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How to cite this article: Bränström, R., Stormbom, I., Bergendal, M., & Pachankis, J. E. (2022). Transgender-based disparities in suicidality: A population-based study of key predictions from four theoretical models. *Suicide and Life-Threatening Behavior*, 52, 401–412. https://doi.org/10.1111/sltb.12830

Letters to the Editor

Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process

On October 4, 2019, we published an article by Bränström and Pachankis in which it was reported that observed reductions in mental health treatment utilization lent support to the decision to provide gender-affirming surgeries to those who seek them (1). After this article's publication, we received several letters calling into question the statistical analyses employed and the conclusions drawn from said analyses. These letters follow this comment (2–8).

We enlisted the services of a statistical reviewer to look again at the article as well as the letters we received. We then sent the letters we received and the results of this statistical review, which called for a matched-pairs analysis, to the original authors. The study authors complied with the request to perform an additional analysis, as presented in their letter response (9).

We sent the original letters, statistical review, and author response to a second statistical reviewer. The response from this consultation convinced us that, given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" was too strong. In the August 2020 issue of the *Journal*, we are publishing a correction to this effect and including an addendum to the article pointing to this postpublication discussion and process, both of which were composed with contributions and approval from the original article authors.

We thank the letter writers, statistical reviewers, and the original study authors—as well as the editorialist we invited to place this study's findings in context (10)—for helping us to make clear to our readers and for the literature what the article shows and what still remains to be investigated in future research.

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Editor-in-Chief

The American Journal of Psychiatry

Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803

Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery

TO THE EDITOR: The article by Bränström and Pachankis (1) has the stated aim "to ascertain the prevalence of mood and anxiety disorder health care visits and antidepressant and anxiolytic prescriptions in 2015 as a function of gender incongruence diagnosis and gender-affirming hormone and surgical treatment in the entire Swedish population." The authors conclude that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." In support of this claim, the authors report that the time since "last gender-affirming surgery" (in 2005-2014) was associated with reduced "mental health treatment" (a combined variable of outpatient visits with a diagnosis of a mood or anxiety disorder and/or prescriptions for antidepressants or anxiolytics) during 2015 (adjusted odds ratio=0.92, 95% CI=0.87-0.98). The authors have also

shown that the group of people diagnosed with gender incongruence have a dramatically worse overall mental health outcome than the general population, which is, in fact, the answer to their stated aim and research question, but this finding is not even referred to in the title or in the Conclusions section of the article.

In view of the claim that surgery was shown to be an efficient treatment for gender incongruence, the following issues have to be raised:

- 1. Variables, hypotheses, and analytical strategies were not described pre hoc. Adequate power analyses and corrections for multiple comparisons were not provided.
- 2. The article is vague or noninformative with respect to key aspects. Biological sex ratios are not provided. Surgeries for complications or even unrelated surgeries (e.g., in the skin or the larynx) may have been included. Lithium and atypical antipsychotic medications were not included as treatments for mood disorders, while a histamine blocker such as hydroxyzine, which is mainly used for non-mental health problems, was. Outpatient visits for mood and anxiety disorders were included as "mental health treatment" but not care for sleeping disorders, substancerelated disorders, major mental disorders, or any inpatient psychiatric treatment.
- 3. The nonnormal distribution of data, known secular changes, age effects, or people who left Sweden and moved abroad, died from suicide or other causes, or had surgery to desist were not considered in the interpretation of the analyses.

As the article stands, we actually have no way of knowing whether the four reported analyses of purported treatment effects (time elapsed since start of hormones OR since last surgery BY outpatient mental health treatment OR suicide attempt-related hospitalization), one of which was statistically significant by a small margin, were the first analyses made or the final setup chosen for publication after a "fishing expedition" in the database.

These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender noncongruence based on the results presented in this article.

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The authors report no financial relationships with commercial interests. Accepted May 18, 2020.

Am J Psychiatry 2020; 177:764-765; doi: 10.1176/appi.ajp.2020.19111117

Gender-Affirmation Surgery Conclusion Lacks Evidence

TO THE EDITOR: We have concerns regarding severe shortcomings in the study by Bränström and Pachankis (1) that call into question the authors' conclusion that it "provides timely support for policies that ensure coverage of gender-affirming treatments."

This study covered outcomes only for calendar year 2015 for all individuals living in Sweden on December 31, 2014. The retrospective metric of "time since last genderaffirming surgery" in Figure 1 in the article is easily misinterpreted as a prospective 10-year follow-up that did not occur and leaves open the question of number and type of prior surgeries.

The 2,679 individuals diagnosed with gender incongruence in Sweden is a full order of magnitude below prevalence expectations from DSM-5. Table 3 in the article indicates that 38% of these individuals had any kind of gender-affirming surgery, but only 53% of those had surgery of reproductive organs. Given that such treatment in Sweden is free, ample loss to follow-up is implied.

Measured outcomes were limited to "mood and anxiety disorder health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after a suicide attempt." This selection excludes completed suicides, suicide attempts without subsequent hospitalization, health care visits and hospitalizations for other medical or psychological issues still related to gender-affirming surgeries, individuals refusing treatment, and individuals choosing self-medication with alcohol or illicit substances. Again, significant loss to follow-up must be considered before declaring success.

Dhejne's cohort study of 324 persons in Sweden undergoing sex-reassignment surgery used 30 years of data, population controls, and matching by birth year, birth sex, and reassigned sex (2). Through the Hospital Discharge Register, the authors evaluated discharge diagnoses, external causes of morbidity and mortality, and surgical procedure codes. Compared with the general population, patients who had sex reassignment surgery had 19 times the rate of completed suicide, almost three times the rate of all-cause mortality, nearly three times the rate of inpatient psychiatric care, and close to five times the rate of suicide attempts.

These important findings could have been updated to the current period, given the sharp rise in adolescent case presentations, use of puberty blockers, and changes in cross-sex hormones from agents like ethinyl estradiol to 17β-estradiol.

For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation? A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring.

The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls.

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The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its progender-affirmation surgery

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Study of Transgender Patients: Conclusions Are Not Supported by Findings

TO THE EDITOR: The study of transgender individuals by Bränström and Pachankis claims to demonstrate a reduction in mental health treatment utilization after gender-affirming surgery but, in fact, demonstrates no such thing (1).

The only result they present that they claim is statistically significant is that there is an association between years since last gender-affirming surgery and recent mental health treatment (adjusted odds ratio=0.92, 95% CI=0.87-0.98). This result makes no sense as it stands because analysis of a quantitative measure against an outcome does not produce an odds ratio. Presumably, the authors must mean that each year since surgery is associated with an odds ratio of 0.92. There are also discrepancies between the data discussed in the text and in the tables. For example, the authors quote the percentage of patients with gender incongruence who received no treatment as 29% in the text but 29.6% in Table 3 and, more importantly, the percentage of patients who received surgery as 48% in the text but only 38.0% in the table. However, the key statistical criticism is that they have failed to carry out standard corrections for multiple testing. As they tested two interventions, hormone treatment and surgery, against two outcomes, mental health treatment and suicide attempts, they performed four tests. Because the upper confidence interval that they quote is very close to 1, it is obvious that if appropriate correction for multiple testing had been applied, then none of the results would have been deemed significant.

When one views the data on which these analyses are based, as presented in Figure 1 in the article, some very clear features emerge. First, there is obviously no general correlation between the outcomes and time since surgery. Rather, a spike in suicide attempts is seen in the year after surgery (in 2.8% of the patients), which falls off over the next 1-2 years, and to a lesser extent, there is also a spike in the proportion of patients receiving mental health treatment in the first year, going up to 45.3%. There is also a low rate of mental health treatment among patients who received surgery 10 or more years earlier. This may reflect the fact that in the past, patients with mental health problems would have been less likely to be offered surgery.

The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery and that increased support in this period might be indicated.

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Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological **Distress**

TO THE EDITOR: The study by Bränström and Pachankis (1) shows a reduction in mental health treatments and hospitalization after suicide attempts with increased time after masculinizing or feminizing surgeries.

The data presented in Figure 1 in the article support findings from previous studies showing that transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress.

According to the study, mental health utilization rates were highest in the perioperative period. However, the data also could be interpreted as showing that masculinizing or feminizing surgeries were the actual cause of increased mental health utilization. Surgery is a known risk factor for the development of depression (2) and may have caused a

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The only result they present that they claim is statistically significant is that there is an association between years since last gender-affirming surgery and recent mental health treatment (adjusted odds ratio=0.92, 95% CI=0.87-0.98). This result makes no sense as it stands because analysis of a quantitative measure against an outcome does not produce an odds ratio. Presumably, the authors must mean that each year since surgery is associated with an odds ratio of 0.92. There are also discrepancies between the data discussed in the text and in the tables. For example, the authors quote the percentage of patients with gender incongruence who received no treatment as 29% in the text but 29.6% in Table 3 and, more importantly, the percentage of patients who received surgery as 48% in the text but only 38.0% in the table. However, the key statistical criticism is that they have failed to carry out standard corrections for multiple testing. As they tested two interventions, hormone treatment and surgery, against two outcomes, mental health treatment and suicide attempts, they performed four tests. Because the upper confidence interval that they quote is very close to 1, it is obvious that if appropriate correction for multiple testing had been applied, then none of the results would have been deemed significant.

When one views the data on which these analyses are based, as presented in Figure 1 in the article, some very clear features emerge. First, there is obviously no general correlation between the outcomes and time since surgery. Rather, a spike in suicide attempts is seen in the year after surgery (in 2.8% of the patients), which falls off over the next 1-2 years, and to a lesser extent, there is also a spike in the proportion of patients receiving mental health treatment in the first year, going up to 45.3%. There is also a low rate of mental health treatment among patients who received surgery 10 or more years earlier. This may reflect the fact that in the past, patients with mental health problems would have been less likely to be offered surgery.

The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery and that increased support in this period might be indicated.

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The author reports no financial relationships with commercial interests. Accepted May 18, 2020.

Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131

Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological **Distress**

TO THE EDITOR: The study by Bränström and Pachankis (1) shows a reduction in mental health treatments and hospitalization after suicide attempts with increased time after masculinizing or feminizing surgeries.

The data presented in Figure 1 in the article support findings from previous studies showing that transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress.

According to the study, mental health utilization rates were highest in the perioperative period. However, the data also could be interpreted as showing that masculinizing or feminizing surgeries were the actual cause of increased mental health utilization. Surgery is a known risk factor for the development of depression (2) and may have caused a

deterioration in mental health in a population of individuals who already had more psychological distress, which abated with time since surgery. It is just as possible that mental health improved as individuals had fewer surgeries.

After the initial 11% drop in mental health visits in the first year after surgery, there was very little change in mental health visits (5.6% over 9 years), and there was a further 11% fall in the ≥10-year group. It is not clear what caused the reduction in the two markers for mental health distress past the 10-year mark. Loss to follow-up, death from suicide of the most psychologically distressed individuals, or death from cardiovascular disease, all known to be increased in the transgender population, could have falsely skewed the ≥10year data. Comparisons with a control group would be best to answer these questions.

In addition, there are only 19 people in the ≥10-year group who underwent gender-affirming surgery. A total of 21.1% of them received mental health treatment, which is only four people. This means that a single mental health utilization event in either direction would change the calculated rate of utilization by 5%. However, the assertion that genderaffirming surgeries reduce mental health visits by 8% is highly dependent upon this sudden drop in rates in the ≥10-year group of only 19 people.

Finally, no information is given about the composition of the year 1 and ≥10-year groups, but given the changing epidemiology of gender dysphoria in Sweden (3), the year 1 group likely included a higher percentage of younger natal females than the ≥10-year group, which likely had more older natal males, making comparisons between the year 1 and ≥10year groups problematic.

Because of the limitations in the study design, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. Therefore, the authors' conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries cannot be supported.

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Am J Psychiatry 2020; 177:766-767; doi: 10.1176/appi.ajp.2020.19111149

The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided

TO THE EDITOR: In this issue of the Journal, Bränström and Pachankis study mental health treatment and suicide attempts in persons diagnosed with gender dysphoria in Sweden (1). Their claim that the study shows that gender-affirming treatment reduces the risk of mental health treatment and suicide attempts is misleading because the study design is flawed.

The authors first found what was already known (2): the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population. The authors then explored if the risk for mental health treatment changes as a function of years since starting hormonal treatment. They find no effect (odds ratio=1.0), but they do find a trend toward increased risk of suicide attempts as a function of years since starting hormonal treatment. In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate these negative outcomes to the number of years since surgery. Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question.

First, the authors include only persons who were alive in 2014. That means that those who died by suicide before 2014—and hence were at highest risk for suicide attempt—are excluded and confound the results. Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment; it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, by definition, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and is not a proxy for improved mental health.

Because the authors do not present data prior to genderaffirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity. Moreover, the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes.

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Am J Psychiatry 2020; 177:767-768; doi: 10.1176/appi.ajp.2020.19111165

Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article

TO THE EDITOR: The article by Bränström and Pachankis (1) examines the psychiatric health of persons who have obtained a diagnosis of gender dysphoria between 2005 and 2015 compared with the general population. The variables examined were psychiatric diagnosis, prescription of psychiatric drugs (anxiolytics and antidepressants), and hospitalization for suicide attempt in 2015.

The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population.

However, the title of the article implies that gendercorrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide genderaffirming surgeries to transgender individuals who seek them." In my opinion, this conclusion is not supported by the data presented in the article.

The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not.

Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment").

By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last

surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender-corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery.

This corresponds to an odds ratio of 2.37 (95% CI=1.01–5.56, p=0.047). Hence, among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not. Whether this is a causal relation (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined. Nevertheless, the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria.

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Confounding Effects on Mental Health Observations After Sex Reassignment Surgery

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Except for a reduction after the perioperative year, Bränström and Pachankis found no further significant decrease in mental health treatment between the first and ninth years after surgery. They allowed for the increase in sex reassignment surgery from 2005 on but overlooked the increase in co-occurring mental health issues, which rose after 2005 but especially from about 2009 (2). A simple qualitative model illustrates how a dramatic change over time in mental health issues will affect the number of individuals accessing mental health treatment in 2015. In our Figure 1, the upper line depicts the rise in the number of sex reassignment surgeries, and the lower dark line depicts the rise in co-occurrence of mental health issues, assuming a final rise of 200% and a final co-occurrence of 75% (3).

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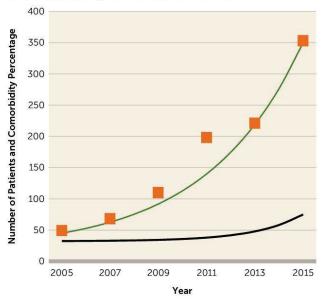
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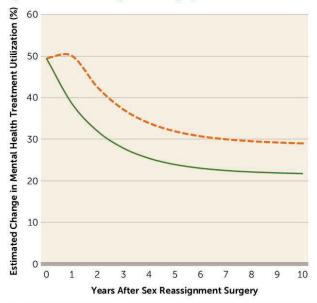
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FIGURE 1. Qualitative model of the number of sex reassignment surgeries and co-occurrence of mental health issues among individuals accessing mental health treatment^a



^a The orange boxes indicate the number of patients, the green line indicates the number of sex reassignment surgeries, and the dark line indicates the percentage of co-occurrence of mental health issues.

FIGURE 2. Estimation of mental health utilization by individuals in the years after sex reassignment surgery^a



^a The dotted line portrays projected mental health treatment utilization assuming aggravation of a mental health condition after sex reassignment surgery. The solid line portrays projected mental health treatment utilization assuming no aggravating effects after sex reassignment surgery.

issues than those whose surgery happened longer ago, we would expect the decline in mental health treatment to be pronounced (see the solid line in Figure 2), and with a beneficial effect of the surgery over time, the fall should be even more significant. Yet surprisingly, Bränström and Pachankis found only a very small decline over time.

However, if in fact this surgery aggravates a mental health condition by, say, 25%, then a more moderate fall in mental health utilization results (see the dashed line in Figure 2). The qualitative approximation of this curve with the reduction described by Bränström and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of increased mental health treatment due to this surgery, fits the data in the article and overturns the authors' conclusions, suggesting that sex reassignment surgery is in fact associated with increased mental health treatment.

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The authors report no financial relationships with commercial interests. Accepted May 18, 2020.

Am J Psychiatry 2020; 177:768-769; doi: 10.1176/appi.ajp.2020.19111169

Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters

TO THE EDITOR: Increasing attention has been paid to identifying the best way to support transgender individuals seeking gender-affirming care. This attention springs from the increasing number of individuals seeking such care in many countries worldwide, coupled with a lack of sufficient knowledge to provide evidence-based treatment recommendations. This attention is also reflected in the letters to the editor (1–7) submitted in response to our article in this issue in which we describe mental health treatment utilization among transgender individuals seeking genderaffirming care in Sweden compared with the general population, and as a function of time since last gender-affirming surgery (8).

The letter writers question our conclusion that our study "lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." Their concerns about this conclusion can be summarized into three types:

REDUCTION IN MENTAL HEALTH TREATMENT UTILIZATION AFTER GENDER-AFFIRMING SURGERIES

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Correction to Bränström and Pachankis

After the article "Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study" by Richard Bränström, Ph.D., and John E. Pachankis, Ph.D. (doi: 10.1176/appi.ajp.2019.19010080), was published online on October 4, 2019, some letters containing questions on the statistical methodology employed in the study led the Journal to seek statistical consultations. The results of these consultations were presented to the study authors, who concurred with many of the points raised. Upon request, the authors reanalyzed the data to compare outcomes between individuals diagnosed with gender incongruence who had received gender-affirming surgical treatments and those diagnosed with gender incongruence who had not. While this comparison was performed retrospectively and was not part of the original research question given that several other factors may differ between the groups, the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison. Given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and lower use of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" is too strong. Finally, although the percentage of individuals with a gender incongruence diagnosis who had received gender-affirming surgical treatments during the follow-up period is correctly reported in Table 3 (37.9%), the text incorrectly refers to this percentage as 48%. The article was reposted on August 1, 2020, correcting this percentage and including an addendum referencing the postpublication discussion captured in the Letters to the Editor section of the August 2020 issue of the Journal (1).

1. Kalin NH: Reassessing mental health treatment utilization reduction in transgender individuals after gender-affirming surgeries: a comment by the editor on the process (letter). Am J Psychiatry 2020; 177:765

LETTERS

Letters to the Editor

Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process

On October 4, 2019, we published an article by Bränström and Pachankis in which it was reported that observed reductions in mental health treatment utilization lent support to the decision to provide gender-affirming surgeries to those who seek them (1). After this article's publication, we received several letters calling into question the statistical analyses employed and the conclusions drawn from said analyses. These letters follow this comment (2–8).

We enlisted the services of a statistical reviewer to look again at the article as well as the letters we received. We then sent the letters we received and the results of this statistical review, which called for a matched-pairs analysis, to the original authors. The study authors complied with the request to perform an additional analysis, as presented in their letter response (9).

We sent the original letters, statistical review, and author response to a second statistical reviewer. The response from this consultation convinced us that, given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" was too strong. In the August 2020 issue of the *Journal*, we are publishing a correction to this effect and including an addendum to the article pointing to this postpublication discussion and process, both of which were composed with contributions and approval from the original article authors.

We thank the letter writers, statistical reviewers, and the original study authors—as well as the editorialist we invited to place this study's findings in context (10)—for helping us to make clear to our readers and for the literature what the article shows and what still remains to be investigated in future research.

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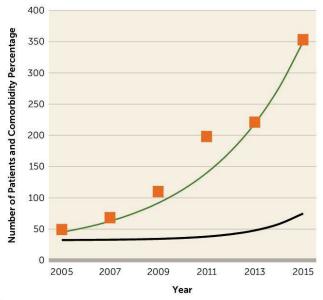
The American Journal of Psychiatry

Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803

Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery

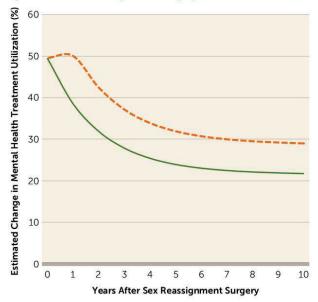
TO THE EDITOR: The article by Bränström and Pachankis (1) has the stated aim "to ascertain the prevalence of mood and anxiety disorder health care visits and antidepressant and anxiolytic prescriptions in 2015 as a function of gender incongruence diagnosis and gender-affirming hormone and surgical treatment in the entire Swedish population." The authors conclude that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." In support of this claim, the authors report that the time since "last gender-affirming surgery" (in 2005-2014) was associated with reduced "mental health treatment" (a combined variable of outpatient visits with a diagnosis of a mood or anxiety disorder and/or prescriptions for antidepressants or anxiolytics) during 2015 (adjusted odds ratio=0.92, 95% CI=0.87-0.98). The authors have also

FIGURE 1. Qualitative model of the number of sex reassignment surgeries and co-occurrence of mental health issues among individuals accessing mental health treatment^a



^a The orange boxes indicate the number of patients, the green line indicates the number of sex reassignment surgeries, and the dark line indicates the percentage of co-occurrence of mental health issues.

FIGURE 2. Estimation of mental health utilization by individuals in the years after sex reassignment surgery^a



^a The dotted line portrays projected mental health treatment utilization assuming aggravation of a mental health condition after sex reassignment surgery. The solid line portrays projected mental health treatment utilization assuming no aggravating effects after sex reassignment surgery.

issues than those whose surgery happened longer ago, we would expect the decline in mental health treatment to be pronounced (see the solid line in Figure 2), and with a beneficial effect of the surgery over time, the fall should be even more significant. Yet surprisingly, Bränström and Pachankis found only a very small decline over time.

However, if in fact this surgery aggravates a mental health condition by, say, 25%, then a more moderate fall in mental health utilization results (see the dashed line in Figure 2). The qualitative approximation of this curve with the reduction described by Bränström and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of increased mental health treatment due to this surgery, fits the data in the article and overturns the authors' conclusions, suggesting that sex reassignment surgery is in fact associated with increased mental health treatment.

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Am J Psychiatry 2020; 177:768-769; doi: 10.1176/appi.ajp.2020.19111169

Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters

TO THE EDITOR: Increasing attention has been paid to identifying the best way to support transgender individuals seeking gender-affirming care. This attention springs from the increasing number of individuals seeking such care in many countries worldwide, coupled with a lack of sufficient knowledge to provide evidence-based treatment recommendations. This attention is also reflected in the letters to the editor (1–7) submitted in response to our article in this issue in which we describe mental health treatment utilization among transgender individuals seeking genderaffirming care in Sweden compared with the general population, and as a function of time since last gender-affirming surgery (8).

The letter writers question our conclusion that our study "lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." Their concerns about this conclusion can be summarized into three types:

Concern 1: The analysis focused on mental health treatment utilization during one specific year (i.e., 2015) rather than during a longer follow-up period, such as before and after provision of gender-affirming treatment.

Concern 2: The study did not employ an adequate comparison group.

Concern 3: The study did not sufficiently highlight the elevated mental health care needs of transgender individuals seeking gender-affirming care during the perioperative period.

Our study was motivated by two aims informed by the literature and the need for more knowledge in this field: first, to examine if transgender individuals seeking genderaffirming care have an increased risk of mental health treatment utilization compared with the general population; and second, to examine if mental health treatment utilization among transgender individuals who received gender-affirming care decreases as a function of number of years since receiving gender-affirming care.

In our article, we describe the background to our analytic decisions and discuss the limitations that our particular study design and analytic approach introduce. Many of the concerns raised by the letter writers are discussed at the conclusion of the article. In the article, we specifically call for further longitudinal studies that assess within-person changes in mental health treatment utilization before and after treatment. In the article, we also note that our approach was capable of ascertaining mental health only among those alive in 2015 and did not capture outcomes among the deceased. Several of the letter writers' concerns are drawn from assumptions about what our study methodology theoretically should have been or could have been but ultimately was not.

The letter writers suggest more ideal methodologies for identifying any causal impact of gender-affirming care on mental health treatment utilization, similar to what we wrote in our article. As outlined below, we join them in aspiring toward such methodologies capable of more rigorously establishing this impact. We also perform additional analyses permitted by our current data to start to move toward that goal.

Our Analytic Strategy

There is a great need for higher-quality studies using more representative samples of transgender individuals seeking gender-affirming care to better understand this population's mental and physical health care needs and the effects of gender-affirming care. Much current evidence derives primarily from small studies with cross-sectional designs, nonprobability samples, and self-reported treatment exposures and mental health outcomes. Our study does not. Although it is not capable of overcoming all threats to validity, our study design represents an improvement over much previous research.

Ours is an observational study based on registry data regarding mental health treatment utilization among individuals with a gender incongruence diagnosis. We focus on mental health treatment utilization during one specific year (the latest for which we had data), and we used the total Swedish population as a comparison group. First, to answer whether transgender individuals seeking gender-affirming care have an increased risk of mental health treatment utilization compared with the general population, we compared the prevalence of treatment for mood and anxiety disorders among those with and without a gender incongruence diagnosis among all individuals living in Sweden. Second, to answer whether odds of mental health treatment utilization among transgender individuals who received genderaffirming care are lower as a function of number of years since receiving gender-affirming care, we evaluated mental health treatment utilization in 2015 among those with a gender incongruence diagnosis as a function of time since the initiation of gender-affirming hormone treatment and the last gender-affirming surgical treatment.

As outlined below, although this design is capable of ruling out certain threats to validity (e.g., confounding by secular trends), it is incapable of ruling out others (e.g., loss to mortality).

Responses to the Letters

Response to concern 1. The first concern is that our analysis focused on mental health treatment utilization during one specific year (i.e., 2015) rather than during a longer follow-up period, such as before and after provision of gender-affirming treatment. This decision was made to control for several important factors. First, the situation for transgender individuals has changed rapidly in the past 10-15 years. In Sweden, legislation affecting transgender individuals (e.g., removal of sterilization as a requirement for change of legal gender; increased protection of transgender individuals in hate-speech legislation) has improved at the same time that population attitudes have become more accepting (9, 10). Second, the proportion of individuals in the population treated for mental health problems has increased over time. Third, access to gender-affirming care has also increased over time. By restricting our outcome assessment period to one year, 2015, the most recent year for which we had data, we were able to remove the influence of these secular trends in transgender acceptance, visibility, and treatment utilization (both gender-affirming treatment and mental health treatment).

Although our chosen strategy addressed many of the problems of these secular effects, it has several drawbacks. Because we looked at mental health treatment utilization in one specific year, we could not follow individuals over time. Our analysis of time since last gender-affirming surgical treatment compared groups of individuals with varying lengths of time since their last treatment. It is possible that other factors, such as age and a changing proportion of individuals of different legal genders who have sought gender-affirming care over time, could influence these comparisons. Therefore, we controlled for those sociodemographic

factors in our analyses. Another drawback to using only one year of mental health treatment utilization data is that our analysis contains a very small number of suicide attempts and no information about previous attempts and completed suicides. Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming care. Any conclusion regarding suicidality in our present study should be interpreted with this limitation in mind. This limitation is reported in our article.

Response to concern 2. The second concern is that our study design lacked an adequate comparison group. To answer whether transgender individuals seeking gender-affirming care have an increased risk of mental health treatment utilization compared with the general population, we used the total population without a gender incongruence diagnosis as a comparison group. Because the total population differs in significant ways from the group diagnosed with gender incongruence, we adjusted our analysis for all available sociodemographic variables (i.e., age, legal gender, education, income, urbanicity, and country of birth). An alternative way of testing this aim would be to create a comparison group matched on important demographic variables, which we have now done. Specifically, we now compare individuals diagnosed with gender incongruence with an equally sized group without such a diagnosis matched by age, legal gender, education, and country of birth. The results are presented in Tables S1 and S2 in the online supplement, and they indicate a similar pattern of results as reported in our article, with only a slightly reduced disparity in the odds of mental health treatment utilization when individuals diagnosed with gender incongruence are compared with matched control subjects (instead of with the full population without gender incongruence, as was done in the original analysis).

To determine if mental health treatment utilization among transgender individuals receiving gender-affirming care decreases as a function of number of years since receiving genderaffirming care, we did not use a comparison group but tested the association between both year since initiation of genderaffirming hormone treatment and year since last genderaffirming surgical treatment with mental health treatment utilization in 2015. As a reference, we included the proportion of the general population treated for mental health conditions in 2015 in Figure 1 of our article. We have added the proportion of the matched control subjects treated for mental health problems in 2015 to Figure S1 in the online supplement.

Like some of the letter writers suggest, we also considered using a stronger comparison group but found the options unsatisfactory, if not impossible. Perhaps the most obvious comparison would have been individuals with a gender incongruence diagnosis who had not received surgical treatment. This would be a strong comparison group if all individuals diagnosed with gender incongruence are, in fact, seeking gender-affirming surgical treatment. However, this is not the case. Some individuals diagnosed with gender

incongruence seek only gender-affirming hormonal treatment and not gender-affirming surgical treatment; others seek no treatment at all. The group diagnosed with gender incongruence not receiving surgery is a heterogeneous group, including those with no intention to seek surgery, that would be inappropriate as a comparison group for those receiving surgery. However, to be responsive to some of the letter writers' interest in comparing individuals with a gender incongruence diagnosis who received and did not receive gender-affirming surgery, we have created a matched group of individuals with a gender incongruence diagnosis who have not received surgery. These individuals were each matched to an individual with a gender incongruence diagnosis who had received gender-affirming surgery by age, legal gender, education, and country of birth. When comparing the mental health treatment outcomes between the two groups (Table 1), we found no significant difference in the prevalence of treatment for mood disorders and no significant difference in the prevalence of hospitalization after suicide attempt. However, individuals diagnosed with gender incongruence who had received gender-affirming surgery were more likely to be treated for anxiety disorders compared with individuals diagnosed with gender incongruence who had not received gender-affirming surgery. As reported in the article, the statistical test for hospitalization after suicide attempt must be interpreted with caution. As noted above, limited information can be drawn from this particular comparison.

Another comparison group could have involved individuals without a gender incongruence diagnosis undergoing a surgical treatment for which a thorough mental health assessment is required, as it is for gender-affirming surgery. However, we are unaware of any such surgical treatment. Such a comparison group would have, theoretically, enabled us to partially overcome two threats to the validity of our finding that odds of mental health treatment are lower as a function of time since final gender-affirming surgery. The first threat is that people are required to be screened for mental health problems before gender-affirming surgery and might therefore have particularly high odds of mental health treatment in the perioperative year because of their perhaps involuntary receipt of mental health services. These individuals might be less likely to voluntarily seek treatment for mental health problems with greater time since surgery. The second threat is that because we assessed only the mental health of individuals who were alive in 2015, individuals who died by suicide or migrated would not be included; greater time since last surgical treatment comes with greater time for suicide or migration to happen.

Response to concern 3. The third concern is that the study did not sufficiently highlight the elevated mental health care needs of transgender individuals seeking gender-affirming care during the perioperative period. The letter writers highlight this important finding of our study that we did not sufficiently emphasize originally. Specifically, regardless of the effect of gender-affirming care on mental health treatment

TABLE 1. Mood- and anxiety-related health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after suicide attempt in 2015 among individuals diagnosed with gender incongruence in Sweden between 2005 and 2015, by gender-affirmative surgery status

	Individuals Diagnosed With Gender Incongruence Who Have Received Gender-Affirmative Surgery (N=1,018)		Individuals Diagnosed With Gender Incongruence Who Have Not Received Gender-Affirmative Surgery (N=1,018) ^a		Analysis	
2015 Treatment Outcome	N	%	N	%	Odds Ratio	95% CI
Psychiatric outpatient visits Any mood disorder Any anxiety disorder	98 85	9.6 8.3	88 62	8.6 6.1	1.13 1.40	0.83-1.52 1.00-1.97
Prescribed medication Any antidepressant treatment	301	29.6	292	28.7	1.04	0.86-1.26
Any anxiolytic treatment	215	21.1	149	14.6	1.56	1.24-1.96
Inpatient visit (hospitalization after suicide attempt)	13	1.3	7	0.7	1.87	0.74-4.70

^a Control group matched by age, gender, education, and country of birth.

utilization, our results show that the mental health care needs of this population are substantial in the year surrounding the last gender-affirming surgery. These results highlight the need for further research and clinical attention to be paid to the stressors and needed supports of this period (11).

In sum, the letter writers point out that although our study design addressed some threats to validity (e.g., confounding by secular trends), it introduced others (e.g., loss to mortality). While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, like most extant research on the topic, the design is incapable of establishing a causal effect of genderaffirming care on mental health treatment utilization.

Should the Concluding Message of Our Study Have Been More Moderate?

Our conclusion based on the findings at hand in the article, which used neither a prospective cohort design nor a randomized controlled trial design, was too strong. However, given the urgent need for more knowledge about the mental health of transgender individuals and the potential consequences of gender-affirming care, this large-scale observational study serves an important purpose and fills an important knowledge gap. Specifically, this study highlights the substantially increased risk of mental health problems among individuals diagnosed with gender incongruence, and in particular, among those in the process of receiving genderaffirming surgery. The study also lends support for expecting a reduction in mental health treatment as a function of time since completing such treatment, at least among those who are still living in Sweden.

We thank the letter writers for their attention to this important topic and, recognizing the importance of approaching this topic with triangulated, rigorous methodologies, look forward to further collaborative research using even higher-quality methodologies to move closer to establishing the causal impact of gender-affirming care on the well-being of the transgender population.

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Accepted May 22, 2020.

Am J Psychiatry 2020; 177:769-772; doi: 10.1176/appi.ajp.2020.20050599



1(14)

STM038:00/2020

Recommendation of the Council for Choices in Health Care in Finland (COHERE Finland)

Medical treatment procedures for dysphoria related to minors' gender variances



2(14)

STM038:00/2020

Concepts

Suppression treatment Pubertal suppression with gonadotropin-releasing hormone

analogues (a medicine suppressing the gonadotropin-releasing

hormone activity) for suppressing the secondary gender

attributes consistent with the biological gender

Cisgender/Cis person A person whose experienced gender identity matches the

gender assigned at birth (identifies and is satisfied with the gender assigned at birth and generally also expresses his/her

gender accordingly)

Other gender A person, who feels that he/she is neither a man or a woman;

instead, for instance, something in between, asexual, crossing

gender barriers, is outside them or multigendered

Transgender A person, whose experienced gender has a gender identity or

gender expression that differs from the gender assigned at birth, whose experienced gender does not correspond with the legal and biological gender assigned to him/her at birth but,

instead, with the opposite gender



3(14)

STM038:00/2020

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Recommendation 4(14)

STM038:00/2020

1. Bases for preparing the recommendation

As the number of patients, also minors, referred to the Helsinki University Hospital's and the Tampere University Hospital' multi-professional outpatient clinics with the examination and treatment of gender dysphoria has increased, COHERE decided to prepare a recommendation for medical treatments for function-reducing dysphoria, i.e., anxiety related to a minor's gender variances. The gender identity variance refers to the gender identity placing anywhere at the man-woman scale or outside it, not being only divided into men and women. Only for a part of the patients, the gender identity variance includes significant suffering and decreased functional capacity and only some hope to get medical treatment.

This recommendation is based on the legislation valid upon the acceptance of the recommendation, on research evidence and on the clinical experience of the Helsinki University Hospital's and Tampere University Hospital's multi-professional units with expertise in gender dysphoria examination and treatment. The recommendation's knowledge base is described in a separate Preparatory Note and its appendices. They include a description of the organizing the treatment and the implementation of the medical procedures, a literature review of medical treatments, an extensive ethical analysis, and meetings with the patients and organizations.

The Finnish legislation has defined the prerequisites for confirming the gender of a transsexual (Act on the Confirmation of Gender of a Transsexual 536/2002). As the matter concerns the confirmation of a transsexual person's gender, a decree (1053/2002) will later be enacted with a more precise focus on research on gender reassignment and on the implementation of treatment. The Trans Act and the related decree apply to adults. There is no special legislation on the need of and organizing treatment for other than adult transgender persons; instead, the sections of the Health Care Act of Finland (1326/2010), especially § 7 (Harmonized principles of care), § 7a (Bases for the service choices), § 8 (based on evidence and good practice, is of high quality, safe, and appropriate) and § 10 (justifications for centralization) and also the Constitution of Finland (11 June 1999/731), § 6 on equality and § 19 on the right to sufficient social and health care services of apply to them. The Act on the Status and Rights of Patients of Finland (785/1992), especially §§ 5, 6, and 7, must also be taken into consideration.

2. Recommendation's target group

This recommendation applies to those minors, who, due to dysphoria related to gender identity variance, seek to have an assessment of the need for medical examination and treatment in a situation where the child or adolescent feels that s/he matches the opposite gender (transgenderism), is entirely non-binary, both a girl and a boy, or something in between (other genderism).



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3. Procedure to be assessed

This recommendation consists of those medical treatment procedures whose aim is to decrease a minors' gender-identity-related suffering and decreased functional capacity caused by it.

4. Current care

The identification, even strong, with the opposite sex in childhood generally disappears in puberty, but for some, it can become stronger. Gender anxiety can also appear or get stronger only upon the commencement of puberty. For both genders, individual variance in pubertal timing is wide. The early-stage treatment for gender anxiety is psychosocial support and, as necessary, psychotherapy and treatment in line with the need for a possible concomitant psychiatric disorder.

If counselling is needed (for parents/treatment professionals) because a child identifies itself with the opposite gender and/or experiences gender anxiety, children (before puberty) can have consultation appointment at the Tampere University Hospital's or Helsinki University Hospital's minors' gender identity examination work group, but possible support or the need for other psychiatric treatment is organized through local services.

If, before the onset of puberty, a prepubertal patient has a distinct gender dysphoria symptom that becomes stronger in puberty, the patient can be referred to the assessment of gender suppression treatment by the gender identity examination groups at the Tampere University Hospital or Helsinki University Hospital. If no contraindications are found for early intervention, to prevent the development of the secondary gender attributes matching the biological gender, pubertal suppression with GnRH analogues (a medicine suppressing the effect of gonadotropin-releasing hormone) can be considered.

Those adolescents already past puberty experiencing gender anxiety but do not have some other concomitant symptom requiring psychiatric treatment and whose transgender experience does not disappear with the possibility to reflect own identity can be referred to gender identity examinations at the Helsinki University Hospital's or Joint Authority HUS's minors' gender identity examination work group. Transforming hormone therapy (testosterone/estrogen and anti-androgen) is started after the diagnostic examinations, but no earlier than at the age of 16. In addition, 3-6 months before the transforming hormone therapy that suppresses the patient's own gonad's hormonal activity, GnRH analogue treatment is often started for adolescents below the age of 18. No surgeries transforming the sexual phenotype are not performed on minors.

5. Effectiveness and safety and related factors of insecurity



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During the literature review, two studies were found with the total of 271 persons diagnosed with gender identity disorder and related gender or body anxiety that worsens in puberty (Preparatory Note Appendix 1, Tables 15 and 16, pages 46-48).

In a smaller study following 70 adolescents, puberty was suppressed with the GnRH analogue at the average age of 14.8 (variance interval 12-18 years) and treatment was 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 did not decrease and no changes manifested in the body image. In a more extensive study consisting of 201 adolescents, 101 patients with the average age of 15.5 (variance interval 12-18 years) started an 18-month psychologic supportive intervention, and, additionally at six months, pubertal development was suppressed by starting GnRH analogue treatment. Another 100-person group only received psychologic supportive intervention for 18 months. In both groups, the general functional capacity increased at 12 and 18 months statistically significantly and, for those having received only psychologic intervention, functional capacity increased statistically significantly already at the first 6 months. Long-term treatment follow-up until adulthood is missing from both studies.

The effect on the functional capacity, on the advancement of adolescents' development tasks, and on psychiatric syndrome of transgender hormone therapy started in adolescence was also studied in one Finnish study published after the literature review was completed. During the transgender hormone therapy, problems in those areas did not decrease.

Possible risks of the GnRH therapy include bone mineralization disorders and the currently still unknown effects on the central nervous system. In trans girls, early pubertal suppression has an effect on penis growth so that other tissue grafts must be used for a possible later vaginoplasty. The effect of pubertal suppression therapy and transgender hormones on fertility is not known.

6. Ethical assessment

The ethical analysis did not systematically discuss children's and adolescents' special issues, but they often emerge in several paragraphs (Preparatory Note, pages 52-62 and Appendix 5).

According to the Health Care Act (§ 8), health care services must be based on evidence and good treatment policies. As far as minors are concerned, there are no evidence-based health care procedures. On the other hand, it has been found that minors increasingly have gender identity dysphoria. In this situation, it is most important that the child or adolescent is being heard and given a possibility to talk about his or her own feelings. Experience reflection should be easily accessible in the child's own living environment's health care system (school or student health care, basic health care), and those feelings must not be construed as immediately requiring specialized medical examinations or treatment procedures.



Recommendation 7(14)

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As far as children and adolescents are concerned, the ethical issues especially address gender identity modelling normal in teenage and possible treatments' effects on it. It has been suggested that hormone therapy (e.g., pubertal suppression) changes gender identity development, in other words, in practice, they can establish the gender identity that would have changed during pubertal development for a part of the adolescents treated. The reliability of such treatment examinations that do not have a comparable control group is very uncertain, and based thereon, no such decisions can be made that can permanently transform a still maturing minor's mental and physical development.

From the patient organizations' perspective, instead of the suppression treatments postponing adolescence, it is thought to allow consideration time for a minor. The idea is that no permanent gender-expressing transfers would have enough the time to develop, which is estimated to socially facilitate and provide time for diagnostic examinations. Additionally, a patient organization presents that, if the person ends up having gender transforming treatments, hormone treatments that are started early would partially enable a better outcome. On the other hand, professionals consider it important that, to secure that such irreversible procedures that may also have considerable adverse effects, both physical and mental, are only performed for those persons who are able to understand the permanent transformations related to the treatment procedures and the possibility of problems and for whom the possibility to regret is unlikely. It is almost unknown, how the hormonal suppression of gender attributes' development effects the consideration and decision-making ability.

The Act on the Status and Rights of Patients (1992/785) states that the patient shall be provided with a clarification of his/her health status, the implications of the treatment, the different treatment options and their effects, and other issues concerning the treatment that have an effect on making the treatment decision. In a situation where a minor is found to identify with the opposite gender that causes long-term and severe dysphoria, it is important to make sure that he/she understands the realistic possibilities of gender reassignment treatments to have an effect on gender-expressing attributes, the meaning of a life-long commitment to medicotherapy, the permanency of the effects, and the treatments' possible physical and mental adverse effects. Although it is possible to regret, after the reassignment treatments, there is no going back to the non-reassigned body and its normal functions. Brain development continues up to the early adulthood (up to the age of ca. 25 years), which also has an effect on minors' ability to assess the decision's consequences on one's own future and rest of life.

It is also harmful, if there is no awareness of a very common concomitant psychiatric illness of gender-problematizing adolescents. It is not possible to decrease other psychiatric symptoms with hormonal medicotherapy or with surgical treatments and they must not be employed for controlling the gender experience. A young person's identity and personality development has to be stable, so that he/she is genuinely able to meet and discuss his/her gender-identity related anxiety and assess the meaning of own feelings and the need for different treatment options.

For children and adolescents, the above-described factors are crucial justifications for postponing the treatments to adulthood.



Recommendation 8(14)

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7. Conclusions

The early-stage treatment for gender variances during childhood and adolescent years is psychosocial support and, as necessary, gender sensitive therapy and possible concomitant psychiatric disorder treatment. It should be possible to discuss the confusion related to gender identity taking into consideration the symptoms' degree of difficulty and the treatment need in line with the phasing the at the school's health care service, student health care service, own municipality's health care service, or specialty care service.

As regards adolescents, psychiatric illness and developmental difficulties may expose to the manifestation of gender dysphoria experience. They need to have treatment organized, and, before starting to clarify the gender identity, the child's/adolescent's mental situation has to be stable.

According to a clinical experience, autistic spectrum disorders are overrepresented among the adolescents suffering from gender anxiety, and, even if the adolescent is to problematize sex, rehabilitative intervention for autistic spectrum patients must be properly taken care of.

In the light of research evidence, reassignment treatments started as minors are experimental. Based on the studies conducted in minors' gender identity examination groups, when the transgender identity is affirmed, it is possible to consider hormonal gender reassignment treatments before adulthood, but careful consideration must be used in the case and no irreversible treatment should be started. Gathering knowledge of the hormone treatment procedures' possible problems is very slow, and it is not systematically reported. Information on the hormone treatments' benefits and problems must be acquired through reliable study settings.

As a minimum, a consultation appointment before puberty at the Tampere University Hospital includes an extensive assessment appointment costing EUR 369. As necessary, it is possible to arrange an outpatient clinic consultation day costing EUR 1,408.

Minors' gender identity examination process costs ca. EUR 4,300 at the Tampere University Hospital and Helsinki University Hospital. At the lowest, the costs in a situation where it is found that the time is not right for the examination process are EUR 640. An initial assessment/consultation by phone costs EUR 100.

For the first year, the planning and follow-up costs for the suppression treatment are ca. EUR 2,000 and for the continuing years ca. EUR 1,200. The minimum costs for the planning and follow-up of hormone treatments are EUR 400 per year.

The psychosocial support provided in the home locality, a possible need for psychiatric treatment, or hormone treatment's medication costs have not been accounted for in the aforementioned costs.

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8. Summary of the recommendation

COHERE considers that

- 1. Psychosocial support must be organized through school and student health care services and basic health care services for the treatment of a minor's dysphoria resulting from gender identity variance, and it must be sufficiently knowledgeable.
- 2. Child or adolescent psychiatric consultation and the needed psychiatric treatment and psychotherapy must be locally organized in line with the agreed phasing of the treatment.
- 3. If a child or adolescent experiencing gender anxiety has other concomitant psychiatric symptoms requiring specialized treatment, as no conclusions can be made on the stability of the gender identity during the disorder period caused by a psychiatric illness hindering development and the manifestation of the symptoms, treatment in line with the nature and stage of difficulty must be organized through local services.

COHERE considers that the consultation, examination periods, and treatments by the Tampere University Hospital's or the Helsinki University Hospital's minors' gender identity examination work groups must be carried out according to the following principles:

- Based on a long-term and difficult identification with the opposite gender and/or anxiety related to gender dysphoria, children whose puberty has not started can be referred to a consultation appointment at the Tampere University Hospital's or Helsinki University Hospital's minors' gender identity examination work group. A need for support exceeding a possible consultation appointment or other need for psychiatric treatment must be treated according to the problem's nature and difficulty at a local service.
- 2. If, before the onset of puberty, a child is found to have had a long-term experience of identifying with the opposite gender and a gender anxiety symptom that becomes stronger in puberty, after the onset of puberty, the minor can be referred to the assessment of suppression treatment to the Tampere University Hospital's or Helsinki University Hospital's minors' gender identity examination groups. If there are medical indications for it and there are no contraindications, based on those studies, on a case-by-case basis, after careful consideration and appropriate diagnostic examinations, possible pubertal suppression treatment can be started. Also, therapeutic amenorrhea, i.e., menstrual suppression, is medically possible.
- 3. If the gender identity variance and related dysphoria do not manifest themselves as typical for the adolescent development stage, as passing identity search, or as development to some other direction when the adolescent has an opportunity to reflect his/her identity and, instead, the adolescent's identity and personality development seems stable, the adolescent already through puberty can be referred to the Tampere University Hospital's or Helsinki University Central Hospital's outpatient clinic for minors' gender identity examination for extensive gender identity examinations.
- 4. Based on a careful individual consideration, hormonal interventions transforming gender attributes may be started before adulthood only, if the identification with the opposite gender can be secured to be of permanent nature and causing severe dysphoria, and the adolescent is able to understand



Recommendation 10(14)

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- the meaning of the irreversible treatments and the benefits and the problems related to a possibly life-long hormone therapy and no contraindications are found.
- 5. If an adolescent experiencing gender anxiety has had or has concomitant psychiatric symptoms requiring specialized care, in case the need for it continues after the psychiatric symptoms have yielded and the adolescent development tasks' progress has normalized, it is possible to consider gender identity examinations. In such a case, it is possible to refer the adolescent to an extensive specialty-level gender identity examination by his/her own locality's adolescent psychiatric specialize care service to the Tampere University Hospital's or Helsinki University Hospital's minors' gender identity examination work group, where diagnostic examinations are started, and based thereon, the need and timing of medically justified treatments are individually assessed.

Surgical treatments permanently transforming the body are not part of the treatment procedures for dysphoria caused by a minors' gender dysphoria. The starting and follow-up of minors' hormone therapy must be centralized to the Helsinki University Hospital's and Tampere University Hospital's outpatient clinics for minors' gender identity examination.

9. Additional evidence gathering and follow-up of the recommendations' effect

For the reassessment of the recommendation, the following information is needed on the patients diagnosed and having received treatments in Finland:

- number of new patient referrals
- number of patients starting the examination period, new transgender F64.0 and other gender diagnoses F64.8 made
- do the diagnoses remain the same in follow-up or does the gender experience change
- those having discontinued the examination period and the reasons for the discontinuation
- treatment discontinuations and reasons for the discontinuations
- treatments' adverse effects (especially long-term effects and effect on fertility)
- number of patients regretting the hormone therapy
- research periods' and treatments' effect gender dysphoria points (GCLS),
- examination periods' and treatments' effect on functional capacity and quality of life
- Adjuvant psychiatric diagnoses (also neuropsychiatric F80-F90) for persons seeking treatment/diagnosed and whether the adjuvant diagnoses have an effect on the benefit (decrease in gender dysphoria) received from the research periods and treatment procedures
- do the research periods and treatment procedures decrease the number of suicide attempts
- do the research periods and treatment procedures decrease depression and anxiety

10. Appendices

Preparatory note, with Appendices 1-5.



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Care of children and adolescents with gender dysphoria*1

National knowledge support¹ with recommendations for professionals and decision-makers



^{*} Unofficial translation by the Society for Evidence-Based Gender Medicine (SEGM), 2023 v.1.1

ISBN 978-91-7555-596-6

Article number 2022-12-8302

Published www.socialstyrelsen.se, December 2022

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Foreword

The National Board of Health and Welfareⁱ 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." 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.

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 genderaffirming 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.

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.

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. 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.* 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).

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. 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.

⁷ Cf. prop. 2013/14:106 p. 119

⁸ Prop. 2013/14: 106 p 66.

⁹ Chapter 14, Section 1 of the SoL.

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 demanddriven 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)

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.

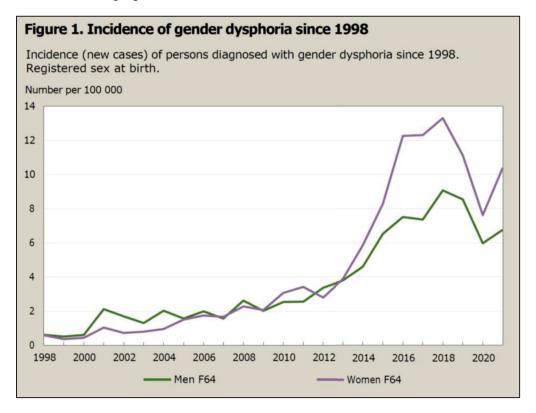
It has been noted that coverage in PAR has increased over time and that trends in the prevalence of gender dysphoria may therefore be overestimated [20]. The National Board of Health and Welfare's assessment is that under-coverage may be driving some of the increase in the early part of the time series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

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].



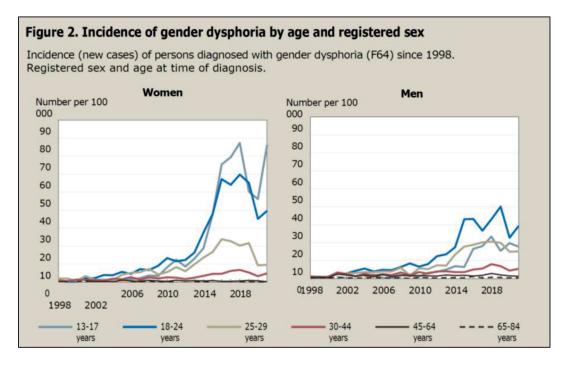
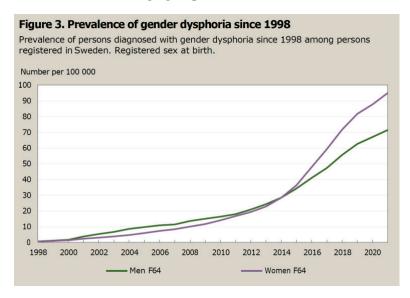
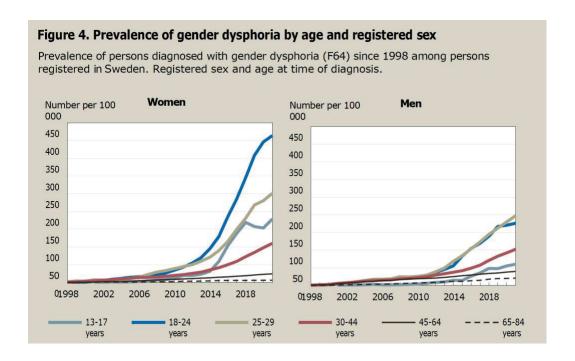


Figure 3 shows that the prevalence of gender dysphoria, i.e., the number of people per 100,000 who had a gender dysphoria diagnosis in a given year, continued to increase after 2018. This is partly explained by the high incidence among young people in the previous year. Figure 4 shows the prevalence 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 the 13 - 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.





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.

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 treatmentxiv

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.

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. 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 careseekers 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 from 2 to 23 per 100,000, respectively [19]. Subsequently, the number of new cases

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