



Clinical Commissioning Policy: [Gender Identity Services]

Reference: NHS England xxx/x/x

NHS England

Clinical Commissioning Policy: Gender Identity Services

First published: Month Year

Prepared by NHS England Clinical Reference Group for Gender Identity Services

Published by NHS England, in electronic format only.

Contents

Policy Statement	4
Equality Statement	4
Plain Language Summary	4
1. Introduction	5
2. Definitions	6
3. Aim and objectives	7
4. Epidemiology and needs assessment	7
5. Evidence base	8
6. Rationale behind the policy statement	19
7. Criteria for commissioning	20
8. Patient pathway	
9. Governance arrangements	37
10. Mechanism for funding	38
11. Audit requirements	38
12. Documents which have informed this policy	38
13. Links to other policies	39
14. Date of review	39
References	39

Policy Statement

NHS England will commission in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Gender dysphoria refers to discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves with respect to gender) and that person's sex assigned at birth (and the associated gender role, and/or primary and secondary sex characteristic). This encompasses both binary gender (male or female) and non-binary gender (pan-gender, poly-gender, a-gender, and others). It is not a lifestyle choice and can best be described as a neuro-developmental disorder.

It is a debilitating condition that has a profound effect on almost every aspect of the sufferer's life, leading in many cases to high levels of contact with primary care and mental health services, and disengagement with the wider society and from ordinary activities of life such as employment, education and meaningful activity. Suicide rates for sufferers are significantly higher than the national average.

Many people who experience gender dysphoria desire to live and be accepted as a person of the gender congruent with their gender identity, usually with congruent physical sex characteristics. Some people will make a social role transition only; others will require physical transition, through hormonal, physical and surgical interventions.

Gender Identity Services offer a pathway of care, treatment and support through psychological, social and physical transition, co-ordinating interventions provided directly by the service with interventions offered by other providers.

Efficacy of this care pathway is high, with several studies reporting extremely high levels of transgender patient satisfaction with surgical reconstruction and subsequently a significantly higher quality of life. Once discharged from specialised services, most patients go on to lead full and productive lives under the care of their GP.

1. Introduction

Specialised Gender Identity Services provide assessment, care and treatment for people affected by concerns regarding gender identity, role and/or expressions that differ from the cultural norm for their birth-assigned sex.

The need for Specialised Gender Identity Services varies considerably. It frequently affects almost every aspect of the affected person's life, from very early childhood to end of life. This policy addresses the needs of adult persons in England, defined for the purpose of this policy as age 18 years and older. The needs of children, adolescents and younger adults are addressed in a separate policy and service specification.

Delivery of care is facilitated through a Specialised Gender Identity Clinic (GIC) which either directly provides interventions 'in house' or co-ordinates as a 'Lead provider' their delivery by other providers through a network.

Specialised Gender Identity Services offer advice and assessment for people affected by gender dysphoria, and advise them as to the options that might be pursued to address the condition. These options may include, but are not limited to, treatments facilitated by the specialist GIC. The GIC may offer to facilitate a variety of therapeutic practical, physical, medical and surgical interventions for people affected by gender dysphoria. The services and interventions that specialist GICs are required to provide are described in section 7 of this policy. The number and type of interventions applied and the order in which these take place will vary from person to person. Individuals may not need or desire some of these interventions.

In addition, GICs provide patients with the opportunity to prepare for their future in their acquired gender role. This should include preparation for relationships, exploration of sexual identity and sexual expression, and the promotion and maintenance of optimal physical and mental health for the whole of life, from the present to the end of life. This requires cooperation and collaboration of the patient's GP.

However the purpose of all NHS provided GICs is to ensure that all patients are fully informed, comfortable with and prepared for life in the acquired gender and that the appropriate checks and balances are satisfied before clinicians facilitate, and the NHS fund what are likely to be permanent and irreversible changes through medical and possibly surgical interventions.

Since 2013, NHS England has actively engaged with trans people, so as to better understand their healthcare needs and their experience of the NHS, good and bad. There have been two threads to this process: a review of how the NHS serves trans people, under the chairmanship of Prof Steve Field, and a patient engagement process, conducted under the auspices of NHS Voice. Prof Field's draft review findings, and the views of service users identified through on-line communication and a series of large-scale stakeholder meetings, underpin this commissioning policy

2. Definitions

Transsexualism is the desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment (ICD-10 code F64.0).

Gender Identity is the individual's personal sense of their own gender. It includes both binary and non-binary experiences of gender. Binary experience implies that an individual identifies either exclusively as a man or exclusively as a woman. However, there is growing recognition that many people do not regard themselves as conforming to the binary man/woman divide and that this will impact on their treatment. Self-descriptions include: pan-gender, poly-gender, neutrois and gender queer. A few people who reject the gender concept altogether, and see themselves as non-gendered (agendered), may require gender neutralising treatments from appropriate clinical services.

Gender dysphoria refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristic). Trans and gender variant people are not necessarily gender dysphoric.

There are gradations of gender experience between the binary 'man' or 'woman', some of which cause discomfort and may need medical intervention; others may need little or none.

A few people who reject the gender concept altogether, and see themselves as non-gendered, may require gender-neutralising treatments from appropriate clinical services.

Terminology

Language, in the field of gender dysphoria is constantly evolving; different usage exists between communities, and even side by side within communities. The terms

'transgender' and 'trans' are sometimes used as umbrella terms to cover a wide variety of atypical gender experiences which usually leads to permanent change of gender role but may not necessarily lead to surgical intervention.

In this document, an individual who has been assigned as female at birth on the basis of genital appearance, but who later identifies as a man, is described as a trans man; similarly, an individual who has been predicted to identify as a man, having been assigned as male at birth, but who later identifies as a woman is described as a trans woman. It is important to note that many people who have acquired a new gender role that is congruent with their gender identity simply want to be described as "men" or "women" without the "trans" prefix.

3. Aim and objectives

Aim

The aim of this clinical commissioning policy is to specify the conditions under which Gender Identity Services and procedures within the associated pathway will be routinely commissioned and/or funded by NHS England.

It is a means of ensuring patients receive equitable access to treatments and interventions that allow an individual to feel comfortable with their gender role and to experience an improved quality of life, reducing dependency, both emotionally and financially on wider state systems, reducing poor mental health and associated use of services and lowering high suicide intent and morbidity rates.

This will be achieved through equitable commissioning practice across all Area Teams responsible for Specialised Services and by ensuring that all aspects of a patient's pathway are commissioned to an acceptable level and quality.

Objectives

To clarify core treatments and procedures on the pathway

To set out criteria for access to the treatments and procedures on the pathway

To define the conditions under which additional treatments may be commissioned and the criteria for access to those treatments

To define those procedures that were considered by the Clinical Reference Group but that will not be commissioned by NHS England

4. Epidemiology and needs assessment

Gender variance is not uncommon. A survey of 10 000 people undertaken in 2012 by the Equality and Human Rights Commission found that 1% of that population was gender variant to some extent. This figure cannot necessarily be assumed to be representative of the whole population. Historically, more pregender surgery or pre- certificated women sought treatment than men but this difference is reducing and some gender identity clinics are reporting numbers that are close to parity. Personal communications from Clinical Directors of GICs in England suggest that referral rates to their services have been increasing by around 20% per year for the past several years; in 2012/13, the referral rate to specialist gender clinics in England was around 2500 people a year. Not all of these people will be transsexual persons, nor will all be seeking to transition.

Gender variant people and gender non-conforming people do not necessarily have gender dysphoria and the population shows great diversity.

It would be wrong to assume that there is a typical pre gender operative or pre-certificated woman or man. Increasing numbers of individuals now present at an earlier stage in life, equally there are many who may have lived with their dysphoria for decades before feeling confident enough (or having the opportunity) to seek to resolve their issues. Gender variance knows no social, ethnic, religious or socioeconomic boundaries but is likely to be more hidden in some cultures than in others.

5. Evidence base

Clinical outcomes data must be at the heart of planning for all NHS services. This policy document is based upon a review by the SGIS CRG of evidence for the wide range of interventions (pharmacological, surgical, physical and psychosocial) that comprise the gender dysphoria care pathway. Although domiciled within the Mental Health Programme of Care, gender dysphoria is usually the consequence of variant gender identity development and, as such, it may better be understood as a somatic disorder with the potential for profound physical and psychosocial consequences.

In 2011, the suicide rate in the general UK population aged 15 years and older was 11.8 deaths per 100,000 population. The average cost per suicide in England is £1.7 million. Untreated gender dysphoria kills people: a 2011 study² of 500 consecutive patients with gender dysphoria but no other psychiatric comorbidity in Japan reported the lifetime prevalence of self-mutilation, including suicide attempts, as 31.8%; 72.0% of the sample reported suicidal ideation. A 2012 survey in Ireland reported that 78% of trans people had thought about ending their lives and 40% had attempted suicide. In a 2013 study 4, the rate of suiciderelated events among gender dysphoria-diagnosed Veterans Health Administration (VHA) veterans was more than 20 times higher than were rates for the general VHA population. In a 2011 long-term follow-up study of mortality in transsexual people receiving treatment with cross-sex hormones, the suicide rate amongst trans women was much lower, although it was still six times greater than in the general population.⁵ Although these studies are not strictly comparable because of methodological differences, the difference in suicide and self-harm rates tallies with clinical experience.

1

¹ Knapp M, McDaid D, Parsonage M (editors) (2014) *Mental health promotion and mental illness prevention: The economic case.* https://www.gov.uk/government/publications/mental-health-promotion-and-mental-illness-prevention-the-economic-case; Accessed on 15 July 2014

² Terada S, et al. *Suicidal ideation among patients with gender identity disorder.* Psychiatry Res. 2011 Nov 30;190(1):159-62. doi: 10.1016/j.psychres.2011.04.024. Epub 2011 May 25.

³ http://www.teni.ie/news-post.aspx?contentid=673; Accessed on 15 July 2014

⁴ Blosnich JR, et al. *Prevalence of gender identity disorder and suicide risk among transgender veterans utilizing veterans health administration care.* Am J Public Health. 2013 Oct;103(10):e27-32. doi: 10.2105/AJPH.2013.301507. Epub 2013 Aug 15.

⁵ Asscheman H, et al (2011). A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. European Journal of Endocrinology 164 635–642

There is a strong economic case for treating gender dysphoria effectively, as well as a moral case.

As part of the policy and service specification process, sub-groups were established within the CRG to review evidence, develop treatment recommendations and establish service standards for these various interventions. When reviewing this evidence, it should be remembered that the overarching aim of treatment for gender dysphoria is "to enable affected persons to achieve lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfilment." The range of interventions described in this commissioning policy are needed to achieve this treatment goal and are recommended as components of a comprehensive, need-related package of care in all relevant, authoritative clinical guidelines. All these interventions must be available to all patients within the care pathway, on the basis of their individual clinical need (but not their personal social preference), as assessed by SGIS clinicians, although many patients will not need all of them.

The evidence base for treatment of gender dysphoria is largely comprised of low- graded (with respect to "level of evidence" scoring systems) papers. Expert opinion consensus papers are the commonest form. Some of the reasons for this paucity of high-level evidence are discussed at the end of this section.

Psychological therapies

Psychological therapies will be provided for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support, improving body image; or promoting resilience.

Therapists assess clients' gender dysphoria in the context of an evaluation of their psychosocial adjustment (Bockting et al., 2006; Lev, 2004, 2009). The evaluation includes, at a minimum, assessment of gender identity and gender dysphoria, history and development of gender dysphoric feelings, the impact of stigma attached to gender nonconformity on mental health, and the availability of support from family, friends, and peers (for example, in-person or online contact with other transsexual, transgender, or gender nonconforming individuals or groups).

Therapists educate clients regarding the diversity of gender identities and expressions and the various options available to alleviate gender dysphoria. The therapist and the client discuss the implications, both short- and long-term, of any changes in gender role and use of medical interventions. These implications can be psychological, social, physical, sexual, occupational, financial, and legal (Bockting et al., 2006; Lev, 2004).

The format of the provision (one-to-one, number of sessions, length of sessions, etc., etc.) is based upon expert consensus opinion of UK practice of psychological therapies for gender dysphoria. There is no data to support a recommendation for use of a specific format or system of psychotherapy.

Endocrine interventions and genital reconstruction surgery

A literature review was undertaken to identify evidence of clinical effectiveness and cost effectiveness of cross-sex hormone therapy and gender realignment surgery.

11 studies were found which met the inclusion criteria- Two reviews (Murad et al. 2010 and Sutcliffe & Dixon 2002), one Health Technology Assessment (Day 2002), one survey and seven qualitative studies. The studies included the following outcomes—mortality, safety, psychological functioning, quality of life (QoL), personal experiences, relationships and satisfaction of treatment of transsexuals with cross- sex hormones. No studies were found on the impact of cross-sex hormone therapy and SRS on physical morbidity, physical functional status and cost-effectiveness.

Studies appear to suggest a positive impact of treatment on gender dysphoria, psychological status, sexual functioning and quality of life. Mortality from suicides seems to be high despite treatment. However, the quality of evidence which these findings are based is low, and in some instances there are conflicting results.

Cross-sex hormone therapy appear to be safe, with mortality rates of those undergoing treatment the same as that of the general population. Hormone dependent tumours might be a cause of the use of cross-sex hormones but findings need to be supported by further research. A 2012 study by Asscheman et al⁶ reported a three-fold increase in risk from cardiovascular death with current (but not previous) use of ethinyl oestradiol. The authors concluded that increased mortality in hormone-treated trans women was mainly due to nonhormone-related causes and that the use of testosterone in trans men at doses used for the treatment of male hypogonadism seemed safe. Also in 2012, Seal⁷ et al reported that treatment with conjugated equine oestrogen was associated with a higher incidence of thromboembolism than treatment with other oestrogen types, and that self-medication, particularly with spironolactone, associated with increased subsequent requests for augmentation mammoplasty. Overall, there is only limited evidence to demonstrate the efficacy of hormonal therapy or gender reassignment surgery with regard to long-term complications or physical functional status.

There is no available evidence regarding cost-effectiveness of the treatment.

In 2009, the Endocrine Society published a Clinical Practice Guideline⁸ on the endocrine treatment of transsexual persons. This is a well-structured review and carefully describes "levels of evidence"; it remains the principal source of clinical guidance for endocrine intervention for gender dysphoria.

Seal LJ, et al (2012) Predictive Markers for Mammoplasty and a Comparison of Side Effect Profiles in Transwomen Taking Various Hormonal Regimens J Clin Endocrinol Metab, December 2012, 97(12):4422–4428

⁶ Asscheman H, et al (2011). A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. European Journal of Endocrinology 164 635–642

⁸ The Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline Journal of Clinical Endocrinology & Metabolism, September 2009, 94(9): 3132–3154

With respect outcome data for genital reconstructive surgery, the available data is limited; almost all of the outcome studies in this area have been retrospective. They are well-summarised in the World Professional Association for Transgender Health's Standards of Care document, version 7⁹:

"One of the first studies to examine the post-treatment psychosocial outcomes of transsexual patients was done in 1979 at Johns Hopkins University School of Medicine and Hospital (USA) (JK Meyer & Reter, 1979). This study focused on patients' occupational, educational, marital, and domiciliary stability. The results revealed several significant changes with treatment. These changes were not seen as positive; rather, they showed that many individuals who had entered the treatment program were no better off or were worse off in many measures after participation in the program. These findings resulted in closure of the treatment program at that hospital/medical school (Abramowitz, 1986).

Subsequently, a significant number of health professionals called for a standard for eligibility for sex reassignment surgery. This led to the formulation of the original Standards of Care of the Harry Benjamin International Gender Dysphoria Association (now WPATH) in 1979.

In 1981, Pauly published results from a large retrospective study of people who had undergone sex reassignment surgery. Participants in that study had much better outcomes: Among 83 FtM patients, 80.7% had a satisfactory outcome (i.e., patient self-report of "improved social and emotional adjustment"), 6.0% unsatisfactory. Among 283 MtF patients, 71.4% had a satisfactory outcome, 8.1% unsatisfactory. This study included patients who were treated before the publication and use of the Standards of Care.

Since the Standards of Care have been in place, there has been a steady increase in patient satisfaction and decrease in dissatisfaction with the outcome of sex reassignment surgery. Studies conducted after 1996 focused on patients who were treated according to the Standards of Care. The findings of Rehman and colleagues (1999) and Krege and colleagues (2001) are typical of this body of work; none of the patients in these studies regretted having had surgery, and most reported being satisfied with the cosmetic and functional results of the surgery. Even patients who develop severe surgical complications seldom regret having undergone surgery. Quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2003). The vast majority of follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on postoperative outcomes such as subjective well-being, cosmesis, and sexual function (De Cuypere et al., 2005; Garaffa, Christopher, & Ralph, 2010; Klein & Gorzalka, 2009). although the specific magnitude of benefit is uncertain from the currently available evidence. One study (Emory, Cole, Avery, Meyer, & Meyer III, 2003) even showed improvement in patient income.

_

⁹ World Professional Association for Transgender Health: Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. http://www.wpath.org/uploaded_files/140/files/IJT%20SOC,%20V7.pdf Accessed 14 July 2014

One troubling report (Newfield et al., 2006) documented lower scores on quality of life (measured with the SF-36) for FtM patients than for the general population. A weakness of that study is that it recruited its 384 participants by a general email rather than a systematic approach, and the degree and type of treatment was not recorded. Study participants who were taking testosterone had typically being doing so for less than 5 years. Reported quality of life was higher for patients who had undergone breast/chest surgery than for those who had not (p<.001). (A similar analysis was not done for genital surgery). In other work, Kuhn and colleagues (2009) used the King's Health Questionnaire to assess the quality of life of 55 transsexual patients at 15 years after surgery. Scores were compared to those of 20 healthy female control patients who had undergone abdominal/pelvic surgery in the past. Quality of life scores for transsexual patients were the same or better than those of control patients for some subscales (emotions, sleep, incontinence, symptom severity, and role limitation), but worse in other domains (general health, physical limitation, and personal limitation).

It is difficult to determine the effectiveness of hormones alone in the relief of gender dysphoria. Most studies evaluating the effectiveness of masculinizing/feminizing hormone therapy on gender dysphoria have been conducted with patients who have also undergone sex reassignment surgery. Favorable effects of therapies that included both hormones and surgery were reported in a comprehensive review of over 2000 patients in 79 studies (mostly observational) conducted between 1961 and 1991 (Eldh, Berg, & Gustafsson, 1997; Gijs & Brewaeys, 2007; Murad et al., 2010; Pfäfflin & Junge, 1998). Patients operated on after 1986 did better than those before 1986; this reflects significant improvement in surgical complications (Eldh et al., 1997). Most patients have reported improved psychosocial outcomes, ranging between 87% for MtF patients and 97% for FtM patients (Green & Fleming, 1990). Similar improvements were found in a Swedish study in which "almost all patients were satisfied with sex reassignment at 5 years, and 86% were assessed by clinicians at followup as stable or improved in global functioning" (Johansson, Sundbom, Höjerback, & Bodlund, 2010). Weaknesses of these earlier studies are their retrospective design and use of different criteria to evaluate outcomes.

A prospective study conducted in the Netherlands evaluated 325 consecutive adult and adolescent subjects seeking sex reassignment (Smith, Van Goozen, Kuiper, & Cohen-Kettenis, 2005). Patients who underwent sex reassignment therapy (both hormonal and surgical intervention) showed improvements in their mean gender dysphoria scores, measured by the Utrecht Gender Dysphoria Scale. Scores for body dissatisfaction and psychological function also improved in most categories. Fewer than 2% of patients expressed regret after therapy. This is the largest prospective study to affirm the results from retrospective studies that a combination of hormone therapy and surgery improves gender dysphoria and other areas of psychosocial functioning. There is a need for further research on the effects of hormone therapy without surgery, and without the goal of maximum physical feminization or masculinization.

Overall, studies have been reporting a steady improvement in outcomes as the field becomes more advanced. Outcome research has mainly focused on the outcome of sex reassignment surgery. In current practice there is a range of identity, role, and physical adaptations that could use additional follow-up or outcome research (Institute of Medicine, 2011)."

Treatment involving a combination of hormone administration and usually some combination of gender-confirming surgical procedures, following psychological assessment and accompanied by psychological support, is deemed to lead to good outcomes. A study using the post-genital-surgery end-point showed only a 3.8% regret rate and indicates that regrets are few (Landén *et al*, 1998). The study revealed that regrets were more likely where there was a lack of family support.

A review of more than 80 qualitatively different case studies over 30 years demonstrated that the treatment is effective (Pfäfflin & Junge,1998). Lawrence (2003) found that the most significant factor for regret was a poor surgical outcome.

Smith *et al* (2005) undertook a prospective study and found that no patient was actually dissatisfied, 91.6% were satisfied with their overall appearance and the remaining 8.4% were neutral. This study did indicate that women who had lived as heterosexual men before transitioning to live as women were at risk of fewer satisfactory outcomes. This was particularly the case where physical appearance and psychological functioning were unfavourable and the gender dysphoria experienced was inconsistent.

Those with added difficulties were at greater risk of dropping out of treatment altogether and those that continue may need additional therapeutic guidance up to and even after surgery.

Factors that help to support successful outcomes are a consistent gender identity and psychological stability before and after surgery, adequate psychological preparation and transition at an early age (De Cuypere *et al*, 2006), including properly informed consent about benefits, risks and outcomes.

A survey in the UK showed a high level of satisfaction (98%) following genital surgery (Schonfield, 2008). Two studies on outcomes in women and men showed that they function well on a physical, emotional, psychological and social level (Weyers *et al*, 2009; Wierckx *et al*, 2011).

Overall, there are a number of studies that report extremely high transgender patient satisfaction with genital reconstructive surgery.

Gonadectomy

Gonadectomy without genital reconstructive surgery (GRS) is an uncommon intervention in UK practice. In the US and other countries where patients must self-fund treatment for gender dysphoria, it is more commonly practiced because of its low cost in comparison to GRS. It is sometimes requested by patients who will not fulfil the physical fitness criteria required for GRS. The evidence of its efficacy in the treatment of gender dysphoria is expert consensus opinion.

Voice and Communication Therapy

In 2013, Geifer and Tice reported on a study 10 that examined how effectively listeners' perceptions of gender could be changed from male to female for male-to-female (MTF) transgender (TG) clients based on the voice signal alone, immediately after voice therapy and at long-term follow-up. Short- and long-term changes in masculinity and femininity ratings and acoustic measures of speaking fundamental frequency (SFF) and vowel formant frequencies were also investigated. Five MTF TG clients, five control female speakers, and five control male speakers provided a variety of speech samples for later analysis. The TG clients then underwent 8 weeks of voice therapy. Voice samples were collected immediately at the termination of therapy and again 15 months later. Two groups of listeners were recruited to evaluate gender and provide masculinity and femininity ratings. Perceptual results revealed that TG subjects were perceived as female 1.9% of the time in the pre-test,

50.8% of the time in the immediate post-test, and 33.1% of the time in the long-term post-test. The TG speakers were also perceived as significantly less masculine and more feminine in the immediate post-test and the long-term post-test compared with the pre-test. Some acoustic measures showed significant differences between the pre-test and the immediate post-test and long-term post-test. They concluded that 8 weeks of voice therapy could result in vocal changes in MTF TG individuals that persist at least partially for at least 15 months. However, some TG subjects were more successful with voice feminization than others.

In a 2004 paper 11 , Soderpalm and colleagues explored the effect of speech therapy and treatment satisfaction on transsexual individuals who, as part of their reassignment process, were referred to the voice clinic at the Sahlgrenska University Hospital in Göteborg, Sweden, between 1991 and 2002. The group comprised 22 male-to-female and 3 female-to-male transsexuals. A comparison between acoustic analyses before therapy and at follow-up visits showed increased fundamental frequencies for male-to-female individuals (p = < 0.01). Vocal fatigue was reduced. Degree of satisfaction with the post-therapy voice was not related to number of therapy sessions.

-

¹⁰ Gelfer MP, Tice RM. Perceptual and acoustic outcomes of voice therapy for male-to-female transgender individuals immediately after therapy and 15 months later. J Voice. 2013 May;27(3):335-47.

¹¹ Söderpalm E, Larsson A, Almquist SA. *Evaluation of a consecutive group of transsexual individuals referred for vocal intervention in the west of Sweden.* Logoped Phoniatr Vocol. 2004;29(1):18-30

Reduction of facial hair growth and donor site hair epilation

Electroepilation

An on-line search of the PubMed database for scientific literature, using the search terms "facial hair" and "electrolysis" or "electroepilation", reported only one relevant publication in the past 25 years. This referred to a study of a population of natal women; no studies of trans women were identified.

In a 2014 study of NHS epilation treatment by Harris et al¹², twenty-five women, referred for hair removal by electrolysis, were enrolled in a split face study to treat facial hirsutism; one-half of the face with electrolysis and the other side with an intense pulsed light source. Patients were evaluated with respect to reduction in hair counts, side effects and discomfort during treatment. Re-growth was assessed at 3, 6 and 9 months following treatment. All patients, except one with very sparse, fair hair growth, preferred treatment with the Intense Pulsed Light and rated their average hair reduction with this method as 77% after five treatments. The overall patient satisfaction rates as determined by visual analogue scales were 8.3 out of 10 for IPL and 5.4 out of 10 for electrolysis.

Whilst this study reports an inferior outcome for electrolysis in comparison to IPL, it does provide some evidence of efficacy. For people with white, red or very fair hair, or very dark skin, it may be their only option for epilation treatment, as photoepilation is either ineffective or inadequately tolerated in these groups

Laser hair removal

A Cochrane systematic review assessed the effects of epilation with lasers and light sources from randomised controlled trials (RCTs) (Haedersdal and Gøtzsche 2006). It identified eleven RCTs in the review, none of which were of high quality. There appeared to be a short-term effect of approximately 50% hair reduction with alexandrite and diode lasers up to six months after treatment, whereas there was little evidence for an effect with intens pulsed light, neodymium:YAG or ruby lasers. Long-term hair removal (9 months after treatment) was not recorded for any treatment. Infrequently reported adverse effects were pain, skin redness, swelling, burned hairs and pigmentary changes. Pain, skin redness, swelling, burned hairs and pigmentary changes were infrequently reported adverse effects. A variety of factors can influence laser hair removal outcomes, the review does not take them into account.

15

¹² Harris K, et al (2014) *A comparative study of hair removal at an NHS hospital: Luminette intense pulsed light versus electrolysis* J Dermatolog Treat. 2014 Apr;25(2):169-73

Sadighha and Mohaghegh Zahed (2009) undertook a meta-analysis of various laser sources for hair removal .All clinical trials related to hair removal lasers in 1998–2003 were identified. 24 trials which met the criteria for combining the results. Results were synthetized on the basis of kind of laser. The study suggests that hair reduction at least 6 months after the last treatment and hair reductions were 57.5, 42.3, 54.7, and 52.8% after three sessions for diode, Nd:YAG, alexandrite and ruby, respectively. Results were also reported suggesting diode laser is the most effective, and Nd:YAG has the least effect of hair removal. It maybe be that diode and alexandrite lasers are appropriate for hair removal, but require high fluence in the darker skin types and this is accompanied with higher complications, therefore diode might be appropriate for lighter skin, and alexandrite laser for darker skin types.

In an RCT (n=30) comparing laser and intense pulsed light (IPL) devices for axillary hair removal it was reported that both devices significantly reduced hair counts following six treatments with each device carried out at 4-week intervals (Klein et al 2013). Mean reductions from baseline (3 and 12 months after the last treatment) were 59.7% and 69.2% for diode laser (DL) and 42.4% and 52.7% for IPL treatment (P<0.01), respectively. DL treatment induced significantly more pain [3.7±2.1 (DL) vs. 1.6±1.4 (IPL); P<0.01; visual analogue scale] but could be conducted faster [33.1±3.8 s (DL) vs. 40.1±5.0 s (IPL); P<0.01]. No severe side-effects were observed for either therapy. DL was found to be more effective than IPL treatment. DL treatment was reported to be more painful but less time-consuming than IPL therapy.

The long-term hair removal efficacy beyond 6 months postoperatively and onwards was evaluated in one RCT and seven controlled trials and evidence of effectiveness was found for a long-term hair removal efficacy after repetitive treatments with the alexandrite laser (two to four treatments) and the diode laser (two to four treatments) (Haedersdal and Wulf 2006). The best long-term hair reduction was reported for the alexandrite and diode lasers after four repetitive axillary treatments with 84–85% hair reduction 12 months postoperatively (maximum tolerated fluences) (Lou et al 2000).

Several studies have also reported that efficacy is improved when repetitive treatments are given and there is evidence that the short-term efficacy from photoepilation is superior to conventional treatments with shaving, wax epilation and electrolysis (Haedersdal and Wulf 2006).

Chest surgery

Trans women

In a 2013 paper by Weigert, "Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male-to-Female Transsexuals" (PRS 2013; 132:1421-1429) used the "Breast-Q" scoring system, developed and validated for use in female breast reconstruction after cancer surgery. This study reported improved satisfaction with breasts, and improved sexual and psychosocial wellbeing 4 months after surgery and later, p<0.05.

Trans men

In a 2012 paper by Berry, entitled "Female-to-male transgender chest reconstruction: A large consecutive single-surgeon experience" (JPRAS 2012; 65:711-719), satisfaction with chest reconstruction in 100 patients was self- assessed on a 1 to 5 linear analogue scale. The mean satisfaction score was 4.5 out of 5. A small study by Nelson L (JPRAS 2009; 62:331-4) also reported a positive outcome, although only 12 patients of a sample of 17 responded; 11 reported that they were "satisfied" with the outcome of surgery.

Phonosurgery

Trans women

Objective results are variable at present (Wagner, *et al*, 2003), although personal satisfaction rates are high (Kanagalingam, *et al*, 2005). In a 2002 paper, Neumann *et al* described 67 MtF transsexuals who had undergone phonosurgery at a single unit in The Netherlands. Whilst pre-operatively none of the patients had a feminine speaking voice pitch, after surgery about 30 percent attained a voice pitch within the feminine range, and 38 percent attained at least a neutral voice pitch. In the long-term, mostly combined with further voice training, the results proved to be of a permanent character, and in 45% of cases, a further increase was observed. The operation technique in question has proved to be generally successful with a minimum of risk. In most cases, vocal feminization improved the social integration of treated trans women.

Trans men

There have been attempts to lower the pitch further with surgery (e.g. Isshiki type III thyroplasty), but both subjective and objective results are not favorable at present.

¹³ Neumann K, et al (2002). Satisfaction of MtF Transsexuals with Operative Voice Therapy – A Questionnaire-based Preliminary Study. Int Journal of Transgenderism; Volume 6, Number 4, 2002

Thyroid Chondroplasty

Thyroid chondroplasty may also be offered to reduce the prominence of the thyroid cartilage for cosmetic appearance (Sandhu, 2007).

Thyroid chondroplasty is also offered in combination with phonosurgery, as the typical procedure of cricothyroid approximation often increases the prominence of the thyroid cartilage. In a 2003 paper, Mattai et al reported that 86% of patients thought their laryngeal profile had improved, 79% thought their voice had improved, and 55% thought that surgery and 21% thought that speech therapy had helped more in improving the voice. Overall, 79% were satisfied with the results of the surgery. They concluded that cricothyroid approximation and thyroid chondroplasty have a high patient satisfaction rate.

Comments on the evidence base for the treatment of gender dysphoria

There is, to date, only limited outcome evidence for the treatment of gender dysphoria. In addition, such evidence of efficacy and treatment satisfaction that is available is generally of a low level. There are several reasons for this:

- There is no generally accepted and validated clinical outcome measure for "gender dysphoria"; two have been developed in the past twenty years but none has been widely used.
- Outcome research for individual interventions, such as facial hair epilation, is largely derived from their use in other populations; expert opinion is that this cannot always be generalised and applied to a trans population. For example, a woman with facial hirsutism may be distressed by her facial hair growth, a response which she shares with a trans woman, but she does not usually fear misidentification as a man; the impact of hirsutism on well-being may be different between trans and non-trans populations. Simple scales that count hairs per cm² may be a valid assessment of the efficacy of a hair reduction treatment but will not measure its efficacy in modifying the trans woman's experience of gender dysphoria, The same may be said of other interventions used in the treatment of gender dysphoria that were originally developed for other applications. Manufacturers of drugs may not apply to regulatory agencies for a new indication for the treatment of gender dysphoria because of the relatively high cost of such applications and the small volume of sales that will result.
- It is near impossible to evaluate the impact of any single intervention in isolation, as they are often given concurrently and may have accessed directly by service users. Authoritative clinical guidelines on the treatment of gender dysphoria recommend concurrent use of several interventions; the delay to completion of treatment and the resulting increase burden of dysphoria upon patients renders sequential use of interventions impractical and ethically dubious.

- With respect to drug therapy, there are substantial variations in current UK prescribing practice and inadequate evidence or even consensus to agree what constitutes "best practice"
- Past prescribing practice has involved the use of hormone regimens that would, in the UK at least, be considered unacceptably high-risk in the general population. In other countries, self-funding drives patients to use the cheaper rather than optimal interventions. Consequently, older studies and international studies may not be relevant to contemporary UK practice.
- Worldwide, most people have been treated for gender dysphoria in private practice settings; people paying for their own treatment are not usually willing to participate in clinical trials.
- There remain significant differences in models of practice between SGIS providers in the UK; this issue needs to be addressed as soon as possible.

As described at the beginning of this section, there is considerable risk of harm to patients from suicide and self-harm, and also depression, anxiety and substance misuse, if gender dysphoria is not treated, whatever the inadequacies of the current evidence base. The deficiencies of the evidence base must be addressed as soon as possible.

Since October 2013, NHS England has assured equitable access to a consistent range of interventions for the treatment of gender dysphoria and will, under this policy, seek to provide robust efficacy and outcomes data in the future. Central to this policy is a parallel process of "evaluation of interventions" that will run concurrently with the process of "provision of interventions". The policy requires providers to undertake service outcome research, as well as to provide the services themselves. For the present, commissioning must be based upon the limited available evidence; in the future, as a consequence of this policy, it can be based upon robust outcomes data.

6. Rationale behind the policy statement

NHS England has commissioned Gender Identity Services since April 2013. Previous to the inception of NHS England these services were commissioned to varying degrees by Specialised Commissioning Groups (SCGs) and Primary Care Trusts (PCTs).

There was significant variation throughout England in access and funding arrangements which were largely dependent on where a patient lived and under what commissioning organisation Gender Identity Services sat. This was unacceptable, was a contravention of the NHS constitution and left NHS England vulnerable to legal challenge under equity laws.

NHS England has worked closely with the Trans community, stakeholders, patients, clinicians and commissioners to identify the inequalities previously experienced by users of the service and have attempted to address this through the development of this single, England wide Clinical Commissioning Policy for the provision of Specialised Gender Identity Services.

The policy gives a brief description of each potential procedure and intervention on the pathway, sets out the criteria under which a patient will be funded for that intervention should they require it and lays down the service standards that commissioner's should expect from each service provider.

It aims to give commissioners a tool that will clarify current commissioning arrangements, inform planning for future commissioning and ensure consistency, equity and protection from legal challenge.

7. Criteria for commissioning

This section will give a list and brief description of the interventions or procedures associated with this complex pathway and will identify the key standards and criteria that commissioners must consider when commissioning services. A more detailed description of the interventions and procedures and the quality standards expected of each service component can be found in the associated Gender Identity Services Service Specification.

Core treatments (those treatments that will be routinely commissioned) Access to a Specialised Gender identity Clinic (SGIC)

The Specialised Gender Identity Clinic (SGIC) currently acts as the focal point of an individual's care and treatment and as a co-ordination hub for the patient pathway. They are the Lead Provider within the clinical network and will provide or facilitate a range of interventions. Hitherto this policy will refer to that network of services as the Specialised Gender Identity Service (SGIS).

Referrals will be accepted from a GP or other specialist service. There are no inclusion criteria apart from permanent residency in the UK and that the patient must be registered with a GP in England.

SGIS will be established on a multi-disciplinary, multi-professional basis and may

include general practitioners, psychology, psychiatry, psychotherapy, nursing, voice and communication therapy, endocrinology, dermatology, surgery, social work and other related professions, all of whom should have a special expertise in gender identity and its issues.

A typical clinical network would consist of one of the seven Gender Identity Clinics (GIC) in England working with other providers of surgery, epilation, voice and communication and other services. The GIC provides overall clinical leadership for personalised treatment programmes for individual service users, and refers for, and co-ordinates, the interventions delivered by other providers within the clinical network. Other models of service delivery may be commissioned in the future.

Each clinical network shall have a lead provider. The Lead Provider will:

- a) Maintain a Clinical Network with other SGIS providers, so as to be able to arrange delivery of all the interventions for service users described below and in the service specification
- b) Provide clinical leadership in delivery of personalised care agreements
- Be responsible for referring service users to other Clinical Network providers for delivery of interventions set out in the personalised care agreements
- d) In collaboration with other Clinical Network providers and the service user's GP, monitor the safety, tolerability and efficacy of interventions delivered by other Clinical Network providers

Services provided by SGIS providers and clinical networks

The lead provider will arrange, through direct provision or referral to another specialised provider within their clinical network, for service users to receive the following interventions, according to individual service user need and as described in their personalised care agreement:

i. Specialised psychological therapies (psychotherapy, specialised counselling, specialised education and behavioural advice)

Description

The role of counselling or psychotherapy by the counsellor, psychotherapist, psychologist or psychiatrist should be to facilitate the process of exploration for the patient. Psychological therapies should be available to be used as part of the patient's treatment programme. It should enable people, through a variety of approaches, to be clearer about their gender identity including whether they want to commence, continue or reverse treatment.

Standards

Practitioners have a responsibility to monitor and maintain their fitness

to practice at a level that enables them to provide an effective service. They must belong to and be accredited/registered with one or more of BACP, BABCP, UKCP, BPS, COSRT, and HCPC, which would mean that practitioners are bound to an accepted code of practice.

ii. Support through a period of living in the gender role that is congruent with the individual's gender identity

Description

A period of time, usually at least 12 months, living in a gender role that is congruent with the gender identity is a requirement for those who seek genital surgery. The SGIC or network will support the patient through this time whilst they are acquiring documentation or evidence of the gender role change.

Standard

A period of time, usually at least 12 months, living in a gender role that is congruent with the gender identity.

iii. Provision of recommendations for endocrine and other pharmacological interventions to relieve gender dysphoria and facilitate changes in sex- specific characteristics.

Description

Hormone prescribing in this field, under the guidance of a SGIS or Network has been shown to be safe. For some people experiencing gender dysphoria, the changes associated with endocrine treatment may be sufficient and the person may choose not to proceed to make other social changes or undergo any surgery.

Wherever possible, physiological end organ response should be the aim of any endocrine treatments. This should be based on management of circulating hormone levels to allow accurate and individual dose titration together with the suppression of the hormone effects associated with the undesired gender. Treatment should be flexible and patient-led as far as is consistent with clinical safety and with the agreement of the prescriber, accompanied by a full explanation of the principles behind the treatment regimen and taking account of the views of the individual's views of their needs.

Treatments will include:

- a) Feminising and virilising hormone therapy (sex steroids, GnRH analogues, modifiers of sex steroid receptor function); SGIS providers are not commissioned to prescribe hormonal or any other pharmacotherapy
- b) Depilatory and hair growth-inhibiting agents

Prescribing and monitoring of any medication for the treatment of gender dysphoria recommended, or the cost of such prescription medication and monitoring procedures are not the responsibility of the SGIS. Arrangements for prescribing and monitoring are described in a Specialised Services Circular, "SSC1417 *Primary Care responsibilities in relation to the prescribing and monitoring of hormone therapy for patients undergoing or having undergone gender dysphoria treatments*"

Criteria

Persistent and well documented gender dysphoria
Capacity to make fully informed decisions and to consent to treatment
If significant medical or mental health concerns are present, they must be reasonably well controlled

iv. Provision of interventions to enhance desirable changes in voice and communication (Specialised Voice and Communication Therapy, including specialised voice and communication therapy provided by a Speech and Language Therapist (SLT) and/or voice coaching

Description

The overall purpose of Voice and Communication Therapy is to help trans people adapt their voice and communication in a way that is both safe and authentic, resulting in communication patterns that patients feel are congruent with their gender identity and that reflect their sense of self.

Voice and communication therapy enables trans people to work towards communication skills that are more appropriate for their gender. SLTs working with trans people aim to develop voice and communication skills that are congruent with age, physical appearance and consistent with the expectation of both the individual and society for that person's gender identity. SLTs may be involved in the care of transsexual, transgender and gender non-conforming people, be they trans masculine or trans feminine.

Standards

Voice and communication therapy will be provided by qualified Speech and Language Therapists (SLT), working in specialist adult voice services (serving voice specific caseloads) or SGIS clinics. Relevant qualifications and membership of accountable bodies include a degree certificate in Speech & Language Therapy or Masters Qualification; membership of the Royal College of Speech and Language Therapists (RCSLT) and membership of Health and Care Professions Council (HCPC).

SLTs should only accept the referral if the therapist is clinically competent in this specialised area and has access to specialist colleagues and national support networks.

SLTs undertaking voice and communication therapy for trans people will participate in clinical supervision and clinical networks.

SLTs providing voice and communication therapy will work as part of recognised SGIS multidisciplinary teams, with links to other members, especially psychotherapist colleagues. However, their location may constrain their capacity to attend meetings. Where this is not possible, therapists should contribute to the MDT process through two-way, written communication with the SGIS clinic.

v. Provision of interventions to reduce facial hair growth

Description

For trans women, the existence of facial hair exposes them to fear and risk of harm and reduces significantly their chance of a successful transformation.

Hair removal by either photoepilation or electroepilation is provided in both clinical and non-clinical environments. For example, many laser clinics that provide hair removal are private concerns, but based within NHS hospitals, while electrolysis is mainly provided within beauty salons.

Criteria

- The provision of hair removal will be delivered in blocks of treatment, since it is recognised that the time required to achieve acceptable reduction of facial hair growth varies considerably between individuals. Each block will consist of either eight sessions of photoepilation (laser or intense pulsed light, IPL) or, for electroepilation (electrolysis), 80 hours. The need for further treatment after a particular block shall be determined on the basis of a visual assessment by the service provider and service user. Further confirmation, if required, will be provided by the referring SGIS.
- On completion of each block of treatment, assessment should be made of the effectiveness of the treatment. Further blocks for the same modality should only be funded if persistent epilation is demonstrated and the maximum number of treatment blocks has not been reached.
- NHS England will fund up to two, eight session blocks of laser

hair removal, three eighty-hour blocks of electroepilation (electrolysis) or a combination of one, eight session block of photoepilation and one eighty-hour block of electroepilation. Additional sessions will not be funded.

Standards

Electroepilation should be provided within a clinical environment or by a beautician who is either a member of a professional association recognised as a provider of epilation for trans people or who can demonstrate both two years' experience since obtaining a level 3 qualification in electro-epilation (e.g VTCT, NVQ etc) and has treated successfully at least five trans clients in the previous 12 months or engage in regular supervision with an experienced provider.

Providers of electroepilation in a non-clinical environment, where byelaws exist, will be required to register with the appropriate local authority. An example of such regulation is provided by North Devon Council

[http://www.northdevon.gov.uk/index/lgcl business/lgcl business and street trading licences/lgcl personal treatment licences/nonlgcl elect rolysis.htm]. This must be followed as a minimum standard of care by all providers unless contradicted by this policy or associated service specification.

The provision of photoepilation is not currently regulated, but providers will be required to follow the MHRA guidance "Guidance on the safe use of lasers, IPL systems and LEDs - DB 2008(03)".

Photoepilation should be provided within a clinical environment or by a trained beautician, technician or nurse who can demonstrate training [ideally a level 4 VTCT Certificate in Laser and Intense Pulsed Light Treatments (IPL)], at least one years' experience and the successful treatment of at least five trans clients in the previous 12 months.

All service providers will hold appropriate indemnity insurance and public liability insurance.

Certain medical conditions, medical devices and medication are contraindicated for photoepilation or electrolysis and the service provider is expected to liaise with the service user's GP or the SGIS when required.

All service providers should provide evidence of CPD for personnel

A final report on facial hair reduction will be written by the hair reduction service provider, and made available to the service user and the SGIS. This report will describe the treatment outcome and provide an assessment of the course of treatment, whether completed or not.

If the treatment did not achieve the objectives the reason will be fully explained and include, where applicable, the required actions for fulfilment of the objectives.

vi. Donor site hair epilation

Description

Donor site epilation is intended to achieve the permanent removal of hair from the donor site. It is required by both trans women and trans men prior to certain gender surgery and intended to prevent post- operative complications that result from the presence of hair in areas that are inaccessible or cannot be treated effectively following surgery. An assessment whether the hair removal treatment has either met the target of persistent hair removal or reached a point where further treatment is ineffective should be initially made by the service provider. The final determination of any further need for donor-site hair removal should be made by the surgical team.

Hair removal by either photoepilation or electroepilation is provided in both clinical and non-clinical environments. For example, many photoepilation (laser/IPL) clinics that provide hair removal are private concerns, but based within NHS hospitals while electroepilation is mainly provided within beauty salons.

Criteria

 Donor site epilation is not limited by funding but will be commissioned in blocks of 40 hours and will continue until a clinically acceptable outcome is achieved.

Standards

Standards for donor site epilation are identical to those required of facial hair depilation (see section v. above).

vii. Provision of virilising (bilateral partial mastectomy and male chest reconstruction, female-to-male chest surgery) chest surgery

Description

Bilateral partial mastectomy and male chest reconstruction is frequently the only surgical procedure desired by trans men. This, along with appropriate hormone treatment allows many trans men to feel comfortable with their gender identity and to live their lives in comfort. For many however it is the first surgical intervention of several that confirm their gender identity.

Trans men desiring chest surgery will often opt to have their surgery as early as possible in the pathway. This allows them to undergo the period of living in a gender role that is congruent with the gender identity without the need for chest binding, which is often painful and can cause permanent damage.

There are essentially two techniques, the Double Incision Technique & Peri-Areolar Technique. Surgeons should be familiar with both techniques and should be prepared to compare and contrast both. A specific consent form is suggested. Other techniques, such as liposuction, may also be provided in appropriate cases.

The choice of technique will be made on the basis of the surgeon's clinical judgement, informed by discussion and service user preference.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- Single opinion from a gender specialist

Standards

A unit offering chest surgery for gender reassignment will be expected to perform a minimum of 10 operations (including at least 5 trans woman or at least 5 trans man) in a calendar year, so that the skills of the entire unit are maintained. New units should be able to demonstrate that they will receive sufficient referrals to maintain a satisfactory volume of cases.

A chest reconstructive surgeon is likely to be either from a breast onco- plastic or plastic surgical background, and as such will be on the appropriate specialist register and have received the relevant training in mastectomy and related reconstructive techniques such as breast augmentation and breast liposuction.

A specialist nurse is able to support the service user through the surgical pathway and will ideally be involved from the outset i.e. pre- operatively as well as being available for advice/support whilst an in- patient and out-patient.

The most common complications are those of haematoma and infection. Both rates should be less than 5%. Revision surgery should be required in less than 5% of service users. Venous thromboembolism and its prophylaxis must be considered and provision will depend on local protocol and procedure.

viii. Provision of feminising or virilising genital reconstruction surgery Description

SGIS providers and Clinical Networks will provide Genital Reconstructive Surgery for Gender Dysphoria for service users on the basis of clinical need and service user choice.

The aims of genital reconstructive surgery (GRS) are to achieve one or more of the following goals

- · Remove superfluous anatomy
- Enable sexual function
- Permit acceptable urinary function (which in the case of trans man patients this may include use of a urinal
- Provide visually acceptable external genitalia
- Minimise donor site scarring

The surgery provided as part of SGIS consists of one or more of the following procedures;

For Trans woman patients

- Penectomy
- Orchidectomy
- Vaginoplasty
- Clitoroplasty
- Labioplasty

For Trans man patients

- Hysterectomy
- Salpingo-oophorectomy
- Vaginectomy
- Metatoidioplasty
- Phalloplasty
- Urethroplasty
- Scrotoplasty
- Implantation of testicular prostheses
- Implantation of penile prosthesis

Not all service users have all procedures and whilst most trans women require the full range of procedures some do not; for example some choose not to have a vaginoplasty, or choose orchidectomy alone. Likewise, some trans men will not require phalloplasty and some of those who do, will not require urinary or sexual function and thus will not require urethroplasty or penile prostheses.

Some procedures, particularly phalloplasty, require multiple stages. Individual components of the pathway should be combined when appropriate to minimise the number of admissions. Service users' surgical pathways will be tailored to fulfil individual requirements, so as to maximise outcomes within the optimum number of admissions.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they
 must be reasonably well controlled
- Two opinions, at least one of which is from a gender specialist and another from either a gender specialist or GP
- 12 months continuous endocrine treatment as appropriate to the patient's goals
- Concurrence of referral and eligibility criteria by surgical MDT

Service Standards

A unit offering GRS will be expected to perform a minimum of 25 cases in a calendar year, so that the skills of the entire unit are maintained. New units should be able to demonstrate that they will receive sufficient referrals to maintain a satisfactory volume of cases.

Surgeons performing genital surgeries should be urologists, gynaecologists, plastic surgeons, or general surgeons, and certified as such by one of the Royal Colleges. They should have specialised competence in genital reconstructive techniques as indicated by documented further training with an experienced genital reconstructive surgeon. Surgeons should regularly attend professional meetings where new techniques are presented and visit other units to see other techniques and exchange ideas.

Surgeons should be knowledgeable about the full range of surgical techniques for genital reconstruction so that they, in consultation with service users, can choose the most appropriate technique for each individual. They should ideally offer a range of techniques but if a surgeon is skilled in a single technique and this procedure is either not suitable for or desired by a service user, the surgeon should inform the service user about other procedures and offer referral to another

appropriately skilled surgeon, possibly by another provider.

Each service user will be assisted to understand and make appropriate informed decisions regarding the types and variations of surgical intervention, as appropriate, to ensure confidence about these decisions.

Each service user will receive detailed verbal, written and pictorial information on available surgical interventions, including likely outcomes and possible limitations and complications of surgery, and appropriate aftercare.

Service users who are offered surgery will be assessed by a member of the surgical team to confirm their physical suitability and fitness for surgery.

During admission to hospital for surgery, service users should be admitted to a ward where there are nurses experienced in caring for this group, or where care can be supervised by a clinical nurse specialist. Nurses working in these units should undergo training in pack removal, recatheterisation and other skills needed in this group, and only trained nurses, or the surgeons, should undertake these procedures. As an in-patient, service users must be offered the option of use of side rooms/personal rooms.

On discharge from the hospital, service users will be given contact details for a Clinical Nurse Specialist or other team member, who may be contacted in case of problems. A member of the surgical team will be available to answer queries from other practitioners to whom the service user might go in the event of complications, such as A&E units, GP's and other non-gender surgical units.

Service users undergoing GRS will be offered follow up appointments in the unit providing the primary surgery, or by a surgeon from that unit who may visit a clinic geographically closer to the service user. Further follow up continues until the surgeon is confident that complete healing has taken place.

Revision surgery

In cases where revision procedures are appropriate, this is usually apparent within the first year after surgery, and arrangements for such procedures should normally be made within that timescale and provided as a part of SGIS. Service users should be made aware, however, that there are inevitably limitations to the quality of the cosmetic and functional result which can be achieved. If a service user feels that further revisions might improve the cosmetic appearance, which the surgeon does not consider practical or appropriate, it would

be open to the service user to seek a second opinion, either from a different surgeon in the same unit, or from another unit. If the second opinion agrees with the first opinion, further surgery will not be funded by NHS England.

Longer term problems may arise that require further surgery. These are normally related either to malfunction of a prosthesis or stricture formation within a neourethra.

Service users seeking revision surgery more than a year after their primary surgery would normally be expected to be referred to a unit de novo. Such referrals might either originate with the GP or a GIC clinician. Service users should be advised of any facilities that are available to manage the problem that has occurred within their local area and a referral organised where appropriate.

ix. Provision of gonadectomy (hysterectomy and bilateral salpingooophorectomy or bilateral orchidectomy) when feminising or virilising genital reconstruction surgery is not included in the personalised care agreement

Service

Service users undergoing gender reassignment surgery as part of a female-to-male(FTM) transition usually have hysterectomies and oophorectomies to remove the primary sources of female hormone production. This reduces the requirement for hormonal control of natal sex characteristics. For health reasons, some trans men have these organs removed prior to full gender reassignment surgery, as it reduces risk for developing Polycystic ovary syndrome and other ovarian and uterine problems due to the higher doses of testosterone being administered as part of the process; some, however, wait to have a hysterectomy and oophorectomy as part of the full gender reassignment surgery procedure to avoid having multiple surgeries over the course of their transitions.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- Two opinions, at least one of which is from a gender specialist and another from either a gender specialist or GP
- 12 months continuous endocrine treatment as appropriate to the patient's goals

Standards

A unit offering gonadectomy for gender dysphoria will have published policies on provision of care for trans, non-binary and non-gendered people, specifying arrangements for out-patient consultations, in-patient accommodation and training of all staff, clinical and non-clinical in caring for their needs, and respecting their dignity.

Surgeons performing gonadectomy should be urologists, gynaecologists, plastic surgeons, or general surgeons, and certified as such by one of the Royal Colleges.

x. Gamete storage

Service

Cryopreservation is a technique that freezes an individual's eggs or sperm for use in future fertility treatment. Cryopreservation of sperm is a well-established technique used to maintain an individual's fertility. Cryopreservation of eggs is a newer technology, though has been widely used in relation to cancer treatment for a number of years.

Patients eligible for NHS-funded gamete cryopreservation should be about to commence a treatment that may cause permanent infertility as a result of that treatment. Treatments considered appropriate for commissioning of prior gamete cryopreservation are:

- Feminising endocrine therapy
- Virilising endocrine therapy
- Gonadectomy, either as a part of genital reconstructive surgery or as a separate procedure

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they
 must be reasonably well controlled
- Registered with a GP in England
- Receiving care for gender dysphoria through NHS Englandcommissioned SGIS
- People with ovaries of reproductive age up to 42 years old (stimulation treatment to take place prior to individual's 43rd birthday)
- People with testes of reproductive age up to 55 years old (sperm retrieval to take place prior to individual's 56th birthday)

- Written consent to treatment and gamete storage is required
 Individuals will **not** be eligible for NHS-funded gamete cryopreservation if:
 - Gametes are being frozen for non-medical or non-surgical reasons, such as for social reasons
 - They have previously been sterilised
 - Their infertility is as a result of a congenital disorder

Standards

A unit offering gamete collection and storage for service users will have published policies on provision of care for trans, non-binary and non-gendered people, specifying arrangements for out-patient consultations, in-patient accommodation and training of all staff, clinical and non-clinical in caring for their needs, and respecting their dignity.

Gamete storage will only be funded at centres licensed by the Human Fertilisation and Embryology Authority. Access into services for gamete cryopreservation will be by referral by a clinician at the lead provider of SGIS.

xi. Thyroid chondroplasty

Description

SGIS providers and Clinical Networks will provide thyroid chondroplasty for Gender Dysphoria for service users on the basis of clinical need and service user choice.

Thyroid chondroplasty may be combined with other surgical procedures, such as phonosurgery, if the eligibility criteria for each procedure are fulfilled, if it is appropriate in the clinical judgment of the surgeon, and if this is the service user's preference.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- Recommendation and referral from a clinician working as part of the MDT of the Lead Provider service of a Clinical Network.

Standards

Service users will be treated in a clinically-appropriate area. In outpatients, this will include giving the option of attending a separate clinic for transitioning patients or in a clinic separated in time from service

users of a different group. As an in-patient, service users must be offered the option of use of side rooms/personal rooms.

Consent will be obtained at a specific pre-op appointment, so as to allow an informed process and give the service user adequate time to consider any relevant options/alternatives in the less formal setting of out-patient service users rather than on the morning of surgery. Each service user should receive detailed oral, written and pictorial information on available surgical interventions, including likely outcomes and possible limitations and complications of surgery, and appropriate aftercare. Service users who have been offered surgery will be assessed by a member of the surgical team to confirm their physical suitability and fitness for surgery.

Service users should undergo the relevant pre-op laboratory tests according to local protocol. The service user's GP will normally be asked to arrange these tests locally.

The time of gender transition surgery is a vulnerable point and service users undergoing this should be cared for in an appropriate environment. As an in-patient, service users must be offered the option of use of side rooms/personal rooms. Nursing staff should be experienced in the care of such service users.

It is important to note that the surgical procedure is only a part of the overall surgical management and it would be expected that the patient would be seen both pre and post-operatively for surgical assessment and on more than one occasion if clinically indicated.

Communication with the referring specialist and GP should occur by letter at the time of discharge from hospital and at all subsequent post-operative out-patient consultations. If on-going surgical follow-up is indicated, this should be communicated to the referring specialist and GP.

A member of the surgical team will be available to answer queries from other practitioners to whom the service users might go in the event of complications, such as A&E units, GP's and other non-gender surgical units.

A unit offering thyroid chondroplasty for gender dysphoria will have published policies on provision of care for trans, non-binary and non-gendered people, specifying arrangements for out-patient consultations, in-patient accommodation and training of all staff, clinical and non-clinical in caring for their needs, and respecting their dignity. As an in-patient, service users must be offered the option of use of side rooms/personal rooms.

surgeons offering thyroid chondroplasty as part of SGIS should perform at least five procedures per year per unit, and be certified by one of the Royal Colleges.

Xiii Second Line Treatments

In specific circumstances for specific procedures where the primary treatment has failed, second line treatments will be commissioned. Second line treatments for gender identity disorders are listed below with a brief description including the specific circumstances for access and the criteria that must be met

a) Feminising chest surgery (breast augmentation; augmentation mammoplasty)

Description

The choice of technique will be made on the basis of the surgeon's clinical judgment, informed by discussion and service user preference.

Augmentation mammoplasty should not be confused with breast enhancement in natal women. It is a necessary and vital part of gender reassignment for the minority of trans women for whom the First Line Treatment of endocrine therapy has had little or no effect on breast tissue development. Breast tissue development is a major determinant of a successful outcome for many trans women.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- At least 24 months of adequate feminising hormone therapy (to include adequate suppression of testosterone)
- Failure of First Line Treatments to facilitate adequate breast tissue growth as judged by the Lead Provider Service MDT
- A single recommendation and referral from a clinician working as part of the Multi-Disciplinary-Team of the Lead Provider Service of a Clinical Network

Standards

Augmentation mammoplasty should be performed by surgeons with appropriate experience of subglandular and submuscular implant positions with specific reference to transgender service users.

A unit offering chest surgery for gender reassignment will be expected to perform a minimum of 10 cases (including at least 5 trans woman or

at least 5 trans man) in a calendar year, so that the skills of the entire unit are maintained. New units should be able to demonstrate that they will receive sufficient referrals to maintain a satisfactory volume of cases.

A chest reconstructive surgeon is likely to be either from a breast onco-plastic or plastic surgical background and as such will be on the appropriate specialist register and have received the relevant training in mastectomy and related reconstructive techniques such as breast augmentation and breast liposuction.

The most common complications are those of haematoma and infection. Both rates should be less than 5%. Revision surgery should be required in less than 5% of service users. Venous thromboembolism and its prophylaxis must be considered and provision will depend on local protocol and procedure.

b) Phonosurgery

Description

Phonosurgery (voice-modifying) may be offered as a part of SGIS to patients who engage in speech and language therapy but do not achieve treatment goals, and who are assessed by a Speech and Language Therapist (SLT) and surgeon as being likely to benefit from such surgery. To be eligible for referral, patients must agree to engage in further speech and language therapy, which is essential to voice and communication development, after phonosurgery.

The surgical technique provided as part of SGIS is cricothyroid approximation, sometimes with thyroid chondroplasty, if this is considered necessary in the surgeon's clinical judgment.

Criteria

- Persistent and well documented gender dysphoria
- Capacity to make fully informed decisions and to consent to treatment
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- Completion of a course of therapy supervised by a qualified

Speech and Language Therapist

- A recommendation for referral to the Lead Provider Service of the Clinical Network by the qualified SLT
- Referral to a phonosurgery provider will only be accepted from a clinician working as part of the MDT of the Lead Provider service of a Clinical Network, who will include the written recommendation of the SLT with their referral.

 Provision of voice surgery procedures will include follow-up sessions with a SLT.

Standards

A unit offering phonosurgery for gender dysphoria will have published policies on provision of care for trans, non-binary and non-gendered people, specifying arrangements for out-patient consultations, inpatient accommodation and training of all staff, clinical and non-clinical in caring for their needs, and respecting their dignity. As an in-patient, service users must be offered the option of use of side rooms/personal rooms.

Surgeons offering phonosurgery as part of SGIS should perform at least five procedures per year per unit, and be certified by one of the Royal Colleges.

The following interventions are **not** provided by SGIS and will not be commissioned or funded by NHS England:

- i. Prescribing and monitoring of any medication for the treatment of gender dysphoria recommended by SGIS providers, or the cost of such prescription medication and monitoring procedures. Arrangements for prescribing and monitoring are described in a Specialised Services Circular, "SSC1417 Primary Care responsibilities in relation to the prescribing and monitoring of hormone therapy for patients undergoing or having undergone gender dysphoria treatments"
- ii. Facial feminising and masculinising surgery
- iii. Lipoplasty
- iv. Hair transplant
- v. Body hair removal (other than donor site)
- vi. Body contouring

This list is not exhaustive

8. Patient pathway

See Appendix 1

9. Governance arrangements

Specialised Gender Identity Services should only be delivered by those services accredited by NHS England and able to meet the standards described in this document and the associated Service Specification

10. Mechanism for funding

NHS England contracts with suitably accredited Specialised Gender Identity Services or Networks via the relevant Area Team. NHS England will not pay for Gender Identity services from providers they do not have contracts with.

11. Audit requirements

There is currently no centrally-held database to which Specialised Gender identity Services or Networks report. They do however report to the relevant Area Team on locally agreed data sets.

Area Team Commissioners will develop a consistent national data set against which all Gender identity services or Networks report and will work nationally to audit that data.

The data should provide information about:

- Numbers referred
- Waiting times
- Numbers in service
- Length of stay
- Number of Second Line Treatment pathway referrals
- Discharges

Commissioners will also work with providers to measure;

- Patient satisfaction data
- Quality of Life indicators pre and post service

Lead Service Providers will continue to supply Patient Notification Forms to host and originating Area Teams for all interventions and procedures accessed by service users.

12. Documents which have informed this policy

UK Inter Collegiate Good Practice Guidelines for the assessment and treatment of adults with gender dysphoria – October 2013

- World Professional Association for Transgender Health Standards of care
 7th version 2012
- Gender Identity Services CRG sub group report on Hair Reduction
 Colthurst M.J March 2014
- Gender Identity Services CRG sub group report on Voice and Communication Therapy Greener Dr Helen Marie April 2014.

 Gender Identity Services CRG sub group report on Chest Surgery in Trans patients – Yelland Dr Andrew – October 2012.

13. Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed in April 2016 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

Haedersdal M, Gøtzsche PC. *Laser and photoepilation for unwanted hair growth.* Cochrane Database of Systematic Reviews 2006, Issue 4. Art. No.: CD004684. DOI: 10.1002/14651858.CD004684.pub2

Sadighha A, Mohaghegh Zahed G. *Meta-analysis of hair removal laser trials.* Lasers Med Sci. 2009 Jan;24(1):21-5.

Haedersdal M, Wulf HC. *Evidence-based review of hair removal using lasers and light sources.* J Eur Acad Dermatol Venereol. 2006 Jan;20(1):9-20.

Lou WW, Quintana AT, Geronemus RG, Grossman MC. *Prospective study of hair reduction by diode laser (800 nm) with long-term follow-up*. Dermatol Surg 2000; 26: 428–432.

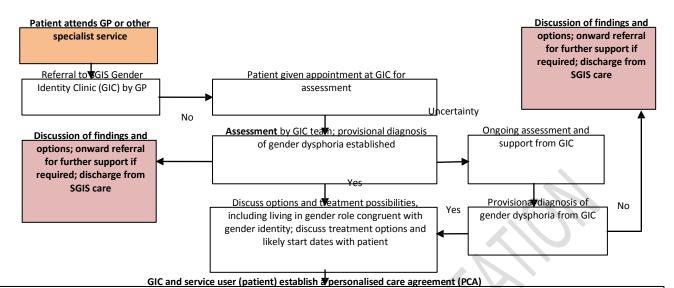
Klein A, Steinert S, Baeumler W, Landthaler M, Babilas P. *Photoepilation with a diode laser vs. intense pulsed light: a randomized, intrapatient left-to-right trial.* Br J Dermatol. 2013 Jun;168(6):1287-93.

Murad MH, Elamin MB, Garcia MZ, Mullan RJ, Murad A, Erwin PJ, Montori VM. Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. Clin Endocrinol (Oxf). 2010, 2(2):214-31.

Day P. *Trans-gender reassignment surgery.* 2002. [Online] New Zealand Health Technology Assessment (NZHTA) 2002: 25. Available at http://nzhta.chmeds.ac.nz/publications.htm [Accessed 26 April 2010]

Sutcliffe P., Dixon S., 2002. [Online] *Gender reassignment surgery, evidence-based commissioning collaboration.* The school of health and related research (ScHARR), University of Sheffield. Available at http://www.pfc.org.uk/files/ScHARR.pdf [Accessed 21 May 2010].

Appendix 1



PCA is agreed between service user and GIC, with provisional timelines for interventions; second opinion from another GIC and transfer of care may be requested

GP and service user provided with copies of PCA

Regular follow up appointments as agreed with GIC including signposting sessions for family members, partners and carers, as necessary and as agreed with service user

Continuing review and discussion of PCA at each consultation, and update with MDT, as necessary

If progressing towards genital surgery, should complete agreed period living in gender role congruent with gender identity

GIC, acting as Lead Provider, co-Trdinates delivery of the PCA

Care will be delivered in accordance with Good Practice Guidelines for the Assessment & Treatment of Adults with Gender Dysphoria (Royal College of Psychiatrists CR181; October 2013)

Interventions are provided according to clinical need, in an order appropriate for the individual; not all service users will require all these interventions

- Information-giving and provision of advice to service users
- Specialised psychological therapies
- Gamete collection and storage
- Endocrine therapy
- Voice and communication therapy
- Epilation
- Surgery
 - o Genital reconstruction
 - Gonadectomy
 - o Chest reconstruction (special criteria apply for augmentation mammoplasty for trans women)
 - Phonosurgery (special criteria apply)
 - o Thyroid chondroplasty

Establishment of a shared care agreement with the referring GP

Effective communication with service user's GP, giving information on progress through the PCA and its impact on gender dyphoria, recommendations for prescribing and safety monitoring, providing professional support and information, and discharge planning

Second opinion from another GIC and transfer of care may be requested

Discharge to Primary Care for long-term treatment needs, including hormone therapy, safety monitoring and health maintenance/promotion

Following discharge to Primary Care, GP may request advice from GICs about hormone therapy, safety monitoring and health maintenance/promotion

Re-referral to SGIS GIC required if gender dysphoria recurs

ORAFI FOR PUBLIC ONSULTATION

ORAFI FOR PUBLIC ONSULTATION