descriptions of several informants can be weighed together and form the basis for assessment.

When the evaluation starts after age 18, assessments are often based solely on the patient's own description.

Maintaining the two-gender norm

According to the Dutch treatment criteria, which the National Board of Health and Welfare considers should be used as a guide for individual cases, there is no documentation about puberty-suppressing and gender-affirming treatment for young people with non-binary gender identity. One consequence noted from the patients' perspective is that in this way, healthcare contributes to the maintenance of the two-gender norm. At present, there is a lack of documented experience, as well as a lack of experience among participating experts, of hormonal treatment for adolescents with non-binary gender identities.

The scope for including people with non-binary gender identities in care and treatment has increased as a result of the revisions to the DSM system and ICD classification that have taken place over the last ten years. The 2015 National Board of Health and Welfare guidelines [1, 8] also state that care interventions can generally be relevant for youth and adults with gender dysphoria regardless of the ICD-10 classification, and that the person's needs and situation should be the determining factors when deciding on each individual intervention.

During the revision work, the National Board of Health and Welfare noted that the clinical judgements and decisions about medical treatment for adult patients can be particularly difficult when the patient's gender identity is non-binary. Some of the factors that may contribute to this are the great heterogeneity within the population and the lack of knowledge to guide the assessment of when certain treatments may be beneficial for an individual patient (See *Non-binary gender identity - knowledge and need for clarification*). The available experience in adult care needs to be gathered and compiled in connection with the updating of the guidelines *Good Care of Adults with Gender Dysphoria* [8].

Overall assessment by the National Board of Health and Welfare

The expected benefits and potential side effects and risks of puberty-suppressing treatment with GnRH analogues and gender-affirming hormone therapy are described in the section *Hormonal treatment for gender dysphoria in adolescents*. In this section, possible negative consequences of the updated recommendations of the National Board of Health and Welfare have been described, some of which have been identified and taken into account during the course of discussions with participating experts, and others that were expressed by patients, relatives, and interest groups. On the part of the National Board of Health and Welfare, the survey has aimed to gather information that is important to convey to decision-makers in the health and medical regions who are responsible for the care activities in question. In the light of the comments regarding the draft, stating that the survey was done only after the recommendations had been decided upon and that the risks of not giving treatments have not been taken into account, the National Board of Health and Welfare would like to clarify the overall assessment and the basis on which recommendations on care measures have been given.

In the risk-benefit assessment that healthcare services make in the case of an individual young person, the expected benefits of the treatment in question need to have been made clear, and the benefits must be judged to outweigh the risks (See *Hormonal treatment for gender dysphoria in adolescents*). In the individual assessment, the expected benefits and risks of not providing the treatment in question also need to have been clarified and considered. In contrast, the recommendations of the National Board of Health and Welfare provide guidance at the population level. They are based on scientific and experience-based knowledge of the efficacy and safety of the treatment measures concerned, and on an ethical analysis.

The revised recommendations reflect the assessment that at the population level, the risks of the treatments are likely to outweigh the benefits, and are based on the uncertainties of knowledge and the factors previously mentioned in this section. The section shows that the evidence base in 2022 is unchanged compared to 2015 in that the scientific evidence is still considered insufficient to comment on either the benefits of the treatments or on the risks of the treatments for adolescents with gender dysphoria [2]. Although adolescents and young adults interviewed described access to the treatments as crucial to their mental health and sometimes as directly lifesaving [15, 36], there is (still) no evidence to conclude that the treatments have such benefits for the patient population [2]. Similarly, there is also no scientific evidence to draw conclusions about the risks that have been pointed out, such as the risk of offering psychosocial care but not puberty-suppressing and hormonal treatment.

Care must be provided on the basis of science and proven experience and the principle of doing good and not harm. In revising the recommendations, the National Board of Health and Welfare has taken into account the fact that the efficacy and

safety of treatments, benefits, and risks are not proven, and that three factors have shifted the balance between benefits and risks in a negative direction:

- the increased prevalence of gender dysphoria among young people [19], particularly among young people registered female at birth, and that the reasons for the increase and the relative shift between the sexes are not yet known
- that medical detransition among young adults has been documented [3], and it is not known how commonly it occurs
- that the experience-based clinical knowledge among participating experts is less uniform than it was in 2015.

For decision-makers

Young people suffering from gender dysphoria need to be able to promptly begin evaluation and be offered appropriate care based on needs assessments by the healthcare service. The various gender-affirming treatments listed in the different sections of the guidelines need to be offered once they have been deemed indicated. Good psychosocial care is essential. The patient population is heterogeneous and psychosocial care must be clearly inclusive of young people with non-binary gender identities.

Psychosocial care

In accordance with child psychiatric practice, the psychosocial care of young people with gender dysphoria needs to be adapted to the needs of the individual adolescent. Psychosocial support that helps the adolescent deal with natal puberty without medication needs to be the first option when choosing care measures. For those suffering from mental health problems, measures such as supportive counselling, psychotherapy, child psychiatric treatment and suicide prevention need to be offered and adapted to the nature and severity of the mental health problem and the young person's overall situation.

Regardless of the causes, healthcare services have a general mandate to seek to prevent suicide, as well as a specific responsibility to offer the best possible care, treatment, and support to people with thoughts or plans of suicide. The suicide risk of young transgender people is elevated compared to the suicide risk of young people in the general population (See *Support for young people and their families*). Healthcare professionals encountering young people with gender dysphoria need to be continuously vigilant to detect serious mental health problems, and suicidal thoughts in particular. It is important that procedures are in place to concretize suicide prevention work, in line with the forthcoming national strategy for mental health and

suicide prevention. Support for suicide prevention can be found on the National Board of Health and Welfare's website.[21]

Include measures to promote mental health

In addition to interventions aimed at reducing mental health problems, several reports point to the importance of care interventions that promote mental health in young transgender people [15]. Some are described and exemplified elsewhere in the guidelines:

- psychosocial support aimed at promoting resilience and self-esteem and at reducing the effects of minority stress
- psycho-educational interventions provided in a validating context and aimed at providing a greater knowledge and understanding of one's own situation.

See also Support for young people and their families.

In the report *I am not alone, there are others like me*[xvi] [15], MUCF provides an updated picture of the living conditions of young LGBTQI persons and suggestions for continued measures to reduce the vulnerability of transgender persons. Among the measures proposed in the report are:

- provision of "safe spaces" where young LGBTQI people can meet others in the same situation
- increased resources and competence for youth clinics, school health, primary care, and psychiatry to meet and create forums for young trans people in need of professional support.

The report also describes the experiences of sixteen young transgender people regarding what has worked to strengthen their mental health [37]. The interviews show that opportunities to meet other transgender people, as well as to feel safe, supported and accepted by family, friends, school, and work, are important for mental health. Participating in activities and contexts where one can freely explore oneself (e.g., through role-play), as well as physical activity and freedom of movement in comfortable settings are also perceived as strengthening.

[21] https://www.socialstyrelsen.se/kunskapsstod-och-regler/omraden/psykisk-ohalsa/

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Information about why the recommendations have changed

According to the participating experts, adolescents today come to the clinic with a great deal of suffering that has worsened due to long waiting times. Consistent with the testimonies above, some adolescents are firmly convinced that medical treatment is the only thing that can make them feel better. Even guardians may sometimes question why the only (as perceived by individuals) effective treatment for gender dysphoria is not offered to the adolescent who feels a strong need for it. It is important that young people and families are provided with information that helps paint a more nuanced picture and facilitate the understanding of why the recommendations regarding medical treatments have become more restrictive.[22]

Such information may state, for example that:

- young adults detransition and sometimes regret gender affirming treatment, despite their previous conviction that treatment was the right solution [3, 4], and that we do not currently know how commonly this occurs [2]. This is a problem because care measures must be provided based on science and proven experience and on the principle of doing good and not harm.
- results from various types of correlation studies, which are sometimes cited as support for the benefits of treatments, generally have low reliability because the study designs do not allow to draw conclusions about efficacy and safety.

[22] The information above and other key information in the knowledge support will be considered when updating the information material "For those with gender dysphoria".

Non-Binary Gender Identity – Knowledge and Need for Clarification

During the revision process of the section on hormonal treatment (October 2021), comments were received from the patient's perspective, including comments on the fact that a cross-gender identity was put forward as a criterion for puberty-suppressing and gender-affirming hormone treatment. The responses pointed out that gender dysphoria and the need for treatment should be the guiding principle, not the pronoun or gender identity of a person. Furthermore, it has become clear during this work that the participating experts are not entirely united on this issue and that there are also related issues concerning the care and treatment of adults with non-binary gender identity. The aim of this section is to provide an initial picture of the state of knowledge about the care and treatment of people with non-binary gender identity and issues that the National Board of Health and Welfare believes need to be addressed and clarified.[23]

Background

Non-binary gender identity refers to a gender identity outside the binary division of man/woman, boy/girl. The group is heterogeneous and includes, for example, people who identify as both masculine and feminine, somewhere between masculine and feminine gender identities or as gender neutral. Others may identify as a specific third gender, as multiple genders or as all genders (pangender) [38]. The terms people use to describe their nonbinary gender identity vary among individuals, and an individual's nonbinary gender identity can sometimes vary over time and depending on the context [39].

The proportion of people with non-binary gender identity varies in different studies, depending on factors such as the population studied and how study participants are recruited. A 2020 literature review based on international studies [40] found that 11-15% of young people enrolled in gender identity clinics had non-binary gender identities. Similarly, a Swedish publication from 2021 found that 26 people in a total

[23] The inventory of the state of knowledge has included the referral version of the Standards of Care version 8 (SOC8) from WPATH ("Chapter draft for public comment - Nonbinary") that was made available in December 2021 and scientific publications that the National Board of Health and Welfare identified during a survey in September 2020 (See the separate appendix Knowledge base with methods description).

patient group of 232 (11.2%) stated that they preferred a pronoun other than she/he; the median age in the group was 24 [41].

The scope for including people with non-binary gender identities in care and treatment has increased as a result of the revisions to the DSM system and ICD classification that have taken place over the last decade. Since the 2013 publication of the DSM-5, the diagnosis of gender dysphoria (302.85) may be made regardless of whether the gender identity is binary or non-binary. The ICD-11, adopted by the WHO in 2019, allows for the use of the code Gender Incongruence (HA60) regardless of whether the gender identity is binary or non-binary. See *Clinical diagnosis and statistical classification* in the *Introduction* section for more information.

In line with the DSM-5, the recommendations of the 2015 guidelines [1] were for young people with gender dysphoria in general, i.e., including young people with non-binary gender identity.

Knowledge of care needs

Two literature reviews published in 2019-2020 compiled studies examining the health and social situations of people with non-binary gender identities [40, 42]. One literature review looked at people up to age 25 [40], while the other looked at people of all ages [42]. The authors of both reviews concluded, that among other factors, it is (also) important that young people with non-binary gender identity are offered psychosocial support in order to reduce the consequences of marginalization and minority stress (See also the previous section and section *Support for young people and their families*).

A 2021 Swedish study suggests that the majority of healthcare seekers with binary and non-binary gender identities feel a need for gender-affirming hormonal treatment and some form of surgical treatment [41]. People with non-binary gender identity have varying needs and desires for physical changes. Some have no need for gender-affirming treatment and some describe needs and desires similar to those of people with binary gender identity, i.e., a clear feminization/masculinization in relation to the registered sex at birth. Others may have needs and desires for an increased or decreased, relative to their registered sex at birth, degree of feminization/masculinization of, for example, hair, body shape, and vocal pitch [43].

Knowledge of care and treatment

In recent years, assessment instruments have been developed that can be used as a basis for discussion or to support assessments during the diagnostic evaluation, regardless of the person's gender identity (See *Evaluation of young people with gender incongruence*). One instrument was developed specifically for non-binary gender identities and is intended to support diagnostic assessment when gender-

affirming treatment is being considered for this group [44]. Psychological support specifically for people with non-binary gender identity has also been described [45].

Regarding GnRH analogue and gender-affirming hormone therapy, there appears to be a complete lack of documentation for the group of youth with non-binary gender identities. In the Dutch protocol, cross-gender gender identity is a criterion for both puberty-suppressing and gender-affirming hormone therapy [5, 6]. According to participating pediatric endocrinologists, there is a lack of experience in treating youth with nonbinary gender identity, both in the Nordic countries and internationally. The "Non-binary" section in the WPATH version of SoC8 states that an individual's need for gender-affirming treatment cannot be determined on the basis of gender role behaviors, gender expression, or gender identity. The section also states that knowledge is limited with regard to adults, while explicit references to "adolescents" are missing.[24]

An article from 2020 [43] suggests how hormonal treatment in particular can be adapted to people with non-binary gender identity. Suggestions for treatment pathways for people registered as male and female at birth are described in a flowchart, however the article makes no reference to adolescents.

A 2019 US study [46] reported that 58 of 458 (13%) of patients with gender dysphoria who underwent gender-affirming breast surgery from 2012 to 2017 had non-binary gender identities. All 58 persons with non-binary gender identity were persons registered female at birth who had undergone mastectomy; the mean age was 29.5 years (sd=7.60).

Need for clarification

At present, descriptions of puberty-suppressing and gender-affirming hormonal treatment for adolescents with non-binary gender identity appear to be completely lacking in the literature, and very little is available on gender-affirming treatment for the adults. The National Board of Health and Welfare concludes that the experience, questions, and considerations related to the assessment and treatment of this patient population need to be discussed at the national level. For example, important questions concern the possibilities and limitations of health care to meet different types of wishes for bodily changes in the adult patient population based on medical and surgical considerations, and how the indication for treatment is determined. For the adolescent population, a pressing issue is to clarify the conditions under which

[24] The National Board of Health and Welfare was able to access the consultation version of SoC8 as preliminary information in December 2021. The conditions remain in the final version of SoC8 published in September 2022.

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adolescents with non-binary gender identities can be offered hormonal treatment in the context of research.

Support for Young People and Their Families

The number of young people referred for gender dysphoria assessment has increased significantly over the past decade. The increase is seen both nationally and internationally and is particularly evident among adolescents registered female at birth [25, 26]. The experience of the evaluation teams in recent years is that [currently], the young people being evaluated are also a more heterogeneous group than in the past.

Young people whose gender incongruence begins in childhood and for whom the onset of puberty causes clear distress are a smaller group. In these cases, the child's exploration and the evaluation team's contact with the family often extends over many years. Time is an important factor in the certainty of assessments, and the diagnosis is relatively straightforward once evaluation begins. It is usually relatively easy for the young person, guardians, and the evaluation team to reach a consensus on care needs and treatment measures in these cases.

For most of the young people encountering evaluation teams [currently], the situation is different. Many seek care later in puberty, largely describing longstanding gender incongruence that was noticeable before and worsened with puberty. There may be aggravating circumstances to consider, which make life challenging for the young person and complicate diagnosis and certainty of assessment for the evaluation team. In the experience of the evaluation team, psychosocial support of various kinds needs to be provided over a longer period of time for most young people, before a consensus on care needs and interventions is reached by the young person, guardians, and the evaluation team. The psychosocial support described in this section is often an integral part of the evaluation.

The content of this section applies generally to youth with gender incongruence and includes people with non-binary gender identities.

Broad psychoeducational approach to initial support

Often, evaluation teams see a need to initially offer support with psychoeducational elements that relate not only to gender identity but also to identity development more

generally.[25] The content of the interventions and the form in which they are delivered are individualized. The aim of the interventions is both to provide a safe and validating context, and to provide information that can help the person to gain a better knowledge and understanding of their own situation and how they can deal with it. The themes addressed vary and may include:

- teenage years
- friends (past, present, and future)
- well-being (physical and mental health)
- the body
- the family and the context in which you grow up
- fears, uncertainty, and ambivalence
- the Internet (is its use supportive or not?)
- difficult life experiences
- autism/ADHD/ADD
- other psychiatric conditions
- gender norms, and their impacts
- relationships, sexuality, sexual orientation
- what it means to them to be transgender
- values, e.g., how I see myself and others, dare to fight/dare to back down
- transphobia and minority stress (See below).

The experience of the evaluation teams is that this approach facilitates continued unconditional exploration of gender identity during the evaluation. Some young people reassess their situation over time and choose to end the evaluation at a relatively early stage.

Minority stress and protective factors

Several government reports and literature reviews show clear differences in health between young LGBT people and young people in general [47, 48]. The differences are most evident in the area of mental health, where anxiety, depression, and stress are more prevalent among LGBT people compared to the general population.

According to a FORTE evidence review on health and living conditions among young LGBT people [48], growing research supports the notion that the increased risk of ill health among LGBT people can be at least be partly explained by the

[25] According to the description of the participating experts, in some regions this type of intervention can be provided by youth clinics, before the young person is referred for gender incongruence assessment.

minority stress model [49, 50].[26] The theory describes increased psychosocial stress specifically associated with a person's sexual orientation or gender identity deviating from the norm, which is an additional contributor to general life stress. Sources of minority stress are external: being discriminated against, rejected and subjected to prejudice and violence; and internal processes that arise as a result: living in a state of readiness and fear of being discriminated against, rejected or subjected to violence, feeling the need to keep one's identity secret from those around them, and internalized homophobia, biphobia and transphobia, i.e., the negative attitudes of the environment becoming part of the person's self-image [50].

Research in this area shows that young LGBTQ people are at increased risk of being exposed to violence and other types of bullying, both in physical and digital contexts [48]. Results from the Public Health Agency's 2015 survey [33] also suggest that the high rate of suicidal ideation among transgender people is linked to specific negative life conditions with experiences of abuse, discrimination and violence, as well as low trust in social institutions such as healthcare and schools.[27] Similar conclusions are drawn in the 2020 report on Public Health Agency's qualitative interview study about mental health, suicidality, and self-harm among young transgender people [36].

According to the theory, minority stress can be countered by various methods aimed at creating change at the structural and policy, as well as individual levels [50]. For example, psychosocial support aimed at promoting resilience and self-esteem of individuals is thought to contribute to reduced minority stress and improved mental health.

Knowledge about promotion methods and protective factors

In 2017, the Public Health Agency stated that the state of knowledge regarding effective methods to promote good health and prevent poor health among LGBTQ people was unclear [51]. At the time, the number of studies was small, and the majority had weak study designs. Studies suggested that school-based interventions that include LGBTQ people and increase the visibility of different identities related to gender and sexuality could counter suicidal behavior. Studies also suggested that the mental health of LGBTQ people might be improved by participating in support

[26] The model was originally developed to explain differences in mental health based on sexual orientation [5, 6] but has since been extended to understand the increased risk of ill-health in other minority groups.

[27] A total of 796 transgender people aged 15–94 responded to the survey. A total of 36% reported that they had seriously considered taking their own lives at least once in the past year. Among young transgender people aged 15–19, this proportion was 57%, compared to 7% among young people in general in the 16–29 age group according to the National Health Survey. These results need to be interpreted with caution, particularly because the transgender survey respondents were recruited via a self-selected web-based survey.

groups with other LGBTQ people and by cognitive behavioral therapy with a focus on affirming their LGBTQ identity. However, the evidence in the review was not sufficient to conclude these effects. Subsequent reviews of the literature have also reported similar findings [52].

For children, adolescents, and their families, support groups and activities organized by interest groups or health services can be important. According to FORTE's literature review [48], research shows that social support from friends and family can act as a protective factor against poor mental health among young LGBTQ people. Other reported protective factors include a positive LGBT identity, positive experiences of 'coming out,' belonging at school and in families, and feeling safe at school.

The Public Health Agency's 2020 interview study [36] and MUCF's 2022 report [15] also highlight protective factors that can reduce psychological distress and promote mental health among young transgender people. Examples include receiving support from relatives and school, receiving adequate care for their gender dysphoria and/or psychiatric diagnoses, and being seen and affirmed in their gender identities.

Information, support, and advice for families

It can be overwhelming for family and friends when a child or adolescent shows signs of gender incongruence or gender dysphoria. At first, family and friends may not know what it means. It is common to worry about the reactions of the community and that the young person will be harassed or harmed.

Relatives and friends may also face lack of understanding and negative reactions from the environment in relation to the child, sibling, peer, or partner transgressing gender norms or showing signs of gender incongruence. Interventions to promote the resilience and coping skills, similar to those offered to the affected young person may be needed by family and friends.

Information, support, and counselling may be needed for shorter or longer periods of time, depending on the needs of the family and the development of the child's or adolescent's gender incongruence. Psychosocial support for family members and friends may be provided together with the child or adolescent. They can also be provided individually or in groups with other family members and friends.

The issue of social transition in children

Some children with signs of gender incongruence or gender dysphoria express early on that they want to start living in accordance with their gender identity at school and in other contexts, for example by changing their first names, hairstyles, and style of

dress. The ability to express oneself is important for children in general, and there is research supporting the observation that the ability to socially transition is associated with good mental health in children [53].

At the same time, caregivers need to be informed about research suggesting that for many children, early signs of gender incongruence and gender dysphoria disappear before or around puberty. In a 2016 review [31], the proportion of "persisters" (people whose gender dysphoria is deemed to have persisted since childhood) in the ten studies included ranges from two to 39 percent. In a 2021 publication [54], 17/139 (12%) of participants registered male at birth were reported as "persisters".

The advice to guardians currently is to continue to pay attention to the development of the child's gender incongruence and how the child is doing, and to be open to the fact that the child may change their mind over time. An important task for healthcare services is to support guardians in finding strategies and contexts where the child is free to be him or herself which are appropriate to the young person's individual circumstances and needs, and to frame them such that the child feels free to change should the gender incongruence later cease.

Children who show early signs of gender incongruence or gender dysphoria and their families are regularly followed by the assessment teams at varying intervals based on the family's support needs. Guardians are also encouraged to make contact if concerns about the child arise in the interim. If signs of gender incongruence or gender dysphoria persist as puberty approaches, an evaluation needs to be considered. It is important to start an evaluation when there is a need for care, and it is deemed to be to the child's benefit.

Guardians may also need support liaising with societal functions and social contexts in which the child participates, for example to inform or coordinate approaches with school staff, or to facilitate the everyday life of young people who already live in accordance with their gender identities (See also *Assisting the young person in liaising with community functions* below).

As with other care, the recommended measures on information, support, and counselling for families require the availability of health professionals with the right competence for the task. (See also *Competences for evaluation*, section *Evaluation of gender incongruence in children and adolescents)*.

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Recommendations on psychoeducational interventions, support, and counseling for families

Legal guardians of children and adolescents admitted to healthcare services for signs of gender incongruence or gender dysphoria should be provided with psychoeducational measures, support, and counselling.

Relatives and those in the immediate environment of children and adolescents admitted to healthcare services for signs of gender incongruence or gender dysphoria should be provided with psychoeducational measures, support, and counselling.

Reasons for the recommendations

Background: People with gender incongruence and gender dysphoria are generally a vulnerable group in society. For young people with signs of gender incongruence and gender dysphoria, it is particularly important to feel support and acceptance from guardians and others in their immediate environment. In turn, guardians, other relatives, and friends may need information, support, and counseling themselves in order to support the child or adolescent in the best possible way.

The expected benefit (purpose) of the measures is that family and relatives will be supported as needed and enabled to support their child, sibling, partner, or friend so that the young person can develop with a positive self-image. The aim is also to enable guardians to make informed choices about the issues that arise, and to support the child's exploration in the best possible way.

Possible risks: No clear risks associated with the measures have been identified, provided that the professional has the required competence and that the information provided is comprehensive. For example, information to guardians needs to highlight both research suggesting that the possibility of social transition is associated with good mental health for the child, and research highlighting uncertainty about the child's future gender identity.

Knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description*.

Benefit/risk balance: The National Board of Health and Welfare deems that the expected benefits of these measures outweigh their possible risks.

Supporting young people interacting with societal functions

Young people with gender dysphoria who live in accordance with their gender identity report feeling excluded in social contexts, and they are at increased risk of bullying and exposure to violence [48]. Young people are also often limited in their opportunities to opt out of social contexts such as school and place of residence. Healthcare services can help to reduce psychosocial risk factors by assisting young people in their contacts and through collaboration and cooperation with, for example, schools, social services, and youth clinics. A prerequisite is that depending on the current situation and the child's age and maturity, guardians and/or the child consent to the collaboration and to the provision of information (see Sections 12, Sections 2 and 3 of the Public Access to Information and Secrecy Act [2009:400], OSL).

It is important that support is flexible and adapted to what the adolescent experiences as problematic in their everyday life. This can include, for example, informing school staff about gender dysphoria and treatment, and practical measures in the case of sex-segregated education, such as arranging changing rooms for sports.[28] The need to solve such problems can arise and re-emerge, for example, when the young person changes school or place of residence and during social transition/retransition. Strategies for schools to increase students' knowledge of different gender identities and to prevent bullying and harassment can also be addressed.

The young person and guardians may also need information and help with the practical details of a name change.[29]

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[28] The Swedish National Agency for Education's support material for sex and sexuality education in the later years of primary school states that schools need to consider how to facilitate participation in education for transgender people, for example by offering the possibility of separate changing rooms and by consistently avoiding working with gender-segregated groups (2013; p. 114).

[29] On 1 July 2017, the Personal Names Act (2016:1013) was introduced at the same time that the Names Act (1982:670) was repealed. Provisions on first names can be found in sections 26–28 of the Personal Names Act. The application for a change of name must be made to the Tax Agency.

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Recommendation to assist the young person in contacts

Healthcare services should assist children and adolescents in their contacts with the relevant societal functions such as schools and social services, in order to prevent and reduce the problems that young people with signs of gender incongruence or gender dysphoria perceive as relating to their condition in their everyday lives.

Reasons for the recommendation

Background: Young people with gender dysphoria who live in accordance with their gender identities can experience problems in their everyday lives that affect their quality of life and self-esteem. In this context, health care should contribute to reducing psychosocial risk factors by assisting the young person in contacts and interacting with, for example, schools and social services.

The expected benefit (purpose) of the measures is to enable a functional everyday life for young people living in accordance with their gender identities, to reduce the risk of poor mental health and to contribute to a good psychosocial adaptation.

Possible risks: No clear risks have been identified with the measures, provided that the professional has the required competence for the task.

Knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge-base with methods description*.

Benefit/risk balance: The National Board of Health and Welfare deems that that the expected benefits of the measures outweigh their risks.

Evaluation of gender incongruence in children and adolescents

This section describes what an evaluation of gender incongruence in children and adolescents should include, based on science and proven experience from the perspective of patient safety.

The content of the section applies generally to the evaluation of gender inequality in young people and includes people with non-binary gender identities.

Purpose of the evaluation

The purpose of a gender incongruence evaluation is to decide whether there is a need for care and which interventions are justified and appropriate for the individual young person. This includes assessments of the young person's gender incongruence and gender dysphoria and whether there are co-occurring conditions and factors to consider.

A longer period which involves support measures

The term "evaluation" in health care often refers to a relatively short and limited period of time. Evaluation of gender incongruence in young people, who are in a period of intense physical and mental development, usually needs to last for several years and is prolonged when there is a high degree of uncertainty in the assessment. The time between initial support measures and the start of the evaluation is not always clearly delineated, for example when the family has made contact at an early age with the child. See also the section on *Support for young people and their families*.

General considerations

Competencies for evaluation

Where health care activities are conducted, there must be the staff needed to provide Good Care (Section 5, Section 2 of the Health Care Act [2017:30], HSL). Health care staff must carry out their work in accordance with science and proven experience. A patient must be given expert and caring healthcare that meets these requirements (Section 6, Section 1 of the Patient Safety Act [2010:659], PSL).

In December 2020, the National Board of Health and Welfare made a decision [22] that certain gender dysphoria-related care, including evaluation, will constitute “national highly specialized care” and will be provided at three units. According to

the decision, multidisciplinary competence, and collaboration between different professions, with special expertise for this patient population, is required. See also *Competence for Good Care and treatment* in the section *Introduction*.

In terms of assessment of children and adolescents, according to proven experience, it is important that the diagnostician has developmental psychological and child and adolescent psychiatric competence, as well as the ability to recognize and diagnose co-occurring psychiatric conditions and differential diagnoses in children and adolescents [30, 55].

Individualized evaluation

Health care activities must be carried out such that the requirements of Good Care are met. This means, among other things, that the care must be of good quality, meet the patient's needs for security, continuity, and safety and be based on respect for the patient's self-determination and integrity (Chapter 5 § 2 Health Care Act [2017:30], HSL[xvii]). According to preparatory work on the previous HSL, good care means, among other things, that it must be adapted to the individual patient's particular circumstances. The preparatory works also states that it must be assumed that the care meets people's needs for security and safety in medical terms (prop. 1981/82:97 on the Health and Medical Care Act etc. p. 56).

The content and duration of the evaluation need to be adapted to the medical, psychological, and social circumstances of the child or adolescent. The type of evaluation needed varies from one young person to another, depending on:

- the age and physical and mental maturity of the young person at the time when the evaluation is initiated
- whether the gender incongruence started during childhood, at the onset of puberty or later in puberty/after puberty
- the extent to which healthcare services have had prior awareness of the young person's gender incongruence of the family
- whether there are co-occurring conditions or aggravating factors that need to be evaluation and considered
- the stability of the gender identity
- the young person's maturity and ability to understand the long-term consequences of gender-affirming treatment (if it is being considered)
- the extent to which information needed for the evaluation is provided in the referral.

The evaluation needs to last as long as necessary to meet its purpose and ultimately minimize the risk of mistreatment. Ultimately, the young people themselves, the guardians, and the evaluation team all need to feel confident about the outcome of the evaluation.

Long evaluation times can be psychologically stressful for the young person. Collaboration with other health care providers involved, e.g., for the evaluation and treatment of co-occurring conditions, needs to be efficient so that the evaluation is not delayed. It is important that, when deemed appropriate, interventions for co-occurring conditions or aggravating factors are carried out in parallel with the evaluation of the gender incongruence.

Information about the evaluation

Each patient shall be provided with individually tailored information including their health condition, and the methods available for evaluation, care, and treatment. The patient must also be informed about when he or she can expect to receive care and about the expected course of care and treatment (Section 3, Section 1 of the Patient Act [2014:821]). The information must be provided to the young person and to the guardian, provided that provisions on confidentiality or professional secrecy do not prevent this (Sections 3 and 5 of the Patient Act).

Although it is not possible to say in advance exactly how long an evaluation will last, or which support and treatment interventions will be involved in the individual young person's case, it is important that the evaluation team explains the following to the young person and the guardians:

- the different parts of the evaluation and their aims
- what the evaluation will answer
- what the evaluation team needs to rule out
- that other child and adolescent psychiatric interventions may need to be initiated if the assessment team identifies a need for them
- that the evaluation team collaborates with others, including child and adolescent psychiatry, social services, and physical health professionals
- which rules, guidelines, and care practices the evaluation team has to consider
- that the aim is to work with the young person and guardians to determine the best course of action if gender dysphoria persists throughout the evaluation.

The information detailed above must be provided at the beginning of the evaluation and then continuously as the need arises.

Finally, it is important to inform young people and their guardians about the possibilities and limitations of different gender-affirming treatments during the evaluation [30]. Often, the person under evaluation has their own ideas about what gender-affirming treatment means.

Even when it is unclear that gender-affirming treatment will be an option, it is essential that the young people and their caregivers have a realistic picture of what the treatments will mean in the short and long term, and time to process this information.

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In cases where gender affirmation treatment is later deemed indicated and appropriate, the young person and guardians must be informed again. The information must be given by the person directly responsible for the type of care under consideration, e.g., information on hormone treatments is given by the child's endocrinologist.

Evaluation methods and informants

As a rule, guardians are involved in the evaluation.[30] Close relatives should also be given the opportunity to participate if the child or adolescent so wishes.

Recommendation on evaluation methods and informants

> Healthcare services should carry out the psychological, psychosocial, and psychiatric components of gender incongruence evaluation using valid assessment methods, investigative interviews, and life histories obtained from the child or adolescent and from the guardians.

Reasons for the recommendation

Background: As with all evaluation, it is important that the health service gets as good and complete a picture of the patient and their situation as possible.

The expected benefit (purpose) is that the young people themselves, guardians and the evaluation team should feel confident about the outcome of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks of the measures are that they may create anxiety and feelings of suspicion, should differing views of the adolescent's suffering and needs emerge, or if guardians find it difficult to understand and accept the young person's gender incongruence. Since the support and understanding of guardians is of great importance for the mental health of the young person, risks can be reduced by providing appropriate psychosocial support to the young person, and by providing information, support, and advice to guardians when needed. Risks can also be

[30] The starting point is that it is the guardian who has the right and obligation to decide about matters of health and medical care for the child. However, as the child's age and maturity increase, greater consideration must be given to the child's wishes. A child may be considered mature enough to decide on his or her own about certain care or treatment if he or she can assimilate the relevant information and understand the consequences of his or her decision. However, considerable maturity is required for a child to be able to decide on more extensive treatments and interventions (cf. prop. 2013/14:106 p. 119).

reduced by the evaluation team by describing and justifying the purpose of the evaluation to the young person and the guardians (See *Information about the evaluation* above).

Knowledge on expected benefits and risks is based on experience gained from international publications on the subject [56, 57], as well as from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description*.

Benefit/risk balance: The National Board of Health and Welfare deems that the expected benefits of these measures outweigh their risks and that the need for the measures is great. The patient safety aspect is the overriding reason for a strong recommendation.

Diagnostics

The diagnostic evaluation focuses on the young person's gender identity, how the gender incongruence has developed over time and how it affects the person's health and quality of life. Diagnosis is made and coded according to criteria in the DSM and ICD systems (See *Introduction*).

Examples of instruments that may be used as a basis for discussion or to support the assessments in other ways are:

- Gender Congruence and Life Satisfaction Scale (GCLS) [58]
- Transgender Congruence Scale (TCS) [59]
- Utrecht Gender Dysphoria Scale-Gender Spectrum (UGDS-GS) [60]
- Genderqueer Identity Scale (GIQ) [44]
- Body Image Scale (BIS) [61].

The first four instruments in the list above were developed in recent years. Unlike several earlier instruments, they cover the full range of gender identities, i.e., not just binary gender identity (female/male). One exception is the GIQ [44] that has been developed specifically for genderqueer (including nonbinary) gender identities and is intended to support diagnostic assessment when gender-affirming treatment is being considered for this group.

This document is an unofficial English translation of a document prepared in Swedish.

When these sections were first published (March 2021), the GCLS, TCS and BIS were translated into English and are available through the Gender Dysphoria Registry.[31]

Psychosocial support for exploration

As much of a young person's life can affect both the development of identity more generally, and the development of gender identity, it is important that psychosocial support for exploration is provided as part of the evaluation.

Properly designed support enables young people to openly explore experiences, thoughts, and feelings related to identity and gender identity in a safe and validating context. The key starting points are:

- there are many gender identities and ways of expressing one's gender identity
- there are many things in life that can affect identity and gender identity
- identity and gender identity can change over time
- reflecting and trying things out in the real world is important in order to gain personal experience on which to base decisions
- attention needs to be paid both to the situation here and now, and to well-being through the life-long perspective.

The unconditional nature of the exploration means that the young person's uncertainties and doubts are also included in the discussions. This requires a good alliance with the young person, a clear understanding that this is part of the evaluation and that any doubts are not seen as negative by the evaluation team. Psychoeducational interventions are normally used during the exploration (See *Broad psycho-educational approach for the initial support* in the section *Support for young people and their families*).

In order to support the young person's own exploration of gender identity, professionals need to be supportive yet neutral, thereby minimizing the risk that their own values or expectations will influence the young person in any specific direction. If the young person has a concurrent neuropsychiatric disability, good knowledge of autism spectrum disorders and ADHD/ADD is also required for the task (See also section *Specific conditions and factors to consider*).

[31] GCLS dated 190521, translated by Dhejne C, Byström M, Görts-Öberg K & Södersten M. TCS dated 151201, translated by Södersten M, Johansson A, Beckman U, Östberg P & Dhejne C. The translations were completed according to WHO recommendations.

Recommendation on psychosocial support for exploration

> Healthcare services should provide psychosocial support for the unconditional exploration of gender identity during the evaluation of gender incongruence in children and adolescents.

Reasons for the recommendation

Background: Providing space and psychosocial support for exploration in the context of the evaluation is fundamental, as identity development and gender identity can both affect, and be related to, a young person's life. The extent to which psychoeducational interventions need to be included, and the amount of time for exploration, depend on the conditions under which the evaluation is carried out for the individual (See *Individualized evaluation* above and *Broad psycho-educational approach for the initial support* in the section *Support for young people and their families*).

The expected benefit (purpose) of the measures is to allow the young person to reflect on what may have influenced the gender incongruence in their own case and what may influence it in the future, and thus to define their gender identity on a broader basis. From a healthcare perspective, research is necessary to obtain diagnostic certainty and to provide healthcare interventions that also will be beneficial for the young person in the longer term. In the longer term, the purpose is to give young people themselves, guardians, and the evaluation team confidence in the results of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks of the measures are that young people who do not feel they need exploratory talks may feel questioned and mistrusted. These risks can be mitigated by the professional clarifying the purpose of the measures, the neutrality of the investigative team in relation to the outcome, and the fact that the measures do not constitute questioning the young person's gender identity or experiences. Information about the experiences of the evaluation team and the fact that adolescents' gender identity and wishes for treatment sometimes change during the course of the evaluation can provide freedom in the exploration and prevent adolescents from feeling locked into what they have previously thought, felt, and verbalized. Furthermore, professionals need to be supportive and neutral, minimizing the risk of their own values or expectations influencing the young person in any direction. Attempting to change the young person's perception of their gender identity with so-

called conversion therapy is currently considered unethical [30] and, according to an American study [62] may contribute to poor mental health later in life.[32]

The knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence about the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge-base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems the expected benefits of the measures to outweigh their risks, and that the need for the measures is great. The patient safety aspect is an overriding reason for a strong recommendation.

Special conditions and factors to consider

Neuropsychiatric conditions

Several international literature reviews show that neuropsychiatric disability is more common among young people with gender incongruence/gender dysphoria than among young people in the general population [63-66]. National statistics from 2016-2018 also show that autism diagnoses and ADHD/ADD diagnoses are very common among people with gender dysphoria diagnosis (F64) compared to the general population [19]. Among young people aged 13-17 and registered female at birth, 15% have a concurrent autism diagnosis (vs. 1% of the population) and 19% have a concurrent ADHD diagnosis (vs. 4% of the population). Among young people in the same age group registered male at birth, 12% have an autism diagnosis (vs. 2% of the population) and 13% have ADHD/ADD-diagnoses (vs. 8% of the population).

Implications of concurrent autism spectrum disorder (ASD)

A 2018 consensus document [67] describes the collective experience of a group of international experts about young people with gender incongruence and concurrent autism spectrum disorders (ASD). The document refers to young people with ASD from puberty to age 19, who do not have severe language impairment or intellectual disability. A related publication from 2018 describes the results of in-depth interviews with young people with gender incongruence and concurrent ASD [68].

The experience of the group [67] is that concurrent ASD needs to be considered from the very beginning of the evaluation. Because there is wide variation between people

[32] A cross-sectional study by Turban et al. (2019) included 27,715 trans people. It found an association between psychological problems, suicidal thoughts and suicide attempts in adulthood, and having undergone conversion therapy in childhood.

with autism diagnoses, the evaluation team needs an ASD assessment to gain knowledge of the impact of the condition on the individual young person. This is done in order to gain a better understanding of the individual and to be able to adapt the evaluation and support measures accordingly.

Furthermore, in the group's experience [67], ASD-related ways of functioning can sometimes contribute to gender incongruence. For example, minor concerns about gender identity can sometimes lead the young person to the conclusion that complete gender-affirmative treatment is necessary.

Support interventions focusing on ASD may therefore be needed during the evaluation. If, in the course of the evaluation, it becomes clear that the young person's desire for transition has been caused by symptoms of ASD or some other concurrent condition, the team will need to assess the young person's possible need for further psychosocial support at the end of the evaluation.

Furthermore, ASD-related ways of functioning [67] can sometimes lead to the young person's gender incongruence not being taken seriously, e.g., because the person spends less or no time on their appearance to be perceived by others as a male or female, has no opinion about their name and cares less about the opinions of others more generally. The absence of such common outward signs may raise questions about the young person's credibility among parents and professionals. However, in the experience of the group [67], many such adolescents may have clear and persistent gender incongruence. In a related study [68], gender dysphoria and gender identity in 18 of 22 adolescents with concurrent ASD were unchanged at follow-up from baseline measurements; the duration of follow-up was 22 months.[33]

According to the consensus document [67], the greater complexity of the assessments in concurrent ASD means that the diagnostic evaluation usually needs to last longer and that any decisions on medical treatment need to be taken at a slower pace. The consensus document [67] also stresses that ASD should not exclude an adolescent from a diagnosis of gender dysphoria or from relevant treatment when indicated.

Implications of concurrent ADHD/ADD

No guidelines or consensus documents describing the management of co-occurring ADHD/ADD during the evaluation of young people with gender incongruence have been identified. The National Board of Health and Welfare also learned that the

[33] The researchers followed 22 adolescents aged 13–21 with gender incongruence and concurrent ASD over a 22-month period. At follow-up, 18/22 were stable in their gender identity and gender dysphoria in relation to baseline measurements. For 4/22, a change in gender identity had occurred since baseline measurement: from transfeminine to non-binary (n=2), from transfeminine to cisgender (n=1) and from non-binary to cisfeminine (n=1). The four also no longer met the DSM-5 criteria for gender dysphoria.

clinical experience of evaluation teams regarding the impact of ADHD/ADD on young people's gender incongruence is not uniform, nor is the experience regarding the need for early knowledge from the neuropsychiatric evaluation for the subsequent assessment. Therefore, until such time as this information becomes available, the National Board of Health and Welfare's assessment is that knowledge of possible ADHD/ADD is primarily needed by the evaluation team so they have a broad understanding of the young person and can tailor information and support to the individual during the course of the evaluation. In accordance with child and adolescent psychiatric practice, a neuropsychiatric assessment with ADHD/ADD issues may be initiated later in the evaluation, if deemed justified.

Recommendation on early identification of signs of autism spectrum disorder (ASD) and ADHD

> Healthcare services should, prior to or at an early stage of gender incongruence evaluation, systematically screen all children and adolescents for signs of ASD and ADHD. In cases where there are signs of ASD, neuropsychiatric assessment should be initiated.

Reasons for the recommendation

Background: Autism spectrum disorders and ADHD are more common among young people with a diagnosis of gender dysphoria than in the general population [19]. ASD and ADHD/ADD do not exclude a young person from a diagnosis of gender dysphoria or from treatment when indicated but are important to consider during the diagnostic evaluation. When signs of ASD are present and have not been previously assessed, a neuropsychiatric assessment needs to be conducted either by the evaluation team if the expertise is available, or by referral.

The expected benefit (purpose) of the measures related to ASD is to allow for possible concurrent ASD to be taken into account during the evaluation of gender incongruence in young people, as information and support need to be tailored to the individual during the evaluation. Because ASD-related ways of functioning can sometimes contribute to gender incongruence, and as there is a wide variability between people with autism diagnoses, the evaluation team needs to gain knowledge from the neuropsychiatric assessment of how the condition affects the individual young person early [in the process]. This is to gain a better understanding of the person and to be able to adapt the assessment and support interventions to the young person's circumstances and needs. In the longer term, the purpose is to give the young person people themselves, guardians, and the evaluation team confidence in the results of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks are that the measures may create anxiety among young people that gender incongruence is not taken seriously and feelings of suspicion among young people and their families. Experiences of not having been taken seriously by the health care system in the past can sometimes have an impact, e.g., for young people who have been refused a referral for an evaluation. Risks can be reduced by having the assessment team establish an alliance with the young people and their guardians, clarifying what concurrent ASD/ADHD/ADD means and that it is relatively common for them to coexist, and [explain] the purpose of the interventions. Another significant risk is that long evaluation times can be psychologically stressful for young people. Collaboration with other health care providers involved, e.g., for the evaluation and treatment of co-occurring conditions, needs to be efficient so that the evaluation is not delayed.

Knowledge base: The knowledge about expected benefits and risks consists of experience-based knowledge, gathered partly from an international consensus document [67], and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. (See separate appendix *Knowledge base with methods description)*.

Benefit/risk balance: The National Board of Health and Welfare deems the expected benefits of the measures to outweigh their risks and that the need for the measures is great. Patient safety is an overriding reason for the strong recommendation.

Psychiatric conditions

A 2016-2018 survey by the National Board of Health and Welfare shows that psychiatric conditions are common among young people with a diagnosis of gender dysphoria (F64) and significantly more common than among young people in the general population. Among young people aged 13-17 and registered female at birth, 29% have a depression diagnosis, 32 percent had an anxiety diagnosis and 8 percent engaged in self-harm, including suicide attempts (compared to 3, 4 and 1 percent [respectively] in the same age group in the general population) [19]. Among young people aged 13-17 years and registered male at birth, 14% have a depression diagnosis, 21% an anxiety diagnosis, and 4% engaged in self-harm, including suicide attempts (compared to 1%, 2% and 0.5%, [respectively] in the same age group in the general population). Past trauma and eating disorders are also relatively common in the experience of the participating experts, and important to identify and consider during the evaluation.

The psychiatric conditions may:

- be a consequence of gender incongruence (gender dysphoria)
- be distinct from gender incongruence or gender dysphoria. In these cases, if the problems are not identified or remain untreated, they cause distress to the young person and may also complicate the diagnostic evaluation. It is

therefore important to pay attention to psychiatric conditions, self-harm, and suicidal tendencies and to offer adequate treatment when necessary. When treatment is provided by a healthcare provider other than the evaluating unit, it is important to offer guidance to practitioners who lack knowledge of gender incongruence [30].

- be a consequence of the vulnerability and discrimination that people who deviate from societal norms may experience (See *Minority stress and protective factors*, section *Support for young people and their families*). Psychosocial support that promotes the young person's resilience, self-esteem, and skills can therefore contribute to reducing poor mental health.
- in some cases, need to be considered continuously throughout the course of the evaluation. For the young person to have the courage to disclose sensitive information, such as sexual abuse, often requires more time and establishment of trust by the evaluation team.

Recommendations on identifying and reducing poor mental health

Healthcare services should:

- Systematically identify and assess any potential concurrent psychiatric conditions before or at an early stage of the evaluation of gender incongruence in all children and adolescents.
- Offer psychosocial support and psychiatric treatment to reduce potential poor mental health throughout the course of the evaluation of gender incongruence in children and adolescents.

Reasons for the recommendations

Background: There is a high co-occurrence of psychiatric conditions among young people with gender incongruence/gender dysphoria compared to young people in the general population. These may be unrelated to gender incongruence, a consequence of gender incongruence and/or a consequence of minority stress.

The expected benefit (purpose) of the measures is to be able to take into account any psychiatric conditions during the evaluation and to offer adequate help when they are present. The possibility that a concurrent psychiatric condition contributes to the gender incongruence for an individual needs to be considered, and if so, how this affects the evaluation. In the longer term, the primary aim of interventions is to give the young people, the caregivers, and the evaluation team confidence in the outcome of the evaluation. Otherwise, potential decisions on gender-affirming treatments otherwise risk being made on the wrong basis.

Possible risks of the "identify and assess" measure are that it may create anxiety and feelings of suspicion among children and adolescents and their families. Risks can be reduced by the evaluation team establishing an alliance with the young person and with guardians, making clear the relative prevalence of co-occurring psychiatric conditions, and the purpose of the measures. For the measures "psychosocial support and psychiatric treatment" no clear risks have been identified, provided that the professional has sufficient knowledge about gender incongruence for the task, or there is a possibility of supervision, if it is lacking.

Knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description*.

Benefit/risk balance: The National Board of Health and Welfare assesses that the expected benefits of these measures outweigh their risks and that the need for the measures is great. Patient safety is an overriding reason for a strong recommendation.

Psychosocial aggravating factors

The evaluation includes consideration of whether there are any psychosocial factors that may hinder further evaluation or any gender-affirming treatment, and if so, which support measures are appropriate. These [factors] may include, for example, a lack of support from guardians, or a long absence from school and a lack of other social contexts that limit young people's opportunities for exploration. In these and similar situations, the evaluation team will need to consider what support is appropriate and whether liaison with schools, other care providers or social services should be initiated.

Recommendation to assess the psychosocial situation

> Healthcare services should assess the psychosocial situation of the child or adolescent, including strengths and weaknesses in family functioning, support from guardians, the school situation and peer relationships, at an early stage of the gender incongruence evaluation.

Reasons for the recommendation

Background: When there are problems in the young person's or family's psychosocial situation, support measures may need to be initiated by the evaluation team, or in collaboration with entities such as schools, health care providers, and social services.

This document is an unofficial English translation of a document prepared in Swedish.

The expected benefit (purpose) is to assess how psychosocial factors affect the young person's ability to explore and access gender-affirming care, if deemed indicated, and to initiate support interventions if needed. In the longer term, the purpose of these measures is to give the young people themselves, the guardians, and the evaluation team confidence in the results of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks are that the assessment may create anxiety and feelings of mistrust among young people and their families, and that a prolonged period of evaluation when support is needed may place a significant strain on the young person. These risks can be reduced by clarifying the purpose of the measures and by offering psychosocial support where necessary. Collaboration with other health care providers involved, e.g., for the evaluation and treatment of co-occurring conditions, needs to be efficient so that the evaluation is not delayed.

The knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems the expected benefits of the measures to outweigh their risks and that the need for the measures is great. Patient safety is an overriding reason for a strong recommendation.

Consider the need for external psychosocial support

It is common for the members of the evaluation team to have dual roles; they are expected both to investigate the person's gender incongruence, and to provide psychosocial support. The advantage of such an arrangement of roles is that the person providing support or counselling knows the young person and has specialist-level expertise in the area.

The disadvantage is that individuals may feel scrutinized in situations where they are primarily opening up to receive support. Young people may also feel hesitant to talk about sensitive issues because they are unsure whether the information will reach their guardians. An important part of building trust is informing the young person whether guardians have the right to know, or will be informed of, what the young person tells caregivers in one-to-one conversations.

Recommendation on external psychosocial support

During the evaluation of gender incongruence, healthcare services should monitor whether children and adolescents are able to access the psychosocial support offered by the evaluation team, and whether they feel it is adequate. If necessary, healthcare services should offer children and adolescents appropriate support or treatment contact outside the evaluation team.

Reasons for the recommendation

Background: The dilemma of the evaluation team's dual role of both investigating the young person's gender incongruence and providing psychosocial support can often be countered with a good alliance and information. If, in the case of an individual young person, it is deemed impossible to offer psychosocial support from within the investigative team in a manner in which the young person feels free from judgement, the healthcare service should instead offer it in a separate unit that can interact with the investigative team.

The expected benefit (purpose) is that all young people should have the space to explore their gender identity and related aspects without feeling judged. In the longer term, the purpose of these measures is to give the young people themselves, the guardians, and the evaluation team confidence in the results of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks: No clear risks have been identified, provided that the professional has sufficient knowledge of gender incongruence for the task or there is a possibility of supervision, if it is lacking.

Knowledge of the expected benefit/risk is experience-based knowledge, gathered from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems the expected benefits of the measures to outweigh their risks and that the need for the measures is great. Patient safety is an overriding reason for a strong recommendation.

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Maturity assessment

As children grow older and more mature, more consideration should be given to their wishes.[34] In order to be able to consider treatment options and give consent for a healthcare intervention, children must be able to understand the information provided and consider the consequences of their decision.[35]

One of the prerequisites for offering gender-affirming hormone therapy to an adolescent [is] that the person demonstrates mental maturity and an understanding of the outcomes that can be expected from gender-affirming hormone therapy, as well as the medical and social risks of the treatment (See also *Hormonal Treatment for Gender Dysphoria in Adolescents*).

Before deciding on gender-affirming hormone treatment, the healthcare service needs to carry out a maturity assessment. The publication *Assessing children's maturity for participation - Guidelines for social services, the health service and dental services* [69] describes physical, cognitive, and socio-emotional aspects of children's and adolescents' maturity, with executive function of particular importance for the ability to plan, assess risks, and consider consequences. At the population level, there are strong correlations between chronological age and maturity level, but there is considerable variation between individuals of the same age.

Continuous sensitivity to the child's abilities and experiences is of central importance when assessing the young person's maturity [69]. The various parts of the evaluation and interviews with the young person usually provide a sufficient basis for the assessment. If, for any reason, an in-depth examination of cognitive, emotional, or social aspects is justified for an individual, it should be carried out.

Internationally, there are assessment instruments that are specifically designed to support healthcare providers in assessing when adults' decision-making ability may be impaired [70]. Most of the instruments include assessment of the four abilities described by Appelbaum and Roth in 1982 as necessary for giving informed consent to participate in research [71]. These include the ability to understand information about the condition and about treatment options, the ability to recognize how the information applies to one's own situation, the ability to reason logically based on the information and arrive at a position, and the ability to express one's position. A manual describing how clinicians can structure assessment of a patient's decision-making ability when deciding on medical treatment is available in English [72]. This approach could also be considered for the conduct of adolescent maturity

[34] Chapter 6, Section 11 of the Parental Code (FB) and Chapter 4, Section 3 of the Patients Act.

[35] See prop. 2013/14:106 p. 119

assessments, in order to provide structure to the assessments and facilitate discussions within the evaluation team.

Recommendation to consider psychological dimensions

> Healthcare services should consider, and if necessary examine, psychological dimensions such as cognitive, emotional and social abilities of the child or adolescent when investigating gender inequality.

Reasons for the recommendation

Background: According to the National Board of Health and Welfare's 2015 guidelines, gender-affirming hormone therapy can be offered to an adolescent if it is indicated and otherwise appropriate based on the adolescent's situation and circumstances. An additional prerequisite is that the individual demonstrates mental maturity and an understanding of the results that can be expected from the treatment, as well as of its possible medical and social risks.

The expected benefit (purpose) of these measures is that the information on which the maturity assessment of an adolescent is based should be sufficient. In the longer term, the aim is that the young person, the guardians, and the evaluation team should feel comfortable with a possible decision about gender-affirming hormone therapy.

Possible risks of the measures are that they may create anxiety and feelings of suspicion among children, adolescents, and their families. These risks can be reduced by the evaluation team clarifying the purpose of the measure.

Knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems that the expected benefits of the measures outweigh their risks and that the need for the measures is great. Patient safety is an overriding reason for a strong recommendation.

The latter part of the evaluation

After the preliminary assessment, some young people may need further exploration through social transition and the need for assistive devices.

This document is an unofficial English translation of a document prepared in Swedish.

Trying to live in your gender identity

Some young people are already living socially in accordance with their gender identities when the evaluation starts. For others, living in accordance with their gender identities may become part of further exploration, or later in preparation for gender-affirming treatment, depending on the preliminary assessment during the evaluation.[36] Trying to live in accordance with one's gender identity in preparation for gender affirmation treatment serves two main functions:

- It allows the person to explore what it is like to live in accordance with their gender identity and whether this corresponds to their expectations.
- This makes it easier for the health care staff to support the person optimally in a gender-affirming treatment process, based on the person's conditions, needs, and wishes.

The advantage of a person living in a social role consistent with their gender identity for a longer continuous period is that the person has many different opportunities to experience and adapt socially to the change. The social and psychological aspects of gender-affirming treatment can be more challenging than the physical aspects. Such a period also provides the best possible conditions for making sound decisions about gender-affirming treatment.

Minority stress can increase in the context of social transition, leading to an increased need for support measures. It is sometimes not possible or appropriate to socially transition, e.g., when the young person is at significant risk of exposure, bullying and violence from their environment. In situations like these, the evaluation team needs to consider a number of factors regarding how best to help the young person.

As with care in general, a prerequisite for the recommended action on counseling and support in matters of social transition is that there is access to health care staff with the appropriate competence. See also *Competences for evaluation*, section *Evaluation of gender incongruence in children and adolescents.*

[36] This has implications for anyone applying for a change of legal gender after age 18. According to section 1(2) of the act on the determination of gender identity in certain cases (1972:119), the "gender identity act," the person must have behaved in accordance with his or her gender identity for some time, i.e., have lived in accordance with his or her gender identity in everyday life for an extended period, usually at least one year (see prop. 2011/12:142 p. 33). It has been proposed to remove the requirement that the person has behaved in accordance with their gender identity for a period of time (see Draft proposal - Certain surgical procedures on the genital organs and change of sex as recorded in the population register 2021/07285).

Recommendation on advice and support on social transition issues

> Children and adolescents with gender incongruence or gender dysphoria who are considering social transition or who have already started to live in accordance with their gender identities in social contexts should be offered counselling and support by the healthcare services.

Reasons for the recommendation

Background: Some young people already live in accordance with their gender identity when the evaluation starts. Others try it during the latter part of the evaluation as part of continued exploration of their gender identity. If gender-affirming treatment is being considered, this may be carried out in preparation over a longer continuous period. It is often gradual, with the person coming out to an increasingly wider circle, and eventually consistently behaving in accordance with the desired gender identity at home, school, and in all other social contexts.

The expected benefit (purpose) of the measures is to provide adolescents with support when planning how to proceed and what to do if they later decide not to proceed, and to deal with the social and psychological challenges that arise in the meantime. In the longer term, the purpose is to give the young people themselves, the guardians, and the evaluation team confidence in the results of the evaluation. Otherwise, potential decisions on gender-affirming treatments risk being made on the wrong basis.

Possible risks: No clear risks have been identified with these measures, assuming that the professional has the required competence.

Knowledge about expected benefits and risks is based on experience, gathered partly from an international consensus document [30] and partly from the experts who participated in the development of the guidelines. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems the expected benefits of the measures to outweigh their risks and that the need for the measures is great.

Assistive Devices (Aids)

The fact that the body reflects the sex registered at birth can make it difficult for an adolescent to "pass" during a social transition, i.e., to be perceived by others in accordance with their gender identity. This is often emotionally stressful and may

ultimately make it impossible for an adolescent to try to live in accordance with their gender identity during the evaluation. It is important that the adolescent's needs for assistive devices or aids are assessed and that the authorities offer aids that enable the adolescent to try to live in accordance with their gender identity.

Recommendation on assistive devices

> Following an individual assessment, but no sooner than the preliminary diagnosis of gender dysphoria is made, healthcare services should provide adolescents with aids to facilitate their living in the social role that corresponds to their gender identity.

Reasons for the recommendation

Background: The fact that the body reflects the gender registered at birth can make it difficult for an adolescent to be perceived by others in accordance with their gender identity. Aids that can help include bindings used to hide the breasts or penis, wigs, breast prostheses and various types of penile prostheses.

The expected benefit (purpose) of the measures is to facilitate adolescents who want to live in accordance with their gender identity, and to contribute to an increased quality of life for the individual.

Possible risks: One possible risk is that the measures, if offered too early in the education process, may risk entrenching a gender identity that is not grounded in the individual. This risk can be mitigated by offering aids after a preliminary diagnosis of gender dysphoria at the earliest, and after an individual assessment. The assessment team also needs to alert the adolescent to the fact that regular binding of breasts and penis can have negative physical consequences and help to prevent these consequences should the adolescent choose to use these devices.

The knowledge about expected benefits and risks is based on experience, gathered from the experts who participated in the guidelines work and publications describing young people's experiences of using aids (i.e., binders) [73, 74]. The National Board of Health and Welfare concludes that the scientific evidence on the expected benefits and risks of the measures is likely to be insufficient. See separate appendix *Knowledge base with methods description.*

Benefit/risk balance: The National Board of Health and Welfare deems that the expected benefits of these measures outweigh their risks and that the need for the measures is great.

Hormonal treatment for gender dysphoria in adolescents

This section includes updated recommendations about treatment with gonadotropin-releasing hormone analogue (GnRHa) and gender-affirming hormone treatment, as well as decision support to guide treatment decisions.

Content and extent

This section focuses on fundamental aspects and ethical considerations. For medical issues, reference is made to consensus-based guidelines for endocrine treatment of gender incongruence in adolescents [55]. This refers to issues of evaluation of physical health, testing, preparations and dosing, monitoring, and transition to adult care. Other hormonal treatments such as progestins (low and moderate dosages) and combined contraceptive pills are mentioned but not described in detail.

Basic conditions for hormonal treatment

The National Board of Health and Welfare's assessment is that both GnRH analogue treatment and gender-affirming hormone therapy may be offered under certain basic conditions, which are described in more detail below. Conditions (criteria) specific to each treatment are then described in connection with the specific recommendation.

In the context of research

The National Board of Health and Welfare's assessment is that treatment with GnRH analogues and sex hormones for adolescents with gender dysphoria should be provided within the framework of research. Until a research study with ethically tested inclusion and treatment criteria is in place, the National Board of Health and Welfare's assessment is that the treatment can be provided in accordance with the updated recommendations and criteria in the guidelines. In terms of the research questions that need to be answered, the National Board of Health and Welfare refers to the knowledge gaps for the area of care listed in the SBU database. For more information, see *New recommendations for hormonal treatment - basis and consequences.*

Thorough diagnostic evaluation

Recommendations for conducting the child psychiatric and diagnostic assessment are described in the section *Evaluation of gender incongruence in children and adolescents*. The evaluation places stringent requirements on the psychiatric,

psychological, and psychosocial assessments, and must be tailored to the medical, psychological, and social circumstances of the adolescent.

Multidisciplinary assessment

The decision to initiate GnRH analogue or gender-affirming hormone therapy must be based on a balanced multidisciplinary assessment that considers the adolescent's whole situation. At a minimum, the decision needs to be taken jointly by the multidisciplinary team responsible for the child psychiatric and diagnostic assessment and the pediatric endocrinologist responsible for physical health considerations (For further information, see *Evaluation of gender incongruence in children and adolescents*).

Support and consent from guardians

Legal clarifications of children's right to self-determination and the responsibility of guardians are provided in the National Board of Health and Welfare's bulletin, *Children seeking health care*, number 8/2020. As a starting point, it is the guardian who has the right and obligation to decide on matters of health care for the child. However, as the child grows older and more mature, the child's wishes must increasingly be taken into account. A child may be considered mature enough to decide alone on his or her own about specific care or treatment if he or she can assimilate the relevant information and understand the consequences of the decision. However, considerable maturity is required for a child to be able to contemplate more extensive treatments and interventions.[37]

According to the Gender Dysphoria Registry's 2020 annual report, a consensus between the adolescent, guardians, and health care providers is a prerequisite for offering treatment with GnRH analogue and/or gender-affirming hormone treatment [75]. This treatment should be viewed in the light of the pervasive and lifelong consequences of treatment for the individual.

The support and involvement of guardians is also important for adherence to treatment and for the overall psychosocial situation of the adolescent.

Information that enables an informed decision

Health care providers should seek to achieve the best possible shared understanding with the patient on important issues of care and treatment. A prerequisite for this is that the patient is well informed about his or her health condition and the different

[37] Cf. prop. 2013/14:106 p. 119

treatment options that may be available based on the patient's life situation and personal circumstances.[38]

Legal provisions in the healthcare system's obligation to provide information are set out in Section 3 of the Patient Act. When the patient is a child, the child's guardian must also be informed.[39] The preparatory work for the Patient Act states that in order to be able to make an informed decision, one of the requirements is that the patient should receive scientifically based information about the advantages and disadvantages of the various treatment options for the condition in question. Furthermore, it states in situations where the patient's treatment regimen includes the possibility of waiting before initiating interventions, the patient must also be informed about this, along with the possible consequences of a decision to wait. This information should be provided as early as possible in the care process.[40]

There is no section in health legislation that explicitly states that health care has an obligation to also provide information about the uncertainties and gaps in the knowledge base. However, such information is considered necessary from an ethical and moral perspective, to enable patients and caregivers to make informed decisions [16]. Such information can also be considered consistent with the legal requirements of objectivity and impartiality in public administration.[41]

The responsible pediatric endocrinologist should provide information about the treatment to the child and guardians early in the diagnostic evaluation and then repeatedly, based on the needs that arise as the evaluation progresses (See also *Evaluation of gender incongruence in children and adolescents*).

Assessment of expected benefit-risk for individual

For each individual adolescent, the expected benefits of the treatment in question need to have been made clear, and the benefits must be assessed to outweigh the risks. The expected benefits and risks of not providing the treatment also need to have been made clear and considered [16]. When healthcare is provided to children, the best interests of the child must be carefully considered (Section 1, Section 8 of the Patient Act).[42]

The provision of GnRH analogues to adolescents with gender dysphoria under certain conditions is a practice that has emerged in the Netherlands in recent decades.

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[38] Prop. 2013/14:106 p. 72.

[39] Chapter 3, Section 3 of the Patient Act.

[40] Prop. 2013/14:106 p. 48.

[41] See Chapter 1, Section 9 of the Instrument of Government (RF) and Section 5 of the Administrative Procedure Act (2017:900).

[42] See further the section on the <Child rights perspective> in the <Introduction> chapter.

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Important cornerstones in the development of the "Dutch protocol" have been the clear distress of some adolescents at the onset of puberty and the observation that gender dysphoria was rarely amenable to psychotherapy for these adolescents [76-78]. The importance of applying caution when treating with GnRH analogues is reflected, among other things, in the criteria that the gender incongruence should have started in childhood, persisted until puberty, and that the onset of puberty should have caused clear distress [5, 79].

According to literature reviews by SBU and NICE [2, 80, 81], it is currently not possible to draw firm conclusions about the efficacy and safety of GnRH analogue and gender-affirming hormone therapy for adolescents with gender dysphoria (See separate appendix *Knowledge base with methods description*).

The expected benefits and possible risks of the treatments are described in the following sections.

Treatment with GnRH analogue

Treatment with gonadotropin-releasing hormone analogues has been used since the early 1980s to slow puberty in children with *central precocious puberty* (CPP), i.e., pubertal development that starts before 8 years of age in girls and before 9 years of age in boys. GnRH analogue is also used in various conditions that inhibit growth during adolescence, and in gender dysphoria in adolescents [82].

Endogenous puberty in boys and girls is well described in the literature, including by Nordic research groups, in terms of the gradual increase in sex hormone levels and the timing of these changes [83-93]. Pubertal development is usually considered to have ended when the person reaches their final height. Continued masculinization and feminization of the body occurs for several years after puberty.

Expected benefit of the treatment

Treatment with a GnRH analogue for gender dysphoria is primarily aimed at lowering the distress associated with the development of puberty and reducing the risk of poor mental health. The goal of treatment is to prevent the body from physically developing in a direction that is not consistent with gender identity. If treatment is initiated in early puberty, it also reduces the risk of developing (more or less irreversible) sexual characteristics that are difficult to change or eliminate later in life such as voice pitch, height, hips, jaw and face features and facial hair. In this way, the aim is also to make it easier for the person to be perceived in accordance with their gender identity by the environment, and to contribute to a better quality of life. The need for subsequent hair removal, speech therapy,[xviii] and gender-affirming surgery is thus reduced.

Even in later puberty (Tanner stage 4-5), treatment aims to reduce the distress associated with endogenous development, lower the risk of poor mental health, and to inhibit further masculinization and feminization of body shapes and body composition (further growth of breasts and hips, respectively, additional body hair, roughening of features and lowering of voice, and growth of chest, feet, and hands). Another purpose in later puberty is to reduce the emotional stress that often accompanies erections and menstruation.

Finally, the treatment aims to reduce distress that may facilitate further exploration of gender identity during the course of the evaluation, and thus also has a diagnostic purpose.

Possible side effects and risks of the treatment

In both early and late puberty, weight gain is a common side effect of GnRH analogue. For adolescents who are already severely overweight, treatment may further increase the risk of future health problems and worsen the prospects for possible future gender-affirming surgery (see *Physical health consideration* below).

Withdrawal symptoms such as hot flashes can occur if levels of sex hormone are high enough when treatment with GnRHa is started and are relatively common among adolescents in late puberty. Decreased energy levels and low mood may occur [94]. Decreased sex drive may be noticed when treatment is started after completed puberty.

Available treatment studies and clinical experience suggest that menstruation in girls treated with CPP returns on average one year after treatment ends, but it may take as long as two years. Longer time to menstruation at discontinuation or after completion of treatment can be expected if treatment is started before menarche has occurred [95]. The few, small studies of boys with CPP suggest that testosterone levels and testicular volume are recovered one year after completion of treatment, and that full pubertal development may be reached by late teenage years [96]. These findings are also consistent with sperm recovery in studies of "contraceptive pills for men" in which GnRH analogues were used in combination with high (supraphysiological) doses of testosterone [97].

For young people treated with GnRH analogues in early puberty, there are clear difficulties in offering fertility preservation, especially for young people registered female at birth who have not yet had menarche [98-100]. For young people in early puberty and those registered male at birth, reportedly there are experience-based difficulties producing semen samples for freezing. Descriptions related to fertility preservation are given in the section *Sexual and reproductive health*.

Absence of sex hormones over a long period of time can lead to a risk of reduced bone mineralization and, in the long run, increased risks of osteoporosis and bone fracture in adulthood. No certain conclusions about the risks can be drawn at this

stage from the existing scientific evidence (See the separate appendix *Knowledge base with methods description*).

The extent to which height growth is affected has not yet been studied systematically and is largely dependent on the physical development of the adolescent. If treatment is started early in the development of puberty then remaining height growth will be delayed. Final height is only reached when sex hormone levels have been sufficiently high for a sufficiently long time, and the growth zones are closed. This can be positive or negative for the adolescent and must be considered on an individual basis.

The absence of sex hormones over a long period of time can lead to a risk of negative effects on cognitive development. No certain conclusions about the risk can be drawn from existing scientific evidence (See the separate appendix *Knowledge base with methods description*).

Delayed puberty in gender dysphoria causes the adolescent to be physically and psychologically out of sync with his or her peers.

When treatment is started in early puberty, it results in stunted penile growth, and the growth of the scrotum decreases. Any vaginal construction in adulthood may therefore need to be carried out using methods other than what is currently considered the "gold standard" (constructing a vagina using only skin from the penis).

Finally, if the adolescent does not go through puberty, there is a possible risk that treatment with GnRH analogues may consolidate a gender incongruence that could have proven to be transient over time [31].

Recommendation

Treatment with GnRH analogues for adolescents with gender dysphoria should be provided in the context of research. Until a research study with ethics board approved inclusion and treatment criteria is in place, it is the National Board of Health and Welfare's assessment that treatment with GnRH analogue may be given in exceptional cases, in accordance with the updated criteria in the medical guidelines.

Reasons for the recommendation

At present, no certain conclusions can be drawn about the efficacy and safety of this treatment for young people with gender dysphoria based on existing scientific evidence. There is a small number of studies and most have small numbers of participants and lack comparison groups. For further information, see separate appendix *Knowledge base with methods description*.

For population of adolescents with gender dysphoria as a whole, the National Board of Health and Welfare currently concludes that the risks of treatment with a GnRH analogue are likely to outweigh the benefits of treatment. The basis for this assessment is presented in the section *New recommendations for hormonal treatment - basis and consequences*. The basis for the recommendation to provide treatment with GnRH analogues in the context of research is also presented in the section *New recommendations for hormonal treatment - basis and consequences*.

The basis for the criteria in the guidelines for young people who have reached Tanner stage 3 is experience-based knowledge documented in scientific publications of the "Dutch protocol" [5, 7, 79, 101], the clinical experience of the participating experts and ethical considerations.

The basis for excluding young people in Tanner stage 2 in the recommendation, who are covered under the "Dutch protocol", is the assessment of the participating experts that the adolescent needs time to be exposed to endogenous puberty before starting treatment, which is in line with ethical considerations.

The criteria used in the guidelines for young people who have reached Tanner stage 4-5 are based on the experience of the participating experts.

For information about how experience-based knowledge was gathered and otherwise implemented, see the separate appendix *Knowledge base with methods description*.

Decision support - guidance on treatment decisions

Criteria to consider for adolescent in Tanner Stage 3

- Basic conditions of thorough diagnostic evaluation, multidisciplinary decision-making, consent from guardians, provision of information, and expected benefit/risk assessment are met.
- The adolescent has a stable psychosocial situation and there are no factors that obscure the certainty of the clinical assessments (neuropsychiatric or intellectual disability, untreated psychiatric problems including suicidal risk and trauma, substance use).
- Gender incongruence has existed since childhood and gender identity has remained stable over time.[43] There is a lack of evidence about how long gender incongruence should have existed; a UK publication from 2021 has set the limit at a minimum of 5 years [102].
- The onset and progression of puberty has brought clear suffering.
- DSM-5 diagnostic criteria for gender dysphoria (302.85) are met.

[43] The Dutch protocol was developed for young people with binary (“cross-gender”) gender identities.

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- The adolescent should be between 12 and 15 years old. In a Dutch publication reflecting the "Dutch protocol", treatment with GnRH-analogue was started on average at 14.75 years of age (SD=1.92, range 11.3-18.6) [103]. During the guidelines update process, comments were received both that 12 years is too low a cut-off, and that treatment with extended follow-up may in exceptional cases be justified before the age of 12.

Criteria to consider for adolescents in Tanner stage 4-5

Treatment with GnRH analogue for adolescents whose gender incongruence or gender dysphoria does not appear in childhood but only at puberty is not described in publications of the "Dutch protocol." In the experience of the participating experts, the treatment can in some cases be deemed to be of great benefit, particularly for young people registered male at birth whose masculinization in later puberty makes it very difficult to pass as an adult.

In Sweden, for young people registered female at birth, progestins (low and moderate dosages) and combined contraceptive pills have in recent years become a first-line choice over GnRH analogues.

If treatment with GnRH analogue is offered at Tanner stage 4-5 as described above, then

- the basic prerequisites of thorough diagnostic evaluation, multidisciplinary decision-making, consent from guardians, provision of information, and expected benefit/risk assessment have been met
- DSM-5 diagnostic criteria for gender dysphoria (302.85) are met
- the adolescent, for ethical reasons, must have a stable psychosocial situation and there are no factors that obscure the certainty of the clinical assessments (neuropsychiatric or intellectual disability, untreated psychiatric problems including suicidal risk and trauma, substance use).

Criteria relating to the process

- Treatment with GnRH analogue requires that psychosocial support enabling open exploration of gender identity is provided in parallel. For further information, see sections *Support for young people and their families* and *Evaluation of young people with gender incongruence*.
- Treatment with GnRH analogue is initiated for a limited time. There is no evidence to indicate the maximum duration of treatment. A maximum period of 2-3 years has been mentioned during the update process.
- Adolescents and guardians have been informed about the possibilities, limitations, and uncertainties of fertility preservation measures, as well as about different gender-affirming treatments.
- Growth rate and expected final height are monitored during treatment, and follow-up is otherwise adjusted based on physical health considerations.

- Adolescents and guardians understand that adolescents sometimes choose to discontinue treatment (e.g., because their gender identity changes or because of side effects), that healthcare services sometimes deem that treatment must be discontinued (e.g., if absolute bone density decreases during treatment), and that treatment is not a promise of gender-affirming hormone treatment.

Physical health considerations and possible contraindications

- physical disease with risk of osteoporosis (DXA measurement before starting treatment, consultation with treating physician)
- ongoing cortisone treatment (assessment based on indication, dose, and duration of treatment, DXA measurement before starting treatment, consultation with treating physician)
- being severely overweight (watchful waiting, guidance on dietary habits and support for weight loss is provided as early as possible in the contact)
- other physical disease and ongoing treatments, e.g., malignant disease, catabolic conditions with significant loss of muscle mass (watchful waiting until the condition is stabilized consultation with treating physician).

Gender-affirming hormone treatment

Gender-affirming hormone treatment involves the administration of sex hormones to develop secondary sex characteristics in a feminizing direction (for those registered male at birth), or in a masculinizing direction (for those registered female at birth). When administered to adolescents with gender dysphoria who have not undergone full pubertal development due to previous puberty-suppressing treatment, gender-affirming hormone treatment is intended to induce pubertal development in accordance with one's gender identity. Hormone replacement with estrogen or testosterone often continues for life.

The treatment regimen differs for adolescents vs adults with gender dysphoria [55]. For adults, treatment starts at the full doses of testosterone and estrogen, respectively, while adolescents start treatment at lower doses that are gradually increased. As the dose of the cross-sex hormone is increased, GnRH analogue may be given in parallel to block the endogenous sex hormone.

Adults registered male at birth will continue to need medicines that inhibit the secretion of sex hormones by the congenital gonads, as long as the testicles are not surgically removed. Such "testosterone blockade" for adults is usually achieved with an anti-androgen drug. Adults registered female at birth do not usually need a similar drug in the future, as testosterone itself is often an effective block to estrogen production.

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Expected benefit of the treatment

The aim of gender-affirming hormone treatment is to change the body to better reflect the person's gender identity, thereby reducing gender dysphoria and improving quality of life. The effects of treatment are dose-dependent and vary from person to person [104]. For adolescents registered female at birth, the following physical effects of testosterone treatment are expected [105]:

- lowered voice
- increased facial and body hair
- loss of ovulation and menstruation
- reduced breast tissue
- enlarged clitoris
- increased muscle mass
- reduced proportion of subcutaneous and body fat.

Androgenic alopecia (hair loss) can occur after long-term treatment with testosterone [104]. The androgenic effects on voice, facial and body hair become permanent after approximately six and 12 months of treatment, respectively [104]. Any effects on jaw, height and body proportions are irreversible, with the degree of effect depending, among other things, on the physical development of the adolescent at the start of treatment.

For adolescents registered male at birth, the following physical effects of estrogen treatment are expected [105]:

- breast growth
- reduced erectile function and sexual desire
- reduced testicle size and sperm production
- softer skin
- reduced (not eliminated) facial and body hair
- redistribution of body fat and increased ratio of body fat to muscle mass.

It takes about two years before maximum breast growth is achieved [104]. If treatment is stopped, some breast growth will remain permanent. Any effect on body height is irreversible, with the degree of effect depending on the physical development of the adolescent at the start of treatment.

Possible side effects and risks of the treatment

Oily skin and acne are side effects that can occur mainly during the first six months of testosterone treatment [104]. "Chafing" problems of a growing clitoris may also occur. Individuals registered male at birth may experience decreased sex drive resulting from estrogen treatment (due to the reduced testosterone levels) [105].

Gender-affirming treatment with both testosterone and estrogen has negative effects on reproductive ability. The extent of the effects and the extent to which reproductive

function can be restored if treatment is discontinued are currently unknown [105]. There is no guarantee that an adolescent undergoing fertility preservation will be able to become a genetic parent in the future either. For further information, see *Sexual and reproductive health.*

Individuals registered male at birth who are treated with estrogen are at increased risk of venous thrombosis [104, 105] (See also below on *Physical health considerations*).

Finally, there is a risk that the person may later wish to discontinue or reverse the effects of the treatment, for example because the effects were not as expected or because the person has changed their perception of their gender identity [3].

Recommendations

> Gender-affirming hormone treatment with testosterone or estrogen for adolescents with gender dysphoria should be provided in the context of research. Until a research study with ethics board approved inclusion and treatment criteria is in place, it is the National Board of Health and Welfare's assessment that gender-affirming hormone therapy can be given in exceptional cases, in accordance with the updated criteria in the guidelines.

Reasons for the recommendation

At present, no certain conclusions may be drawn about the efficacy and safety of the treatment for young people with gender dysphoria based on existing scientific evidence.

The studies are few in number, most have small numbers of participants and lack comparison groups. See further the section *Knowledge-base* in appendix 4.

For the group of adolescents with gender dysphoria as a whole, the National Board of Health and Welfare currently deems that the risks of cross-sex hormone therapy are likely to outweigh the benefits of the treatment. The basis for this assessment is presented in the section *New recommendations for hormonal treatment - basis and consequences*.

The basis for the recommendation to provide gender-affirming hormone treatment in the context of research is also presented in the section *New recommendations for hormonal treatment - basis and consequences*.

The basis for the decision support criteria is the evidence-based knowledge documented in scientific publications of the "Dutch protocol" [5, 79, 101], the clinical experience of participating experts, and ethical considerations. For information about how experience-based knowledge was obtained and

implementation in general, see the separate appendix *Knowledge base with methods description*.

Decision support - guidance on treatment decisions

Criteria to consider relating to the adolescent

- Basic prerequisites for thorough diagnostic evaluation, multidisciplinary decision, consent from guardians, provision of information, and risk/benefit assessment have been met.
- The adolescent has a stable psychosocial situation and there are no factors that obscure the certainty of the clinical assessments (neuropsychiatric or intellectual disability, untreated psychiatric problems including suicidal risk and trauma, substance use).
- Gender incongruence has existed since childhood. Gender identity has been stable over time and unchanged during treatment with GnRH-analog.[44]
- DSM-5 diagnostic criteria for gender dysphoria (302.85) are met.
- The adolescent has started to live socially in accordance with their gender identity.
- The adolescent demonstrates mental maturity, including a knowledge and understanding of the outcomes expected from gender-affirming hormone treatment, and from possible future gender-affirming surgery as well as the medical and social risks of the treatments.
- The adolescent is at least 16 years old.

Criteria relating to the process

- The adolescent and guardians are aware of the risk that reproductive capacity may be negatively affected by the treatment, and of the conditions for procurement of gametes for freezing.
- The adolescent understands that fertility preservation does not guarantee that they will be able to become a genetic parent in the future.
- Where fertility preservation measures are possible, the adolescent has been offered such measures.
- The adolescent understands the importance of adherence to treatment and that in adulthood there will be a need for continued regular contact with the endocrinologist and physical health examinations if necessary.

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[44] The Dutch protocol was developed for young people with binary ("cross-gender") gender identity. A pressing issue is to clarify the conditions under which adolescents with non-binary gender identity can be offered hormonal treatment in the context of research.

- Psychosocial support is offered when needed during treatment, for example, for changes in social interactions with the environment, or to manage mood swings and other side effects of medication. Sexual health counselling may also be needed (See the section *Sexual and reproductive health*).

Physical health considerations and possible contraindications

Some risks or medical conditions may be exacerbated by gender-affirming hormone treatment. Healthcare providers need to take these into account before starting hormone treatment. For example, for people registered male birth, it is important to consider thromboembolic risk and the risk of breast cancer before treatment with estrogen. For people registered female at birth, erythrocytosis and effects on the liver are important conditions to consider prior to testosterone treatment. For further information, see the SBU literature review (2022) on hormone therapy for adults with gender dysphoria [106].

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Surgical treatment

Unlike aesthetic plastic surgery, surgical procedures for gender dysphoria are reconstructive in nature since they are performed on medical grounds. The procedures aim to adapt the body to the individual's gender identity, reducing the psychological distress caused by gender dysphoria and helping the individual to achieve a level of functioning as comparable as possible to that of cis-persons.

In light of comments received about a draft version of this section, the National Board of Health and Welfare would like to begin by describing the work that formed the basis for the update. The 2015 guidelines on the care of children and adolescents [1] contained recommendations on five different gender-affirming surgical procedures that required consideration: mastectomy, breast augmentation with implants, reduction of the larynx, liposuction of the hip, and facial surgical procedures.[45] In preparation for the update, the National Board of Health and Welfare identified the extent to which the five procedures have been performed for gender dysphoria before age 18, their expected benefits and risks, and the scientific and experience-based knowledge available when the recommendations were revised. The results of the survey for the five interventions and the ethical evaluation that was carried out are presented in the separate appendix *Knowledge base with methods description*.

Overall ethical analysis

As with gender-affirming hormone treatment, gender-affirming surgical procedures have profound and, in some cases, lifelong consequences for the individual. Many of the uncertainties that have prompted the agency's more restrictive recommendations on hormonal treatment for underage patients also apply to a great extent to gender-affirming surgical procedures.[46] The National Board of Health and Welfare's principal conclusion when revising the evidence base is that gender-affirming surgical procedures should not be performed before the age of 18.

[45] See the chapter <*Introduction*> regarding age limits for gender affirmation treatments

[46] See the chapter <New recommendations for hormonal treatment - basis and consequences>

Ethical analysis of mastectomy and other procedures

The abovementioned survey revealed that 85 operations were performed before the age of 18 for the indication of gender dysphoria between 2004 and 2021; 84 of these are mastectomies and one was breast augmentation with implants.

Mastectomy involves the surgeon removing breast tissue to give the chest a masculine appearance. Often the surgeon also needs to adjust the size and position of the nipples.[47]

Participating experts have pointed out that the benefits of mastectomy may outweigh the risks of the procedure even in the case of a minor, particularly for those with a high level of breast-related distress and who have started gender-affirming hormone treatment with testosterone. The development of secondary sex characteristics such as beard growth and deep voice may in these cases cause difficulties in passing in accordance with the gender identity and cause additional suffering for the individual. A similar risk/benefit ratio has not been assessed for breast augmentation with implants or the other procedures included in the 2015 guidelines (See the appendix *Knowledge base with methods description*). Based on this background, the National Board of Health and Welfare has developed a recommendation and decision support for mastectomy procedures for gender dysphoria before the age of 18, but this has not been done for the other surgical procedures included in the 2015 guidelines.

Expected benefits of mastectomy

Mastectomy is often the first and sometimes only surgical procedure that people registered female at birth choose to undergo. The expected benefits of mastectomy are improved quality of life in terms of reduced personal suffering (gender dysphoria), increased ability to participate in social contexts and activities, and an increased ability to be perceived by others in accordance with one's gender identity. A qualitative study [107] found that for young trans-masculine people, breasts evoke strong negative emotions such as depression, anxiety, shame, and self-loathing. The dysphoria leads to avoidance of social contexts, can cause difficulties in carrying out daily activities such as schoolwork and makes it difficult to participate in physical exercise. The option of binding the breasts may enable participation in social contexts but is less effective in sports. Binding can also have negative physical consequences and has not been found to reduce gender dysphoria by itself [74, 107].

[47] Other indications for mastectomy are breast cancer and increased risk of breast cancer.

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Possible side effects and risks of mastectomy

Serious complications that can occur include necrosis of nipples or residual breast tissue. Aesthetic problems such as asymmetries of the chest itself or the nipples may also occur, as well as visible scars that can sometimes widen. General surgical complications such as bleeding and infection may occur.

In the experience of the participating surgeons, the risk that it will not be possible to breastfeed a child after the procedure is high, but the magnitude of the risk varies depending on the surgical method used. Nipple sensation is adversely affected by transplantation and often disappears completely.

Finally, relating to gender dysphoria, there is a risk that the person may later wish to reverse the effects of the treatment, for example because of a change in their perception of their gender identity [3], and that this is not deemed possible to prioritize or to implement properly by the health care system. The feasibility of reversing the effects of mastectomy with breast implants for an individual case can only be predicted once the mastectomy has healed and other medical factors are known. General plastic surgical considerations are that previous scarring of skin in the surgical area, poorer tissue quality, and the risk of tissue deficit together impair the chances of successful tissue expansion. Reduced and displaced nipples will usually not be able to be repositioned without a further tissue deficit, which adversely affects the shape of the breasts. All in all, this makes it very difficult to achieve a good result with implants after mastectomy with nipple grafting.

Recommendation

> Mastectomy for adolescents with gender dysphoria should be carried out within the framework of research. Until a research study with ethically tested inclusion and treatment criteria is established, the National Board of Health and Welfare's assessment is that mastectomy can be offered in exceptional cases, for adolescents who meet the updated guidelines criteria for gender-affirming hormone treatment.

Reasons for the recommendation

At present, no definitive conclusions can be drawn about the efficacy and safety of mastectomy for young people with gender dysphoria based on existing scientific studies. For further information, see *Knowledge base with methods description.*

For the population of adolescents with gender dysphoria as a whole, the National Board of Health and Welfare currently deems that the risks of mastectomy are likely

to outweigh the benefits of the procedure. The basis for this assessment is presented in the introduction to this section.

The basis for the recommendation to offer mastectomy before age 18 in the context of research is the need to improve knowledge about the outcomes of treatment. Given the new knowledge and uncertainties described in previous sections, there is also a need to ensure that all relevant information is communicated to guardians and young people, and that consent is obtained before treatment is provided.

The basis for the decision support criteria is the evidence-based knowledge documented in scientific publications of the "Dutch protocol" [5, 6, 108, 109], the clinical experience of participating experts, and ethical considerations. See the separate appendix *Knowledge-base with methods description*. The documented, step-by-step approach of the Dutch protocol - where puberty-suppressing treatment, gender-affirming hormones and surgical interventions have been offered to adolescents according to clearly described criteria and where follow-up over time is documented - represents the best available knowledge and should therefore be used.

As for testosterone treatment more generally, according to the experience of the experts involved, it has relatively little impact on the plastic surgery outcome of mastectomy. However, according to the participating experts, it cannot be excluded that a period of hormone treatment for people with small to medium-sized breasts may reduce breast volume sufficiently to allow mastectomy to be performed in a way that leaves less scarring. Another reason for waiting until the testosterone has had time to take effect is to allow the person to adjust to the changes brought about by the hormone treatment. These conditions are highly variable and the benefit of waiting needs to be weighed against the suffering caused to the individual when the effects of hormone treatment become noticeable, and the breasts are difficult to conceal.

Adolescents who meet the criteria for hormone therapy but are unable to start it for any reason also need to be offered mastectomy if the other conditions are met.

Decision support - guidance on treatment decisions

Criteria to consider relating to the adolescent

- Basic prerequisites for thorough diagnostic evaluation, multidisciplinary decision, consent from guardians, provision of information, and risk/benefit assessment have been met. Clarifications on multidisciplinary assessment and information provision specific to mastectomy are provided at the end of the section.
- The adolescent has clear suffering linked to the breasts.

- The adolescent meets the guidelines criteria for gender-affirming hormone treatment (See *Gender-affirming hormone treatment - decision support*).
- In order to prevent the remaining mammary gland from growing and requiring a secondary operation, it is desirable that breast development is completed at the time of the mastectomy.

Criteria relating to the process

- The plastic surgeon has made sure that the adolescent has understood what the procedure entails and has realistic expectations of the results. As part of this, the surgeon has shown images of post-mastectomy surgical results in which the physical conditions match those of the patient as closely as possible, and which include both good and suboptimal results.
- In accordance with general plastic surgery considerations in public health, a BMI ≤ 30 and non-smoking before the procedure is recommended, to reduce the risk of complications during the healing process and for optimal plastic surgery outcomes. When justified, weight loss and smoking cessation have been supported prior to surgery.
- If the medical history has revealed risk for heritable breast cancer, the adolescent has been informed that the risk is not completely eliminated after the procedure, and that self-examination for breast cancer can sometimes be made more difficult due to scarring. In cases of a strongly increased risk of breast cancer, an in-depth oncological assessment is needed. The mastectomy will then be more complete than is usual in cases of gender dysphoria and is performed generally in the same way as a prophylactic mastectomy for cis-women.[48]

Physical health considerations and possible contraindications

- bleeding disorders, obesity, and smoking
- ongoing pregnancy or attempt to become pregnant
- other serious illness that increases the risk of complications
- medical conditions that pose an increased risk during surgery/anesthesia.

Multidisciplinary assessment

Unlike the diagnostic and child psychiatric evaluation and the hormonal treatment of gender dysphoria, mastectomy is not included among the care measures defined as

[48] The current version of *Good Care of Adults with Gender Dysphoria* (2015) recommends general breast cancer screening only for people registered female at birth who have intact breasts (pp 80–81).

national highly specialized care, but shall remain with the regions.[49] Forms of collaboration between the national units and surgical units in the home regions need to be developed to allow multidisciplinary assessments for this intervention for both adolescents and adults with gender dysphoria—a process that to date has often been lacking, according to participating surgeons. Continuity of contact, where surgeons and teams familiarize themselves with one another's assessments, is described as crucial to building a trusting, collegial network where indications and specific patients may be discussed.

For example, private health care providers who receive a request to perform mastectomy must assess whether the desired operation is part of a gender-affirming treatment (and thus is to be considered as healthcare with the relevant regulation in HSL, PSL, PL), [xix] or whether it is desired for purely aesthetic reasons. In the latter case, the procedure is instead regulated by the act (2021:363) on aesthetic surgical procedures and aesthetic injection treatments and is then not allowed before age 18. However, even in such a case, other requirements apply, including the requirements in the HSL[xx] that the procedure must be conducted in such a way that the requirements of Good Care are met and that the PSL[xxi] apply (see §§ 5 and 6). Based on the requirement in Section 6, Section 1 PSL that healthcare personnel must perform their work in accordance with science and proven experience, and that a patient must be given expert and caring treatment that meets these requirements, it is very reasonable that private health care providers who have not examined the patient themselves consult the evaluation team in order to decide whether mastectomy should be offered as part of gender-affirming care.[50]

Information that enables an informed decision

Provisions describing the healthcare system's information obligations may be found in Section 3 of the Patient Act. The person providing the information must, to the extent possible, ensure that the recipient has understood the content and significance of the information provided (Section 3, Section 7 of the Patient Act). When the patient is a child, the child's guardians must also be informed.[51] See also the corresponding text section in the section on *Hormonal treatment for gender dysphoria in adolescents*.

The adolescent needs to be informed about the operation with sufficient time to be able to consider and reflect on it. It is important that there is enough time for the discussion with the plastic surgeon. This may also mean that the information

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[49] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/dokument-webb/ovrigt/nationell-hogspecialiserad-vard-konsdysfori-beslut.pdf

[50] Please note that there may be rules about confidentiality and secrecy that must be considered here.

[51] Chapter 3, Section 3 of the Patient Act.

sometimes needs to be given on repeated occasions. At the consultation, the adolescent and guardians are given information about:

- different surgical techniques in relation to the adolescent's individual characteristics
- advantages and disadvantages of each technique
- typical risks and potential complications of the different techniques.

At this consultation, it is also important to discuss the operation itself and give the adolescent the opportunity to ask questions and discuss aftercare in detail.

As young adults sometimes detransition and wish to reverse the effects of the operation [3], surgeons also need to clarify that it is not possible to determine in advance what the medical conditions for restoring the effects of mastectomy with breast implants will be in an individual patient's case, and whether such surgery will be offered to the individual as part of public healthcare.

Sexual and reproductive health

Sexual and reproductive health is a state of physical, emotional, psychological, and social well-being in relation to all aspects of sexuality and reproduction, and not merely the absence of disease, dysfunction, or injury [110].

Discussions about sexuality take place in several situations during the evaluation of adolescents with gender dysphoria; for example, in connection with exploring gender identity and while providing information about how treatment with sex hormones can affect issues such as sexual desire. An adolescent who is about to start hormonal treatment should also be informed about how the treatment may affect their chances of becoming a genetic parent in the future (See also *Hormonal treatment for gender dysphoria in adolescents*).

In addition, adolescent may have their own needs for sexology counselling, depending in part on their level of maturity and whether they have begun to engage in sexual relations. Some adolescents feel comfortable discussing their sexuality with others. Others do not, which is important to respect. The treating professional needs to be open to discussing sexology issues without forcing the adolescent to talk about them.

Sexology counseling and treatment

Adolescents with gender dysphoria may need to discuss their sexuality with a professional, such as a sexologist or other person with sexology competence. As with other adolescents, there is a wide range of sexual identities, sexual practices, and sexual problems among adolescents with gender dysphoria. Issues of sexuality specific to people with gender dysphoria may include management of gender dysphoria in a sexual relationship and changes in sexual orientation or sexual preferences as part of the exploration of gender identity. Other examples of topics to be addressed in sexology counselling and treatment may include:

- relationships and emotions
- violence and sexual abuse
- what characterizes good romantic or sexual relationships, such as being affirmed in one's gender identity
- sexual dysfunction
- how unwanted pregnancy can be prevented
- that hormonal contraceptives may be a treatment option for people who primarily experience menstruation dysphoria
- that cross-sex hormone treatment is not a safe contraceptive method
- how to prevent the transmission of HIV and other sexually transmitted diseases
- information about HPV vaccination.

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Adolescents who are about to start or have started hormonal treatment may need to discuss the effects this may have on sexual function and desire. The biological changes brought about by the treatment may require support around the ability to feel pleasure and to enjoy sexuality.

Discussing sexuality and sexology issues with adolescents with gender dysphoria places special demands on professionals. It is essential to use respectful and inclusive language based on the terms preferred by the adolescent if there are such preferences, or to suggest alternatives if the adolescent feels uncomfortable with traditional expressions.

When working with adolescents, it is particularly important that the professional shows sensitivity to and has competence in responding to experiences of sexual vulnerability, which may be more common among transgender people than among Swedish adolescents in general [33].

If sexology expertise is lacking within the team, or if these issues are not given sufficient attention during the evaluation or gender-affirming treatment, the adolescent should be referred to alternative care services, such as a sex and sexuality clinic with specific expertise in dealing with people with gender dysphoria. This may also offer the possibility of a gynecological or andrological check-up and testing, the procedures that require a special approach from the treating provider. Local youth centers may also have staff with sexology expertise. In larger towns, there may be clinics that work specifically with people who have had sex for compensation or who have lived with other forms of sexual vulnerability.

Recommendation

Healthcare services should offer sexology counselling and treatment to adolescents with gender dysphoria.

Reasons for the recommendation

According to the National Board of Health and Welfare's recommendation, the healthcare system should offer individualized sexology counselling and treatment to adolescents with gender dysphoria who want it. Such counselling or treatment should be adapted over time and take into account the unique social and medical conditions of the adolescent.

The scientific evidence is insufficient to assess the efficacy and safety of the measure. According to the experience of the participating experts, the measure contributes to an improved quality of life while not entailing any direct risks.

It is important that the counselor is a professional with specialist knowledge in the field. Where possible, counselling should be provided by the evaluation or treatment team. Otherwise, the adolescent should be referred to clinics and practitioners with experience and knowledge of the issues involved and of gender dysphoria. The local youth center is often a valuable resource in this context. In larger towns, there are sometimes clinics that work specifically with people who are or have been sexually vulnerable.

Fertility preservation measures

Fertility preservation is offered to people at risk of fertility problems related to medical treatment. These are usually various cancer treatments but also include other treatments, such as gender-affirming hormonal treatment for gender dysphoria.

In the section *Hormonal treatment for gender dysphoria in adolescents*, it is stated that one criterion for offering GnRH analogue is that the adolescent and guardian have been informed about the possibilities, limitations, and uncertainties of fertility preservation (See below *Fertility preservation that may be relevant for adolescents*). In order to offer gender-affirming hormone treatment with testosterone or estrogen to adolescents with gender dysphoria, the following criteria related to fertility should be met:

- The adolescent and the guardians are aware of the risk that reproductive capacity may be negatively affected by the treatment, and of the conditions for the procurement of gametes for freezing.
- The adolescent understands that fertility preservation is not a guarantee of becoming a genetic parent in the future.
- Where fertility preservation measures are possible, the adolescent has been offered such measures.

Information that enables an informed decision

According to the Patient Act, a patient must be given information about aspects such as their state of health, the methods available for evaluation, care and treatment, the expected course of care and treatment, significant risks of complications and side effects, aftercare, and methods of preventing illness or injury. When the patient is a child, the information must also be given to the child's guardians.

It is, therefore, important that adolescents with gender dysphoria and their caregivers are informed and counseled about the impact of puberty blockers and cross-sex hormones on the adolescent's future fertility before initiating hormone treatment. That also includes information about the possibilities and current limitations of healthcare services to help people become genetic parents.

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Impact of GnRH analogue treatment on fertility

Available treatment studies and clinical experience suggest that menstruation in girls treated with *central precocious puberty* (CPP i.e., puberty onset before 8 years of age in girls and before 9 years of age in boys) returns on average one year after GnRH analogue treatment is discontinued but may take as long as two years. Longer time to menstruation at discontinuation or after completion of treatment can be expected if treatment is started before menarche has occurred [95]. The few existing small studies of boys with CPP suggest that testosterone levels and testicular volume is recovered one year after completion of treatment, and that full pubertal development is attained by the late teenage years [96].

Impact on fertility of treatment with gender-affirming hormone

In adolescent and adults, sperm quality (e.g., number, motility) seems to be negatively affected by cross-sex hormone treatment [98-100, 111]. A 2021 Swedish study also shows that sperm quality in trans women who have received gender-affirming hormone treatment is worse than in trans women who have not received such therapy [112].

Suspension of hormone treatment seems to be able to restore sperm quality, but there is no clear evidence to say how long the suspension should be. Based on the fact that the formation of mature sperm in spermatogenesis in cis men takes about three months, a systematic review suggests this as the minimum-time limit for the interruption of cross-sex hormone therapy, in order to avoid adverse effects [100].

Furthermore, cross-sex hormone treatment with testosterone seems to have a negative impact on egg follicle maturation [111]. The length of time before menstruation returns after cessation of testosterone treatment appears to vary [99, 100]. The extent to which the effect of testosterone on reproductive organs and function is reversible or irreversible is unclear in the current state of knowledge, although there are self-reported cases where the effect appears to be reversible. However, information from longer-term follow-up is lacking [113].

Fertility preservation measures that may be relevant for young people

Fertility preservation in the context of gender-affirming hormone treatment is described in several systematic reviews [98-100, 111, 113], for further information see the separate appendix *Knowledge base with methods description*. It concerns different ways of obtaining and preserving gametes for possible future use in assisted conception. These procedures may also be relevant for young people.

For young people treated with GnRH analogues in early puberty, there are clear difficulties in offering fertility preservation, especially for those registered female at birth who have not yet had menarche [98-100]. According to the experts involved in the development of the guidelines, there are often both psychological and physiological difficulties for young people registered male at birth to produce semen samples for freezing.

Even when gametes can be procured, other conditions need to be in place later to achieve a pregnancy, such as a partner and/or a donor of opposite gametes, and access to various assisted conception methods. Retrieved gametes must be fertilized, an embryo created and developed and successfully implanted in the uterus. Assisted conception also involves legal provisions that may have an impact on the possibility of using procured gametes in practice (See separate section below). There is no guarantee that a person who has undergone fertility preservation treatment will be able to become a genetic parent in the future.

Sperm retrieval in the context of gender-affirming hormone treatment

For persons registered male at birth, sperm freezing is the most established fertility preservation measure [98-100, 111, 113] and may also be relevant for young people in the context of gender-affirming hormone treatment. A basic prerequisite for the possibility of sperm freezing is that the person has reached puberty and, normally, that the person is able to provide a sperm sample through masturbation [98-100].

Sperm can be preserved and frozen before, during, or after a certain period of suspension of treatment with cross-sex hormones [100, 111, 112]. A suspension of gender-affirming treatment may however produce undesirable masculinizing effects [100]. For young transwomen, there may be concerns about having to pause the gender-affirming treatment as well as psychological barriers to masturbating to produce sperm [98].

Egg retrieval in the context of gender-affirming hormone treatment

For people registered female at birth, it is possible to retrieve and freeze unfertilized eggs for possible later use in assisted conception. This may also be relevant for teenagers (after menarche) in the context of gender-affirming hormone treatment.

For example, freezing unfertilized eggs can be done in women who have cancer and where treatment could be harmful to the ovaries and eggs, or due to gender-affirming treatment. In Sweden to date, there have been relatively few unfertilized eggs that were frozen, and later thawed, fertilized, and transferred (in 2019, there were about 100 embryo retransfers, of which a dozen resulted in birth) [114]. According to a 2019 Swedish study [115], the trend among teenagers offered fertility preservation

for various medical reasons is that increasing numbers are opting for egg retrieval and freezing.

The egg retrieval procedure is an established practice for cis-women undergoing in vitro fertilization (IVF). The treatment is demanding, including stimulation with hormones, transvaginal ultrasound, and transvaginal retrieval of eggs from the ovaries. The treatment can potentially be perceived as even more challenging in trans men, and it may reinforce gender dysphoria [100, 116]. The same may be true for people with non-binary gender identity.

Egg retrieval can take place before testosterone treatment, or after a certain period of time off from the treatment [98-100, 111, 113]. However, a break in ongoing testosterone treatment may contribute to increased gender dysphoria in trans men, so early egg retrieval before starting any cross-sex hormone treatment may be preferable [111].

One option to discuss with young people registered female at birth before the initiation of gender-affirming hormone therapy, is the possibility of suspending testosterone treatment later in life in order to go through pregnancy. Trans men can potentially choose to undergo pregnancy either before or after testosterone treatment [99, 100].

Experiences of hormonal stimulation and egg retrieval among trans men

In a 2017 Swedish study [116], 15 trans men aged 19-35 years were interviewed about experiences of fertility preservation (hormonal stimulation and extraction of eggs for freezing). For people who needed to interrupt their testosterone treatment, this could be seen as draining and mentally stressful, as they felt, among other things, that their bodies became more feminine and their voices higher. People who experienced menstrual bleeding after discontinuing testosterone treatment found this to be one of the most difficult parts of fertility treatment, as the bleeding reminded them of something they did not want to be a part of (the gender they had left behind). A majority of the study participants reported that hormonal fertility treatment made them feel less comfortable with their bodies and that the treatment increased their gender dysphoria. Gynecological examinations, especially with transvaginal ultrasound, were perceived as uncomfortable situations because people felt that they were presenting themselves to others as women. The use of the wrong pronouns by the healthcare staff in this situation, referring to them as women, and the mention of gender-specific words such as egg and vagina were also perceived negatively. The same study also described different strategies that participants used to cope with the treatment, such as focusing on the purpose (i.e., the possibility of having genetic children in the future) and getting support from relatives during the treatment [116].

Legal conditions

Gametes (both eggs and sperm) can be frozen and stored for later use in fertility treatment (assisted reproduction). However, assisted fertilization can only be carried out in the Swedish healthcare system when the legal conditions for it are met. Assisted fertilization is regulated in Section 6 (insemination) and Section 7 (in vitro fertilization) of the Genetic Integrity Act (2006:351) and the National Board of Health and Welfare's regulations and general advice (SOSFS 2009:32) on the use of tissues and cells in healthcare and clinical research. There is no regulation stating how long unfertilized eggs or sperm may be kept frozen.

Since January 1, 2019, assisted fertilization with double donation is also allowed in Sweden, which means that both eggs and sperm are donated to the same recipient.

Recommendation

> Healthcare services should offer fertility preservation procedures to adolescents with gender dysphoria who are to undergo treatment that may adversely affect fertility, whenever possible based on the individual circumstances of the adolescent. This is provided on the condition that the young person requests these procedures after having received information on the impact of the treatment on fertility, its possibilities, and limitations.

Reasons for the recommendation

The procedure is primarily justified by ethical considerations and should be seen as part of providing equitable care to all patient groups undergoing treatment that may adversely affect fertility.

The scientific evidence is insufficient to assess the impact of fertility preservation procedures in terms of the rate of pregnancies or births, when offered to adolescents with gender dysphoria. However, egg and sperm retrieval for assisted fertilization is an established practice in other patient populations and can be expected to offer the possibility of genetic parenthood for people being treated for gender dysphoria as well. For further information, see the separate appendix *Knowledge base with methods description*.

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Voice and communication treatment

Voice and modes of communication play a central role in how people's gender expressions are perceived. For adolescents with gender dysphoria, the voice can be a factor that makes it more difficult to be perceived in accordance with their gender identities. This can cause great distress and lead to reduced quality of life [117]. The voice sending the wrong message about gender identity and/or creating uncertainty about how others perceive an individual can lead to anxiety, insecurity, and avoidance of speaking in different contexts. Therefore, adolescents with gender dysphoria may need help to adapt and develop their voices to match their gender identities.

The needs and goals of voice and communication treatment vary between individuals. Some aim to develop their voice and communication in a feminizing or masculinizing direction to the full extent possible, while others, for example those with a non-binary gender identity, may aim to be perceived as more gender-neutral.

Considerations during evaluation and treatment

The overall goals of gender-affirming voice treatment are to reduce adolescents' voice dysphoria, enable them to speak in a way they feel is comfortable, use their voices in the situations they choose and are able to use a favorable voice technique that does not fatigue the voice.

Pretreatment assessment includes taking a history and mapping the person's voice, speech, and communication. Voice and speech are recorded according to a standardized procedure and then analyzed perceptually (via listener assessment) and acoustically. Self-assessment questionnaires are used to document the person's subjective perception of their voice, how it works and any voice problems. Individual, realistic, and relevant treatment goals are established with the person based on their needs and circumstances. When indicated, the speech therapist may refer the patient to a voice specialist for vocal cord testing.

Speech therapy is not provided until the adolescent has been assessed and diagnosed with gender dysphoria. In cases where the diagnosis is not established but is preliminary, referrals may be made by the assessment team to a speech therapist, who will then meet with the person for information and counseling. It is desirable that adolescents registered female at birth are in contact with a speech therapist before starting testosterone treatment for information and documentation of voice [118].

Speech therapists who assess and treat people with gender dysphoria should, according to Swedish experts in the field, have at least two years of experience in speech therapy and documented competence in the field of gender dysphoria [119, 120].

Speech therapy

Speech therapy for people with gender dysphoria aims to help the person achieve a voice that better corresponds to their gender identity and to prevent and reduce voice problems. Treatment goals include several aspects such as changes in vocal pitch, resonance/voice tone, intonation/ melodic phrasing, and articulation [121-125]. Indications for speech therapy are:

- When the voice of trans people registered male at birth, who want the voice to be perceived in accordance with their gender identity, is perceived as too low and the voice tone/resonance too dark. The person may also have difficulty adjusting other aspects of voice and communication. In some cases, the person already speaks in a higher/more feminine voice, but the lower/deeper voice is temporarily noticeable, e.g., raspy, or coarse when coughing or laughing.
- When the voice of a trans person who was registered female at birth and wants the voice to be perceived in accordance with the gender identity is perceived as too high-pitched and the voice tone/resonance too bright. The person may also have difficulty adjusting other aspects of voice and communication. In the case of cross-sex hormone treatment with testosterone, vocal pitch lowers. Other aspects such as resonance, intonation, and articulation are not affected. In cases where the effect on voice is not sufficient, or a person is not treated with testosterone, or a person needs support to change resonance/intonation/articulation, gender-affirming voice treatment is an option.
- When people (both transgender people registered female at birth and transgender people registered male at birth) find it tiring to use their voice in the desired way and symptoms such as voice fatigue (so-called phonasthenia) occur. The voice may sound tense, hoarse, weak, unstable, and pressured.

Content, format, and duration of the treatment

There is no standardized model for the design of gender-affirming speech therapy, but several techniques and programs have been described for adults [121-125]. Speech therapy for adolescents addresses the same aspects of voice, speech, and communication as for adults. Treatment goals are primarily concerned with changing the tone of voice, but this is not enough to make a voice consistent with gender identity. Other variables also need to be changed, such as resonance/voice tone, vocal strength, intonation/sentence melody, and articulation.

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Vocal pitch depends on the rate of oscillation of the vocal cords, which gives the pitch frequency, and is measured in Hertz (Hz). An adult cis-man speaks in a vocal pitch averaging 116 Hz (+/- 15 Hz) and an adult cis-woman 188 Hz (+/-20 Hz) during reading [126]. Studies have shown that individuals registered male at birth need to raise their voice pitch to about 160 Hz for the voice to be perceived by others as a woman speaking [127].

Gender-affirming voice therapy is usually done on an individual basis and can consist of a single visit with counselling or a longer period of treatment. Shorter treatment periods may be appropriate when the person has only phonesthetic [voice fatigue] problems.

All or part of the treatment can take place via digital meetings. Group treatment may also be appropriate, usually after an initial period of individual treatment. The frequency and duration of treatment, as well as the design and goals of the treatment, are determined by the needs, circumstances, and motivation of the adolescent. A treatment period is rarely longer than the number of treatment sessions described below.

- For adolescents registered male at birth who have received GnRH analogue treatment, pubertal development in the masculine direction is halted. GnRH analogue thus prevents masculinization of the voice. In general, less adaptation of the voice is required among these adolescents. For those who have undergone a voice break and wish their voice to be consistent with their gender identity, voice treatment is often needed on a regular basis over a longer period of time, with about 10-15 treatment sessions.
- For adolescents registered gender female at birth who wish their voice to be consistent with their gender identity and who are not treated with testosterone, or where the effect of testosterone is not perceived as sufficient, voice therapy is often recommended on a regular basis with about 5-10 treatment sessions. Gender-affirming speech therapy cannot replace the effect of hormone treatment, i.e., it cannot lower the voice as much as testosterone treatment.
- For adolescents (both adolescents registered male and those registered female at birth) who are satisfied with the gender expression of their voice, but who need treatment for other voice problems, a shorter treatment period of about five treatment sessions is offered. This may be the case, for example, when adolescents registered female at birth develop problems such as hoarseness, unstable voice, or difficulty increasing vocal strength during testosterone treatment [128], or adolescents registered male at birth who have developed their voice on their own so that they are satisfied with their gender expression but become hoarse and vocally fatigued when they speak.

In all cases, adolescents are required to practice on their own between sessions with a speech therapist.

Follow-up

Follow-up takes place six months after the end of the speech therapy, and thereafter as needed.

Persons registered female at birth undergoing testosterone therapy are followed for up six to twelve months after starting hormone treatment [128].

Recommendation

> Adolescents with a preliminary or confirmed diagnosis of gender dysphoria speech therapy should be offered a consultation with a speech therapist, and, if necessary, healthcare services should provide gender-affirming speech therapy treatment.

Reasons for the recommendation

A voice that is perceived as too masculine or feminine for the person to be perceived in accordance with their gender identity causes great suffering and a reduction in quality of life. Furthermore, issues related to phonasthenia [voice fatigue] can occur when the voice is used to reflect the gender identity. In these cases, healthcare services should offer a consultation with a speech therapist and, if necessary, provide speech therapy to adolescents with a preliminary or confirmed diagnosis of gender dysphoria. The condition may have been coded as F64.0, F64.8 or F64.9 according to ICD-10.

The scientific evidence is insufficient to assess the efficacy and safety of this intervention. In the experience of the participating experts, this intervention contributes to a better correspondence between vocal pitch and tone and gender identity and thus to a reduction in gender dysphoria, a reduction in vocal strain, and an improvement in quality of life, while posing no direct risks.

The effects of the treatment are reversible and the risk of phonasthenia is considered less than when people try to change their voices on their own. For further information, see the separate appendix *Knowledge base with methods description*.

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Hair Removal

For adolescents with gender dysphoria registered male at birth, facial and other visible body hair can make it difficult to be perceived by others in accordance with their gender identity. It may therefore be important to get help to remove such hair permanently where possible.

Light- and needle-based hair removal methods

Today, two main methods are used to permanently reduce unwanted body hair. These are:

- Light-based methods (photoepilation): intense pulsed light (IPL) and laser.
- Needle-based methods: electrolysis, diathermy, and blending.

The goal of these hair removal methods is to destroy the hair follicles that produce unwanted hair and thus achieve permanent hairlessness. All hair follicles produce hair in cycles of growth and inactivity. Only hair follicles in the growth phase are susceptible to the damage attempted by the various hair removal methods. One course of treatment will therefore at most be able to destroy a proportion of the patient's unwanted hairs. The time between treatments depends on the length of the growth phase in the skin area in question. In clinical experience, between 5 to 10 regular treatments at least 4 to 8 weeks apart are usually required to reach all hair follicles in the treated area. The hairs that remain in the treatment area may sometimes be perceived as lighter and thinner.

Both light- and needle-based methods require a practitioner with sufficient skills and experience. This is especially true for needle epilation, which requires great craftsmanship to target the hair follicle correctly. Requirements for qualifications and professional competence of the practitioner of IPL and laser treatments are set out in the standard for aesthetic medical services[52].

Light-based methods - IPL and laser

Light-based hair removal means that the practitioner selects a wavelength of light that rapidly heats and destroys the pigment (melanin) present in the hair without affecting surrounding tissue (selective photothermolysis). Photoepilation can be done with IPL or with lasers of different wavelengths (alexandrite lasers, diode lasers, Nd:YAG

[52] 7 Standard SS-EN 16844:2017 Aesthetic medical services - Non-surgical medical procedures

lasers and ruby lasers). IPL uses a spectrum of light, while lasers use a specific wavelength. The practitioner chooses the IPL or laser and settings that are appropriate based on the patient's individual characteristics such as skin color, hair color, and hair thickness. In addition to the choice of laser type, parameters such as treatment area, pulse length, total energy, and type of cooling vary between devices and can be set manually according to the patient's individual circumstances.

With light-based methods, relatively large areas of skin can be treated in a short time. The handpiece of the device is moved over the entire area where the hair is to be removed.

Needle-based methods - electrolysis, diathermy, and blending

Needle epilation electrolysis involves inserting a thin current-carrying needle into the hair follicle for a few minutes, causing a chemical reaction and damaging the follicle. The main disadvantage is that it is a slow method; the needle has to stay in the hair follicle for a long time, sometimes several minutes, and the treatment can be painful. Often several needles are used at the same time to speed up the process.

Diathermy needle aspiration [thermolysis] involves heating body tissue with a high frequency alternating current. The practitioner inserts a current-carrying needle into the hair follicle, turns on the current and pulls out the hair with tweezers. It is a faster method than electrolysis, but with a greater risk of scarring and pigmentation.

All variants of needle epilation are relatively slow because they treat each hair individually. A common way to make electrolysis treatment faster is to mix the technique with diathermy. The treatment is called a blend and combines the efficiency of electrolysis with the speed of diathermy.

Recommendation

> Healthcare services should offer removal of hair from the face and neck, front and back of the trunk, arms, and hands to adolescents with gender dysphoria and registered male at birth, using light or needle-based methods depending on the individual's circumstances.

Reasons for the recommendation

When individuals registered male at birth have body hair that is considered to be too masculine for the individual to be perceived in accordance with one’s gender identity, it causes great suffering and reduced quality of life. In these cases, healthcare services

should offer hair removal with methods aiming at permanent hairlessness on the face and upper body (neck, front and back of the trunk, arms, and hands).

There are a limited number of controlled studies investigating the efficacy and safety of light-based and needle-based methods in comparison to no treatment, placebo, or temporary hair removal methods (e.g., shaving, plucking). The results suggest that laser treatment can reduce hair growth by up to about 50 percentage points in the short term, up to six months after completion of treatment. The results are considered to have low reliability. Other effects cannot be assessed based on the evidence, i.e., effects of laser treatment on hair growth in the long term, effects of IPL and needle-based treatment on hair growth in the short and long term, and the effects on mental health and quality of life (all methods). For further information, see the separate appendix *Knowledge base with methods description.*

According to clinical experience, light and needle-based methods provide a reduction in hair growth that is more pronounced and more lasting than other methods. In the experience of the participating experts, this intervention contributes to a reduction in dysphoria, greater opportunities for the person to be perceived in accordance with gender identity and to improved quality of life. The most common side effects for both light- and needle-based methods are mild and transient, such as pigmentation, skin redness, and swelling. Structural skin changes occur less frequently and can in rare cases become permanent. For further information, see the separate appendix *Knowledge base with methods description*.

A basic prerequisite is that the method and its implementation are adapted to the individual's circumstances. For this to be possible, both light and needle-based methods must be available at the clinics where hair removal is performed.[53]

Considerations during treatment

For people who produce androgens, it takes longer to reduce the hair coverage sufficiently in hormone-sensitive areas. It is therefore advantageous if hormone therapy with estrogen and anti-androgens (alternatively with GnRH analogue for adolescents) has been initiated before hair removal is started.

Following careful assessment of the person's conditions, the healthcare service can offer light-based or needle-based methods or a combination of these methods. To the extent appropriate in the individual case, the patient should be offered light-based methods as these are more accessible and more time- and cost-efficient than needle-

[53] Hair removal is not included among the care measures defined as national highly specialized care and will continue to be the responsibility of the regions.

based methods (See description of implementation above). To be able to remove hair using IPL or laser, it is necessary that:

- the patient has melanin in their hair follicles. Red, gray, or white hair does not respond to light-based treatment, so needle epilation needs to be used in these cases.
- the patient has less pigment in the skin than in the hair follicles. Individuals with darker, more pigmented skin are more likely to suffer from pain, pigment disturbances, and blistering of the skin when hair is treated with light-based methods.
- the dose is high enough, the practitioner has chosen the correct pulse length, there is a large treatment area, and there is adequate cooling of the skin.

Expected degree of hair removal and follow-up treatment

The aim of hair removal is to remove as much hair as possible. Hair growth can vary on different parts of the body during different periods of life. For example, hair growth on the chest and back of people registered male at birth tends to increase up to middle age. Thus, even under optimal conditions, it may be difficult to permanently maintain the achieved hairlessness.

Ongoing interventions to maintain treatment results varies between individuals and depends on the degree of biological maturity reached by the individual. After completion of treatment, there may be a need for one to several treatments per year. If an individual who had not reached full biological maturity at the time of previous treatment experiences the emergence of new hair follicles that started to produce hair in previously treated areas, more treatments may be needed.

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Translator's Notes

[i] [Translator's note: Healthcare in Sweden is decentralized – responsibility lies with the regional councils and, in some cases, local councils or municipal governments. The role of the central government is to establish principles and guidelines, and to set the policy agenda for health and medical care. The National Board of Health and Welfare (Socialstyrelsen) is a government agency under the Ministry of Health and Social Affairs that compiles information and develops standards to ensure good health, social welfare and high-quality health and social care for the whole population. The care is delivered though 21 county councils / regions https://sweden.se/life/society/healthcare-in-sweden]

[ii] [Translator's note: The Swedish term "god vård" is literally translated as "good care." This term came into existence in connection with the publication of the National Board of Health and Welfare's regulations on the management system for quality and patient safety (SOSFS 2005:12). Six areas are highlighted as important prerequisites for "good care" including: appropriate healthcare based on the best available knowledge, safe healthcare, patient-focused healthcare, effective healthcare, equitable healthcare, and timely delivery of healthcare. https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-riktlinjer/2009-11-5.pdf .

[iii] [Translator's note: Appendix 1-3, attached to the Swedish original report, are not included in this translation. They include:

1. Projektorganisation, a list of authors ("organization of the project").

2. Termer och förkortningar, a glossary of terms

3. Förtydliganden av juridiska förutsättningar, "clarifications of legal conditions"]

[iv] [Translator's note: The "knowledge base with methods description" is available at the following link:

https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302-kunskapsunderlag-med-metodbeskrivning.pdf].

[v] [Translator's note: These reports can be found at the following links: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2020-1-6579.pdf

https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2020-1-6580.pdf].

[vi] [Translator's note: The appendix has not been translated.]

[vii] [Translator's note: The separate appendix, *Knowledge base with methods description*, has not been translated. It is available in Swedish at the following link: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302-kunskapsunderlag-med-metodbeskrivning.pdf]

This document is an unofficial English translation of a document prepared in Swedish.

[viii] [Translator's note: Healthcare in Sweden is decentralized – responsibility lies with the regional councils and, in some cases, local councils or municipal governments. The role of the central government is to establish principles and guidelines, and to set the policy agenda for health and medical care. The National Board of Health and Welfare (Socialstyrelsen) is a government agency under the Ministry of Health and Social Affairs that compiles information and develops standards to ensure good health, social welfare and high-quality health and social care for the whole population. The care is delivered though 21 county councils / regions https://sweden.se/life/society/healthcare-in-sweden]

[ix] [Translator's note: The appendix has not been translated.]

[x] [Translator's note: The guidelines are referring to the difficulty of adjusting their current diagnostic process to the upcoming ICD-11 codes. The Swedish healthcare system has traditionally relied on the "unspecified" ICD-10 code of F64.9 as the provisional gender dysphoria code, pending the evaluation. The goal of the evaluation is to establish whether the person suffers from true gender dysphoria or whether other reasons better explain the experience of gender identity not matching the recorded sex. Patients who are confirmed as having true gender dysphoria (not secondary to other causes) are then assigned either a "binary" diagnostic ICD-10 code of F64.0, or a non-binary diagnostic code ICD-10 code F64.8. The report is pointing out that under the ICD-11 system, the "unspecified" code of HA6Z can no longer serve this provision purpose, complicating coding during assessment process. https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/vanligt-med-flera-psykiatriska-diagnoser-hos-personer-med-konsdysfori/]

[xi] [Translator's note: The concept of "child's integrity" involves physical health and mental health integrity. https://commission.europa.eu/aid-development-cooperation-fundamental-rights/your-rights-eu/know-your-rights/dignity/right-integrity-person_en#:~:text=Everyone%20has%20the%20right%20to,procedures%20laid%20down%20by%20law]

[xii] [Translator's note: See https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/meddelandeblad/2020-12-7117.pdf]

[xiii] [Translator's note: Highly specialized care is defined as care often requiring the most advanced technical equipment. In Sweden, such care is concentrated in university hospitals to ensure high quality and greater efficiency, and to enable research and development. https://www.commonwealthfund.org/international-health-policy-center/countries/sweden]

[xiv] [Translator's note: The Swedish term, "gott bemötande" is literally translated as "good treatment." This concept has a specific meaning in the Swedish healthcare system, the fundamental aspect of which is showing respect and interest in the person's situation. 'Good treatment" means showing personal care, acting on the basis of knowledge and experience, respecting the individual's autonomy and integrity and adopting a professional and humane approach. The goal of "good treatment" is to create trust and security in the provider-patient relationship. https://www.vardochinsats.se/missbruk-och-beroende/kommunikation-och-delaktighet/gott-bemoetande/]

[xv] [Translator's note: "Distorted patient histories" referees to the phenomenon of patients altering their medical history in order to qualify for the treatment.]

[xvi] [Translator's note: There appears to be an error in reference in the Swedish original, incorrectly referring to this report as "I am not alone, there are more like me." The actional name of the report says "I am not alone, there are others like me."]

[xvii] [Translator's note: This reference is to the Swedish Health and Medical Care Act https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/halso--och-sjukvardslag_sfs-2017-30#K2]

[xviii] [Translator's note: the literal transition of the term used in the Swedish original is "logopedics," which refers to the speech therapy https://www.merriam-webster.com/medical/logopedics]

[xix] [Translator's note: "HSL" is the Health and Medical Care Act. "PSL" is the Patient Safety Act. "PL" is the Patient Act https://www.vardhandboken.se/arbetssatt-och-ansvar/ansvar-och-regelverk/patientens-rattsliga-stallning/lagstiftning/]

[xx] [Translator's note: "HSL" is the Health and Medical Care Act.]

[xxi] [Translator's note: "PSL" is the Patient Safety Act.]

EXHIBIT 106

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ACTA PÆDIATRICA NURTURING THE CHILD WILEY

REVIEW ARTICLE

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

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Abstract

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

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

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

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

Berit Kriström and Mikael Landén have equal contrbution.

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

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

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

1 | INTRODUCTION

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

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

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

Key Notes

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

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

2 | METHODS

2.1 | Preregistration

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

2.2 | Selection criteria

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

2.3 | Search strategy

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

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

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

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

2.5 | Data extraction

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

2.6 | Statistics

No statistical analyses were performed.

2.7 | Ethics

Ethical approval is not applicable for this systematic review.

3 | RESULTS

3.1 | Identified studies

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

3.2 | Characteristics of the 24 studies

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

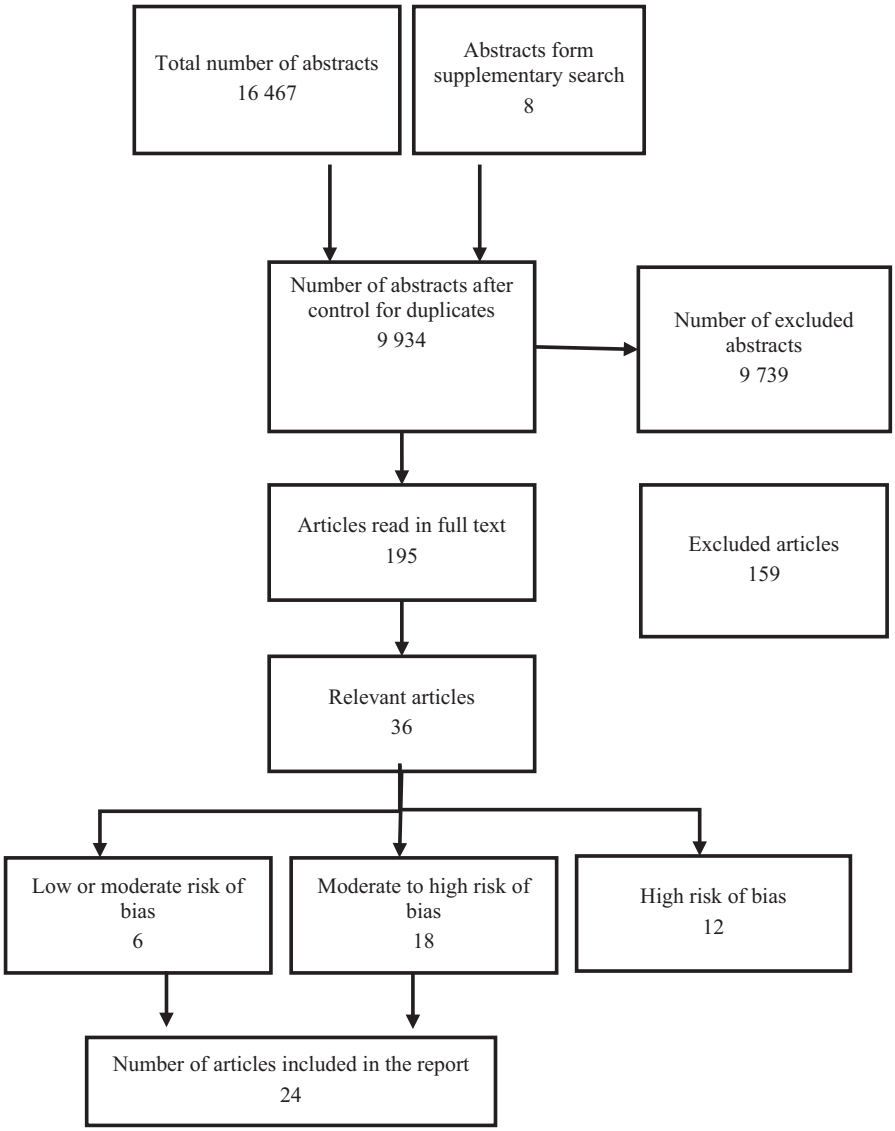

FIGURE 1 PRISMA flow diagram.

3.3 | Psychosocial and mental health

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

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

3.4 | Cognitive outcomes

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

TABLE 1 Overview of 24 included studies.

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

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

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

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

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

[a]Calculated by SBU.

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

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

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

Abbreviation: CGAS, Children's Global Assessment Scale.

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

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

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

could not investigate potential cognitive effects of hormone therapy.

3.5 | Bone health outcomes

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

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

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

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

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

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

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

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

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

3.6 | Body composition and metabolic markers

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

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

3.7 | CSHT in children without prior GnRHa treatment

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

4 | DISCUSSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 | CONCLUSION

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

AUTHOR CONTRIBUTIONS

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

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CONFLICT OF INTEREST STATEMENT

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

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EXHIBIT 107

Summary of a recommendation by COHERE Finland 16.6.2020

Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation

In its meeting on 11 June 2020, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on medical treatment methods for dysphoria associated with variations in the gender identity of minors

The recommendation clarifies the roles of different healthcare operators in a situation where a minor is uncertain about their gender identity. The recommendation presents the medical treatment methods that fall within the range of public healthcare services when it comes to the medical treatment of gender dysphoria in minors.
In COHERE's view, psychosocial support should be provided in school and student healthcare and in primary healthcare for the treatment of gender dysphoria due to variations in gender identity in minors, and there must be sufficient competency to provide such support. Consultation with a child or youth psychiatrist and the necessary psychiatric treatment and psychotherapy should be arranged locally according to the level of treatment needed. If a child or young person experiencing gender-related anxiety has other simultaneous psychiatric symptoms requiring specialised medical care, treatment according to the nature and severity of the disorder must be arranged within the services of their own region, as no conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development.

In Finland, the diagnostics of gender identity variation, the assessment of the need for medical treatments and the planning of their implementation are centralised by law in the multi-professional research clinics of Helsinki University Central Hospital (HUS) and Tampere University Hospital (TAYS). The consultation, evaluation periods and treatments provided by the TAYS or HUS working group on the gender identity of minors shall be carried out in accordance with the following principles.

Children who have not started puberty and are experiencing persistent, severe anxiety related to gender conflict and/or identification as the other sex may be sent for a consultation visit to the research group on the gender identity of minors at TAYS or HUS. Any need for support beyond the consultation visit or need for other psychiatric treatment should be addressed by local services according to the nature and severity of the problem.

If a child is diagnosed prior to the onset of puberty with a persistent experience of identifying as the other sex and shows symptoms of gender-related anxiety, which increases in severity in puberty, the child can be guided at the onset of puberty to the research group on the gender identity of minors at TAYS or HUS for an assessment of the need for treatment to suppress puberty. Based on these assessments, puberty suppression treatment may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications. Therapeutic amenorrhea, i.e. prevention of menstruation, is also medically possible.

A young person who has already undergone puberty can be sent to the research clinic on the gender identity of minors at TAYS or HUS for extensive gender identity studies if the variation in gender identity and related dysphoria do not reflect the temporary search for identity typical of the development stage of adolescence and do not subside once the young person has had the opportunity to reflect on their identity but rather their identity and personality development appear to be stable.

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Summary of a recommendation by COHERE Finland 16.6.2020

Based on thorough, case-by-case consideration, the initiation of hormonal interventions that alter sex characteristics may be considered before the person is 18 years of age only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria. In addition, it must be confirmed that the young person is able to understand the significance of irreversible treatments and the benefits and disadvantages associated with lifelong hormone therapy, and that no contraindications are present.

If a young person experiencing gender-related anxiety has experienced or is simultaneously experiencing psychiatric symptoms requiring specialised medical care, a gender identity assessment may be considered if the need for it continues after the other psychiatric symptoms have ceased and adolescent development is progressing normally. In this case, a young person can be sent by the specialised youth psychiatric care in their region for an extensive gender identity study by the TAYS or HUS research group on the gender identity of minors, which will begin the diagnostic studies. Based on the results of the studies, the need for and timeliness of medically justified treatments will be assessed individually.

Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors. The initiation and monitoring of hormonal treatments must be centralised at the research clinics on gender identity at HUS and TAYS.
Research data on the treatment of dysphoria due to gender identity conflicts in minors is limited. COHERE considers that, moving forward, multi-professional clinics specialising in the diagnostics and treatment of gender identity conflicts at HUS and TAYS should collect extensive information on the diagnostic process and the effects of different treatment methods on the mental wellbeing, social capacity and quality of life of children and youth. There is also a need for more information on the disadvantages of procedures and on people who regret them.

Link to the COHERE website: https://palveluvalikoima.fi/en/frontpage

The Council for Choices in Health Care in Finland (COHERE Finland) works in conjunction with the Ministry of Social Affairs and Health, and its task is to issue recommendations on services that should be included in the range of public health services. Further information: www.palveluvalikoima.fi.

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EXHIBIT 108

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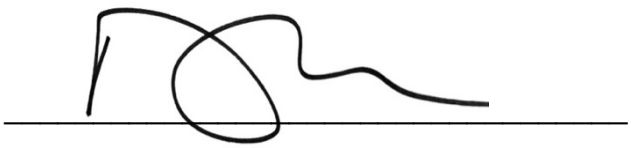
May 18, 2022

CERTIFICATE OF TRANSLATION

Finnish > English > Proofreading of the document titled:

- Recommendation by the Board for Selection of Choices for Health Care in Finland (PALKO / COHERE Finland)

I, Diana M. Arbeláez, with the ATA nr. 251348 at Lingua Franca Translations do hereby certify that the translation herein was completed in accordance with the American Translators Association Code of Professional Conduct and Business Practices and that to the best of my knowledge the translation and proofreading into English herein provided is, in fact, a literal and true interpretation of the statements in the original language Finnish. Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.



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STM038:00/2020

Recommendation by the Board for Selection of Choices for Health Care in Finland (PALKO / COHERE Finland)

Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors

Concepts

Suppression treatment	Pubertal suppression with GnRH analogues (drugs that inhibit gonadotropin-releasing hormone activity) to halt the development of secondary sex characteristics of the biological sex.
Cisgender/Cis person	A person whose gender identity matches the sex determined at birth (identifies, and is satisfied with, the sex determined at birth and generally expresses his/her gender accordingly).
Other gender identity	A person who does not identify as a man or a woman, but rather somewhere along the continuum or outside of it; genderless, nonbinary, or multigendered.
Transgender	A person whose gender identity differs from the legal and biological sex determined at birth but instead aligns with the opposite sex.

STM038:00/2020

Content

1. Criteria for Preparation of these Recommendations

As the number of patients, including minors, referred to the Helsinki University Hospital (HUS) and the Tampere University Hospital (TAYS) multidisciplinary outpatient clinics for assessment and treatment of gender dysphoria has increased, PALKO (Council for Choices in Healthcare in Finland / COHERE Finland) decided to prepare recommendations for medical treatments of gender dysphoria, i.e., distress which is associated with a minor's gender variance and impairs function. Gender variance refers to a spectrum of gender experience anywhere on the male-female identity continuum or outside it, and is not exclusively confined to the dichotomized male/female conception of gender. Not all patients with gender variance experience significant suffering or functional impairments, and not all seek medical treatment.

These recommendations are based on the legislation in force at the time of the adoption of the recommendation, the available research evidence, and the clinical experience of multidisciplinary teams with expertise in gender dysphoria assessment and treatment at HUS and TAYS. The knowledge base supporting these recommendations is detailed in a separate Preparatory Memorandum and appendices and includes a description of planning and implementation of medical treatments, a literature review of medical treatments, an extensive ethical analysis, and feedback following meetings with patients and the advocacy groups who represent them.

Finnish legislation defines the requirements for the legal gender recognition of transsexuals (Act on Legal Recognition of the Gender of Transsexuals (Trans Act) 536/2002). The detailed requirements for providing the assessment and treatment to enable legal gender recognition are spelled out further in a Decree of the Ministry of Social Affairs and Health (1053/2002). The Trans Act and the related Decree apply to adults. For those who are not of legal age, there are no laws governing the provision and needs of transgender healthcare; however, these are subject to the Health Care Act of Finland (1326/2010), in particular section 7 (criteria for integrated care), section 7a (criteria for treatment options), section 8 (evidence-based, high quality, safe and appropriate care) and section 10 (rationale for centralization); and also to the Constitution of Finland (731/1999)'s section 6 on equality and section 19 on the right to adequate social and healthcare services. Finland's Act on the Status and Rights of Patients, (785/1992), and especially sections 5, 6, and 7, are also relevant.

2. Target Population - Recommendations

These recommendations apply to minors suffering from dysphoria related to gender variance who are seeking a consultation regarding an evaluation of medical examination and treatment needs; the children and adolescents may identify with the opposite sex (transgender), or may identify as genderless, non-binary, or anywhere along or outside the male/female gender identity continuum (other gender).

3. Assessed Methodology

These recommendations focus on medical treatment procedures that aim to decrease suffering and functional impairment of gender-dysphoric minors.

4. Current Care

Cross-sex identification in childhood, even in extreme cases, generally disappears during puberty. However, in some cases, it persists or even intensifies. Gender dysphoria may also emerge or intensify at the onset of puberty. There is considerable variation in the timing of the onset of puberty in both sexes. The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders.

Consultation appointments (for parents / caregivers) regarding pre-pubescent children's cross-sex identification or gender dysphoria are provided by the research group on the gender identity of minors at TAYS or HUS. However, ongoing support or other treatment of psychiatric disorders are provided through the local municipal services.

In clear cases of pre-pubertal onset of gender dysphoria that intensified during puberty, a referral can be made for an assessment by the research group at TAYS or HUS regarding the appropriateness for puberty suppression. If no contraindications to early intervention are identified, pubertal suppression with GnRH analogues (to suppress the effect of gonadotropin-releasing hormone) may be considered to prevent further development of secondary sex characteristics of the biological sex.

Adolescents who have already undergone puberty, whose gender dysphoria occurs in the absence of co-occurring symptoms requiring psychiatric treatment, and whose experience of transgender identity failed to resolve following a period of reflection, can be referred for assessment by the research group on the gender identity of minors at TAYS or HUS. Hormone therapy (testosterone/estrogen and anti-androgen) can be started after the diagnostic evaluations, but no earlier than age 16. Additionally, patients under 18 receive three to six months of GnRH analogue treatment prior to the initiation of cross-sex hormones in order to suppress the hormonal activity of the gonads. No gender confirmation surgeries are performed on minors.

5. Risks, Benefits and Uncertainty

The literature review identified two studies with the total of 271 persons diagnosed with childhood-onset gender identity disorder and associated gender or body dysphoria that intensified after the onset of puberty (Preparatory Memorandum Appendix 1, Tables 15 and 16, pages 46-48).

In a smaller study of 70 adolescents, puberty was suppressed with the GnRH analogue at the average age of 14.8 (12-18 years) and puberty blockade continued for an average of 2 years. During the treatment period, the adolescents' mood improved, and the risk of behavioral disorders diminished, but gender dysphoria itself did not diminish, and there were no changes in body image. In a larger study consisting of 201 adolescents, 101 patients with the average age of 15.5 (12-18 years) started an 18-month psychological supportive intervention, and, additionally at six months, pubertal development was suppressed by starting GnRH analogue treatment. The other cohort of 100 only received psychological supportive intervention for 18 months. In both groups, statistically significant increases in global psychosocial functioning were found at 12 and 18 months; among those having received psychological intervention alone, the improvement in global functioning was already significant at the 6-month mark. Both studies lack long-term treatment follow-up into adulthood.

A recent Finnish study, published after the completion of this literature review, reported on the effect of initiating cross-sex hormone therapy on functioning, progression of developmental tasks of adolescence, and psychiatric symptoms. This study found that during cross-sex hormone therapy, problems in these areas did not decrease.

Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system. In trans girls, early pubertal suppression inhibits penile growth, requiring the use of alternative sources of tissue grafts for a potential future vaginoplasty. The effect of pubertal suppression and cross-sex hormones on fertility is not yet known.

6. Ethical Assessment

Although the ethics analysis did not systematically address the issues pertaining to children and adolescents, they have been discussed in several areas in the related documents (Preparatory Memorandum pages 52-62; Appendix 5).

According to the Health Care Act (section 8), healthcare services must be based on evidence and recognized treatment and operational practices. As far as minors are concerned, there are no medical treatment that can be considered evidence-based. At the same time, the numbers of minors developing gender dysphoria has increased. In this situation, it is vital to assure that children and young people are able to talk about their feelings, and that their feelings are acknowledged. The opportunity to reflect on one's experience should be easily accessible through the local health system (i.e., school or student health care, primary care). A young

person's feelings should not be interpreted as immediately requiring specialized medical examinations or treatments.

In cases of children and adolescents, ethical issues are concerned with the natural process of adolescent identity development, and the possibility that medical interventions may interfere with this process. It has been suggested that hormone therapy (e.g., pubertal suppression) alters the course of gender identity development; i.e., it may consolidate a gender identity that would have otherwise changed in some of the treated adolescents. The reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development.

From the point of view of patient advocacy groups, halting puberty is providing young people with a period of reflection, rather than consolidating their gender identity. This is based on the premise that halting the development of one's permanent sex characteristics will improve the minor's social interactions, while allowing more time for diagnostic evaluations. Additionally, patient advocacy groups assert that early intervention with hormonal treatments will lead to improved outcomes for the patients who do eventually pursue gender reassignment. Professionals, for their part, consider it important to ensure that irreversible interventions, which may also have significant adverse effects, both physical and mental, are only performed on individuals who are able to understand the permanence of the changes and the potential for harm, and who are unlikely to regret such interventions. It is not known how the hormonal suppression of puberty affects young people's judgement and decision-making.

The Act on the Status and Rights of Patients (1992/785) states that the patient shall be provided with information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects, and about other factors concerning treatment that have an effect on treatment decision-making. In a situation where a minor's identification with the opposite sex causes long-term and severe dysphoria, it is important to make sure that he/she understands the realistic potential of gender reassignment treatments to alter secondary sex characteristics, the reality of a lifelong commitment to medical therapy, the permanence of the effects, and the possible physical and mental adverse effects of the treatments. Although patients may experience regret, after reassignment treatments, there is no going back to the non-reassigned body and its normal functions. Brain development continues until early adulthood – about age 25, which also affects young people's ability to assess the consequences of their decisions on their own future selves for rest of their lives.

A lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options.

For children and adolescents, these factors are key reasons for postponing any interventions until adulthood.

7. Conclusions

The first-line intervention for gender variance during childhood and adolescent years is psychosocial support and, as necessary, gender-explorative therapy and treatment for comorbid psychiatric disorders. Uncertainty related to gender identity should be dealt with according to the severity of symptoms and the need for treatment and should be handled at the school / student health care, primary health care at the local level, or in specialty care.

In adolescents, psychiatric disorders and developmental difficulties may predispose a young person to the onset of gender dysphoria. These young people should receive treatment for their mental and behavioral health issues, and their mental health must be stable prior to the determination of their gender identity.

Clinical experience reveals that autistic spectrum disorders (ASD) are overrepresented among adolescents suffering from gender dysphoria; even if such adolescents are presenting with gender dysphoria, rehabilitative interventions for ASD must be properly addressed.

In light of available evidence, gender reassignment of minors is an experimental practice. Based on studies examining gender identity in minors, hormonal interventions may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no irreversible treatment should be initiated. Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported. It is critical to obtain information on the benefits and risks of these treatments in rigorous research settings.

At a minimum, a consultation for a pre- pubescent child at the specialist setting at the TAYS includes an extensive assessment appointment costing EUR 369. If necessary, a day-long outpatient consultation can be arranged, costing EUR 1,408.

The consultation and assessment process for minors at the specialist settings of TAYS or HUS costs EUR 4,300. If it is determined that this process would be untimely, the minimum cost is EUR 640. An initial assessment / consultation by phone costs EUR 100.

The planning and monitoring costs for pubertal suppression are EUR 2,000 for the first year, and EUR 1,200 for subsequent years. The costs for the planning and monitoring of hormone treatments are a minimum of EUR 400 per year.

These costs do not take into account the additional costs of psychosocial support provided in the local level, the possible need for psychiatric treatment, or hormone treatment medication costs.

8. Summary of the Recommendations

PALKO / COHERE maintains the following:

1. For the treatment of gender dysphoria due to variations in gender identity in minors, psychosocial support should be provided in school and student healthcare and in primary healthcare, and there must be sufficient competency to provide such support.
2. Consultation with a child or youth psychiatrist and the necessary psychiatric treatment and psychotherapy should be arranged locally according to the level of treatment needed.
3. If a child or young person experiencing gender-related anxiety has other simultaneous psychiatric symptoms requiring specialised medical care, treatment according to the nature and severity of the disorder must be arranged within the services of their own region, as no conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development.

PALKO / COHERE considers that the consultation, periods of assessment, and treatments by the research group on the gender identity of minors at TAYS or HUS must be carried out according to the following principles:

1. Children who have not started puberty and are experiencing persistent, severe anxiety related to gender conflict and/or identification as the other sex may be sent for a consultation visit to the research group on the gender identity of minors at TAYS or HUS. Any need for support beyond the consultation visit or need for other psychiatric treatment should be addressed by local services according to the nature and severity of the problem.

2. If a child is diagnosed prior to the onset of puberty with a persistent experience of identifying as the other sex and shows symptoms of gender-related anxiety, which increases in severity in puberty, the child can be guided at the onset of puberty to the research group on the gender identity of minors at TAYS or HUS for an assessment of the need for treatment to suppress puberty. Based on these assessments, puberty suppression treatment may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications. Therapeutic amenorrhea, i.e. prevention of menstruation, is also medically possible.

3. A young person who has already undergone puberty can be sent to the research clinic on the gender identity of minors at TAYS or HUS for extensive gender identity studies if the variation in gender identity and related dysphoria do not reflect the temporary search for identity typical of the development stage of adolescence and do not subside once the young person has had the opportunity to reflect on their identity but rather their identity and personality development appear to be stable.

4. Based on thorough, case-by-case consideration, the initiation of hormonal interventions that alter sex characteristics may be considered before the person is 18 years of age only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria. In addition, it must be confirmed that the young person is able to understand the significance of irreversible treatments and the

benefits and disadvantages associated with lifelong hormone therapy, and that no contraindications are present.

5. If a young person experiencing gender-related anxiety has experienced or is simultaneously experiencing psychiatric symptoms requiring specialized medical care, a gender identity assessment may be considered if the need for it continues after the other psychiatric symptoms have ceased and adolescent development is progressing normally. In this case, a young person can be sent by the specialized youth psychiatric care in their region for an extensive gender identity study by the TAYS or HUS research group on the gender identity of minors, which will begin the diagnostic studies. Based on the results of the studies, the need for and timeliness of medically justified treatments will be assessed individually.

Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors. The initiation and monitoring of hormonal treatments must be centralized at the research clinics on gender identity at HUS and TAYS.

9. Additional Evidence Gathering and Monitoring the Effectiveness of Recommendations

Moving forward, the following information must be obtained about the patients diagnosed and receiving treatments in Finland before re-evaluating these recommendations:

- Number of new patient referrals
- Number of patients starting the assessment period, and numbers of new transgender (F64.0) vs “other gender” (F64.8) diagnoses
- Whether the diagnosis remains stable or changes during the assessment phase
- Number of patients discontinuing the assessment period and the reasons for the discontinuation
- Adverse effects of treatments (especially long-term effects and effect on fertility)
- Number of patients regretting hormone therapy
- Analysis of the effects of the assessment and the treatment period on gender dysphoria outcomes, as measured by the Gender Congruence and Life Satisfaction Scale (GCLS)
- Analysis of the effects of the assessment and the treatment period on functional capacity and quality of life
- The prevalence of co-occurring psychiatric diagnoses (especially neurodevelopmental diagnoses F80-F90) among those diagnosed with / seeking treatment for gender dysphoria, and whether the presence of these co-occurring diagnoses impacts the ability to achieve the desired outcome (e.g. decreased dysphoria) in the assessment or the treatment phase.
- Whether the assessment and treatment periods lead to a reduction of suicide attempts
- Whether the assessment and treatment periods lead to a reduction in depression and distress

10. Attachments

Preparatory Memorandum, with Appendices 1-5.

EXHIBIT 109

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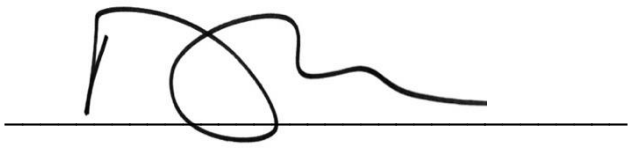
October 12, 2023

CERTIFICATE OF TRANSLATION

Norwegian > English > Translation and proofreading of the document titled:

- Patient safety for children and young people with gender incongruence

I, Diana M. Arbeláez, with the ATA nr. 251348 at Lingua Franca Translations do hereby certify that the translation herein was completed in accordance with the American Translators Association Code of Professional Conduct and Business Practices and that to the best of my knowledge the translation and proofreading into English herein provided is, in fact, a literal and true interpretation of the statements in the original language Norwegian. Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.



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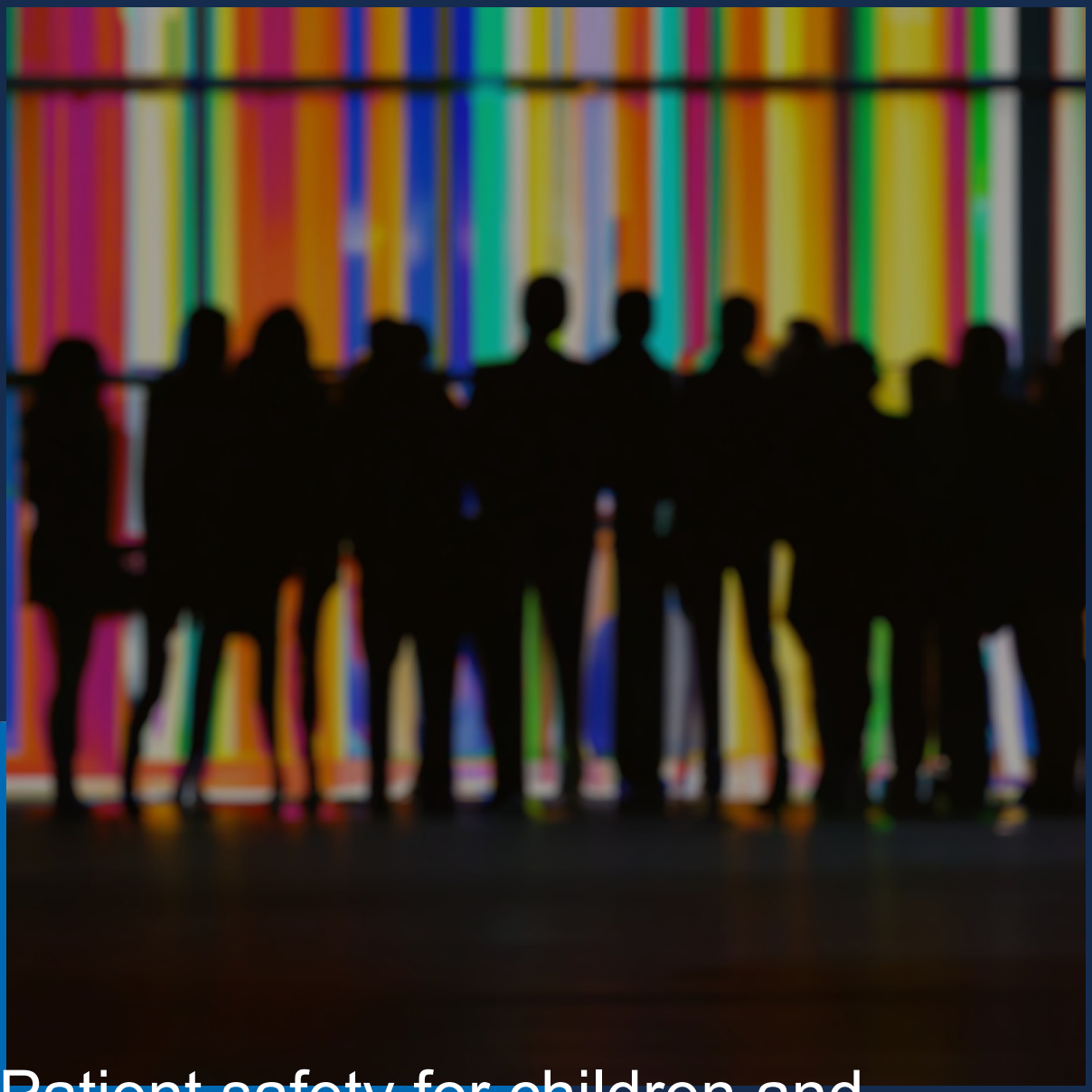

Patient safety for children and young people with gender incongruence

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Patient safety for children and young people with gender incongruence

Published on March 9, 2023 Last updated on March 9, 2023

People with gender incongruence and gender dysphoria have different wishes and needs for healthcare. Many people live well with their gender incongruence and manage it without health care, while others want and need health care. (See glossary in Chapter 13 for explanations of terms)

When Ukom addresses the topic of gender incongruence, we look at how patient safety is ensured in care and treatment services for gender incongruence and gender dysphoria. Our aim is to ensure safe care and treatment for children and adolescents with gender incongruence.

There is an ongoing public debate about treatment options for gender incongruence. This is demanding, and many people are reluctant to participate in the debate. It can be challenging and difficult to participate because there are major disagreements both between groups and within groups. We see that the choice of words and understanding of the complexity is important. The situation of insecurity and disagreement affects the development of health services.

In our report, we have tried to highlight different perspectives. At the same time, it is important for us to be clear about our findings. That is, what challenges patient safety. Many people have worked and are working to establish and build good health services for people with gender incongruence and gender dysphoria, both nationally and internationally. Ukom's report builds on this work. We point out that this field now needs a boost to improve patient safety, especially for the health care to be provided to children and young people in Norway.

Executive summary

Ukom has conducted an investigation into the treatment offered to children and young people with gender incongruence. The background was notifications directly to Ukom from relatives who questioned several issues related to patient safety. Several stakeholders, including the authorities, healthcare professionals and patient and family organizations, are questioning the quality and the organization of the treatment services.

In general, children and young people are the focus of the report. In recent years, the number of enquiries from persons with gender incongruence to the health care has significantly increased. Particularly, there has been a considerable rise in the number of teenage children and young people requesting or being referred to specialized health services for evaluation and treatment. The largest increase is among adolescents and young adults who are registered as female at birth but identify as male. Our attention has therefore been particularly focused on teenagers and young people with gender incongruence and gender dysphoria seeking health care. Children and adolescents are not fully developed physically, mentally, sexually or socially. This requires particular vigilance in terms of patient safety. Our findings and recommendations will also be relevant to the provision of care for adults.

In this report, we have divided our findings into six main areas:

Insufficient knowledge

The evidence base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are not well known. This is particularly true for the adolescent population where the stability of their gender incongruence is also not known. There is a lack of research-based knowledge on the treatment of patients with non-binary gender incongruence. In order to ensure patient safety, Ukom considers it necessary that the knowledge base on gender incongruence and gender dysphoria is strengthened, and that health services are organized in line with the knowledge base.

Overall management - a guideline with a different background

The Directorate of Health's national professional guideline for gender incongruence sets guidelines for the provision of health services. It concentrates on organization, equality and rights. This may have been important at the time the guideline was drawn up, because it was necessary to establish the health service provision for people who experience gender incongruence. At the same time, we consider that deviating from the requirement to develop evidence-based guidelines has created room for uncertainty and conflicting expectations. Health professionals have been given wide scope for interpretation within a relatively narrow field that lacks systematic knowledge synthesis in Norway. The guideline provides rights without clarifying issues related to prioritization and justfiability. This is demanding for the health personnel who administer the services on a daily basis.

Due Diligence Requirements - particularly in relation to children and young people

The national guideline for gender incongruence is not very prescriptive. It does not set specific requirements for assessment or requirements for medical indications for the initiation of treatment. The reference to children's capacity to consent and parents' right to information leaves room for interpretation. The guideline does not establish an adequate standard for the provision of health services, and we believe that for some patients it may pose a patient safety risk. This can go beyond the duty of care, which is widely anchored in health legislation, and can also be demanding for the supervisory authorities.

Right to health care - a gap in expectations

Our survey suggests that there is a gap between what the guideline outlines and what is possible, given the current available services and knowledge base. The national guideline creates expectations among patients that the health service can hardly meet. This includes the right to specialized health services. It is difficult for the service to meet these expectations without a well-documented knowledge base and without a good overview of any negative and harmful aspects of the various treatments. Requiring the use of principles for experimental treatment will provide a framework that ensures information, thorough follow-up and contributes to more knowledge.

Assistance and treatment services - variation in practice and competence

There is great variation in the services and expertise offered in different parts of the country. There is a risk of under-, over- and incorrect treatment of children and young people with gender incongruence and gender dysphoria. In addition, we see that there are challenges in establishing a decentralized service in a narrow and complex field. In order to strengthen the service, Ukom believes that it is important to strengthen the health service provision in the primary health service, build increased interdisciplinary expertise in the specialized health service at regional level and ensure that the national treatment service has sufficient capacity for the current demand.

Climate of expression and interaction

We see that in the field of gender incongruence, a challenging climate of expression has developed. The climate of expression in the public sphere affects the information available to children and young people with gender incongruence and gender dysphoria and their families. There is a significant impact on children and young people, also related to treatment and health services. We hear about fears and fears

of getting it wrong from all sides. Different opinions about what is the right treatment can create difficult cross-pressures. Different emphasis and discussion of what is necessary at the group level can confuse and undermine patient-provider relationships and a personalized approach for the person concerned. There is a need to establish a constructive community for all those involved in good health care for people with gender incongruence.

Ukom recommends

We are committed to ensuring that children and young people with gender incongruence have access to safe and appropriate health services. We therefore make recommendations that can help to ensure that this group receives better and safer health services in the long term. Our recommendations relate to the revision of the guideline, a safe framework for treatment offered to children and adolescents and measures to strengthen the knowledge base. The recommendations will also contribute to systematic data collection and promote follow-up research. It is important that children and young people with gender incongruence and gender dysphoria, including non-binary people, are properly cared for while the development of health services is ongoing.

Ukom recommends:

1. That the Ministry of Health and Care Services commissions the Directorate of Health to revise the National Professional Guideline, Gender Incongruence. The review must be based, inter alia, on a systematic review of the evidence. We point out several elements that should be included in the review.
2. that puberty-delaying treatment (puberty blockers) and hormonal and surgical gender-affirming treatment for children and adolescents be defined as experimental treatment. This is particularly important for teenagers with gender dysphoria,
3. This is particularly important for teenagers with gender dysphoria, that the Ministry of Health and Care Services is considering whether a national medical quality registry should be established for the treatment of children and adolescents with gender incongruence and gender dysphoria. In order to offer an overview, boost quality, and lessen unjustified variance in patient care, necessary steps must be made to build, run, and finance such a national quality registry.

2 Background

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Why has Ukom started an investigation

In 2022, Ukom received two reports of concern from relatives of people who have undergone assessment and treatment for gender incongruence in the age range 16-21 years. In the reports of concern, the relatives refer to several different aspects of the current treatment services that may have an impact on patient safety.

- The relatives question the appropriateness of the process.
- The assessment was demanding and the follow-up was not sufficient in relation to the vulnerable and exposed situation the family members perceived the young people to be in.
- The young people's other medical conditions or issues received little attention, and several parents questioned if gender affirming therapy was the best course of action for their child.
- Parents felt that the assessment and treatment process created a fear among young people that they would not receive treatment or would receive the wrong treatment.
- Information on treatment, efficacy and side effects was incomplete.
- Parents and family were not very involved. This put extra strain on both the young people and their families.
- Parents feel that there are cross-pressures from different quarters and communities that affect their children.

The provision of health services for persons with gender incongruence has received a lot of attention recently, both domestically and abroad. There has been a significant increase in the number of persons who have been referred for treatment of gender incongruence during the past ten years. Established treatment facilities have faced difficulties as a result of this. People with gender incongruence are calling for better health care in Norway. National standards have been developed by the Norwegian Directorate of Health to broaden and increase the group's access to treatment services. At the same time, several stakeholders, including the authorities, healthcare professionals and patient and family organizations, are questioning the rationale behind and the organization of treatment provision.

It is also controversial whether the guideline from the Norwegian Directorate of Health, and other guidelines from the authorities in this area, enable Norway to organize in a suitable manner its treatment services for the group. The care and aid provided to persons with gender incongruence is a topic of constant discussion in the media, on social media, and in work with the health sector.

Different methods of treating gender incongruence are what distinguish the public discourse. The discussion demonstrates that gender incongruence is a problem that goes beyond simple medical care. The issue of gender incongruence relates to one's own identity as well as to the inclusion, acceptance, and rights of a minority group. This is basic and pertains to a variety of patient groups, ailments, and problems. Another political concern is how gender incongruence is addressed. Reconciling medical and non-medical considerations has proven to be very challenging. This is reflected in the public debate.

In many areas, trans people have poorer living conditions and quality of life than the general population. The Government's new action plan for gender and sexuality diversity (2023-2026) states that health services for people with gender incongruence have been inadequate over time.

Uncertainty about what constitutes appropriate treatment has led the authorities in some countries, such as the UK and Sweden, to tighten the treatment offered to people with gender incongruence. In Norway, on the other hand, guidelines have been established to expand and decentralize treatment services.

We started the study by conducting a survey of the treatment services for people with gender incongruence. The mapping revealed a number of unresolved issues with implications for patient safety that are particularly relevant for the treatment of children and adolescents who are developing psychologically, cognitively, physically and socially. Treatment options for gender incongruence can involve irreversible treatment with hormones and surgery that cause invasive changes. As a consequence, we concluded that it was particularly important to look more closely at the patient safety of children and young people receiving treatment for gender incongruence.

In England, in 2022, the Healthcare Safety Investigation Branch (HSIB) published a report on the topic of gender incongruence. The starting point for their investigation was a report of concern about a young person who took his own life while awaiting assessment for gender incongruence. He was then under the care of local mental health services and there was a 24-month waiting time at the gender incongruence clinic. The survey looked specifically at the health service for young people (children and adolescents) with gender incongruence and found that there was a large increase in young people being referred to specialized units for gender incongruence. HSIB has shared experiences from its work with Ukom. The survey showed that the centralized health services lacked the capacity to accommodate the increased referrals and had long waiting times. There was a lack of competence and capacity in non-specialized care services to care for and assess young people with gender incongruence while they were waiting for assessment. HSIB also announced other findings from England (the Care Quality Commission) that healthcare professionals at a specialized treatment unit for gender incongruence did not always feel respected, supported and valued and reported an absence of a culture of openness. Some of the healthcare professionals experienced pressure due to conflicts and lack of consensus on the treatment of children and young people with gender incongruence and told of fear of voicing their opinions.

With this as a starting point, we have conducted an investigation of the health care and treatment services for children and adolescents with gender incongruence. We have looked at how health care and practice work today, and how the framework and guidelines for health care affect patient safety. Ukom does not go into detail about all help and treatment measures for gender incongruence and gender dysphoria, but we point out challenges in the current services to ensure that children and young people with gender incongruence and gender dysphoria receive help in a safe environment.

The report is based on services for children and young people, but several of our findings and recommendations will be relevant to services for all people with gender incongruence and gender dysphoria.

Our findings

Our survey shows several weaknesses in the provision of care for children and young people with gender incongruence and gender dysphoria. The findings show difficult dilemmas related to medical, legal and ethical issues. We have chosen to divide our findings into the following main themes:

- Overall governance - a guideline with a different background Care
- and treatment services - variation in practices and competences
- Insufficient knowledge

- Duty of Care - especially in relation to children and young people
- Right to health care - a gap in expectations
  Climate of communication and interaction

The next chapters deal with gender incongruence and patient and caregiver perspectives, before describing the findings in the following chapters.

3 Briefly about gender incongruence

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Gender incongruence can be defined as a mismatch between a person's gender identity and their registered sex at birth. Gender identity can be understood as a person's self-perceived gender, the internal sense of being a boy/man, girl/woman, not belonging to a gender (non-binary) or being a different type of gender. People with gender incongruence may also experience gender dysphoria in that the mismatch between gender identity and birth sex leads to discomfort and a strong desire to remove or change some or all primary or secondary sex characteristics.

In Norway, medical treatment for gender incongruence has been available since the late 1950s. The National Treatment Service at Oslo University Hospital has for more than 40 years had a national function for the treatment of patients with gender incongruence.

Increased influx - new patients

The health service has seen a marked increase in recent years in the number of patients seeking gender-affirming treatment. The number of people seeking or being referred to health care for gender incongruence and gender dysphoria is also increasing in several other Western countries. In particular, the number of children and adolescents seeking or being referred for such treatment during their teenage years has increased significantly. From 1975 to 1990, there were about four referrals per year for such treatment in Norway. In the last ten years, the National Treatment Service has reported an increase in referrals from approx. 50-70 per year in 2007-2010 to 400-600 referrals per year in 2018-2021. It is unknown why there is a large increase in the number of children and young people seeking or being referred for medical treatment. The largest increase is among adolescents and young adults who are registered as female at birth but identify as male.

Classification

Gender incongruence was previously classified under mental and behavioral disorders in the World Health Organization (WHO) diagnostic manual International Classification of Diseases (ICD). In the latest version of ICD-11, gender incongruence has been moved from the section of diagnoses for mental disorders to a new chapter for sexual health, "conditions related to sexual health". This indicates that gender incongruence should no longer be considered a mental disorder.

At the same time, it was decided that it is important to retain a diagnosis, partly because this triggers

rights, such as healthcare and social security benefits.

The Directorate of eHealth has the main responsibility for the implementation of ICD-11 in Norway. The implementation work is in the preparation phase and has not yet started. The implementation may take several years because it will involve extensive changes to various systems and work processes. In 2020, temporary changes were made to the codes for gender incongruence in Norway pending the implementation of ICD-11. All codes under the chapter F64 Gender identity disorders were then taken out of use. The codes were replaced by new ones under the chapter Z76.8 Contact with health services under other specified circumstances. There are now three codes for gender incongruence; Z76.80 Gender incongruence in adolescence and adulthood, Z76.81 Gender incongruence in childhood and Z76.89 Unspecified gender incongruence. These are directly translated from the corresponding codes in ICD-11. This was done as a temporary solution in the Norwegian version of ICD-10 in anticipation of ICD-11. These codes are now used for medical coding of gender incongruence and are reported to the Norwegian Patient Registry. In addition, procedure codes are used for mapping and surgical procedures. There are no separate procedure codes for the initiation of hormone therapy. Diagnosis codes are used in combination with procedure codes.

Gender diversity and different gender expressions

For many people, exploring their own gender identity is a natural part of the development from child to adult. Today, there is greater acceptance in society of different gender expressions. This acceptance is partly the result of increased knowledge, information and many years of advocacy efforts by various groups and individuals. It has also been argued that social media has made it easier to share, acknowledge and be open about feeling different. Despite the greater acceptance of gender diversity in society, many people with gender incongruence still experience stigma and discrimination. This is relevant knowledge for the health services and an important backdrop for the development of support and treatment services.

Treatments for gender incongruence

For people with gender incongruence and gender dysphoria, various support and treatment measures may be relevant. Interventions and treatment for gender incongruence and gender dysphoria may vary from less invasive help to more invasive treatment, such as various hormonal treatments and surgical treatment. These may include counseling, psychosocial support sessions, coping skills training and speech therapy sessions with voice training. Assistive devices such as wigs, breast prostheses and penile prostheses may also be used. These aids are used in the assessment as "real-life experience". That is, the person lives as the desired gender to assess whether it feels right. These are less invasive measures. Puberty blockers and gender affirmative treatment involve hormonal treatment, and gender affirmative treatment may also involve surgical procedures. Gender affirmative treatment is known to be invasive and irreversible with different consequences and greater risk and potential for harm than less invasive treatment.

Puberty blockers

Children and adolescents who have reached puberty may receive hormonal treatment with puberty blockers (puberty inhibitors) to stop or delay puberty. Puberty blockers have traditionally been given to children who reach puberty too early, but can also be used to treat gender incongruence and gender dysphoria in children and adolescents. The reason for delaying puberty is that children and adolescents may experience increased discomfort, gender dysphoria, when puberty starts, and they experience physical development that is not in line with their own gender identity. The treatment prevents puberty from developing further and thus prevents a possible unwanted development.

Treatment with puberty blockers appears to be most effective in the early stages of puberty, both in terms of the development of sexual characteristics such as breasts, penis, facial and body hair and height growth. Treatment has no age limit, but can start at the beginning of puberty at the earliest.

Treatment can only be given for a few years. After that, a decision must be made whether to stop all hormone therapy or to switch to feminizing or masculinizing hormones. The treatment has known side effects such as weight gain, reduced height growth, hot flushes, lack of energy, depression and reduced bone mineralization. Little is known about the long-term effects.

Gender affirmative treatment

Gender-affirming treatments aim to affirm a person's gender identity. Unlike puberty blockers, which stop or delay unwanted physical development, gender-affirming treatment involves giving the body a development or physical characteristics that are in line with one's gender identity. There are two types of gender-affirming treatment: gender-affirming hormone therapy and surgical treatment.

According to the guidelines, gender-affirming hormone therapy can be offered from the age of 16. Testosterone is given to people whose registered sex is female and oestrogen and antiandrogen to people whose registered sex is male. If the person has had puberty delayed with hormones, sex hormones are given in escalating treatment to simulate the development of puberty. Gender-affirming hormone therapy must be given for life to maintain the desired effect.

In people with registered female gender, physical changes can be expected in the form of deepening of the voice, enlargement of the clitoris to varying degrees, increased growth of facial and body hair, cessation of menstruation, shrinkage of breast tissue, increased sex drive and reduced body fat to muscle mass ratio. In people with registered male gender, one can expect varying degrees of breast growth, decreased sex drive and erections, reduced testicular size and increased body fat in relation to muscle mass.

Surgical treatment can be given to people over 18 years of age. Current treatments include breast removal, ovary and uterus removal and surgery of the external genitalia.

Many of the changes brought about by sex reassignment surgery are irreversible. The treatment has consequences for fertility that are permanently impaired. Possible side effects of the treatment may include liver disease and negative psychological reactions. For male-to-female treatment, there is an increased risk of blood clots, high blood pressure and liver disease. For female-to-male treatment, side effects may include excessive red blood cells, scarring acne and swelling of the body. We do not provide here an exhaustive list of all possible known effects.

4 Input from patients and families

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When discussing gender incongruence and the patient perspective, it is important to clarify that people with gender incongruence have different wishes and needs for healthcare. Many people live well with their gender incongruence and manage it without health care, while others want and need health care.

Listening to the voice of patients, users and relatives is crucial for identifying areas of risk and improvement in health services. In the work on this study, it has been important to bring out several patient voices and perspectives. We have met several patients who are either receiving treatment or have been in a treatment situation, and we have heard about a diversity of needs, preferences, opinions and experiences with the health service.

Messages for health services

Here are some key messages that emerged from the conversations we had:

- Being in the process of exploring gender incongruence and gender dysphoria is demanding, and many people want support in their individual process.
- Gender-affirming treatment should be personalized. It is important that the treatment system sees the individual with the resources and challenges they have.
- Many people with gender incongruence feel that there is a lack of expertise and comprehensive services.
- Many are concerned that respect and tolerance for gender diversity is being lost in the debate on binary gender affirmative action.
- All have highlighted the importance of thinking about the whole person and life course, including for transgender people.
- There is a fear of not being seen, not being heard and not getting the right
- help at the right time. Living with gender dysphoria over time and without help is very painful.
- Health services must provide assistance to both people with binary gender incongruence and non-binary gender incongruence.

"For many, the most important thing is to be seen and heard. And when you have to stand and wait for nine months .... It is heavy. We have to get rid of unnecessary waiting time"

PATIENT ORGANIZATION REPRESENTATIVE/FORMER PATIENT
GENDER INCONGRUENCE

In addition, the people we have spoken to describe experiences of powerlessness, frustration and exhaustion in their encounter with the health service. This is due to processes that are perceived as long and convoluted both in the encounter with the health service, to get access to help, and then in the assessment and treatment process. In addition, there is the burden of the time it takes to put in place a comprehensive health service for people with gender incongruence.

Need for help

Health and social situations are impacted by gender inequality to varying degrees. Numerous variables are at play, such as the fact that the degree of dysphoria is influenced by both social and biological variables. For the individual who experiences severe gender dysphoria, it is extremely unpleasant. Suffering then has a significant impact on daily functioning and life quality. The importance of receiving medical attention for persons who suffer with dysphoria cannot be overstated.

A group that has experienced stigma, prejudice, and marginalization is the transgender community, including when utilizing medical services. The difficulties and issues brought on by gender dysphoria and gender incongruence have not been acknowledged or appreciated in the attitudes that have been shown toward them. It is therefore important for the patient group to work to have a dignified encounter with the health services at all stages of life, and to ensure that those who need treatment for gender dysphoria receive it.

One of the topics on which there are different opinions, including among patients and relatives, is who in the health service can start gender-affirming treatment and when. For example, several people tell us how important it is that a decision on gender-affirming treatment is given time and maturation. It is difficult to fully understand the consequences of the choice, and as many mention, there is "no quick fix".

"There are many people who get a shock after treatment. You have to work on a lot of things. Work on acceptance. For example, I always have to live with the fact that I was born in a girl's body."

PATIENT ORGANIZATION REPRESENTATIVE

At the same time, many also talk about how important it is to start treatment early, because the changes caused by puberty are also permanent.

"Gender-affirming treatment is vital treatment. Not providing treatment is also irreversible."

PATIENT ORGANIZATION REPRESENTATIVE

Everyone we spoke to emphasizes the importance of knowledge about gender incongruence at all levels of the health service, and that those who carry out assessment and treatment need specialized

expertise.

"And then, of course, there's the trauma of going through a puberty you don't want to go through, we shouldn't take it lightly. And that balancing act, about when to start treatment and when it is not right, requires knowledge"

FORMER PATIENT ABOUT ASSESSMENT/TREATMENT FOR GENDER INCONGRUENCE

What recurs in all our meetings with people who have gender incongruence is a desire to put in place better health services. There is also a unanimous wish that everyone who experiences gender incongruence and gender dysphoria should be taken seriously and receive support and help.

Safe care

Relatives tell how important it is that health service staff meet young people with gender incongruence with openness and knowledge, and that relatives are involved as supporters throughout the process. Relatives have information that can be important both in the assessment and in the further process. The need for family members as supporters does not stop at the age of 16 or 18.

"Throughout the process, she has lacked follow-up. She speaks of great loneliness. We are left out all the way. Nowhere have they worked to include us as parents. But everyone, especially young people, need supporters"

MOTHER

Several people tell us that assessment for gender-affirming treatment is a demanding process. On the one hand, it is perceived as very demanding if the process takes a long time. On the other hand, it is also demanding for many to experience time pressure, where the decision to start hormonal treatment must be made early before pubertal development gets too far along.

"We need to be able to talk honestly together. About what is difficult, about what you are unsure about, and about what might feel wrong. Now she's being cheered on, getting lots of support from everyone around her. I'm not sure if she can be honest about everything she feels with her friends, if there is room for doubt."

MOTHER

Parents point out that it is important for services to take the time to see the whole young person, to take the time to involve those closest to them and to explore what is troubling the individual. They believe this is necessary in order to find out what the right help is. There is no time limit for this exploration because there will be individual differences and it requires close follow-up.

"We see in retrospect that it was important that the process takes time, she also understands that now. While in the investigation, it was tough. She had a feeling of having to convince that she deserved to get help, to be approved. This blocked communication."

MOTHER

Several have mentioned that it is difficult to find places they can go to safely explore their own gender expression and identity along with any other challenges they are facing. This is especially true for children and adolescents, but it is also challenging for young adults who are not affiliated with a health center.

"It would be healthy if it was part of the program to talk with someone. So that you could talk about everything, dare to put into words everything that comes with this, what you feel. Both the good and the difficult. Then it is easier to make choices that are right for you along the way. You are more stable if the follow-up takes in the whole package. You're 16 and think that fixing your body will solve all your problems, but it doesn't."

MOTHER

5 Our findings: Overall governance - a guideline with a different background

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In recent years, there has been increased attention to the health care of people with gender incongruence. In 2015, the report Right to the right gender was published. Health services for people with gender incongruence and gender dysphoria were then for the first time the subject of work under the auspices of a publicly appointed working group in Norway. The Government's action plan against discrimination on the basis of sexual orientation, gender identity, gender expression and gender characteristics (2021-2024) strengthened efforts to promote the rights, living conditions and quality of life of queer people.

In 2020, the Directorate of Health's national professional guideline on gender incongruence was published.

In 2023, the Government published an action plan for gender and sexuality diversity (2023-2026). It points out that we are still not at the finish line in the fight for a free, inclusive and safe society for all. Too many queer people live without a good quality of life and good living conditions. The Action Plan aims to improve the quality of life of queer people, ensure their rights and contribute to greater acceptance of gender and sexual diversity. The action plan includes measures related to treatment services for people with gender incongruence.

The national professional guideline, gender incongruence

The Ministry of Health and Care Services commissioned the Norwegian Directorate of Health to: "Prepare a normative document/professional recommendations on the treatment of gender dysphoria and gender incongruence". The assignment was also a result of an expressed desire in the professional, user and interest groups for a confirmation of the health services offered to people who experience gender incongruence. A separate chapter in the guideline on background describes this:

> *"The commission for this national guideline has a rare and special background, unlike other normative publications from the Directorate of Health. It is not common for assignments to prepare professional guidelines to be linked to established grounds for discrimination and a global and national concern for the provision of health services to a patient group. The guideline must be read and understood against this background."*

It is described by many as an important document that represents a turning point in how we think about gender identity, gender incongruence and gender dysphoria, for example in the consultation response from the Norwegian Association of General Practice's LGBT professional group.

At the same time, in the consultation round for the guideline, several people called for clearer clarifications and concretizations, including the Norwegian Institute of Public Health (FHI) and the Norwegian Board of Health Supervision. They pointed to demanding issues related to the soundness and the organization of the service.

The national professional guideline for gender incongruence does not follow the Guidelines for the

development of evidence-based guidelines published by the Directorate of Health, which states:

> *"The advice and recommendations given should be specific, they should help health professionals and patients to make good decisions, and they should help to reduce unwanted variation and promote good quality in health and care services".*

The national guideline on gender incongruence differs in terms of content, knowledge base and standardization. The guideline is overarching, with attention to organization, equality and rights. The aim of the guideline is to provide differentiated, decentralized and comprehensive health services for people with gender incongruence.

The guideline refers to the need to strengthen the knowledge base and research on gender incongruence. It indicated a need to:

- update the evidence base for assessment and treatment of gender incongruence
- strengthen research activity
- develop professional guidelines for health care
- establish a national medical quality register with quality indicators

There was no systematic review on which the national guideline could be based, and the national guideline does not present a systematic and structured overview of the evidence base in line with the Guidelines for the development of evidence-based guidelines.
The Directorate of Health writes that the recommendations are mainly based on experience-based consensus and user participation/user knowledge, but what is included in the guideline's mentioned experience-based evidence base is not documented, transparent or verifiable.

Creating a treatment service is a procedure that is always changing, according to the guidelines. Establishing a particular service, gaining the required knowledge, creating research projects, developing national clinical issue guidelines, and other related tasks will need money and time.

In terms of who can do what, how, where, and when, our study reveals that the standards offer too much opportunity for interpretation. We see that there is ongoing debate in the professional communities and patient organizations, and that this disagreement adds to undesired diversity in the treatment provided for often irreversible and extensive treatments. The guideline performs poorly as a tool for professional standards, according to the comments we have gotten from representatives of the services, and this poses a risk to patient safety.

In summary

According to the results of our survey, the recommendation does not offer the service enough assistance in creating a service offer. With its emphasis on organization, equality, and rights, this guideline is too ambiguous and is not a tool for the service, despite the justification that it is a distinct guideline with a different foundation. We think that for an area of practice to develop, it is critical to have good, unambiguous guidelines. There are various ramifications for the growth of healthcare services as well as for patients when guidelines don't offer enough direction.

6 Our findings: Care and treatment services variation in practice and skills

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The national guideline is intended to contribute to "decentralized, differentiated and comprehensive health services". This means that services should be both close to and at all service levels, consist of different services, and the services should be coherent and coordinated. The guideline for gender incongruence states that most patients should receive help either from the municipal health and care services or at regional level in a specialized health service. This is consistent with other health services, but since there is no clear specification of which tasks are to be performed by whom, it is difficult for the service to establish this.

The Directorate of Health writes in the guideline that it will take time to put in place an adequate range of services for the group, and that the guideline is only a step along the way. As of today, three years after the guideline was issued, an adequate range of services and the desired concrete changes are not in place.

Description of practices for assessment and initiation of treatment

Health centers and GPs are often the first point of contact. GPs will often request that the patient be assessed by local mental health services before referral to the National Treatment Service for Gender Incongruence at Oslo University Hospital HF. The assessment in mental health care may then consist of a survey and assessment of the patient's psychosocial situation, level of functioning and gender identity. Patients are also referred directly to the National Treatment Service by doctors in the primary health service for assessment of the indication for puberty-inhibiting or gender-affirming treatment. On the website of the National Treatment Service treatment of children and adolescents as of February 24, 2023, a waiting time of 3-9 months was stated, although it may vary depending on how many people are being

treated.

The national treatment service for gender incongruence has the national function for the treatment of patients with a diagnosis of gender incongruence in Norway. This means that the national treatment service has the main responsibility for gender-affirming hormonal and surgical treatment.

The assessment of gender incongruence and gender dysphoria at the national treatment service is a comprehensive interdisciplinary process, including mapping of physical and mental health and social challenges. Thorough assessment and the need to spend time is emphasized in order to assess whether gender-affirming treatments are the right thing for the individual. It is a requirement that all persons referred or undergoing assessment have a local treatment contact. Gender identity disorder must be present over time and not be a symptom of mental illness.

Some GPs and health centers offer hormonal gender-affirming treatment directly to patients and puberty blockers to children under 16 years of age. The City of Oslo has a health centre, Helsestasjon for gender and sexuality (HKS), which specializes in topics related to the body, sexuality and gender identity. The health center provides gender-affirming support and treatment at a low-threshold level and can, if desired, make referrals to other services. The health center also provides treatment with puberty blockers and gender-affirming hormones, and refers to mental health care and the National Treatment Service if the need is assessed. Several municipalities are considering establishing their own services for this group.

There is currently variation in what is done and emphasized in assessment, treatment and follow-up, and the professionals involved in the assessments in the primary health service vary. There is a different understanding of diagnostic coding, guidelines and knowledge base. Management is based on individual assessments of the patient and different interpretations of the national guideline.

"Different assessments are made, including in BUP, where one practitioner reads the guideline in one way, and another practitioner reads it in another way."

REPRESENTATIVE OF A REGIONAL HEALTH AUTHORITY

Variation in service provision

Several people we have spoken to point out that the only possibility for many people in Norway to get help with their gender incongruence is to get a referral from their GP to the highly specialized services at the national treatment service. This service is located in Oslo, and requires several consultations over a longer period of time in connection with assessment and treatment. We have heard that many patients living in other parts of the country find it difficult to travel so far to get the treatment they need, especially if they do not have local follow-up. Others may live in areas where local primary care services are available. There are also variations in GP practice for children and young people with gender incongruence, with some GPs going to great lengths to meet the treatment needs of this patient group. Many children and young people who need support to explore their own identity and gender expression do not receive it locally. This can increase the risk of both under- and overtreatment. For example, many may be left without the health care they need over time. It can also lead to them starting treatment on their own. Overtreatment can occur when hormonal treatment is started on the wrong basis and without sufficient opportunity to explore different options within their own gender identity.

"Not everything is about gender. It's about identity and being allowed to be yourself, to be accepted. Both as masculine and feminine regardless of gender."

INFORMANT H

It therefore appears that the assistance offered to children and young people with gender incongruence varies greatly, and can lead to different outcomes for the patient group based on where they live.

The regional health authorities (RHF) are now participating in a collaboration to assess which tasks can be solved regionally and to what extent they need to establish multi-regional services. The work aims to identify needs and challenges in current assistance services across municipal health services and specialized health services.

In 2020, the regional health authorities were tasked with establishing regional treatment services for people with gender incongruence. The Government gave the health authorities until October 1, 2022 to clarify the content of the regional treatment services. In the summer of 2022, Ukom contacted the regional health authorities to obtain updated information about the services for people with gender incongruence. The responses from the regional health authorities showed that there were differences in existing and planned assessment and treatment services. An interregional collaboration is now underway to clarify clinical issues and establish treatment services in the regional health authorities. In connection with this work, various concepts and principles, for example related to prioritization, must be clarified. The guidelines stipulate that the assessment and some of the treatment can take place at regional centers in the specialized health service. In the South-Eastern Norway Regional Health Authority, regional treatment centers are under development, and the other health regions are working to put services in place. In the spring of 2023, a pilot will be launched for a patient pathway for gender incongruence that extends from the primary health service, via a regional service in the specialist health service and to the national highly specialized service at Oslo University Hospital HF.

"We need to be aligned. This is important for patients. The regions must do the same."

REPRESENTATIVE OF A REGIONAL HEALTH AUTHORITY

However, we have heard that some patient and user representatives fear that the regional services under development will in reality become a "new waiting room" and that the treatment services they want will continue to be offered only by the national treatment service.

Lack of capacity and long waiting times

The national treatment service for gender incongruence has capacity problems due to the increased number of applicants, resulting in long waiting times for assessment, examination, initiation of treatment and follow-up. The capacity challenges are exacerbated by the fact that the differentiated service is not in place in the regions.

"It took a very long time from when I went to the GP the first time until I was at Rikshospitalet. That waiting period was very difficult. First of all, the GP didn't know where to refer me and at the DPS I was refused. A new doctor who had worked in a larger city and knew about this beforehand had to come before we could send a referral to the right place. And then there was the wait to get to Rikshospitalet. When I finally got there, I was greeted in a nice way, and was given a review of what gender-affirming treatment entails. Then I was referred back to a sexologist in the region. There I found out that it wasn't gender-affirming treatment I needed, and I got the counseling I needed to find out where I stand in relation to my identity, sexuality and gender expression."

INFORMANT H

We have heard that the long waiting time is one of the reasons why some people choose to start different parts of treatment on their own. Long waiting times pose a risk of sequelae and self-medication, which is a challenge in terms of patient safety.

Need for increased competence and access to cutting-edge expertise

We have been told by both patient organizations and the service that there is a lack of health personnel with expertise in gender incongruence and in the follow-up of people with gender incongruence in both the primary health service and the specialized health service.

"... Many act on the basis of their professional background ... act based on the resources they have. But they don't have expertise in trans health."

PATIENT ORGANIZATION REPRESENTATIVE

Several people we have spoken to have emphasized that children and young people with gender incongruence and gender dysphoria need access to competent health professionals, regardless of whether they need treatment, support measures or whether they want to explore gender expression and gender identity. Since in practice they will meet different professionals depending on where they are in the service, this means that there are several professional groups that

need this competence. The competence needs of the different professional groups must be assessed based on the type of help offered, but knowledge of gender incongruence and how to deal with it must be at the core.

Municipal health and care services are often the first encounter with health services for people exploring their gender identity and their relatives. We have heard that there is generally little expertise and experience with gender incongruence and gender dysphoria in the municipalities. We have identified three factors that are of importance for building up help and support in the municipal health service.

- There is a need for accessible guidance for all those working in primary care settings for children and young people, such as kindergartens, schools and health centers.
- There is a need for family support and parenting guidance services for families with children and young people with gender incongruence, both binary and non-binary.
- There is a need to strengthen the role of the General Practitioner (GP).

The role of the general practitioner is important in assessment and follow-up over time. It is essential for GPs to have access to appropriate support from the specialized health service when needed, as is the case for other conditions and courses of treatment.

The health professionals involved must be well trained in cooperation with the National Treatment Service. Those who will work on this must feel competent."

REPRESENTATIVE FROM A REGIONAL HEALTH AUTHORITY

The general practitioners we spoke with felt it was important that people with gender incongruence have the opportunity to openly and curiously explore gender expression in a safe environment with their general practitioner.

"It's first and foremost about taking care of the person, as long as we approach gender in an open and exploratory way, and don't reject or close doors, then it works well. It is important to clarify that it is not about excluding treatment, but about taking care of the person first."

TREATMENT

In recent years, requirements have been introduced whereby knowledge about gender identity and gender expression must be included in key health professional education programs. In the long term, this may lead to more competence about gender incongruence in the services. However, we have heard from several people that more needs to be done to ensure that there is competence about gender incongruence in the various parts of the services that the group encounters.

A highly specialized field in need of multidisciplinary expertise

Gender incongruence and gender dysphoria is a narrow and highly specialized area within specialist health service. It is therefore essential to build expertise in this field in order to assess, guide and treat in a responsible and safe manner. Ukom has noted that the services want to offer as wide a range of services as possible to the patient group, but that they must also offer good quality services. It is a prerequisite for establishing a sufficiently good service that patients are met by professionals with the right expertise.

An interdisciplinary approach is necessary in the assessment and treatment of gender incongruence and gender dysphoria, and this places clear demands on the structure of the service. Given the complexity of the subject area, the service also needs to have a certain volume of patients in order to gain the necessary experience and knowledge. In the ongoing restructuring of services for children and young people with gender incongruence and gender dysphoria in England, the authorities have calculated that a minimum population of five million is needed to develop a separate service for this patient group. Abroad, we see examples of gender incongruence centers being located in major cities to pool expertise and build a treatment and research environment. This shows some of the challenges of building a decentralized service in Norway.

The service currently faces challenges in recruiting and retaining professionals in the field. One of the reasons given is attrition of professionals.

Stakeholders Ukom has spoken to believe that sufficient expertise on gender incongruence in the municipal health and care services can help ensure that many people's need for health care is met. For children, young people and adults, it is also appropriate for health care to be locally based.

Several stakeholders have also pointed out to Ukom the importance of children and young people with gender incongruence being met by professionals with sexological expertise. Sexologists that Ukom has talked to say that they have special expertise in this field. The Directorate of Health's guidelines also state that sexological competence and knowledge is an important prerequisite for professionals in this field. One argument is that after the latest change in ICD-11, gender incongruence is no longer to be considered a mental diagnosis.

At the same time, sexologist is not a regulated profession with a protected title or regulated education. This means that anyone, regardless of educational and experience background, can basically call themselves a sexologist. This means that the sexologists who see patients in the services may have different competences. It may also vary whether the sexologists have a health professional education and sufficient knowledge about other diseases and mental disorders that may affect the situation of people with gender incongruence. This may contribute to variation in service provision.

Risky self-medication and private surgery

Many people with gender incongruence choose to initiate treatment for gender incongruence outside the public services. They can do this by starting hormone therapy on their own, for example by ordering drugs online or buying them abroad. They can also undergo gender confirmation surgery privately in Norway or abroad.

"I didn't want to wait for an operation at Rikshospitalet, because "I didn't want to wait for an operation at Rikshospitalet, because

Because the hormones will change the structure. I didn't want to hear with that ear, I wanted to fix my chest. Because that was what was visible. Everything else could be hidden, nobody saw the ovary on a daily basis. So I went to a private surgeon in Oslo. He destroyed me."

PREVIOUS PATIENT ASSESSMENT/TREATMENT OF GENDER INCONGRUENCE

Starting hormonal treatment on one's own outside of public services involves risky self-medication. This is a significant patient safety risk, partly because patients are often not assessed before starting treatment. The person is also left alone to administer the treatment. People who have started self-medication will often turn to public health services for help or to obtain prescription medication.

Gender reassignment surgery performed privately in Norway or abroad also involves patient risk. The role of private treatment providers is unclear in the national guideline.

One of the reasons for starting treatment on their own is refusal of hormonal gender-affirming treatment. Several patient and user representatives have pointed out that the current service provision is not designed and organized in a way that allows for a right to a second opinion, even though this right follows from the Patients' and Users' Rights Act. A possibility for a second opinion has long been requested by the patient group. Other reasons for self-medication include lack of local services and support, lack of trust in the health service and long waiting times.

"In terms of patient safety, when capacity is limited there is a vacuum in waiting time and follow-up - where there is no local, regional or national provision. This vacuum is a risk."

PRACTITIONER AND RESEARCHER

In summary

We see that there is great variation in the services and expertise offered in different parts of the country. There is a risk of under-, over- and incorrect treatment of children and young people with gender incongruence and gender dysphoria. In addition, we see that there are challenges in establishing a decentralized offer in a narrow complex field.

In order to strengthen the service, Ukom believes that it is important to strengthen the health service provision in the primary health service, build increased interdisciplinary expertise in the specialized health service at regional level and ensure that the national treatment service has sufficient capacity for the current demand.

7 Our findings: Insufficient knowledge

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The evidence base, especially research-based evidence, for gender affirmative treatment (hormonal and surgical) is insufficient. Little is known about the long-term effects. This is particularly true for the teenage population, which accounts for a large part of the increase in referrals to the specialized health service over the past decade. This represents a new population for health services where evidence on treatment efficacy, side effects and prognosis is lacking or weak. Most often, the studies are about patients with binary gender incongruence, but now there is also increased referral of people with non-binary gender incongruence for which there is little research evidence. Research-based knowledge is incomplete and does not provide clear answers. This is recognized nationally and internationally. A committee set up by the health authorities in England recently described the evidence base as follows:

> *"Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."*

Systematic review of evidence

The lack of an evidence base makes it difficult for health professionals, patients, relatives, authorities and others to get an overview of the current evidence base in the field. Systematic reviews collect and compile available evidence in a systematic, scientific and transparent manner based on explicit and predefined methods according to international standards for how such reviews should be prepared. It should be possible for others to verify results and conclusions. This contrasts with non-systematic reviews ('traditional' reviews), which lack systematic and transparent procedures. It can be difficult to know why some research results are emphasized and others not. Differences in emphasis and coverage can give a misleading picture of the evidence base and consensus. It is important to use available knowledge and experience nationally and internationally in a systematic way.

Different groups and countries have produced different types of summaries and guidelines, for example:

- An Endocrine Society Clinical Practice Guideline was an updated 2017 clinical practice guideline from the American and European Medical Endocrinology Associations (American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society)
- The World Professional Association for Transgender Care (WPATH) has published an update of the Standards of Care, SOC8.
- In 2022, the Swedish National Board of Health and Welfare published an update of the evidence base for "Support, assessment and hormone treatment for gender incongruence in children and adolescents".

SOC8 was published in 2022 and is a guideline developed by the professional and advocacy organization WPATH to guide healthcare professionals to ensure safe and effective care for transgender and gender diverse people. The guideline is based on published literature and expert consensus-based opinions. The guideline and recommendations aim to promote evidence-based care, education, research, public policy and respect for transgender people's health globally.

Swedish health authorities have several times updated the evidence base with summaries (non-systematic and systematic) and revised recommendations for children and adolescents with gender dysphoria and gender incongruence. Swedish health authorities at the National Board of Health and Welfare considered at the last update in 2022 that the risks of puberty blockers and gender-affirming hormone therapy for the group of young people with gender incongruence as a whole outweighed the possible benefit of the treatments. This was based on their updated assessment of the evidence base where they considered it was not possible to conclude on the efficacy and safety of the treatments, and the National Board of Health and Welfare recommended that the treatments be provided within the framework of research. The report emphasized new knowledge on the prevalence of treatment regret among young adults. The National Board of Health and Welfare also highlighted the unexplained increase in the number of people seeking assistance from the health services, particularly a marked increase among adolescents and especially adolescents with registered sex female (girl) at birth.

In Norway, systematic reviews and health technology assessments are used to determine which treatments can be given to different patient groups. There are different types of HTAs. A so-called full HTA is a comprehensive systematic assessment of new or established methods in which efficacy, safety and/or cost-effectiveness are reviewed and assessed. The assessment often also includes questions concerning ethical, legal, organizational and societal consequences. In Norway, no systematic reviews have been conducted on puberty delaying and gender affirming treatments with hormones and surgery. Nor have any health technology assessments of treatments for children and adolescents with gender dysphoria been used. The health authorities in Norway have not provided updates of the evidence base and accompanying benefit and risk assessments of various treatments as, for example, the Swedish authorities have done.

Safety and efficacy of the treatment

There are unresolved questions related to puberty blockers in adolescents. One published study shows that puberty delaying hormones cause slower growth in height and slower increase in bone density. It is also noted that the effects on cognitive development have not been established. There are increasing questions about the unresolved side effects and long-term effects of both puberty blockers (hormone therapy) and gender-affirming hormone therapies. However, experience with other patient groups shows that long-term use of cross-sex hormones can affect disease risk. When people with gender incongruence are treated, it is with significantly longer duration and intensity of hormone treatment than hormone treatments for other conditions. When treatment is started at a young age, it will need to last a lifetime.

Long-term satisfaction with surgical gender confirmation procedures at the group level and the need for surgical reoperations are not known.

Since some of the treatment is established in practice, it is problematic to conduct good randomized trials. It is also ethically difficult to conduct randomized, controlled trials to assess the efficacy of several of these treatments for people with gender incongruence, especially on children and adolescents. There is little and uncertain data on the rates of regret, and this is particularly relevant for the most invasive treatments such as puberty delaying and hormonal and/or surgical gender confirmation treatments. It is not a given that everyone who has received this type of treatment and regrets it will contact the treatment institution. In Sweden, for example, there is not enough scientific evidence to assess how many people discontinue or regret treatment.

There are many studies showing improvement in gender dysphoria, quality of life, psychosocial functioning and psychological tests in the short term after drug and surgical treatment of gender incongruence and gender dysphoria. However, there are few studies of the long-term effects of the treatments, and the quality of the studies is variable. There is a lack of studies comparing outcome measures after different treatment methods and there is usually no control group in the studies. The lack of control groups means that effects are often measured against population data. Effects are often assessed at the group level, rather than the individual level, so that adverse effects for some patients may be masked by improvements in the rest of the group. Sample sizes are often small, and patient dropout can greatly affect the results. There are few long-term studies, and those that exist started before the described increase in teenagers with gender incongruence seeking treatment. It may therefore be difficult to transfer the results from these earlier studies to those who are now being referred, since a large proportion have mental illness, developmental disorders or other conditions not described in the earlier studies.

Suicide incidence

There are varying figures given on the incidence of suicide in people with gender incongruence and gender dysphoria depending on the time period and the type of population studied.

The 2020 report from the National Board of Health and Welfare showed that 0.6 percent of those registered with a diagnosis of gender incongruence in Sweden (39 out of 6334 people) had committed suicide. Professionals and researchers at the Norwegian Institute of Public Health wrote in 2020 about the figures from Sweden:

> *"The suicide risk was significantly higher than in the general population, but at the same level as the suicide risk in common mental disorders such as depression, bipolar disorder and autism. Since these mental disorders are so common among people with gender incongruence, it is not possible to determine whether the increased suicide risk is due to gender incongruence per se or is a consequence of mental disorders. Nor are there studies that provide evidence that suicide risk is reduced as a result of gender-affirming treatment, or that suicide risk increases if gender-affirming treatment is not provided".*

Follow-up data from a cohort of people referred to specialized centers in the Netherlands (1972-2017), also published in 2020, showed for the period 2013-2017 an almost four times increased risk of suicide among transgender people compared to the general risk. Suicides occurred at all stages of transition, with two-thirds occurring in people still in active treatment. Trans women had a higher suicide risk than trans men. There was no change in suicide risk over time in trans men, however, there was a slight decrease in suicide risk for trans women throughout the time period. In Norway, we do not have published overview figures on suicide in persons with gender incongruence and/or gender dysphoria.

Lack of knowledge about the situation of the patients

There is currently no Norwegian overview or systematic mapping of the patients' history, how many are rejected, withdraw during the treatment process, complete the treatment or how patients with gender

incongruence and gender dysphoria fare after treatment. This requires both a national registry and systematic review, neither of which is in place. Researchers at the National Treatment Service for Gender Incongruence have established a local quality register with information on children and adolescents who have been referred to the team for gender identity investigations over the past 20 years. This is data from a selected part of the health service and does not provide a complete overview, since there are several who treat children and adolescents with puberty blockers and gender affirmation treatment.

The 2022 annual report from the national treatment service summarizes these figures: 915 people (268 children and 647 adults) were referred to Oslo University Hospital HF for assessment. Of the children under investigation, 70 (26.1 percent) were registered male and 198 (73.9 percent) were registered female at birth. A total of 2449 adult patients were undergoing assessment, treatment (hormonal and surgical) and follow-up after surgical treatment. This was an increase of 16% from the previous year. 83 patient relationships were terminated during the assessment process by the practitioner, and 40 people terminated the patient relationship themselves. A total of 244 plastic surgeries were performed:

- 78 had their breasts
- removed 24 had breast implants
- 28 had major genital conversions (procedures)
- 96 other gender corrective surgeries (breast/genital)
- 51 gynecological operations, such as removal of the uterus and ovaries

The National Treatment Service has previously reported that 75% of those referred have a mental illness, with depression and anxiety being the most common diagnosis. A significant clustering of different conditions was also found. Approximately one in five of those referred with gender incongruence had autism spectrum conditions, ADHD/ADD or Tourette's. This is consistent with Swedish figures.
The National Board of Health and Welfare has also mapped the prevalence of gender incongruence over time and looked at co-occurring mental disorders and other disorders.

"Nobody knows what happens to those who are rejected - nobody knows anything about groups of patients who are not followed up."

PATIENT ORGANIZATION REPRESENTATIVE

There is no national overview of gender confirmation treatment provided by private providers, neither nationally nor internationally. Furthermore, there is no overview of the extent of self-medication with the purchase of hormonal treatment via the internet.

An overview is needed to promote development, and medical quality registries and research studies can contribute to this. Medical quality registries collect structured information from patient care pathways. Information on assessment, treatment, follow-up and outcome of treatment provides knowledge about unwarranted variation in health care provision and quality of care. The main purpose of medical quality registers is to contribute to better quality of patient care.

User participation and patient-reported outcome and satisfaction measures (PROMs and PREMs) are particularly important in the field where there is a need to develop treatment provision and health services. PROMs can help to provide a comprehensive data base in the field of gender incongruence with the

possibility of capturing health aspects that are important for people with gender incongruence and often not captured by more traditional measurement methods. In the process of establishing a national medical quality registry, it is important to involve patient and family representatives to ensure relevance, language and user-friendliness. It is also important to prepare good information about the purpose and use of registry data in quality assurance and research for people with gender incongruence and gender dysphoria so that there is a clear basis for consent to data collection.

About ongoing research

In general, there is a lack of research-based knowledge about the short- and long-term effects, course and prognosis of different treatments. There is a need for medical clinical and epidemiological studies with longitudinal studies, including on people with gender incongruence who are not offered, do not start or stop the different treatments.

"We need to think from a life-course perspective. What about those who received treatment and those who did not? (...) We should have gone to those who were treated and asked if they would do it again. I would do it again (30 years ago), but for others... not sure."

PATIENT ORGANIZATION REPRESENTATIVE

There are various opportunities for research. All health enterprises are knowledge institutions and should have patient-oriented research as an integral part of their activities. Clinical studies contribute to updated knowledge about the safety and efficacy of treatment and contribute to knowledge about treatment results in clinical practice. Clinical research in the health enterprises has long been a priority area with the aim of strengthening quality and patient safety. This is also in line with the National Action Plan for Clinical Studies for 2021-2025.

Internationally and nationally, there is a lot of research on gender incongruence in several disciplines, including medicine, psychology and sociology. Prospective and retrospective long-term studies with longer observation periods will gradually emerge. Research on rare outcomes and outcomes that can occur long after treatment (such as heart attacks, cancer and osteoporosis) will take a long time to answer.

Efforts are being made in different areas to develop comprehensive national overviews of the field. In Norway, the Norwegian Institute of Public Health launched the Gender Incongruence project in 2020 to study gender incongruence in people under the age of 25. The project will provide more knowledge about gender incongruence in Norway and support proper health care. Approval has been given to link data from national health registers, the National Treatment Service for Gender Incongruence and Statistics Norway. No such epidemiologic studies of gender incongruence have previously been conducted in Norway.

In summary

The teenage population, which accounts for a large proportion of the increase in referrals to specialized health services over the past ten years, is a new population of patients for whom the knowledge base is insufficient both nationally and internationally. The stability of gender dysphoria occurring or expressed in adolescence is not known as there is a lack of follow-up studies. It is uncertain to what extent gender

incongruence and gender dysphoria persist in this patient group compared to previous patient populations. A large proportion have mental illness, developmental disorders or other conditions that were not described in previous studies. The evidence from previous studies is therefore not necessarily transferable to the group of teenagers with gender incongruence and gender dysphoria who increasingly seek puberty delaying and gender affirming treatment. There is a particular lack of research-based knowledge about the treatment of patients with non-binary gender incongruence.

Ukom considers it necessary for patient safety that the knowledge base on gender incongruence and gender dysphoria is strengthened, and that health services are organized in line with the knowledge base. In Norway, no systematic review has been conducted in the field, no updated assessments of recent foreign reviews have been made, and no full health technology assessment of puberty blockers and gender-affirming treatment with hormones and surgery for children and adolescents has been conducted. No medical quality registry with national status has been established to provide an overview and assess the quality of the treatments given to children and adolescents with gender incongruence and gender dysphoria in Norway. Such measures are essential to improve the knowledge base for clinical decision-making and to promote clinical research and development in the field.

8 Our findings: Due Diligence Requirements - especially related to children and young people

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In conversations with us and in the consultation process for the national guideline, several stakeholders have questioned the justifiability of the health care offered to children and adolescents with gender incongruence and gender dysphoria.

When we now assess the requirement for justifiability, we are primarily focusing on interventions of an invasive nature with a potentially high risk of harm, such as puberty blockers, gender-affirming hormones and surgery. Less invasive measures such as counseling, prostheses and hair removal are measures that can help people cope with gender incongruence, but do not have the same risk of harm as more invasive measures. This is therefore excluded from our assessments.

The requirement for justifiability has a broad basis in health legislation. The requirement for justifiability is linked to assessment, treatment and follow-up. National professional guidelines will often help in this work by describing measures and solutions based on up-to-date, recognized professional knowledge and often specify how practice should be. At the same time, professional guidelines will provide guidance on how much deviation from good practice is acceptable before the deviation leads to the treatment being unsafe.

The Norwegian Board of Health Supervision and the State Governor are responsible for ensuring that the service operates responsibly. It is challenging for the Norwegian Board of Health Supervision to exercise control of treatment soundness when the professional guideline, which is intended to be normative, is unclear and vague.

The requirement for justifiability related to children and young people presupposes that all assessment, treatment and follow-up must be in line with the "best interests of the child". For all decisions made in relation to children and young people, an overall assessment must be made of what is in the child's best interests based on the situation and needs. The requirement for soundness also includes the requirement for compassionate assistance.

Requirements for investigation

For children and young people, it is particularly important to clarify whether the desire for treatment for gender incongruence is stable and not due to other causes. When the consequences of a treatment are major and sometimes irreversible, there are stricter requirements for proper assessment. As we have pointed out, the evidence base for the use of puberty delaying treatment, gender affirming treatment with hormones and surgery is insufficient. This means that in order to meet the requirement for soundness, stricter requirements must be set for a thorough investigation when assessing the need for health care. The national guideline does not describe sufficiently clear requirements for assessment and requirements for medical indications for the initiation of treatment. Gender incongruence is not a mental disorder, but a condition that may require both medical and psychological health care. This is particularly true if the gender incongruence has developed into gender dysphoria.

The national guideline states that psychological assessment is not a prerequisite for offering gender-affirming treatment. It is important to avoid pathologizing people with gender incongruence. When the guideline does not set specific requirements for assessment, this can lead to poorer help and care for children and young people. This is a risk, and the study shows that the lack of specific requirements contributes to uncertainty in the services. Health professionals are faced with difficult assessments that require them to consider the potential for harm against what is in the best interests of the child.

Lack of clarity and variation in assessment practices

People with gender dysphoria are a heterogeneous group. This makes treatment particularly demanding, both clinically and in terms of research. Several patients, relatives, therapists and administrators have expressed concern about different practices related to the assessment of patients' mental health. Not all people who experience gender incongruence need mental health care, but a significant proportion of the patients referred to the National Treatment Service have current or previous mental illness, developmental disorders or other conditions. People with gender incongruence may also be at increased risk of developing psychological distress, minority stress and sequelae.

> *"In general, the Norwegian Board of Health Supervision believes that invasive and irreversible measures require a broad differential diagnostic investigation and assessment in order to provide a sound basis for treatment. The requirements for decision-making competence should increase the more extensive the intervention in question. It is therefore supported that the least invasive gender-affirming treatments should always be considered as first choice.*
>
> *Furthermore, it is supported that it is important to clarify the need/indication for gender-affirming treatment, risk factors and contraindications, both somatic and mental disorders, through interdisciplinary cooperation."*
> *(The Norwegian Board of Health's consultation response to the draft national professional guideline for health care for persons with gender incongruence)*

Everyone we have talked to emphasizes the importance of understanding gender incongruence with a biopsychosocial model, i.e. an approach where the whole person is seen and which takes into account physical, psychological and social conditions. However, there is disagreement about the content and scope of the basic assessment for gender incongruence and gender dysphoria.

In our dialog with stakeholders, we have identified various concerns:

- Concerns have been expressed that the requirement for mental health assessments will prevent or delay help with gender incongruence and lead to unnecessary burdens of extensive assessments of children and young people who do not have mental health problems.
- Several express concerns about patient safety because mental health assessments are no longer required. The emphasis now is on avoiding morbidity. This can mean that different mental stresses

and diagnoses are not captured, which means that children and young people do not receive the holistic help they need.

- In addition, concerns have been expressed that a lack of clarity about what constitutes good practice and the discussion around mental health assessment itself means that we are not seeing and acknowledging the whole individual with physical, mental and social needs.

> *"Today, medical practice requires knowledge of biological, psychological and social aspects of gender. Since we only have one word for gender in Norwegian, we have a unique opportunity to think holistically about gender in line with the biopsychosocial medical model."*
> *(Slagstad et al. in Tidsskrift for den norske legeforening, February 2023)*

In one of the reports of concern received by Ukom, the relative's child is in his or her early 20s. The young adult is being assessed for gender dysphoria and wishes to change her gender from boy to girl. She is following the scheduled plan for assessment for gender-affirming treatment, but apart from this she is not offered or assisted with interviews with a psychologist or follow-up at the district psychiatric center (DPS). Follow-up at the DPS has been rejected due to lack of resources, and that it is not considered necessary health care. The daughter is experiencing an identity crisis, but according to relatives she is left to herself and her thoughts. It takes three to four months between each consultation. Relatives also believe that both the consultations and the assessment at the DPS were only schematic, which means that the daughter's problems are not picked up. The mother mentions that eating disorders are part of the picture, but that this has neither been treated nor taken seriously.

In practice, we see that there are variations in the mental health assessments carried out by GPs and the specialized health service at child and adolescent psychiatry (BUP) and DPS, before referral to the National Treatment Service. If children and young people with mental illness are on a waiting list without their mental health being adequately assessed or followed up, this may pose a risk to patient safety.

Several people we spoke to told us that referrals to BUP were refused. Gender incongruence is not described in the prioritization guide, Mental health care for children and adolescents. Several from BUP describe that it is demanding to make assessments about prioritizing the group with gender incongruence against other patient groups defined in the guide. In practice, this means that necessary clarifications and assessments regarding mental health can take time and be difficult to coordinate with simultaneous assessments for gender incongruence.

In addition, we see that the time the services currently spend on assessing children and young people with gender incongruence varies. It is also important how close the follow-up is. That is, how frequently/often the person concerned comes in for a consultation. Patients and relatives we have spoken to are clear that good and sufficiently close follow-up is essential for a safe and good patient pathway. Follow-up during and after the course of treatment is also highlighted as a key need. Gender-affirming treatment can be very demanding to go through.

Consent to health care - involvement of parents

Our findings show variation in how the competence to consent is interpreted and practiced. There are also challenges in how the child's decision-making competence and parental involvement should be assessed in individual cases. The assessment of competence to consent must be made on an individual basis, and must be based on the child's age and maturity. In addition, the assessment must take into account the nature/type of healthcare. The requirements for consent must be seen in relation to the rules for parents' right to information, cf. the Patients' and
- and User Rights Act § 3-4.

The general rule is that the age of majority under health law is 16 years in Norway. For persons under the age of 16, it is generally the parents who must consent to health care. In health legislation, there are exceptions in both directions, cf. section 4-3, first paragraph, letters a-c of the Patients' and Users' Rights

Act.

For some procedures, parental consent is also required for those over the age of 16. As examples of this, the Directorate of Health has referred in its circular to the Patients' and Users' Rights Act to participation in research projects or experimental treatment, painful or risky treatment and treatment that is irreversible, including plastic surgery. Parts of the treatment provided for gender dysphoria are characterized as irreversible. The guideline on gender incongruence also refers to the need for parental consent for irreversible treatment for persons under 18 years of age. However, the guideline is open to interpretation: *"As a starting point, young people between 16 and 18 years of age cannot therefore decide for themselves on invasive and irreversible procedures".* This does not correspond with what is stated in the circular to the Patients' and Users' Rights Act or with the requirements in the Health Research Act for participation in research projects. Here, there are explicit requirements for parental consent for medical interventions and drug trials on children under the age of 18. We note that there are different requirements for consent in research versus trial/experimental treatment. Gender affirmative treatment is an invasive measure that may affect fertility. The guideline refers to the possibility of storing sperm and unfertilized eggs if one is to undergo treatment that will affect fertility. Reference is made in this context to the Biotechnology Act. This shows the complexity of what children and young people are expected to consider before agreeing to treatment. By way of comparison, we would point out that the age limit for consent to sterilization is 25 years in Norway.

The issue of children's competence to consent to gender affirmative treatment has become topical in connection with a controversial court case in England (Bell vs Tavistock). This has led to increased awareness of the issue.

The Patients' and Users' Rights Act allows children under 16 years of age (between 12 and 16) to consent to health care without parental involvement. This is linked to the rule on exempting information to parents, cf. § 3-4 of the Patients' and Users' Rights Act. The requirement is that the child/young person has "reasons that must be accepted". In this context, reference is made to conflicts between parents and children, fear of reprisals and that weighty considerations for the patient speak against involving the parents. The national guideline for gender incongruence refers to the same thing, but the guideline is not clear whether this is also possible even if it involves invasive treatment.

The guideline also allows for information to be withheld from parents even if the child is under 12 years of age, but the guideline specifies that children under 12 years of age cannot consent to health care. § 4-3, sixth paragraph, of the Patients' and Users' Rights Act states that in cases where information can be withheld from the parents, the person providing health care *"may decide on health care that is strictly necessary and that is not invasive in terms of scope and duration" Such a decision can only be made for a limited period until consent can be obtained."*

The regulations relating to children's capacity to consent and relatives' right to information leave room for interpretation, but the guide to the Patients' and Users' Rights Act provides some clear guidelines on the scope for interpretation. At the same time, the national guidelines for gender incongruence are not as clear. Assessing children's competence to give consent is difficult. Competence may vary according to age and maturity and depending on how invasive the measures being considered are. At the same time, there are unresolved questions related to when information from parents can be excluded. The guidelines do not provide clear guidance on these questions.

Several have called for clearer clarification of whether it is justifiable for children under the age of 16 to consent to treatment for gender incongruence and gender dysphoria. In connection with a specific case, the State Administrator in Oslo has asked the Directorate of Health for further clarification of the issue.

One of the reports of concern we have received highlights the issue of consent and involvement of relatives. The young person in question is receiving treatment from the primary health service and has

informed her parents that she is considering starting gender-affirming hormone therapy. They are in contact with others in the same situation via the treatment center.

Relatives state that their adolescent is in an exploratory phase with a lot of doubt and ambiguity in addition to having psychological challenges. Parents have not been informed or contacted by the therapist. The parents feel that in a few months their adolescent is in the middle of a new field with many impressions and influences, including new contacts from the treatment center and through social media. They are afraid that they are about to embark on a fast-track treatment that could make them a patient for life. He wants symptom relief in a complex situation, and his parents fear that he is too immature and has too much to cope with to make such a choice in a short time. The parents are concerned that the patient may regret the choice later in life and that it will cause harm rather than help.

Parents are the closest caregivers and anchors in a situation that is very demanding for the child, siblings and parents. They want to be a resource and maintain a good relationship with their child, but the family experiences a lack of involvement from the treatment center in the process of their child exploring gender identity.

"To involve us parents is to facilitate good relationships for the rest of our lives."

MOTHER

Assessing capacity to consent can be challenging. It is therefore all the more important to involve relatives. There are clear expectations in the current regulations that relatives should be involved unless there are compelling reasons to the contrary.

Assessment and treatment of children and adolescents with gender incongruence and gender dysphoria is complicated. The fact that they are undergoing intense development, both physically and mentally, must be taken into account in the assessments. If children and adolescents are to be able to consent to gender-affirming treatment on their own, it is unclear what it takes to say that the child is mature enough to make such a decision. What requirements should we set in order to assume that the child has sufficient understanding and insight to understand the consequences of the choices made? In addition, there is the question of what information must be available to make the choice. The law sets clear requirements for information to all patients receiving health care. This includes information about their state of health, the content of the healthcare and any risks and side effects. This knowledge is important in order to make informed choices. As we have discussed in the evidence base, we know little about the long-term effects of puberty blockers and side effects of hormone treatment.
Patients must be informed about this, and they must be able to understand the consequences of their choices. Meeting and talking with the healthcare provider will be crucial for the choices to be made by children and adolescents.

> *"It is important that this patient group is met in an open and non-judgmental way so that they feel safe and cared for. In our experience, it is very difficult to balance helping patients to reach a definite position that gender confirmation is what they want, which will often involve probing questions, against making them feel cared for and understood. When the topic is one's own identity, it is easy to fall into the trap of offending."*
> *(Consultation statement from the Norwegian Association of General Practice, Norwegian Medical Association)*

In summary

Our findings show that it is questionable whether all children and adolescents with gender incongruence and dysphoria receive appropriate health care. Children's right to consent to health care and parents' right to information are challenging issues for health personnel to consider. Children and adolescents may have different degrees of physical and mental maturity and may be at different levels of development despite being the same age. If children and young people should be able to consent to gender-affirming treatment on their own, it is unclear what is required to say that the child is mature enough to make such a decision.

The guideline does not require an assessment or a medical indication for starting treatment. The guideline does not function well as a professional standard and constitutes a patient safety risk in its current form.

9 Our findings: Right to health care - a gap in expectations

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The guideline on gender incongruence pays great attention to the patients' right to health care. The right to necessary health care from the municipal health and care services and the specialized health service is laid down in the Patients' and Users' Rights Act. The term "necessary health care" is interpreted as giving a right to (necessary) health care of an acceptable standard based on an individual assessment of need. The scope and level must therefore be assessed specifically on the basis of a health professional assessment of the patient's needs.

The requirement of justifiability shall always be decisive in assessing the patient's right to health care. The right can be linked to the municipal health and care services and to the specialized health service.

The national guideline is not clear on where the level of care should be when a medical assessment of need has been made. It is left to the service to define who is entitled, what they are entitled to, and when they are entitled to different health services. What is considered a specialized health service and what services can be provided by the municipal health service is also not clearly defined. This is more or less left to the services to define based on an assessment of justifiability.

In order to be entitled to healthcare services from the specialized health service, some specific requirements must be met. Firstly, the right is linked to a medical assessment of the patient's need for specialized health care. The guidelines do not say anything about what should be included in a medical assessment of the need, but that it must be based on a proper evaluation of the patient. The guideline states that gender incongruence in itself does not provide grounds for referral to the specialized health service, but there may be a risk of developing a mental disorder. People with gender incongruence may have gender dysphoria, a condition that causes psychological pain, discomfort or other problems that require health care. It is the individual need that determines whether a person is entitled to health care and at what level the care should be provided.

The prioritization regulations elaborate on the assessments that are relevant for determining who is entitled to necessary health care from the specialized health service. In the individual assessment of the patient's entitlement, the expected benefit of the health care must be assessed. The expected benefit of the healthcare is assessed on the basis of whether evidence-based practice indicates that the healthcare can increase the patient's life expectancy and/or quality of life. It must be assessed whether the health care product can increase the probability of: survival or reduced

loss of function, physical or mental improvement of function, reduction of pain, physical or mental discomfort, cf. the Priority Regulation.

As described above, little is known about the long-term effects of puberty-delaying treatment and gender-affirming treatment with hormones. There is a need for more research to be able to say something about short- and long-term effects. It is therefore also difficult to say anything about the expected benefit of the treatment as long as we do not have a sufficient knowledge base.

The right to necessary health care does not include experimental or test treatment, cf. circular I-4/2019. Experimental treatment means all treatment where efficacy and safety have not been sufficiently documented for the treatment to be included in the ordinary treatment offer.
Investigational treatment covers both treatment that is tested in clinical trials and treatment that is given outside clinical trials, but the main rule is that investigational treatment must be offered through clinical research studies. The national principles allow for treatment that is not based on sufficient documentation to be provided to individuals outside clinical trials in exceptional cases when this is professionally justifiable. This is stated in the Directorate of Health's guidelines for investigational treatment. It also points out that although the principles for investigational treatment were developed for the specialized health service, they can also be used as a basis for the use of investigational treatment in the municipal health and care services.

This means that there is room to maneuver to offer experimental treatment, but it is a fundamental prerequisite that the provision of experimental treatment is considered justifiable. The justifiability requirement is a legal standard that changes in line with medical and technical developments, but the core is linked to what is defined as established treatment at any given time. When there is no established treatment option, it is particularly important to have a safe framework for the treatment. Treatment must then take place within a predictable framework and contribute to increasing knowledge. This is particularly important for the group of teenagers with gender dysphoria, who are increasingly seeking the health service for puberty-deferring and gender-affirming treatment where the research-based evidence base is inadequate.

It is the health enterprises that decide what should be available in the service. This is based on a thorough assessment of the available knowledge about the service. Knowledge is obtained, among other things, through HTAs. A full HTA involves a comprehensive systematic assessment of new or established methods in which efficacy, safety and/or cost-effectiveness are reviewed and assessed. The assessment often also includes questions concerning ethical, legal, organizational and societal consequences.

The national guideline for gender incongruence does not use the term experimental treatment and bases the right to necessary specialized health services on experience-based knowledge. This is not consistent with other help provided by the specialized health service. The prioritization regulations stipulate that the patient should benefit from the health care and that the assessment of benefit requires evidence-based practice. The national guideline also points out that evidence-based practice is inadequate and highlights a prerequisite when describing the main elements of evidence-based practice:

> *"It is possible to develop evidence-based recommendations with more emphasis on clinical experience and user knowledge in anticipation of research-based evidence as is done in this guideline. This assumes that health care will be followed by systematic collection of data for research. The basis for making clinical decisions will thus be better in the time to come."*

This lack of connection between the right to health care and ambiguities in the knowledge base means that the health authorities must carry out a thorough assessment of the justifiability in relation to the available knowledge base. They must make this assessment before deciding which services to provide. It will therefore be demanding for the regions to put in place an assistance and treatment service.

Gender-affirming treatment is provided by various actors in Norway. No national register has been established, nor have there been specific requirements or resources allocated for follow-up research with systematic data collection. The knowledge base is thus not strengthened to make better clinical decisions locally at the individual practitioner, regionally or nationally. By defining treatment with puberty blocks, gender-affirming hormone therapy and surgery for children and adolescents as experimental treatment, there will be stricter requirements for a predictable framework for the help. This will contribute to safer and more predictable services. The framework will also contribute to increased knowledge.

Different expectations

Our survey indicates that there is a gap between what the guideline outlines and what is possible given the current available services and knowledge base. When the national guideline states that people with gender incongruence are entitled to health care, without the evidence base being well documented and without a good overview of any negative aspects of the treatment, an expectation is created among patients that the services can hardly meet.

This relates both to expectations of the health service and its organization. Parts of the patient population have an expectation that the right to treatment should be fulfilled on the basis of a subjective need. Thus, it becomes a source of frustration when the Norwegian health system is organized in such a way that requirements for expected benefit, effect and safety are what trigger the type of help and treatment.

For many people with gender incongruence, it can be difficult to know what is the right type of help and treatment. Here, as elsewhere in the service, the GP will first have an important function in helping the person to find the right health care and then as support during the treatment and after the treatment is completed. The GP has a gatekeeper function in the Norwegian health service, and this is important for patient safety in order to avoid overtreatment, among other things. In our study, we see that some actors in this field use the gatekeeper model as an argument for discrimination. The role of the GP in accessing specialized healthcare services applies across patient groups.
The role can be challenging to manage, particularly when unclear frameworks or criteria for treatment meet clear patient expectations. There is a need to clarify the framework for care and treatment and to align expectations.

Health professionals have also reported that it is difficult to relate to the expectations of rights in a field where they are faced with difficult ethical trade-offs between "doing good" versus "doing no harm". Ukom has been told by health personnel that gender incongruence is a field that many are reluctant to enter because of the fear of doing more harm than good.

In summary

We see that when the evidence base is inadequate, the right to health care creates conflicting expectations and demands. One consequence of this is that some patients feel that they are not seen and heard. There is a great need to harmonize expectations and opportunities in patient care for children and adolescents with gender incongruence and gender dysphoria. It must then be considered whether the interventions require a framework that meets the requirements for experimental treatment.

It is important to make the necessary clarifications at system level to reduce the gap between expectations and practice. Unmet expectations are burdensome for patients and their families and create ethical dilemmas for service providers.

10 Our findings: Climate of expression and interaction

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Discrimination and the fight for rights has been an ongoing issue within the trans community. Patient and family organizations and professionals have been active in advocacy work, demanding better patient services and various measures to prevent discrimination against trans people in health services. This has gone hand in hand with important work aimed at promoting the rights of trans people in all sectors of society.

Advocacy and health service development

Diversity and inclusion are also key issues in the ongoing debate around the provision of treatment for people with gender incongruence and gender dysphoria. The debate, the discussion about whether the health service is inclusive and what constitutes good practice, is ongoing in the media, social media and within the health service. In our review of the debate, we see that it is sometimes unbalanced and highly polarizing.

This results in several simplistic messages that are very unfortunate for the field of gender incongruence in terms of establishing a comprehensive and equal health service for those who need help and treatment.

A climate of expression has developed that is characterized by polarization and harsh, judgmental words. The Freedom of Expression Commission, which delivered its report in 2022, specifically highlighted the debates on gender diversity and gender expression as an area where social condemnation can be high for those who choose to express themselves.

"Those who enter the debates risk being labeled as phobic, prejudiced, hostile or reactionary"

THE FREEDOM OF EXPRESSION COMMISSION

Furthermore, the Freedom of Expression Commission writes that this will limit the real freedom of expression for others, including those who wish to contribute new or different perspectives, facts and opinions. Empathy, the ability to put oneself in the shoes of others, requires a shared space of conversation where everyone has the opportunity to participate.

Our report points out that there is still work to be done to put in place a differentiated health service that addresses the different needs of gender incongruence. A health service must embrace the gender diversity that exists in society. To succeed in this, it will be important to establish a climate of cooperation in order to further develop the health services. Our survey shows that parts of the current dialogue from some actors are characterized by ideology and an us-versus-them rhetoric. Ukom is concerned that the current debate and level of conflict inhibits rather than promotes the development of sound health services and treatment options.

In recent decades, there has been a major focus on and further development of patient, user and family participation in the health service. We believe that in the future it is important to use the established systems and methods that have been developed nationally and internationally as a framework for cooperation. User participation at system level can contribute to increased accuracy and quality, both in service development and research. The Norwegian Directorate of Health is working on developing national professional advice for user participation in the field of substance abuse and mental health, with the aim of eventually being able to further develop these for the entire health and care service. The project highlights these system-level benefits:

- User and family knowledge is understood and used as an equal area of knowledge in service development, implementation and evaluation at system and service level.
- User and carer organizations, user-run centres, experience consultants and other patient and user voices have a common understanding of each other's roles and responsibilities.
- Staff and managers in the services facilitate increased user and family involvement.

These points are also good for highlighting some of the conditions for a genuine and respectful climate of cooperation:

- Stakeholders have a responsibility to see each other as equal partners with important knowledge to develop services.
- Stakeholders are responsible for establishing a common understanding of each other's
- roles and responsibilities. The service is responsible for facilitating greater user and family involvement.

Effects of a harsh climate of expression

We have found that the debate taking place in the media and on various social networks affects those with gender incongruence and gender dysphoria, their families and those working in the field. The debate is characterized by sometimes major and fundamental differences of opinion. Particularly prominent is the discussion about what treatment should be offered to young people with gender incongruence and gender dysphoria.

We have found that the debate and disagreements affect four areas in particular, which may compromise patient safety. Impact:

- the relationship between patient and
- carer/treatment provider access to information
- participation in the debate
- recruitment/engagement in the field

Relationship and alliance building between the therapist/helper and the person seeking help/treatment can be affected by disagreements and differing expectations. Conversations and assessments that help to find the right help for the individual require a safe and open climate for expression. It is demanding to build security, trust and alliances in a landscape of uncertainty, distance and fear. We find that within gender incongruence, both trust in therapists and in treatment institutions is affected by a debate about what is good practice in the treatment of gender dysphoria.

In general, it can be difficult for children and young people to find relevant health information. In particular, it can be difficult for children and young people to deal with conflicting messages from professionals and from discussions on the topic in social media. At times, we see that messages about help and treatment for gender incongruence are not very nuanced, and it is difficult to get an overview of the risks and benefits of the treatments.

"Side effects are not talked about very much. There is talk about "as long as I get hormones, my body will go in the direction I want". I think it's important that we have a balance here. The fact that you have side effects, or that you are struggling, does not mean that this is wrong."

PATIENT ORGANIZATION REPRESENTATIVE

"We also need to look at hormones. It can create pleasure and serious side effects. Blood clots and so on. There are also many people I meet who don't understand the seriousness of side effects. This is something that not only affects you on the outside, but also inside your body"

PATIENT ORGANIZATION REPRESENTATIVE

The harsh and judgmental use of language carries the risk that some people may be reluctant to participate in public debate. For some, it may be too challenging to participate and express themselves because they have opinions that they know will not be tolerated by everyone. In this climate of expression, the cost of participating in public discourse with opinions or expertise may be too high.

"So polarized a debate that even as a patient, I risk being verbally trampled on - caught in having to choose sides. Like a divorce debate."

PREVIOUS PATIENT ASSESSMENT/TREATMENT OF GENDER INCONGRUENCE

Recruitment of clinicians and researchers to the field is affected by the debate. The fierce debate may also make practitioners reluctant to work in the field for long periods of time. Professional disagreement and lack of consensus can also increase the burden on practitioners, and a pressurized work environment can compromise patient safety.

"This is a very demanding field to work in. Polarization means that we just keep bumping into each other instead of lifting the field. I have a friend who works in the BUP system, in relation to this topic she says; I go to work, and almost no matter what I do, I make mistakes."

TREATMENT

"Polarization is blocking research."

PRACTITIONER AND RESEARCHER

Fear

The word fear has been repeated by several stakeholders in our survey. Children and young people are afraid of not being believed and understood, and many are afraid of not getting the help and treatment they need. We have been told by several young people who are being examined for gender incongruence that they answer what they think is expected. Young people also share their experiences on social media, and they can get information on how best to respond in order to access gender-affirming treatment.

Relatives are afraid that their child will not receive the right health care and they point out many influences, complexity and climate of expression that make it particularly difficult. Relatives also report that they are afraid to express their concerns and uncertainties about the invasive treatments for fear of being labeled as transphobic. They express that they want to be supportive and caring. Relatives also mention that friends and close family members may avoid asking critical questions to their adolescent for fear of hurting their feelings.

Practitioners say that they are afraid of offending, afraid of ignoring other illnesses or giving treatment that they do not fully know the effects or consequences of, especially they are afraid of harming or not giving proper health care. They express concern about overtreatment, for example, starting hormone treatment unnecessarily or too quickly, or the period of treatment with puberty blockers being too long. They also express concern about malpractice, for example when they have to take over the assessment, treatment and follow-up of children and young people who have started treatment on their own or with other practitioners on varying grounds. One practitioner in the field has recently lost his license for various reasons, and media coverage has conveyed much fear in this regard.
Professionals with different perspectives at different levels of the health service report that they receive harassment and threats, but in conversations with Ukom, these different actors have been primarily concerned with patients, patient safety and soundness. Although the conditions can be demanding, practitioners in the health service also report a lot of support and good patient relations. A number of patient organizations and professionals also express concern about undertreatment and the consequences of this if the decentralized service is not put in place. Many are afraid that the outcome of the ongoing debate on the issue of justifiability will result in a reduced range of treatments.

In summary

The climate of expression in this field in the public domain affects the available information for children and young people with gender incongruence and gender dysphoria and their families. There is a massive impact on children and young people in different communities, also related to treatment and health services. There is a lot of fear and anxiety about getting it wrong from all sides. Different opinions about what is the right treatment can create difficult cross-pressures. Different emphasis and discussion of what is necessary at group level can confuse and undermine the patient-treatment relationship and a personalized approach for the person concerned.

We would like to emphasize that all actors have a shared responsibility for good cooperation. The field needs to establish a constructive community for all those committed to good health care for people with gender incongruence and gender dysphoria. This would make it easier for clinicians and researchers to seek out the field and, not least, for children and young people and their families to seek the help they need.

In addition, interested and affected parties need quality-assured information about the treatment provision in the field of gender incongruence and current knowledge about efficacy and safety. This information needs to be accessible and adapted to different target groups, including children and young people.

11 Our recommendations

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Our survey shows that there are major differences in the health services for children and adolescents with gender incongruence and gender dysphoria. Stakeholders in the health services have different understandings of the knowledge base and different assessments of what constitutes acceptable health care. This has led to a situation with variation in the treatment offered, where patients may encounter different expertise and different approaches to assessment and treatment depending on which provider they seek help to manage their gender incongruence and gender dysphoria. It is now important to strengthen the assistance provided in the municipalities, the specialized health services throughout the country and the national treatment service.

We see that the national guidelines leave too much room for different interpretations, which has resulted in variations in the treatment offered to children and young people. When the authorities decide to grant a group the right to health care, this must be based on a thorough assessment of need, justifiability, cost and benefit. The guidelines must provide the services with the necessary guidance and be a tool for professional standardization that the service can rely on to ensure that patients receive appropriate and equal health care throughout the country. The evidence base for the treatment of gender incongruence and gender dysphoria is inadequate. This is particularly true for the teenage population, which accounts for a large part of the increase in referrals to the specialized health service over the past ten years. The stability of gender dysphoria that occurs or is expressed in the teenage years is not known. It is also true for patients with non-binary gender incongruence and gender dysphoria.

Against this background, Ukom's recommendations relate to the revision of the guideline, a safe framework for the treatment offered and measures to strengthen the knowledge base. The recommendations will also ensure systematic data collection and promote follow-up research. It is important that children and young people with gender incongruence and gender dysphoria, including non-binary people, are properly cared for while the development of health services is ongoing.

1. Revising the national guideline for gender incongruence

Ukom recommends that the Ministry of Health and Care Services commission the Norwegian Directorate of Health to revise the national guideline on gender incongruence. The revision must be based on a systematic review of the evidence.

The following should be included in a revision:

- clarify which treatments can/should be done by primary care, what can/should be done at regional level and what should be done by the national treatment service clearer professional
- guidelines and recommendations for the content of the assessment
- clearer professional criteria for the initiation and completion of treatment
- concrete guidelines on clinical issues that may arise during the course of assessment and treatment, including specifications on indications and contraindications clearer
- requirements for the follow-up of patients before, during and after the end of treatment

- clearer guidance on when and how relatives should be involved in the assessment and treatment process
- clearer guidance on how services should address issues of competence to consent in children and young people seeking treatment for gender incongruence and gender dysphoria
- clearer guidance on the skills required by services to assess and treat children and young people with gender incongruence and gender dysphoria
- clearer guidelines for the care of all people with gender incongruence and gender dysphoria, regardless of whether or not highly specialized treatment is appropriate

A systematic review will also contribute to a common platform, language and terminology for the different actors involved in the field. A systematic review can build on recent reviews from abroad.

2. Ensuring a safer framework for the treatment offered to children and young people

In order to improve the basis for making clinical decisions, it is a prerequisite that health care and treatments are followed up with systematic collection of data for quality assurance and research. Clinical research aimed at improving quality and patient safety is in line with the National Action Plan for Clinical Trials and is necessary in this field. This will help to ensure a safe framework for the treatment and follow-up of children and adolescents until the knowledge base on efficacy and safety is sufficiently documented.

Ukom recommends that puberty blockers and hormonal and surgical gender confirmation treatment for children and adolescents be defined as investigational treatment. This is particularly important for teenagers with gender dysphoria,

3. Strengthening the knowledge base - National Medical Quality Registry

Our findings show that the knowledge base is inadequate, and we therefore make several recommendations that together will help to strengthen the knowledge base.

We believe that there is a need to establish a medical quality register with national status. We consider that the treatment of children and adolescents with gender incongruence and gender dysphoria meets the criteria for establishing a national medical quality register. According to the Norwegian Directorate of Health's national guidelines for approval of medical quality registers for national status, a lack of professional consensus on diagnostics and treatment may be grounds for prioritizing the establishment of a medical quality register with national status.

Ukom recommends that the Ministry of Health and Care Services consider whether a national medical quality register should be established for the treatment of children and adolescents with gender incongruence. In order to offer an overview, boost quality, and lessen unjustified variance in patient care, necessary steps must be made to build, run, and finance such a national quality registry.

12 Procedure for the survey

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In the spring and summer of 2022, Ukom received two reports of concern from relatives of adolescents and young adults with gender incongruence. The reports of concern provided a basis for going into the topic of gender incongruence in more detail. We have not investigated a specific patient history, but we have gathered information from various people with gender incongruence and gender dysphoria. In line with the guidelines in the Act on the National Commission of Inquiry for the Health and Care Services, we have omitted all personal names in the report.

Information basis

Our assessments are based on information from interviews, dialog meetings and public documentation. We have obtained the status of treatment of gender incongruence from the four regional health authorities. We have reviewed statistics, professional literature, research and followed available public debate and media coverage. We have shared our experiences with the Healthcare Safety Investigation Branch (HSIB) and their report on the same topic.

We have also engaged in dialog with various experts and resource persons during different phases of the process.

Collection of data

We initially started a mapping exercise related to the topic. The review and systematization of the collected written documentation was the starting point for some main themes and questions we wanted to elucidate further in interviews and dialogue with various stakeholders.

Conversations and semi-structured individual interviews were conducted with four patients and two relatives. These were people who had personal and family experience with gender incongruence and gender dysphoria.

Our interviews are based on the K.R.E.A.T.I.V. method which aims to obtain as reliable information as possible from the informants.

During the information gathering phase, we had dialogue meetings with the following patient, user, relatives and interest organizations: FRI - The Association for Gender and Sexuality Diversity, Genid, Harry Benjamin Resource Center (HBRS) and the Patient Organization for Gender Incongruence (PKI).

We also had dialog meetings with different treatment environments and levels: The National Treatment Service for Gender Incongruence (NBTK) at Oslo University Hospital HF, the Health Center for Gender and Sexuality (HKS) in Oslo Municipality and the four regional health authorities (RHF) through their technical directors and staff. In addition, we had meetings with the Directorate of Health (Hdir), the Norwegian Board of Health Supervision (Htil) and the Norwegian Institute of Public Health (FHI). In total, we had 11 meetings during this phase, where we presented the topic and presented concerns reported to Ukom.

The various stakeholders decided who and how many people they wanted to bring to the meeting. Some of the meetings were fully digital, some of the meetings were physical, and some of the meetings were hybrid meetings with a large variation in the number of participants. In one hybrid meeting, not everyone who was connected digitally attended the entire meeting.
The interviews were in principle semi-structured with an emphasis on open, exploratory questions. All meetings began with a presentation by Ukom and ended with an open discussion afterwards. Meeting participants chose what they wanted to comment on or raise first. Ukom had a list of topics we wanted to highlight. At meetings with many participants, it was necessary to actively manage the meeting to ensure that more people were allowed to speak and that the desired questions were answered. At other meetings, where only one or a few people attended, they were allowed to speak more freely as long as the requested topic was covered. No audio recordings were made, but notes were taken. The meetings were always attended by several people from Ukom with different professional backgrounds.

We also had five exploratory conversations along the way with professionals with legal, medical, sexological and administrative expertise. In addition, we conferred with people with experience and relevant professional expertise when necessary.

Analysis work

We have sorted and analyzed the collected data to find possible connections, influences and causes of what may constitute a patient risk in the health services for children and adolescents with gender incongruence and gender dysphoria. When we enter a topic to shed light on patient safety, the picture will be complex and the causes of possible risks will be interdependent.

Ukom uses safety methodology to identify underlying causes at the system level. As a basis for those parts of the analysis, we have used the Sociotechnical approach, with MTO (human-technology-organization) keywords and methodology, AcciMap methodology, causal maps, actor maps and influence diagrams. This methodology highlights how relationships at different organizational levels influence each other. This approach provides a holistic understanding of possible causal relationships at different levels. We looked at how different services and systems relate to each other, and we have formulated and tested hypotheses along the way.

Validity requirements

In order to come up with recommendations that could be useful for this field and this patient group, we have conducted dialog meetings and anchored our findings with all stakeholders who have given us valuable feedback and input.
During the work on the survey, we have also received useful input from Ukom's reflection panel. All

informants have been given the opportunity to review any quotes we have used.

All have been anonymized. Those quoted have been involved in shaping how they are

referred to. Stakeholders involved have also been presented with the findings and

topics for recommendations.

Furthermore, the findings and draft recommendations have been discussed with informants, user organizations, other interest groups, professional organizations, enterprises and professional communities in both the clinical and research fields, the administration, authorities and individuals with special knowledge of the topic.

During this phase, we conducted 11 dialog meetings with the following

- bodies: Norwegian Nurses' Association (NSF)
- Norwegian Psychological Association (NPF)
- The Norwegian Medical Association (DNLF) Patient
- Organization for Gender Incongruence, PKI
- Association for Gender and Sexuality Diversity Free, with Queer Youth
- Genid Norway
- Patient organization and user organization Harry Benjamin Resource Center
- National Association for Relatives in Mental Health
- Mental health
- Patient and user representatives
- National Treatment Service for Gender Incongruence (NBTK)
- Health Center for Gender and Sexuality (HKS), Oslo Municipality
- The regional health authorities
- National Treatment
- Service for Gender
- Incongruence (NBTK)
  Health Center for Gender
  and Sexuality (HKS), Oslo
  Municipality The regional
  health authorities

In total, we held 27 meetings with various stakeholders during the survey. In these meetings, we have openly discussed the issues and findings and asked for input. In addition, we have allowed for written input afterwards, which several stakeholders have taken advantage of.

13 Glossary of terms

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This list is taken from Bufdir's Lhbt+ glossary. The terms can be defined in several different ways, and the terminology in the field is constantly evolving. Therefore, some terms may be inclusive to some, but alienating to others.

Non-binary

A person who does not feel that they fit into the categories 'male' or 'female'. Being non-binary is about gender identity and not about what the body looks like. Some non-binary people identify as something in between female and male, others do not identify by gender. In society, gender is often divided into two categories, girl and boy. This division does not apply to everyone

Gender

Gender is often a fundamental aspect of a person's identity. Societal norms play a large part in defining what is typically female and male. What is seen as male and female varies throughout history and between cultures.

Gender can be understood as three different aspects: biological gender (the body you are born with), psychological gender (the gender you feel you are) and social gender (the gender others perceive you as and into which you are socialized).

It is commonly thought that there are two genders, male or female. However, there are people who do not feel at home under these two categories. Therefore, in some countries there is a possibility to register as a gender other than male or female.

- **Biological gender:** Biological gender is made up of biological factors such as external and internal genitalia, genes, chromosomes and sex hormones.
- **Legal gender:** Society's official registration of gender. Legal sex is the sex with which you are registered in the National Population Register. Legal gender does not necessarily correspond to social gender. The Act on Change of Legal Gender came into force in 2016. Under this law, you decide for yourself whether you are registered as a woman or a man in the National Population Register. If you are 6 years old or older, you do not need a medical certificate to change your legal gender. The law applies to people who have reached the age of 16, but people aged between 6 and 16 can apply to change their legal sex with parental permission. Children under the age of 6 can have their legal sex changed if they have a congenital, uncertain somatic gender development. The condition must be documented by a health professional. It is the tax office that decides on the change of legal gender status and assigns a new national identity number.
- **Social gender:** The gender that others perceive you as and that you are socialized into.

Gender identity

Gender identity refers to a person's internal experience of being female, male, both female and male, or neither. Most people identify with the gender they were assigned at birth, but not all. Perceived gender can be used as a synonym for gender identity.

Gender expression

A gender expression is the way we identify ourselves as either female, male, feminine, masculine or outside of society's two-gender norm. Although most people present themselves in a gender expression that is perceived as clearly male or clearly female, some people have a gender expression that breaks the dichotomy between male and female.

Gender affirmative treatment

Health care that helps confirm a person's gender identity. For people who experience discomfort with the mismatch between biological sex and gender identity, this healthcare can be important to improve their quality of life. It may include psychosocial support/care, assistive devices (such as wigs or voice training), sex hormone supplementation or surgical procedures (such as breast removal or vaginal reconstruction). Gender-affirming treatment helps to alleviate gender dysphoria and to enable a person to function in accordance with their gender identity.

Gender dysphoria

Gender dysphoria is a medical term for discomfort caused by a mismatch between a person's gender identity and the sex assigned at birth and the gender role associated with this. Gender dysphoria is a term within the gender incongruence spectrum. People who experience gender dysphoria may wish to undergo gender-affirming treatment to align their body with their gender identity. Not all trans people experience gender dysphoria

Gender incongruence (transgender people)

Gender incongruence is a persistent experience that the gender one was assigned at birth does not match the gender one perceives oneself to be. People with gender incongruence are often referred to as transgender. Not all people who experience gender incongruence define themselves as transgender. Gender incongruence is also a diagnosis that replaces all diagnoses that previously began with "trans"- and is explained as a mismatch between perceived gender and the gender assigned at birth.

Gender characteristics

Gender characteristics refer to the biological or bodily aspect of gender, i.e. physical features, sex chromosomes, sex hormones and genitalia. People with variation in bodily sex development are born with a combination of sex characteristics that vary to a greater extent than we traditionally associate with male and female bodies. Gender characteristics can be divided into primary and secondary gender characteristics:

- **Primary sex characteristics** include sex chromosomes (e.g. XX, XY, X, XXY), external genitalia (e.g. head of penis, foreskin, clitoris, labia, vulva), gonads/sex glands (testes and ovaries), hormones (estrogen and testosterone) and internal reproductive organs (e.g. uterus, fallopian tubes, prostate).
- **Secondary sex characteristics** are characteristics that develop later in life, often in connection with puberty and may be linked to hormonal development. These include body and facial hair, menstrual cycle, breast development, height, muscle distribution and body fat

Gender diversity

Gender diversity refers to the fact that there are many ways of being a woman/man or boy/girl, including gay, straight, lesbian, bisexual and transgender people. The term also opens up the possibility that there are more gender identities than woman and man. The term can help to create space for different gender expressions,
-preferences and identities without categorizing.

Lhbtiq

Lhbtiq is an abbreviation for lesbian, gay, bisexual, transgender, gender variant/intersex and queer. The term Lhbtiq encompasses terms related to sexual orientation (lhbq), gender identity (t) and gender characteristics (i).
The term 'people who transgress gender and sexuality norms' is the most precise and least exclusionary term for this group.

Minority stress

Minority stress is the additional burden that individuals from stigmatized groups face because of their minority position.

Gender and sexuality norms

Norms are unwritten rules, thoughts and ideas that a society, and we who live in it, take for granted. Norms create expectations of how we should behave and how we should be and imply ideas about what is positive and what is negative. Norms vary between societies and cultures and can change over time. Gender norms are widespread beliefs that assume that everyone identifies with the gender they were assigned at birth and that our behavior and how we express ourselves corresponds to this gender. Norms of sexuality revolve around expectations about who we are attracted to, fall in love with, have sex with, how we have sex and what turns us on. In a heteronormative society, it is assumed that everyone is heterosexual

Queer

Skeiv is a Norwegian translation of the English term 'queer'. Many people use "queer" as an umbrella term for anyone who breaks gender and sexuality norms, or as a synonym for lhbtiq. For others, 'queer' is an identity that challenges and transcends the categories of heterosexual, lesbian, gay and bisexual and involves a critique of society's heteronormativity. Queer is also used by people who feel that they do not fit into society's division of people into two genders. Not everyone is comfortable with the word 'queer' being used about them.

14 Ukom's mission

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The National Commission of Inquiry for the Health and Care Services (Ukom) is an independent, governmental body that has been commissioned to investigate serious incidents and other serious matters in the health and care services in Norway.

Ukom will investigate the course of events, causal factors and causal relationships. The purpose of the investigations is to improve patient and user safety through learning and prevention of serious incidents.

Ukom does not take a position on civil or criminal guilt and liability.
Ukom decides which serious incidents or serious conditions are to be investigated, the timing and scope of the investigation and how it is to be conducted.

The investigations are carried out in consultation with the parties involved, i.e. health and care service employees, patients, users and relatives.

The reports from Ukom are public, and they do not contain references to the names and addresses of individuals. It is assessed in each individual investigation whether reference is made to the location of the incident.

Ukom's activities are authorized by Act on the State Commission of Inquiry for Health and care services of 16.06.2017 no. 56.

15 List of references

Published on March 9, 2023 Last updated on March 9, 2023

We have reviewed a large body of literature and we refer here to a selection of references. This is not a systematically complete list of available literature and references. We have included references highlighted by resource persons with expertise and through dialog meetings.

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EXHIBIT 110

The BMJ

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Published: 23 March 2023

Norway's guidance on paediatric gender treatment is unsafe, says review

Jennifer Block

Norway's national guidelines for the treatment of people with gender incongruence and gender dysphoria are inadequate and should be revised to protect patients and better guide health professionals, according to a report from the Norwegian Healthcare Investigation Board (Ukom) released earlier this month.[1] An English language version is expected in April.

Ukom found that the guidelines, which Norway's health directory published in 2020, do not offer a clear enough framework for patient evaluation, treatment, and informed consent, said Stine Marit Moen, Ukom's medical director. This has left too much room for interpretation among clinicians and unwarranted variation in care.

The board received notifications of concern from patients' family members, clinicians, and others, which prompted the investigation and report. "We're concerned that there may be undertreatment, overtreatment, and the wrong treatment, with variation in safeguarding and the extent of multidisciplinary involvement, posing a threat to patient safety," Moen told *The BMJ*.

The report found that there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare. Ukom defines such treatments as utprøvende behandling, or "treatments under trial," said Moen.

National principles govern the delivery of investigational treatment—however, those principles have not been applied in the case of treatments for gender incongruence and dysphoria, said Moen. The board recommended that those principles are followed, and that Norwegian authorities document the outcomes of every young person treated in a national medical registry. "This will increase oversight, reduce unwarranted variation in patient treatment, and result in better quality care," said Moen.

Unlike other guidelines published by Norway's ministry of health, the 2020 guidelines for the treatment of gender incongruence and dysphoria were not based on a systematic review of the evidence.

"At the time, it was important to offer services to people with gender incongruity and dysphoria, and to state that they had a right to healthcare services," said Moen. "But it's our job to assess it from a medical point of view and patient safety, and the guidelines are insufficient in this regard."

Ukom has recommended that updated guidelines should be based on a new commissioned review or existing international up-to-date systematic reviews, such as those conducted in 2021 by the UK's National Institute for Health and Care Excellence. The board has published several other reports since its founding in 2020. Its recommendations are not binding, but Moen expects the report on the treatment of gender incongruence will have an impact.

"We've seen a marked increase in referrals to specialised healthcare services in Norway for teenagers, as seen in many other western countries, and nobody knows the reason. The stability of the gender dysphoria of these teenagers is not known, and the evidence of long term effects of gender affirming treatments for this young population is insufficient," said Moen. "It's not just a question of rights, it's a question of the requirements for our health system to ensure the best and safest treatment possible for everybody."

Norway's Directorate for Health and Social Affairs told *The BMJ* that its current guidelines acknowledge the limited evidence base on treatments for gender incongruence with recommendations "limited to the organisation and content of services on different treatment levels necessary to fulfil patient rights, as required by Norwegian health regulation." It said that it planned to start talks with clinicians and patient representatives to decide whether the guidelines needed to be revised.

On 23 March we added a comment from Norway's Directorate for Health and Social Affairs.

1 Ukom. Pasientsikkerhet for barn og unge med kjønnsinkongruens. March 2023. https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag

EXHIBIT 111

Gender Service for Young People at Sandyford

The Young People Gender Service at Sandyford is a multi-disciplinary team who specialise in working with those under the age of 18 experiencing uncertainty or distress about their gender.

Important service update – Young Person's Gender Service

Referrals from the Sandyford Sexual Health Services to Paediatric Endocrinology for the prescription of Puberty Suppressing Hormones have been paused for any new patients assessed by our Young Person's Gender Service.

Patients aged 16 to 17 years old who have not been treated by Paediatric Endocrinology, but who are still seeking treatment for their gender incongruence, will no longer be prescribed gender affirming hormone treatment until they are 18 years old.

If you are already being treated by Paediatric Endocrinology and being prescribed either of these medications, you will have been contacted and advised that there will be no change to your course of treatment. You will also have been informed that you can contact your clinician if you have any concerns.

This service update follows research from NHS England and the publication of the Cass Review while we work with the Scottish Government to engage in research with NHS England that will generate evidence of safety and long-term impact for therapies.

We are committed to providing the best possible clinical care for young people accessing and understand the distress that gender incongruence can cause. While this pause is in place, we will continue to give anyone who is referred into the Young People Gender Service the psychological support that they require while we review the pathways in line with the findings. A number of support networks are also available via
Mental Health Support (sandyford.scot). (/sexual-health-services/gender-service-at-sandyford/mental-health-support-for-gender-service-at-sandyford/)

If you're waiting for an appointment with our service, please be assured that this service update won't impact your position on the list.

Mental Health Support

If you are on the waiting list and feel
mental health support would be beneficial, please see how to
access mental health support (/sexual-health-services/gender-service-at-sandyford/mental-health-support-for-gender-service-at-sandyford/)
.

Oestrogel Product Recall

The manufacturer of Oestrogel™ (Besins Ltd) have advised of a defect of the pump system in 2 of their batches. As such these products with the following batch number and expiry date are being recalled:

74800, expiry date: 31/07/2026

74830, expiry date: 31/08/2026.

There is no concern regarding the gel within the device itself, and the manufacturer estimates only around 11% of products were affected. Therefore, if you have not

> Mental Health Support for Gender Service at Sandyford (/sexual-health-services/gender-service-at-sandyford/mental-health-support-for-gender-service-at-sandyford/)

had any issues with administering your gel, there is no reason to return the product.

If your oestrogel pump is affected, you should return this to a pharmacy to be disposed of, and your GP should provide you with a new prescription to receive a replacement.

If you have any questions, please contact your GP/community pharmacy in the first instance.

20th March 2024

Referral Information

We accept self-referrals and referrals from other service providers e.g. your GP or a key support worker.

Information required

Your full birth name (e.g. Nicky Smith)
The name you wish to use on our system, if you have changed or do not use your birth name (e.g. Jane Smith)
Your date of birth
Your CHI number. You can get this number from your GP practice
Your current address (we will not send correspondence to your home address if you do not want us to)
Your mobile phone number, home phone number, or both

Waiting list update

For the Young Person Gender Service, we are currently allocating appointments to those referred during the following period:

The name of your current GP and the GP practice you are registered with (we will not contact them if you don't want us to)

If it is ok for us to contact you on your phone number -please say yes or no

If it is ok for us to contact you on your email address - please say yes or no

If it is ok for us to send letters to your home address - please say yes or no

If it is ok for us to copy letters to your GP or send correspondence to your GP about your treatment - please say yes or no

If it would be ok for us to contact you for research purposes - please say yes or no

What kind of help would you/young person like to get from attending the Young Person's Gender Service?

Are there any other services currently involved with you/young person (for example CAMHS, Social Work etc.)?

Contacting the Gender Service

If your query is regarding a patient currently being seen by our service, it will be passed to the relevant clinician. However, our service is currently experiencing significant pressures, so a response may take up to 2 weeks.

If your query is regarding a person who is not currently being seen in the service, then sorry we will not be able to respond.

If your query is regarding a new referral or a patient on the waiting list, please note that due to the pressures within the service, patients are currently experiencing significant waits. We are working hard to address the challenges within our service, and we are moving as quickly as we can to recruit

Patient Information

If you are expecting a letter regarding commencing hormone treatment or changes to your hormone schedule, please expect a wait of roughly six weeks (subject to change).

Please allow ample time when requesting a Gender Recognition Certificate.

Note that we are unable to offer any advice or support on hormones sought out from private companies.

Please remember to update your details with your GP so that your CHI number is up to date, as this can cause delays when applying for surgery

new staff, however we acknowledge and apologise for the stress and anxiety this might cause for any person or family/friend of a person waiting to access our service.

If you are concerned about mental health, please see how to access mental health support (/sexual-health-services/gender-service-at-sandyford/mental-health-support-for-gender-service-at-sandyford/)
.

If you do not inform us that you are not able to attend, you risk being removed from the list as there are many patients waiting for appointments.

Information on Travel Expenses for Surgery

Once you have received your appointment letter from the surgical team (for either pre-surgery assessments or surgical procedure), you can contact Sandyford on our generic email: **sandyford@ggc.scot.nhs.uk** for further details on how to claim back travel expenses.

Already on our waiting list and need to update your details?

Please get in touch if your details have changed, especially your address. Due to the high demand for appointments within the service, we are asking patients to email any updates to the appropriate teams below:

Young People address:

YoungPeopleGender.Sandyford@ggc.scot.nhs.uk (mailto:YoungPeopleGender.Sandyford@ggc.scot.nhs.uk)

Adult service address:

Adultgender.Sandyford@ggc.scot.nhs.uk (mailto:Adultgender.Sandyford@ggc.scot.nhs.uk)

If you have changed your name by deed poll, updated your CHI or email addresses please contact our mailboxes above.

Please remember that we are not provided these details by your GP and rely on our patients to update us.

If you are unable to access emails, please call our main switchboard number on 0141 211 8130 and the switchboard team can update your details over the phone. If you would prefer you can also write to us at the following address for the attention of the Gender Service:

Sandyford Sexual Health Service, 6 Sandyford Place, Glasgow, G3 7NB.

Please note that the service is unable to reply to enquiries on your waiting list position, however, please be assured if you have requested to join one of our waiting list's, we will contact you when you reach the top. This also is the case for the switchboard team, and they will be unable to confirm your position.

As a paper-light service, we aim to contact patients via email first before we write to your address on file. If we have been unable to reach you within 4 weeks, we will remove you from the waiting list.

EXHIBIT 112

The New York Times https://www.nytimes.com/2024/04/18/health/scotland-pauses-hormones-puberty-blockers-transgender.html

Scotland Pauses Gender Medications for Minors

The change followed a sweeping review by England's National Health Service that found "remarkably weak" evidence for youth gender treatments.

By Azeen Ghorayshi

April 18, 2024

Scotland's National Health Service has stopped all new prescriptions of puberty-blocking drugs and other hormone treatments for minors, citing a sweeping review of youth gender services released in England last week. It is the sixth country in Europe to limit such treatments, and its changes are among the most restrictive.

The review, commissioned by N.H.S. England and carried out by Dr. Hilary Cass, an independent pediatrician, over the course of four years, concluded that the evidence for benefits of youth gender treatments was "remarkably weak" and that pressing questions remained about potential long-term risks.

This month, following recommendations by Dr. Cass, N.H.S. England halted puberty blockers for children outside of clinical trials. Hormone therapies, including estrogen and testosterone, are still available to teenagers in England aged 16 and up.

Scotland's new changes go further, pausing prescriptions of puberty blockers while also restricting hormone therapies until teenagers turn 18. The changes will not affect patients already getting these medications from the country's Young People Gender Service.

"We will continue to give anyone who is referred into the Young People Gender Service the psychological support that they require while we review the pathways in line with the findings," said Dr. Emilia Crighton, director of public health for

N.H.S. Greater Glasgow and Clyde, which houses Scotland's sole youth gender clinic, Sandyford Sexual Health Services.

Concerned about soaring demand for adolescent gender treatments in recent years, health officials in Finland, Sweden, Norway, Denmark and England have changed national health guidelines to limit medical treatments for adolescents with gender distress, known as dysphoria.

Transgender advocacy groups in Scotland criticized the changes, saying they were motivated by a rising backlash against transgender people.

"We're saddened that this change will result in some young people being unable to access the care they need at all, or having to wait even longer for it," Vic Valentine, manager of the advocacy group Scottish Trans, said in a statement.

Prescriptions for puberty blockers in Scotland have been "exceptionally rare and cautious," leading to long waiting lists, the group said.

According to public records obtained by The Guardian, the Sandyford clinic referred 71 children for puberty blockers from 2016 to 2023. And BBC Scotland reported that by the end of 2023, 1,100 children were on the waiting list for youth gender services, with some waiting for more than four years to be seen.

In 2022, a proposed law that would have made it easier for transgender people to change gender markers on identification documents in Scotland galvanized a coalition of conservative lawmakers and feminists pushing for the exclusion of transgender women from women's spaces.

Top health officials in Scotland welcomed the recommendations from Dr. Cass's review, citing an increasingly polarized debate over transgender rights that had compromised medical care for youth.

"We agree with Dr. Hilary Cass when she highlights that 'increasingly toxic, ideological and polarized public debate' does nothing to serve the young people accessing this care," Neil Gray, the Scottish health secretary, said in a statement. "They are who should be at the center of our thoughts when we discuss this issue."

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A version of this article appears in print on , Section A, Page 5 of the New York edition with the headline: Scotland Clamps Down On Gender Medications For Minors, Citing Risks