

*"We need to be able to talk honestly together. About what is difficult, about what you are unsure of, 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."*

MOR

Parents point out that it is important that the services take the time to see the young person as a whole, take the time to involve those closest to them and find out what is bothering 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 afterwards that it was important that the process takes time, she herself understands that now. During the assessment, it was tough. She had a feeling that she had to convince people that she deserved to get help, to be approved. This blocked communication."*

MOR

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 have been healthy if it was part of the program to talk to 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's 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."*

MOR

## PATIENT SAFETY FOR CHILDREN AND YOUNG PEOPLE WITH GENDER INCONGRUENCE

# 5 Our findings: Overall governance - a guideline with a different background

Published on March 9, 2023

Last updated on March 9, 2023

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 on 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 the provision of treatment for people with gender incongruence.

## The national professional guideline, gender incongruence

2020??

The Ministry of Health and Care Services commissioned the Directorate of Health to: "Prepare a normative document/professional recommendations on the treatment of gender dysphoria and gender incongruence". The assignment is also a result of an expressed wish 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 clarification and specification, 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 organization of the service.

The national professional guideline on gender incongruence does not follow the Guidance for the development of evidence-based guidelines published by the Directorate of Health, which states:

The advice and recommendations provided should be specific, should help health professionals and patients to make good decisions, and 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 the need to:

- update the evidence base for the assessment and treatment of gender incongruence
- strengthen research activities
- develop professional guidelines for health care
- establish a national medical quality register with quality indicators

There was no systematic review of the evidence 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.

The guideline points out that establishing a treatment service is an evolving process. It will require resources and time to establish a specific service, acquire the necessary expertise, develop national guidelines on clinical issues, and establish research projects.

Our investigation finds that the guidelines leave too much room for interpretation regarding who can do what, how, where and when. The scope for interpretation contributes to undesirable variation in the treatment offered for sometimes irreversible and extensive procedures, and we see that the disagreement in the professional communities and patient organizations continues. The feedback we have received from representatives of the services is that the guideline functions poorly as an aid to professional standardization, and this constitutes a patient safety risk.

## **In summary**

Our survey shows that the guideline does not provide the service with sufficient help in developing a service offer. Despite the explanation that this is a guideline with a different background, with its focus on organization, equality and rights, it is too unclear and thus not a tool for the service. In our view, good and clear guidelines are important for the development of a field of practice. When guidelines do not provide sufficient guidance, there are many consequences for the development of health services and for patients.

## **PATIENT SAFETY FOR CHILDREN AND YOUNG PEOPLE WITH GENDER INCONGRUENCE**

# **6 Our findings: Support and treatment services variety of practices and competences**

**Published on March 9, 2023**

Last updated on March 9, 2023

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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. It follows from the guideline for gender incongruence that most patients should receive help either in the municipal health and care services or at regional level in the specialist 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 adequate 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 referring the patient 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

The National Treatment Service for Gender Incongruence has the national function for the treatment of patients diagnosed with gender incongruence in Norway. This means that the national treatment service has the main responsibility for gender-confirming 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 issues 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 assessments in primary care 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 lead to an increased 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



*"It's not all 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 services provided to children and adolescents with gender incongruence are highly variable and may 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 services across municipal health services and specialist 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 guideline provides for the assessment and some of the treatment to take place at regional centers in the specialist 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 on 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 have to do it the same way.'*

REPRESENTATIVE OF A REGIONAL HEALTH AUTHORITY

However, we have heard that some patient and user representatives fear that the regional services being developed will effectively 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 differentiated services are not in place in the regions.

*"It took a very long time from the first time I went to the GP until I was at Rikshospitalet. That waiting time 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 to patient safety.

### **Need for increased skills and access to expertise**

We have been told by both patient organizations and the service that there is a lack of health professionals with expertise in gender incongruence and in the follow-up of people with gender incongruence in both primary and specialist health services.

*"... Many people act on the basis of their professional background ... act according to the resources they have. But they don't have expertise in trans health."*

REPRESENTATIVE PATIENT ORGANIZATION

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 according to 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 the health service for people exploring their gender identity and their relatives. We have heard that there is generally little competence 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 parental 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 GP.

The role of the GP is important in assessment and follow-up over time. It is essential for GPs to have access to appropriate support from specialist services when needed, as is the case for other conditions and pathways.

*"The health professionals involved must be well trained in cooperation with the National Treatment Service. Those who will be working on this must feel competent."*

REPRESENTATIVE FROM A REGIONAL HEALTH AUTHORITY

The GPs we spoke to 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 GP.

*"It is first and foremost about taking care of the person, as long as we approach gender in an open and exploratory way, and do not reject or close doors, it works well. It's important to clarify that it's not about excluding treatment, but about taking care of the person first."*

TREATMENT

In recent years, requirements have been introduced to include knowledge about gender identity and gender expression in key health 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 of specialist health care. It is therefore fundamental to build competence in this field in order to assess, counsel 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 putting in place a sufficiently good service that patients are met by professionals with the right expertise.

In the assessment and treatment of gender incongruence and gender dysphoria, an interdisciplinary approach is necessary, 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 the attrition of professionals.

Stakeholders Ukom has spoken to consider 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 with whom Ukom has had a dialog 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 of 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 on the internet or by 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 there was a long wait, I didn't want to listen to my therapist who told me that my chest also needed time to mature. Because the hormones will change the structure. I didn't want to listen 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 GENDER INCONGRUENCE

Starting hormonal treatment on one's own outside of the public health care system entails risky self-medication. This is a significant patient safety risk, in part because patients are often not assessed before starting treatments. The person is also left alone to administer the treatment. People who have started self-medication will often seek public health services for help or to obtain prescription medication.

Gender confirmation 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 such a way that it 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 decentralized services in a narrow, complex field.

To strengthen services, Ukom believes that it is important to strengthen health services in primary care, build more interdisciplinary expertise in the specialist health services at regional level and ensure that the national treatment services have sufficient capacity for the current demand.

## PATIENT SAFETY FOR CHILDREN AND YOUNG PEOPLE WITH GENDER INCONGRUENCE

# 7 Our findings: Insufficient knowledge

Published on March 9, 2023

Last updated on March 9, 2023

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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 specialist health services over the last decade. This represents a new population for health services where evidence on treatment effects, side effects and prognosis is lacking or weak. Most often the studies are on patients with binary gender incongruence, but now there is also an increase in referrals 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 the evidence

The lack of 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 synthesize available evidence in a systematic, scientific and transparent manner based on explicit and predefined methods according to international standards for the preparation of such reviews. 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.

- An Endocrine Society Clinical Practice Guideline which was an updated 2017 clinical practice guideline from 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 National Board of Health and Welfare in Sweden 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 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 HTAs 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-confirming treatments with hormones and surgery. Nor have HTAs 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 issues related to puberty blockers in adolescents. One published study shows that puberty-delaying hormones cause slower growth in height and slower increases 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 substantially 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.

Since some of the treatments are established in practice, conducting good randomized trials is problematic. 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 for 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 insufficient 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 mental health 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. Samples 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 of these earlier studies to those who are now being referred, since a large proportion have mental illness, developmental disorders or other conditions that were not described in the earlier studies.

## **Suicide incidence**

Varying figures are 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 Swedish figures:

***"The suicide risk was significantly higher than in the general population, but at the same level as the suicide risk of 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. There are also no 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"***

Data from the follow-up of a cohort of people referred to specialist 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 in all phases 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 of the situation of patients**

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There is currently no Norwegian view or systematic mapping of the patients' history, how many are rejected, withdraw during the course of treatment, complete the treatment

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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 registry 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 affirming 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 examination, 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 health and other disorders.

*"No one knows what happens to those who are turned away - no one knows anything about groups of patients who are not followed up."*

#### REPRESENTATIVE PATIENT ORGANIZATION

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.

There is a need for oversight to promote development, and medical quality registries and research studies can contribute to this. Medical quality registers 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 improving the 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

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services. PROMs can contribute to a comprehensive database 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

## About ongoing research

In general, there is a lack of research-based knowledge on the short- and long-term effects, course and prognosis of different treatments. There is a need for medical clinical and epidemiological studies with outcome studies, including on people with gender incongruence who are not offered, do not start or stop the different treatments.

*"We have to think in terms of the life cycle. What about those who received treatment and those who did not receive treatment? (...) 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."*

### REPRESENTATIVE PATIENT ORGANIZATION

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, much research on gender incongruence is ongoing 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 be answered.

Various efforts are being made to produce 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 specialist health services over the last ten years, is a new population of patients for which the evidence 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



not necessarily transferable to the group of teenagers with gender incongruence and gender dysphoria who increasingly seek puberty-suspending and gender-affirming treatment. There is a particular lack of research-based knowledge on 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 register 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.

## PATIENT SAFETY FOR CHILDREN AND YOUNG PEOPLE WITH GENDER INCONGRUENCE

# 8 Our findings: Due diligence requirements - in particular related to children and young people

Published on March 9, 2023

Last updated on March 9, 2023

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Summary

In conversations with us and in the consultation process for the national guideline, several stakeholders **have questioned the soundness of the health care offered to children and adolescents with gender incongruence and gender dysphoria.**

When we now assess the requirement for justifiability, **we focus primarily 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 contribute to coping 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 of defensibility has a broad basis in health legislation. The requirement for defensibility relates 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 what practice should be. At the same time, professional guidelines will provide guidance on how much deviation from good practice can be accepted before the deviation leads to the service being indefensible.

The Norwegian Board of Health Supervision and the State Governor are responsible for ensuring that the service operates responsibly. It is difficult for the Norwegian Board of Health Supervision to exercise control of soundness when the professional guideline, which should be normative, is unclear and vague.

The requirement of soundness in relation 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 best interests of the child based on their situation and needs. The requirement for soundness also includes the requirement for compassionate help.

## Requirements for Investigation

For children and adolescents, 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 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-deferring treatment, gender-confirming treatment with hormones and surgery is inadequate**. This means that in order to meet the requirement for justifiability, 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.

If GI is not a disorder, then why may it require medical and psychological treatments?

If GI leads to GD, treatment may be needed, but do we know what is best?

If GD does exist, psych tx IS NOT needed per current guidelines.

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.**

## Ambiguities and variations in investigation practices

People with gender dysphoria are a **heterogeneous group**. This makes treatment particularly challenging, 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 is of the opinion 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. **It is therefore supported that the least invasive gender-affirming treatments should always be considered as the 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, in interdisciplinary cooperation."*

*(The Norwegian Board of Health's consultation response to the draft national 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.** Nevertheless, there is disagreement about the **content and comprehensiveness 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.

- Many experts concern about patient safety because mental health assessments are no longer required. The emphasis is now on avoiding morbidity. This may mean that different mental health

stresses and diagnoses go unrecognized, resulting in children and young people not getting 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 wants 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 her own devices and 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 specialist health service in child and adolescent psychiatry (BUP) and DPS, before referral to the National Treatment Service. If children and young people with mental illness are on waiting lists without their mental health being adequately assessed or followed up, this may pose a risk to patient safety.

Several people we have spoken to tell us that referrals to BUP have been 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 an interview. Patients and relatives we have spoken to are clear that good and sufficiently close follow-up is absolutely necessary 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 healthcare - parental involvement**

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. patient - and Users' Rights Act § 3-4.

The general rule is that the age of majority in Norway is 16 years. 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.

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For some procedures, parental consent is also required for those over 16 years of age. 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. Some of the treatment provided for gender dysphoria is 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 capacity to consent to gender affirmative treatment has been highlighted in connection with a controversial court case in England (Bell vs Tavistock). This has led to an increased awareness of the issue.

The Patients' and Users' Rights Act allows children under the age of 16 (between 12 and 16) to consent to health care without parental involvement. This is linked to the rule on exempting information to parents, cf. section 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 on 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. Section 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 make a decision on health care that is strictly necessary and that is not invasive in terms of scope and duration. Such a decision may only be taken 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. It is difficult to assess children's competence to consent. 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 that children under the age of 16 can consent to treatment for gender incongruence and gender dysphoria. In connection with a specific case, the State Governor of 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 a treatment center.

Relatives state that their adolescent is in an exploratory phase with a lot of doubt and ambiguity in addition to having mental health challenges. The parents have not received any information or been 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 child 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's exploration of gender identity.

*"Involving us parents is to facilitate good relationships for the rest of our lives."*

MOR

Assessing capacity to consent can be challenging. It is therefore all the more important to involve relatives. **There is a clear expectation in the current regulations that relatives should be involved unless there are compelling reasons to the contrary.**

The assessment and treatment of children and adolescents with gender incongruence and gender dysphoria is complex. The fact that they are undergoing intense physical and psychological development must be taken into account. 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 need to be informed about this and 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 young people.

*"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 arrive at a definite position that gender-affirming measures are what they want, which will often involve probing questions, against making them feel cared for and understood. When the issue is one's own identity, it is easy to fall into the trap of offending."*

*(Consultation statement 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 it takes 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 the start of treatment. The guideline does not function well as a professional standard and constitutes a patient safety risk in its current form.