



Guide on healthcare related to gender identity



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Preamble

On 22 September 2017 we issued a new guide on healthcare related to gender identity issues, that introduced a number of changes to the professional approach, i.e. by stressing that care should be primarily based in somatic specialized services, while at the same time stressing the importance of a multidisciplinary approach. At the same time we also introduced a number of changes in our national planning of specialized services, and we approved a new center at Aalborg University Hospital.

In December 2017 the Danish Parliament passed changes to section 115 of the Health Law re. Castration, which implies that only in very selected cases should the Danish Health Authority approve castrations. As a consequence of this change, we have updated our guide, and the new guide therefore replaces guide no. 9921 of 22 September 2017.

This publication is an English translation of the guide issued in July 2018, and is for information purposes only. The legally binding guide in Danish can be accessed at retsinformation.dk using the search term 'kønsidentitetsforhold'.



Søren Brostrøm
Director General

1. Introduction

The gender identity of individuals may differ from the sex assigned at birth, and from the social and cultural standards associated with this sex.

This incongruence between gender identity and the sex assigned at birth from the congenital sexual characteristics may cause individuals to experience gender discomfort, which can lead to individuals seeking treatment in order to modify or stop the development of their sex characteristics.

There are thus a number of healthcare tasks related to supporting the relief of gender discomfort and/or support of the individual's gender identity and gender expression, including counselling and clarification of gender identity questions and treatment solutions to remedy gender dysphoria. It is the healthcare provider's responsibility to ensure equality in health by providing help for investigation and treatment of any somatic or psychiatric disorders in the healthcare system in general, as well as specifically with respect to gender reassignment treatment.

The aim of this guide is to ensure a high quality and equal access to healthcare related to gender identity in Denmark. Healthcare includes counselling and supportive conversations on gender identity, just as it includes medical treatments to block the development of sex characteristics (hormone blockers) or to modify them (gender reassignment treatment with hormones or surgery). Furthermore, psychosocial support should be a natural part of the overall healthcare.

The healthcare must be holistic, coherent and multidisciplinary to support the individuals as much as possible.

2. Scope

This guide stipulates the due diligence and conscientiousness which healthcare professionals must show in their work related to gender identity (1). This guide furthermore establishes the framework for the entire healthcare and designates responsibilities among the involved healthcare professionals (2). The Danish Health Authority's national planning of specialized hospital services is also relevant for the healthcare, however, in this guide, references are made to the separate regulations on specialized hospital services which can be found on the Danish Health Authority's website (3). Finally, this guide also specifies the medical investigation and recommendations that form the basis of the Danish Health Authority's treatment of applications for castration according to Section

115 of the Danish Health Law. This guide does not include the act of legal gender recognition which is regulated by the law on The Civil Registration System (4). Reference is made to a number of other rules and guides which may have been amended after the publication of this guide, for which reason these should be accessed directly for clarification of matters described therein.

3. About rights and access of individuals to healthcare services related to gender identity

Healthcare related to gender identity is in general included under the provisions of the Danish Health Law regarding the responsibilities of the regional council to provide public healthcare. To the extent that the main aim of the treatment, including surgery, is to alleviate gender dysphoria defined as the experience of incongruence between the sex assigned at birth and the gender identity, this treatment is in legal terms defined as non-cosmetic. Cosmetic treatment (e.g. surgery) is defined as a treatment with the main purpose of changing or improving the appearance.

Individuals seeking healthcare related to gender identity should receive equitable healthcare. This entails easy and equal access to healthcare, treatment of high quality, consistency between services, freedom of choice, easy access to information, a transparent healthcare system and short waiting times for treatment.

3.1. Respect and involvement

Healthcare professionals must be particularly attentive to the fact that individuals experiencing gender dysphoria may have been exposed to stigmatisation in society as well as in the healthcare system. In general, the healthcare professionals should avoid focusing on gender identity when the individual in question is seeking help and treatment for conditions unrelated to gender dysphoria. Specifically, healthcare professionals must show respect and prevent stigmatization by using the name or pronoun preferred by the individual as well as by respecting the individual's preferences regarding use of terms to describe body parts etc.

When providing healthcare related to gender identity, the staff should pay special attention to providing support in respect of the individual's situation and preferences and in a manner that does not stigmatize.

The healthcare must be based on respect, responsiveness, inclusiveness and flexibility. The individual should be regarded as the best source for understanding their experience and situation, and the healthcare must be provided in a framework and atmosphere in which the person feels at ease. The staff must be accessible and it should be possible to obtain aid and support whenever relevant.

The individual's values and perspectives should be included when considering the total treatment option and in order for the treatment course to be planned according to the individual's wishes and prerequisites - as far as possible. Together with the responsible healthcare professionals, the individual should determine the objectives of the entire investigation and treatment, and any treatment offered to the patient should be explained in an understandable, neutral and respectful language.

Gender reassignment treatment may entail significant physical and psychological changes with both positive and negative social consequences. Some changes may be irreversible. When offering gender reassignment treatment, the healthcare assessment of the need for treatment (indication) should include the individual's desires and needs, as well as any adverse effects of the treatment. Information from the healthcare professionals should be given on both advantages and disadvantages of the offered treatment and the staff should provide information on other treatment options as well as a proper time frame for reflection.

3.2. Information and Consent

The general rules regarding information and consent also apply to healthcare related to clarification and development of gender identity, as well as to alleviating gender dysphoria with hormone blockers or gender reassignment treatment (5). Therefore, any treatment should not be started or continued without the individual in question having given their informed consent, unless otherwise provided by law or provisions laid down by law. The requirement for informed consent emphasizes the individual's right to self-determination and any consent for treatment is therefore the individual's voluntary acceptance of wanting to receive a specific offered treatment.

Informed consent must be given based on adequate information. This requires that, prior to making the decision, the individual has received the necessary and sufficient information regarding treatment options, adverse effects etc., and that the individual is capable of foreseeing the consequences of their consent. An individual may at any time withdraw his/her consent to the treatment. Consent must be given for a specific treatment, implying that it must be clear and unambiguous what the consent includes, both in terms of the type of treatment, the treatment method and purpose of the treatment.

Informed consent is a necessary but not sufficient requirement for a healthcare treatment. The healthcare professional responsible for the treatment has an independent professional responsibility that the offer is provided based on a solid, professional assessment

of the individual's need for treatment (indication), expected benefit, possible adverse effects and the current professional knowledge and practice in this field. The healthcare staff must always include the individual's desires and preferences in the assessment; however, the individual is not entitled to specific treatment options that cannot be medically justified.

4. Professional framework

The Danish Health Authority determines criteria and approves the safeguarding of specialized services for regional hospitals and publicly funded hospital services by private operators as described in the national regulations on specialized hospital services. In Denmark, the 5 regions have the main responsibility for the provision of healthcare services. The regions operate the public hospitals and are responsible for the medical practice sector's functioning. For example, the regions are the guarantors for all Danes having access to a practicing physician. The regions also enter into agreements with a number of privately practicing specialist physicians. Thus, privately practicing medical specialists may only offer publicly funded hospital services if specifically agreed upon with the regions. The provisions in the Certification Act regarding due diligence and conscientiousness, as specified in this guide, apply in general to both publicly funded hospital services, services funded by health insurance, as well as privately funded services at medical specialists, private hospitals, clinics and the like.

Treatment with hormone blockers and gender reassignment treatment must be carried out by healthcare professionals with experience and distinct qualifications regarding counselling, investigation and treatment of gender dysphoria, or be under the supervision of healthcare professionals with such qualifications. Qualifications in both physical and mental health as well as social relations are important and it may be relevant to include nurses, psychologists and medical specialists within somatic and psychiatric specializations, joined in a multidisciplinary team to secure the availability of sufficient knowledge and qualification on any somatic and psychiatric matters relevant to the investigation and/or the treatment (see section 4.1). However, psychologists or psychiatrists being a part of the investigation and treatment does not mean that the individual seeking care should be viewed upon as having a mental disorder. Neither does it entail that the individual seeking support is viewed upon as having a somatic disorder if a healthcare professional with a somatic specialization participates in the investigation.

The involved healthcare professionals must have timely and continuous professional training on gender identity and gender reassignment treatment, participate in ongoing consultation with other healthcare professionals with significant experience in the field and participate in professional networks, conferences etc. on both a national and international level. The involved healthcare professionals must also participate in quality devel-

opment and research in the field. Additionally, the involved healthcare professionals should develop a broader understanding of gender identity on an ongoing basis, for example through dialogue with user representatives and by following the general societal debates.

4.1. The Multidisciplinary Team (MDT)

The overall healthcare must be holistic and coherent, requiring substantial multidisciplinary cooperation. The multidisciplinary team should have a well-established framework for cooperation with clear allocation of responsibilities between the involved healthcare professionals and the cooperation should be anchored in a fixed multidisciplinary team (MDT) with regular conferences.

One of the medical specialists in the MDT must hold the overall responsibility for the investigation and treatment course, even though this person may delegate healthcare to other healthcare professionals including nurses, psychologists and doctors. The responsible medical specialist must ensure that the investigation and treatment program is holistic and coherent and that all necessary elements are carried out in a competent manner with no unjustified prolongation.

The medical specialist responsible for the overall care should ensure that the MDT conferences are held on an ongoing basis and whenever the need arises, as well as ensure the participation of both the medical specialists and other staff involved in the care. In addition, a status on the investigation and treatment on a given individual should be prepared on an ongoing basis. The person responsible for the treatment will usually be a pediatric medical specialist or an obstetrician-gynecologist, since a significant part of the treatment is based on somatic treatment principles.

The organizational and physical framework should support a coherent and holistic approach that does not stigmatize, for example by establishing physical or virtual multidisciplinary gender identity clinics. With reference to the above, it would be beneficial if gender identity clinics were placed in close relation to the relevant somatic treatment options.

Allocation of responsibilities and special qualifications in the team must be adjusted in accordance with the content and complexity of the treatment. When carrying out gender reassignment treatment – as well as in the evaluation hereof – the team must have relevant medical specialist qualifications including obstetrician-gynecologists or endocrinologists (medical specialist doctor in internal medicine in the field of endocrinology). Furthermore, the multidisciplinary team should involve relevant qualifications in relation to the assessment of the psychosocial aspects, among these psychologists and psychiatrists with relevant qualifications and experience.

Medical specialists in plastic surgery with special qualifications as well as obstetrical and gynecological specialist etc. should be added to the team when performing gender reassignment surgery on adults.

In relation to the investigation and treatment of gender identity for individuals under the age of 18, the team must be comprised of relevant medical specialists qualified in pediatrics (pediatric endocrinology, growth, and reproduction) as well as in child and adolescent psychiatry, since managing this target group requires specific qualifications and experience with growth and development in children and adolescents as well as family and social matters etc.

The overall team and the healthcare professionals must build and continuously maintain distinct qualifications in the field. Considering the complexity of the field and the principle of a critical mass for maintaining the robustness of professional competencies within the team, medical specialists performing either medical or surgical treatment related to gender identity should initiate new treatment courses with an average frequency that ensures that more than one new patient per month is treated, corresponding to a level of at least 20 new courses of treatment annually. The Danish Health Authority monitors the professional development in the field to determine whether more precise requirements can be outlined. Concerning publicly funded hospital services, further specific criteria and requirements for administration may form part of the Danish Health Authority's procedure related to the planning of specialized hospital services.

5. Counselling and support on gender identity

The individual may be undecided as to his/her own gender identity and own preferences for treatment and may therefore need counselling and support from the regional gender identity clinics before initiating a process of investigation and treatment. In this part of the process, often referred to as the clarification phase, it is not a prerequisite that the individual is seen by a medical specialist, neither is any extensive evaluation of somatic or psychiatric disorders relevant. If the investigation concludes that the individual desires to initiate gender reassignment treatment, any further investigation and treatment should not be delayed.

Healthcare professionals and other staff including psychologists, social workers, doctors, and nurses etc., may offer counselling and support in the clarification phase. This should be carried out by staff not directly involved in any subsequent decision-making regarding treatment options.

The gender identity clinics must offer publicly available and updated information regarding medical and surgical treatment options related to gender discomfort and gender dysphoria as well as options for counselling on psychosocial aspects of gender identity. It is recommended that the clinics host public information meetings and the like on a regular basis.

6. Assessment before treatment

Hormone blockers and gender reassignment treatment are generally effective treatments of gender dysphoria, with few patients regretting. However, as with any type of treatment, there may be adverse effects. Before the healthcare professional can begin a treatment, a clear medical assessment and justification (indication) must therefore be present. Moreover, the doctor must clarify any medical reservations for the treatment (contraindications) including factors which can increase the risks of the treatment or discourage such treatment.

The purpose of the investigation is to clarify the indications and contraindications. The medical assessment of the indications, such as the nature of gender discomfort, must be described in the medical record, as well as any conditions or disorders which may constitute contraindications.

Relevant healthcare should be offered independently of the individual's current status or preference regarding legal gender recognition.

A psychiatric evaluation is not a general condition for offering healthcare related to gender identity and should only be carried out where appropriate and based on a specific and individual professional assessment. Standardized test methods of both somatic and psychosocial matters may be used on the basis of a specific and individual evaluation, and to the extent that such methods are relevant and valid in relation to the investigation and do not contribute to stigmatization.

7. Gender reassigning medical treatment on adults

For the investigation and gender reassignment treatment of adults, the multidisciplinary team must include one or more medical specialists in gynecology and obstetrics as well as in psychiatry. This medical specialist may be an endocrinologist or a gynecologist, depending on local conditions. The medical specialists must have distinct experience and qualifications in the field of gender reassignment treatment. One of the specialists must have the overall responsibility for the investigation and treatment course but may delegate elements of the course to other healthcare professionals including nurses, psychologists and doctors (see also section 4.1).

7.1. Requirements for the investigation

The investigation must include an assessment of the individual's gender identity including the severity of the gender dysphoria, as well as an assessment of any concurrent somatic or psychiatric conditions or disorders that require treatment prior to any gender reassigning treatment or that may wholly or partly contraindicate the treatment. The content of the investigation is organized by the medical specialist responsible for the treatment. It should be based on the established professional practice, taking into account the national and international professional guidelines etc., and should be adapted to suit the individual's situation and personal preferences.

Both the somatic and psychosocial part of the investigation should be balanced reasonably compared with the purpose of the total investigation and the requested treatment level. Gender reassignment medical treatment for adults with a decided gender identity and without any contraindications will typically not require a long or comprehensive investigation.

The extent of the overall investigation and the individual elements thereof should always be adjusted to the individual's situation and preferences without any unnecessary lengthy and medically unjustified time.

7.2. Requirements for starting treatment

The initiation of gender reassigning medical treatment for adults is carried out by the team's obstetrician-gynecologist or by the endocrinologist. The medical specialist must ensure the following:

- That the individual is experiencing gender dysphoria and is seeking gender reassigning medical treatment
- That psychosocial aspects and psychosocial consequences of any irreversible changes have been clarified
- That contraindications have been addressed and that somatic or psychiatric disorders have been identified and treated appropriately
- That the individual is well-informed about the expected effects and possible adverse effects of the treatment, including the fact that the changes may be irreversible and that there may be lasting effects on reproduction
- That individualized follow-up assessments are planned according to the individual's preferences with the aim of ongoing adjustment of the treatment, as well as assessment of any adverse effects etc. This includes medically relevant follow-up imaging and paraclinical tests as well as supportive dialogues.

The commencement of gender reassignment medical treatment provided by the regional health care service, i.e. the Danish public hospitals, is part of the Danish Health Authority's current plan on specialized services. In private clinics initiation of medical treatment of adults is performed according to the provision of the Danish Certification Act regarding due diligence and conscientiousness as specified in this guide regarding qualifications, multidisciplinary cooperation, holistic assessment of the indications and contraindications etc. The MDT may be established outside the public hospitals, for example as a fixed (perhaps virtual) cooperation between medical specialists with relevant qualifications.

The maintenance treatment and control or parts thereof takes offset in the planned follow-up program. The maintenance treatment may, based on a concrete and individual assessment of the treatment by the medical specialist in charge of the treatment in the MDT, be carried out at the local hospital, clinic of the medical specialist or at the individual's own general practitioner (e.g. as 'shared care'). Minor adjustments of treatments, such as changing the dosing of medication, are usually performed decentralized in 'shared care'; however, if changes to the scheduled treatment and follow-up program are necessary, this must be referred to or discussed with the medical specialist in the MDT.

If the individual has just recently begun exploring their gender identity or if the gender discomfort has just surfaced, appears periodically or only to a lesser degree affects the individual's overall life situation and gender comfort, special care should be taken and time for reflection should be recommended.

It may in specific cases be necessary to offer gender reassignment treatment without all of the above criteria being met, i.e. when taking over a treatment course initiated abroad or when substituting self-medication. In these cases, the medical specialist responsible for the treatment is also responsible for evaluating the indication and for making sure that relevant investigation and follow-up is initiated.

Existing psychiatric or somatic disorder is not in itself a contraindication against gender reassignment treatment. Depending on the nature and severity of the disorder, it may be

necessary to treat the disorder prior to or concurrent with initiating gender modifying medical treatment.

Somatic contraindications and precautionary conditions in gender reassignment medical treatment with estrogens include, among other things, thromboembolic risk, cerebrovascular illness including migraines, severe liver disease, breast cancer etc. Somatic contraindications and precautionary conditions in gender reassignment medical treatment with androgens includes pregnancy, unstable cardiovascular disease, a haematocrite > 50%, hormone sensitive tumors, very severe acne etc. Absolute contraindications in gender reassignment medical treatment will only appear in rare cases.

Psychiatric contraindications and precautionary conditions in both medical and surgical gender reassignment treatment may for instance be certain psychotic conditions or autism with a special interests (fixation) of relevance for the gender identity treatment.

8. Gender modifying surgery on adults

Gender reassignment surgery on adults includes procedures on breasts and chest ('upper' surgery) as well as procedures on genitals ('lower' surgery). In general, the procedures are irreversible, destructive and constructive surgical interventions on healthy organs with significant both positive and negative physical and mental consequences.

Any gender reassigning surgery is connected with the risk of serious and lasting adverse effects, for which reason the requirements for the physician's due diligence and conscientiousness are generally increased, including the requirements for the assessment of medical indications and contraindications. The duration and nature of the gender dysphoria and results of previous gender modifying treatment must be evaluated, and combined with a weighed assessment of any somatic or psychiatric disorders and conditions, as well as to other risk factors that may contraindicate surgery. The offered surgical treatment, including the type, scope, order, combination etc., must follow established professional practice and national and international professional guidelines etc. When applying new treatment principles, relevant and systematic collection of experience as well as quality assurance must be ensured (6).

When performing gender reassignment surgery on adults, the team must be supplemented with at least one specialist plastic surgeon with particular experience and qualifications in the field. The same requirements for MDT conferences etc. described above apply to the medical specialist responsible for the treatment when initiating gender reas-

signment medical treatment. Other specializations may be included if relevant, for instance specialist urologists.

Prior to initiating gender reassignment surgery, a current investigation and assessment must be present as described in the section on gender reassignment medical treatment. The investigation must be complemented, to the extent that it is relevant, with a physical examination of the chest and genital organs. Relevant physical and psychosocial relations regarding the individual's sexuality and sexual life must be identified and any future reproductive wishes must be discussed.

Gender reassignment surgery given as part of publicly funded hospital services is covered by the Danish Health Authority's current plan for specialized services. After evaluation and recommendation from the MDT, selected parts of a surgical treatment for adults may be performed at the level of basic hospital services within the framework of the current plan for specialized services valid at any time, i.e. breast surgery and castration.

In private hospitals and clinics both medical and surgical treatment of adults may be administered on a fee-for-service basis in accordance with the provision of the Certification Act regarding due diligence and conscientiousness as specified in this guide regarding qualifications, multidisciplinary cooperation, holistic assessment of the indications and contraindications etc.

8.1. Gender modifying surgery on the breasts or chest

For individuals who have been assigned female gender at birth, gender modifying surgery to breasts or the chest includes procedures with removal of breasts (bilateral mastectomies) and reconstruction of chest wall with possible reconstruction of the nipple-areola.

Gender reassignment surgery to breasts or chest on individuals with the male sex assigned at birth includes procedures with breast augmentation, including insertion of implants.

After discussion and recommendation from the team's MDT conference, the treatments are administered by certified plastic surgeon specialists. The plastic surgeon carrying out these procedures must ensure the following when obtaining informed consent for the surgery:

- That the individual is experiencing gender dysphoria and wishes gender reassignment surgery on the breasts or chest
- That psychosocial matters have been adequately addressed, amongst these matters related to sexuality and psychosocial consequences of potentially irreversible changes

- That the duration and nature of the gender dysphoria as well as the results of previous gender reassignment treatment have been evaluated adequately and can justify the surgical intervention
- That contraindications and risk factors have been addressed, including identifying and appropriately treating any somatic or psychiatric disorders
- That the individual has been fully informed about expected positive effects as well as possible adverse effects of the treatment. Expected changes should be visualized
- That the individual is well-informed about matters related to prevention and detection of breast cancer.

Reversible and less invasive treatments should be offered before surgery whenever appropriate. A thorough medical evaluation of indications and contraindications must be carried out in the specific cases where this principle is not followed.

For individuals assigned with the male sex at birth, breast augmentation with insertion of implants should normally be offered no earlier than after 12 coherent months of gender reassignment treatment with estrogens. Otherwise, the surgical result may be less satisfactory, since sufficient time should be allowed for the effect of the hormone therapy on the breast growth. Up to 18-24 coherent months of estrogen treatment is preferred in many cases. The length of the period of awaiting an effect of hormone therapy should always depend on a medical assessment carried out by the relevant healthcare professional. Estrogen treatment may be contraindicated by certain conditions cf. section 7.2.

Regarding the indication gender dysphoria (as opposed to a cosmetic indication), breast augmentation can only be offered to augment the breasts anatomically proportional to the normal build of the body, as assessed by the specialist plastic surgeon. Any request for a non-anatomically proportional breast augmentation is not covered by publicly funded hospital services, but is instead covered by the rules on cosmetic treatment in addition to the present guide (7).

There are no fixed requirements for previous hormone therapy for individuals assigned the female sex at birth; however, it may in specific cases be appropriate to await the effect of the hormone therapy and any physical training before offering removal of the breasts (bilateral mastectomies). Restraint should generally be shown with newly arisen gender discomfort, since removal of the breasts are irreversible changes.

8.2. Gender modifying surgery on the genital organs

Gender reassignment surgery on the genital organs of individuals assigned the female sex at birth includes removal of the uterus, fallopian tubes and ovaries (hysterectomy and salpingo-oophorectomy), removal or closing of the vagina (vaginectomy or colpocleisis), elongation of the urethra (urethroplasty) and construction of a penis (phalloplasty or metoidioplasty).

Surgery to the genital organs of individuals assigned the male sex at birth includes removal of testes (orchietomy), penis amputation (penectomy) as well as construction of a vagina, clitoris and labia (vaginoplasty, clitoroplasty and labiaplasty).

The procedures can to a varying extent be carried out in one step or in series. The procedures are often supplemented with permanent hair removal on the outer genitals, using laser depilation, electrolysis etc.

Gender reassignment surgery on the genital organs is performed by a specialist plastic surgeon with the involvement of obstetrician-gynecologists and other relevant medical specialists. The surgical procedure takes place after discussion and recommendation from the team's MDT conference. The medical specialist must ensure the following when obtaining informed consent for the surgery:

- That the legal criteria for castration is met when offering removal of ovaries or testes, i.e. that an approval from the Danish Health Authority has been obtained if this is required by law, cf. section 13
- That the individual experiences gender dysphoria and seeks gender reassignment surgery to the genital organs
- That psychosocial aspects related to sexuality as well as psychosocial consequences of potentially irreversible changes have been adequately addressed
- That the duration and nature of the gender dysphoria as well as the results of previous gender reassignment treatment have been evaluated adequately and can justify the surgical intervention
- That contraindications and risk factors have been addressed, including identifying and appropriately treating somatic or psychiatric disorders
- That the individual is well-informed about expected positive effects as well as any adverse effects of the treatment, including irreversible changes to fertility, changed sexual function, risk of unsatisfactory functional and cosmetic result, risk of permanent discomforts from ureter etc.
- That expected changes are visualized with emphasis on the fact that the changes are irreversible.

Before removing the uterus, fallopian tubes, ovaries or testes, a minimum of 12 coherent months of gender reassignment hormone therapy should be carried out unless this is contraindicated.

Before removal or closing of the vagina (vaginectomy or colpocleisis) as well as extension of the urethra (urethroplasty) and construction of the penis (phalloplasty or metoidioplasty), or before penis amputation (penectomy) and the construction of vagina, clitoris and labia (vaginoplasty, clitoroplasty and labiaplasty) a thorough assessment of the duration and nature of the gender dysphoria should be made. Considering the destructive and irreversible nature of the procedures and the risk of unsatisfactory functional and cosmetic result, the nature of the gender discomfort must in general be persistent with a desire for surgery. The gender identity of the individual should for a minimum of 12 coherent

months have been in accordance with the sexual characteristics sought to be achieved with the desired surgery. There should however not be any specific requirements for the individual's active gender expression.

It should be noted that regarding constructive surgery of neovagina or neopenis the accepted professional practice in this area is binary, as the aim of the surgery is to create either male or female sexual characteristics. The order and combination of treatments/measures should furthermore be balanced with regards to the individual's preferences, good professional and international standards.

Removal of ovaries or testes prior to or at the same time as other gender reassignment surgery, as described above, must always be professionally justified. Conversely, it is not a prerequisite for the removal of testes or ovaries that the individual would want further gender reassignment surgical treatment to the genital organs.

Removing the uterus, fallopian tubes, ovaries, testes, or penis on medical indication, including conditions derived from gender reassignment treatment such as cell changes of the uterine lining as a result of testosterone treatment are not covered by the rules on castration as part of gender reassignment or the professional recommendations of this guide.

If ovaries or testes have been removed on previous medical indication, any following gender reassignment surgical treatment on the genital organs is not covered by the rules for approval as described in section 13.

9. Treatment of individuals under 18 years of age

The medical counselling, investigation and treatment of gender dysphoria for individuals under the age of 18 requires special expertise. This expertise should be anchored in a fixed multidisciplinary teamwork including both specialist pediatricians with particular experience in the field and qualifications in pediatric endocrinology, growth, reproduction and gender identity, as well as specialists in child and adolescent psychiatry with special experience and qualifications in gender dysphoria among children and young adults.

Other medical specializations and professional groups such as psychologists and obstetrician-gynecologists may be included. Specialist plastic surgeons with relevant experience and qualifications in gender identity and gender dysphoria may be involved where appropriate, for instance with information and planning of subsequent gender reassignment surgery.

Medical counselling, investigation and treatment of gender dysphoria among children and young adults requires a very special focus on the development of the child or young adult as well as family and social conditions etc. The treatment option must be adapted to the need and wishes of the family and the child or young adult. Persons under the age of 18 seeking healthcare related to gender identity, as well as their parents, must be offered counselling and supportive talks before initiating any treatment. It is furthermore critical to ensure a coherent and holistic approach that is continually adapted according to the age and development of the child or young adult.

Starting treatment with hormone suppression therapy (hormone blockers) and gender reassignment treatment requires assessment by a medical specialist. The medical specialist should assess, in cooperation with a discussion in the MDT, when the young adult can be included in an investigation and treatment. There is no minimum age, but distinct and enhanced professional attention should be given if treatment is offered earlier.

The medical specialist has the overall responsibility for obtaining consent and for informing the child or young adult and his/her parents at all times. Healthcare professionals must pay particular attention to the diligence rules in the Health Law on information and consent, including that persons above the age of 15 may themselves give informed consent to treatment (8). To the extent that there is disagreement between the parents and the young adult older than the age of 15, and if the young adult according to the healthcare professionals' assessment understands the consequences of their own decision, the competence to give consent is ultimately the decision of the young adult.

The medical specialist responsible for the overall care must ensure that the overall treatment is holistic and coherent and that all necessary elements are carried out in a competent manner.

The investigation should take offset in a developmental perspective and must include a thorough assessment of the development, the psychosocial situation and family matters of the child or young adult and matters related to sexuality and fertility planning should furthermore be included. The investigation program must also involve a thorough assessment of the existence of somatic or psychiatric conditions and disorders which require assessment and treatment prior to treatment or which may contraindicate this.

The content of the care offered is organized by the medical specialist responsible for the treatment and is based on established professional practices as well as national and international professional guidelines etc. There is presently limited experience with treatment of gender dysphoria in children and young adults, for which reason there are particular enhanced requirements for professionals, including due diligence and conscientiousness as well as enhanced requirements for information and consent. Considering that treatment principles are new relevant and systematic collection of data and continuous quality assurance must be ensured (9).

The medical specialist responsible for the treatment must ensure that the MDT conferences, with the participation of the medical specialists involved as well as other staff, are held on an ongoing basis and when the need arises, and that status of the course is prepared on an ongoing basis. Within the general framework and guidelines laid down by MDT, the medical specialist can regularly adjust and adapt the treatment offered.

Treatment of children and young adults includes reversible treatments like hormone suppression therapy ('hormone blockers' such as GnRH analogues), potentially irreversible gender reassignment treatments with estrogens or androgens and in rare cases irreversible breast surgery. A thorough assessment of psychosocial conditions must be made before any treatment offer, and any offer should be considered from a developmental point of view. The treatment offer must be considered and evaluated step-by-step from reversible to irreversible, and when increasing the intensity of the treatment both the young adult and their parents must acknowledge the full effects of the treatment.

Treatment with hormone blockers and gender reassignment medical treatment of persons under 18 years of age must be performed by the team's medical specialist in pediatrics with particular experience and qualifications in pediatric endocrinology, growth and reproduction. The medical specialist must prior to implementation of any new treatment ensure that there is a current and thorough professional assessment of the effect of any previous treatments, indications and contraindications. Moreover, it must be ensured that this status is discussed at the MDT conference where appropriate. Taking offset in the fixed treatment and follow-up program, parts of the treatment, such as hormone injections, may be performed on a local pediatric specialized clinic in the context of formal cooperation agreements.

In hormone suppression therapy (hormone blockers) and treatment with estrogens or androgens, the medical specialist in pediatrics must ensure that there is a updated assessment of the following conditions with a proportionate consideration of the risks and reversibility of the requested treatment when implementing any new treatment offer:

- That the person is experiencing gender dysphoria which has developed or is exacerbated by the onset of puberty and that the individual requires treatment
- That the psychosocial aspects have been addressed, including psychosocial consequences of the treatment
- That contraindications and risk factors are addressed, including that somatic or psychiatric disorders are identified and treated as appropriate
- That the child or young adult and their parents (guardian) are thoroughly informed about the consent to the treatment, including information on expected effects and possible adverse effects. It should especially be emphasized that these are new treatment principles with limited experiences
- That counselling and support is offered for the young adult's clarification of their own gender identity
- That an individually adapted follow-up program is organized with the aim of an ongoing adjustment of the treatment and with assessment of effects and possible

adverse effects, including assessment of growth in height, bone health, relevant ongoing imaging and biological studies etc.

Hormone suppression therapy (hormone blockers) may in general be offered in Tanner stage 2 or higher. Gender reassignment medical treatment with estrogens or androgens may be offered when the effect of the hormone suppression therapy has been assessed and furthermore requires a current and thorough professional and individual assessment taking into account the individual's situation and preferences.

Reference to depilation, cf. section 10, may be relevant in some cases. In exceptional cases, referral for breast surgery may be offered after discussion at the MDT conference on the basis of a current assessment. Other gender reassignment surgery may not be offered to individuals under the age of 18.

10. Other options

The individual may freely contact their municipality of residence for an investigative dialogue assessing the offer of speech therapy with the aim of modifying the voice and speech. The individual person may also file an application to the residential municipality for a grant for a wig or other headgear with permanent hair loss as an adverse effect of the gender reassignment treatment.

Additional treatment as part of the gender reassignment treatment may be offered on a regional level if the conditions for the treatment are met in an individual assessment that has also been discussed at the MDT conference. For individuals assigned the male sex at birth, referral to an ear, nose and throat specialist clinic concerning vocal cord surgery is possible in cases of insufficient effect of speech therapy. Similarly, referral to a dermatological clinic or medical specialist is possible concerning hair removal by laser depilation, electrolysis etc. on the face. Other procedures, such as facial surgery, larynx reduction, liposuction, etc. can only very exceptionally be offered in a regional context and only in case of significant functional and psychological discomforts.

11. Rights

Gender reassignment surgery is exempted from the rules on extended free choice of hospital (10). This implies that an individual having completed a full examination and who has been referred to gender reassigning 'upper' or 'lower' surgery cannot choose to be

treated at a private hospital or clinic if the residential region does not offer gender reassignment surgery within 30 days. In consideration of the fact that gender dysphoria can be associated with a significant effect on the individual's life situation and that the individual may have had lengthy investigation and treatment, gender reassignment surgery should be offered within reasonable time limits.

The general rules for free and extended choice of hospitals and for entitlement to investigation, if possible, within 30 days etc., apply for the entire investigation and for all other treatments as described in this guide.

Complaints related to healthcare may be addressed to the Danish Patient Safety Authority. Sanctionable healthcare does not only encompass treatment and care carried out by healthcare professionals but also matters related to information and consent, preparation of medical documents, record keeping and the violation of rules on professional secrecy. It is only possible to file complaints on matters which are maximum five years old from the day the complaint is submitted digitally to the Danish Patient Safety Authority. However, the period for lodging a complaint is shortened to only two years if the complainant has had or should have had knowledge of any malpractice.

Violation of patients' rights may also be reported to the Danish Patient Safety Authority, for example if the individual believes that the hospital or region has infringed such rights regarding free and extended choice of hospital, right to investigation, obligation to providing information etc.

Complaints about the region's level of service, for example staff behavior, work organization, the surroundings, food and cleaning should be directed to the management of the region.

In case of injury related to a treatment or an examination compensation may be filed for from the Danish Patient Compensation Association.

12. Registration

In general, healthcare professionals are obliged to document healthcare practice and regions, municipalities, private healthcare professionals and private clinics etc. have a duty to report information on the healthcare to the central authorities.

The Classification System of the Danish Health Care System (SKS) is developed and maintained by the Danish Health Data Authority and primarily used in hospitals, i.e. in connection with recording healthcare benefits in patient administrative systems and subsequent reporting to the National Health Register (LPR).

The SKS applies Danish versions of international classifications, for example based on the World Health Organizations' ICD-10 and the classification of surgery procedures based on the Nordic NCSP. The codes in section DF64 have since January 1 2017 been discontinued in the SKS.

For registration of contacts regarding gender identity and dysphoria the contact code DZ768E1 (contact related to being transgender) generally applies to gender reassignment investigation and treatment – both medical and surgical – on adults, as described in this guide, while DZ768E2 (contact related to gender identity in childhood) may also be used in the investigation and treatment of persons under 18 years of age.

When coding treatment, the contact codes should be supplemented with relevant treatment and service codes, for instance BBHG0 (treatment with female sex hormone), BBHG1 (treatment with male sex hormone), BBHF5 (treatment with hypothalamic hormones and analogues), KLEE40 (construction of vagina) etc. Conditions or disorders which are existing, or which are recognized in the process, must be coded as secondary diagnoses as appropriate, according to general principles for documentation.

13. About castration

According to the current rules (11) an individual may be castrated as part of gender reassignment if the person is transgender, has a persistent wish for castration and understands the consequences thereof.

Castration is a procedure whereby the gonads (testes or ovaries) are removed or treatments whereby they are permanently deactivated. Castration as part of gender reassignment is a procedure where the testes or ovaries are removed without any medical indication other than gender dysphoria with a desire for gender reassignment treatment.

Castration does not require permission from the Danish Health Authorities, except in the cases outlined in section 13.1. It is hence a clinical decision made by the responsible specialist with the involvement of the patient and where relevant with peer review at the MDT-conference, cf. section 8.2.

Castration of persons under the age of 18 is not permitted.

13.1. Special conditions requiring approval for castration

Under exceptional circumstances, as described in §§ 110 and 111 of the Health Act, the individual, or his or her guardian, must apply for permission for castration as part of gender reassignment from the Danish Health Authority. These rules apply in cases where the individual due to insanity, mental retardation, serious health issues or other reason, has a permanent or long-standing lack of understanding of the significance of the procedure or

in cases where it may be considered that the person, due to insanity, mental retardation, or other mental conditions, including low intelligence, serious health issues or other reason, should not be allowed to independently request a castration.

The rules entail specific requirements for the application as well as requirements for medical guidance on the nature of the procedure, direct consequences and the risk which must be assumed to be associated with the procedure. It also follows from the rules that the Danish Health Authority must not allow castration of persons under 18 years of age, just as there are specific rules for the guardianship of incapacitated adults.

Either the individual applying for castration as part of gender reassignment or his or her guardian must send an application to the Danish Health Authority.

The application must be dated, signed and contain the following information:

- The applicant's name, place of residence and social security number
- Which gonads are requested to be removed, how long the desire for castration has been prevalent and justifications for the desire for castration as perceived from the individual's situation and gender identity
- Who has carried out the past investigation and gender modifying treatment
- Permission for the Danish Health Authority to obtain an expert opinion from the medical specialists in the MDT, where the investigation and gender reassignment treatment is performed as well as – if relevant – permission to obtain an expert opinion of the Legal Medical Board.

The Danish Health Authority will hereafter obtain a statement from the specialist psychiatrist from the MDT where the applicant has been investigated and treated. If an applicant has not been investigated or treated in Denmark, the Danish Health Authority will advise the applicant to get a referral to a gender identity clinic at a public hospital closest to the applicant's residence. Results of foreign investigations may, based on a specific assessment from a specialist psychiatrist in the MDT, replace all or parts of the investigation.

If the Danish Health Authority evaluates that the applicant satisfies the conditions, the Danish Health Authority will send a permission for castration to the applicant and at the same time notify the gender identity clinic that has prepared the statement of such permission.

If the Danish Health Authority is unsure about the basis for providing permission from the statement, the Authority may obtain an expert opinion from the Legal Medical Board. If the Danish Health Authority assesses that the conditions are not fulfilled, the applicant should be granted an individual hearing before the Authority reaches a final decision.

The statement must be drawn up or be approved by the specialist psychiatrist responsible for the treatment and include the following:

- A report of the overall course of investigation including the most significant conditions of the medical history and significant results of examinations and assessments
- A description of the gender reassignment treatment which the applicant has received, including type, duration and result
- An assessment of the duration and scope of gender dysphoria and wish for castration
- A description of the medical guidance which has been provided regarding the nature of the castration procedure and the direct consequences, as well as the adverse effects assumed to be associated with the procedure
- An assessment of the applicant's capabilities, including whether the applicant is able to understand the consequences of the castration, with a special emphasis on assessments of insanity, mental retardation and other relevant mental issues, as described in §§ 110 and 111 of the Health Act
- Other healthcare matters which are assessed to be relevant for the Danish Health Authority's treatment of the application.

The statement must contain a summary and a conclusion for the course of the investigation, indicating whether there are crucial circumstances that based on a thorough professional assessment contradict the applicant's wish for castration as part of the gender reassignment.

Upon receipt of applications for permission for castration as part of gender reassignment, the Danish Health Authority will send the applicant a receipt as well as any information regarding missing formalities for the application within 8 calendar days after receipt. After receipt of a satisfactory application, the Danish Health Authority will, no later than 8 calendar days after receipt, obtain statement from the gender reassignment clinic where the applicant has been investigated. Usually, the clinic must submit the statement no later than 30 calendar days from receiving the Danish Health Authority's inquiry. When receiving the satisfactory statement from the gender identity clinic, the Danish Health Authority will forward the permission for castration to the applicant no later than 30 calendar days from receipt of the statement. If the need for obtaining expert opinion from the Legal Medical Board arises, the Health Authority's case management will be suspended until receipt of the Department's opinion.

Decisions made by the Danish Health Authority in accordance with §§ 110 and 111 of the Health Act may be appealed before the Ministry of Health, which, however, cannot reverse the professional assessments made by the Danish Health Authority.

14. Glossary

Castration	Surgical removal of the ovaries or testes or other irreversible reduction of their function.
Contraindication	Medical reservations against treatment. Condition or factor which increases the risk of carrying out a specific treatment. An absolute contraindication is a condition, which prohibits the use of the treatment in general.
Gender discomfort	A condition of discomfort as a result of the incongruence between the gender and gender identity.
Gender dysphoria	Gender dysphoria is defined by strong, persistent feelings of identification with the opposite gender and discomfort with one's own assigned sex that results in significant distress or impairment.
Gender expression	The way of expressing one's gender, for example through appearance, dress and behavior.
Gender identity	The individual person's internal and individual experience of their gender. Gender identity can correlate with assigned sex at birth, or can differ from it. All societies have a set of gender categories that can serve as the basis of the formation of a person's social identity in relation to other members of society.
Gender incongruence	Incompatibility between the gender and gender identity.
Gender modifying treatment	Medical or surgical treatment designed to change gender characteristics and support.
Gender reassignment surgery	Gender modifying surgical treatment.
Hormone blockers	Drugs which inhibits the individual person's production of sex hormones or the impact of these. Also known as hormone blocking agents, hormone suppression treatment etc. GnRH analogues are one type of synthetic hormone blockers.

Healthcare support	Counselling, support, investigation, observation, treatment, follow-up, rehabilitation etc. provided by healthcare professionals and by the healthcare system.
Healthcare staff	Persons with a medical education, which are authorised by the central authorities. For example nurses, doctors and specialists.
Indication	A medical assessment of the need for treatment and justification for a specific treatment option.
Informed consent	A person's voluntary permission to treatment, granted in full knowledge of the possible consequences, typically that which is given by an individual to the healthcare professional responsible for the treatment with knowledge of the possible risks and benefits.
Investigation	A healthcare effort where the relations of the individual person are identified systematically, including both physical, mental and social matters.
Legal gender recognition	The term used to define the legal process whereby a person is formally recognised by the state in his/her "new" gender role. In Denmark, it is the formal and legal change of the gender description, social security number, as well as first name in CPR, i.e. the Central Population Register.
Sex assigned at birth	A biological sex is assigned at birth, depending on the appearance of the genitals.
Sex characteristics	The bodily characteristics which differentiate the sex, including primary sex characteristics as type of internal and external genital organs, which can be observed at birth, or the secondary sex characteristics as facial hair, breast development etc. which may develop at puberty.
Sex hormones	Steroid hormones of the types androgens, estrogens or progesterone. Sex hormones are produced naturally in the body by the gonads (ovary or testes) and to a lesser extent in the adrenal glands as well as in fatty and liver tissue. Can be supplied to the body as synthetically manufactured drugs.

Sexuality	An integral part of any person's personality. Sexuality is a basic human need and one aspect of what it means to be human, which cannot be separated from other aspects of life. Sexuality must not be confused with sexual orientation or sexual practice.
Treatment	Healthcare delivered with the purpose of affecting at physical or mental processes, conditions and matters in a particular direction.

15. References

- (1) Consolidation Act no. 990 of the 18th of August, 2017. Executive order of the law on certification of healthcare professionals and healthcare operations (The Certification Act). Cf. Section 17.
- (2) Consolidation Act no. 1188 of 24th of September, 2016. Executive order on the Health Law (The Health Law). Cf. Section 214.
- (3) Cf. Sections 207-209 of the Health Law, please also see: Guidance no. 9053 of 27th of January, 2014 on the implementation of Section 208 of the Health Law regarding specialised hospital services.
- (4) Consolidation Act no. 646 of 2nd June, 2017. Executive order on amendment of The Civil Registration System's Act.
- (5) Chapter 5 of the Danish Health Law, cf. publication no. 665 of 14th September 1998 on information and consent as well as disclosure of health information etc. as well as publication no. 161 of 16th September 1998 on information and consent as well as disclosure of health information etc.
- (6) The Danish Health Authority's guide no. 11052 of 2nd July, 1999 regarding the introduction of new treatments in the healthcare system.
- (7) Publication no. 834 of 27th of June, 2014. Publication on cosmetic treatment.
- (8) Consolidation Act no. 1188 of 24th of September, 2016. Publication of the Health Law. Cf. Section 17.
- (9) The Danish Health Authority's guide no. 11052 of 2nd July, 1999 regarding the introduction of new treatments in the healthcare system.
- (10) Consolidation Act no. 1188 of 24th of September, 2016. Publication of the Health Law. Cf. Section 82b and section 87. Publication no. 293 of 27th March, 2017. Publication on the right to hospital treatment etc. Cf. Section 21.
- (11) Consolidation Act no. 1188 of 24th of September, 2016. Publication of the Health Law. Cf. Section 115(1)(3) as well as section 116. See also: Publication no. 957 of 28 August, 2014. Publication on sterilization and castration.

