

Gender Dysphoria COMMISSIONING POLICY

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Author:	Susan Thompson, Acting Commissioner, Mental Health Specialised Services, HCW
Owner:	Susan Thompson, Acting Commissioner, Mental Health Specialised Services, HCW
Client:	Stuart Davies, Acting Chief Executive HCW

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1 Introduction

The purpose of this Commissioning Policy is to clearly set out the circumstances under which patients will be able to access the services specified.

The policy clarifies the referral process, indicates which organisations are able to provide services for Welsh patients and defines the criteria that patients must meet in order to be referred.

In addition the policy provides background information to support the proposed level of access; this includes the epidemiology and anticipated outcomes.

1.1 Relationship with other Commissioning Policies

This policy should be read in conjunction with the following policies:

Health Commission Wales (HCW) Commissioning Plan.

1.2 HCW approach to specialist gender identity services

Gender Dysphoria is a rare condition in which there is an experience of oneself as male or female, which is incongruent with the external characteristics of the body. An individual with profound and persistent Gender Dysphoria may need medical treatment to facilitate a transition of status to live in accordance with his or her core gender identity rather than with the phenotype.

1.3 Review

The Health Commission Wales Commissioning Policy Group will review this policy on an ongoing basis pending development of specialist services in Wales. All reviews will take into account publication of relevant guidance, for example, from National Institute for Clinical Excellence (NICE).

2 Clinical Definition

Two main diagnostic systems for Gender Dysphoria in operation,

*International Classification of Diseases (ICD-10) category F64.0*¹

Gender Dysphoria is defined as:

A desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex.

Diagnostic and Statistical Manual of Mental Disorders (IV) category 302.85 (DSM) ²

All the following criteria must be met for the diagnosis of Gender Dysphoria to be made:

- A strong desire or persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).
- Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.
- The disturbance is not congruent with a physical intersex condition.
- The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

3 Epidemiology

A recent survey carried out in general practices in Scotland ³ estimated the prevalence of Gender Dysphoria (including those not currently accessing services, those receiving Gender services, and post Gender Reassignment Surgery (GRS) individuals to be 8.18 per 100,000 population in those aged 16 years or over, with a ratio of 4 male to female individuals to 1 female to male individual.

Using Welsh Assembly Government data the population for Wales in 2005 was 2,391,912 ages 16 years or over, indicating a prevalence figure of 196 (1:12,225) for the population in Wales.

Olsson SE and Moller AR ⁴ reported an annual incidence rate of .019 per 100,000 population over 15 years of age in Sweden. Using Welsh Assembly Government data this indicates an incidence figure of 4.5 per annum in Wales.

4 Evidence Base

Studies in Gender Dysphoria are limited by the following:

- Lack of randomised controlled trials; mainly cohort studies and case series
- Lack of standardised selection criteria in most studies. A review of effectiveness conducted by the Aggressive Research Intelligence Facility (ARIF) ⁵ at the University of Birmingham in July 2004 concluded that “The degree of uncertainty about any of the effects of gender reassignment is such that it is impossible to make a judgement about whether the procedure is clinically effective.” The authors also stated that, due to the flawed nature of the research, the only way to reduce uncertainty is to undertake a well designed Random Controlled Trial (RCT).

Best and Stein ⁶, conducted a review in 1998 and their conclusions are as follows:

- The evidence to support GRS is limited
- The actual magnitude of harm and benefit cannot be determined due to lack of good evidence

Peter Day ⁷ conducted a Health Technology Assessment on gender reassignment surgery in 2002 and his conclusions are as follows:

- There is insufficient evidence to prove the efficacy of Sex Reassignment Surgery (SRS) for specific subgroups.
- The study designs of the included studies had methodological weaknesses.
- There is limited evidence that early rather than delayed SRS may offer greater benefit to carefully selected individuals.
- SRS may be of benefit to carefully assessed and selected transsexual people.

Smith et al in 2005 ⁸ prospectively studied outcomes of sex reassignment, potential differences between subgroups of transsexuals, predictors of treatment course and outcome in consecutive 325 patients of whom 162 completed the study. Their conclusions are as follows:

- After treatment the treated group were no longer gender dysphoric
- The vast majority functioned well psychologically, socially and sexually
- Two non-homosexual male-to-female transsexuals expressed regrets
- Post-operatively, female to male and homosexual transsexuals functioned better in many respects than male-to-female and non-homosexual transsexuals

Mate-Kole et al ⁹ did a small controlled study of two groups of 20 patients accepted for gender reassignment surgery; one was offered early operation and therefore had surgery by follow-up two years later, while the second was still awaiting operation at two-year follow-up. Their conclusions are as follows:

- Significant differences emerged at follow-up in terms of neuroticism and social and sexual activity
- The early operated group benefited by the earlier intervention
- Eldh et al ¹⁰ in 1997 studied the long-term follow-up of 136 patients who had undergone GRS. Their conclusions are as follows:
 - Optimal results of the operation were essential for a successful outcome
 - Personal and social instability before operation, unsuitable body build, and age over 30 years at operation correlated with unsatisfactory results
 - Adequate family and social support important for postoperative functioning
 - GRS had no influence on a person's ability to work

5 Commissioning Responsibility

As specified in Welsh Health Circular (WHC), (2003) 63,¹¹ Health Commission Wales (Specialist Services) has responsibility for funding of care of patients requiring specialist gender identity services.

5.1 Gender Identity Services

- Specialist assessment
- Specialist monitoring of Real Life Experience (RLE) and hormone treatment
- Gender Reassignment Surgery

Patients accessing specialist services will remain under the care of local services on a shared care basis.

6 Quality

Gender Identity services commissioned by Health Commission Wales will comply with the Harry Benjamin International Gender Dysphoria Association (HBIGDA) standards of care and Good Practice Guidelines for the Assessment¹² and Treatment of Gender Dysphoria, RCPsych Intercollegiate SOC Committee.¹³

7 Performance Management

HCW will be responsible for commissioning services in line with this policy. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this policy the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care
- Health Commission Wales will conduct performance and quality reviews on an annual basis

8 Service Provision

The availability of services across the country is very limited. There is no nationally recognised service in Wales offering an assessment and treatment service.

There is currently no provision of surgery for sex reassignment in Wales. There are a number of NHS surgical units in England performing GRS procedures, including Leicester General Infirmary, Hammersmith Hospital and University College Hospital London.

It is generally recognised that in established centres, two levels of intensity of service are provided, while maintaining the Harry Benjamin standards of care reflecting different levels of patient need for support. The two levels of intensity are:

- Level one: for patients who are actively progressing through the treatment stages and who require regular psychotherapy and monitoring every one to three months.
- Level two: for patients requiring ongoing input from Gender Identity specialist professionals on a six-monthly to yearly basis.
-

Although there is no single model for treatment, the care pathway for individuals with Gender Dysphoria includes assessment, supportive psychotherapy, the 'real life experience', hormone therapy and surgical interventions. Patients accessing specialist services will also continue to have access and support from local services.

8.1 NHS Service Providers

Gender Identity Clinic, West London Mental Health Trust
Hammersmith Hospital
University College Hospital London
Leicester Royal Infirmary

8.1.1 Criteria for Designating a Provider

The commissioner will set out the specific criteria that a provider must fulfil in order to be considered as a designated provider.

Where appropriate Health Commission Wales will establish Service Level Agreements with designated tertiary provider(s). The Service Level Agreements allow Health Commission Wales to monitor performance and activity, together with the quality and clinical governance standards expected from the provider(s).

8.1.2 Requirements of Designated Provider

- Compliance with the Welsh Gender Dysphoria Commissioning Guidance
- Compliance with national standards of care.
- Continued engagement with referring clinical team.
- Provision of timely and accurate activity information as specified by Commissioner.
- Provision of progress reports as specified by the Commissioner.

9 Care Pathway

9.1 *Real Life Experience*

- The progression from one gender role to the other requires supervised progress through changes in social, domestic and work life.
- The Real Life Experience is a period of time, usually one to two years, living in the gender role with which the individual identifies, with the aim of assisting the patient and the professional's decisions about how to proceed.
- The quality of the real life experience is assessed through the patient's ability to maintain employment, voluntary work or education and training, to acquire a legal gender-identity-appropriate first name and to demonstrate that people are aware that they are living in their new role.

9.1.1 *Hormone Therapy*

Hormone therapy treatment is an important component in the medical treatment of Gender Dysphoria. The administration of sex hormones of the opposite gender induces development of secondary sexual characteristics, some of which are irreversible, and has potential negative medical side effects. Hormones are administered only after all the necessary health checks are completed, informed consent is given and the patient fulfils the following criteria.

- Full assessment undertaken by the specialist service; and
- Competent to consent to receive treatment consistent with safe clinical practice; and
- The patient is at least 18 years of age; and
- Demonstrable knowledge of what hormones medically can and cannot do, and their social benefits and risks; and
- A documented real-life experience of at least 3 months prior to administration of hormones or;

Note: HCW is advised by clinicians specialising in the treatment of Gender Dysphoria that it is preferable that hormone treatment is not commenced prior to specialist assessment as it could compromise the assessment and may delay or jeopardise further treatment.

9.1.2 *Surgery*

Gender Reassignment Surgery (GRS) aims to alleviate the psychological discomfort of patients with profound Gender Dysphoria through irreversible changes to the body in line with the individual's gender identity.

9.2 *Waiting Times*

The service is not subject to waiting time targets.

9.3 Advisory Panel

All applications for funding will be considered against the criteria outlined in the Commissioning Policy. This function will be carried out by a panel of clinicians who will act as advisors to HCW. The panel will assess each application for appropriateness of referral and robustness of clinical evaluation by the referring clinician.

In order to achieve and maintain a balanced approach membership will consist of NHS clinicians who have a registered special interest in Gender Dysphoria and suitably qualified NHS clinicians who have experience of the condition and wish to progress in this area. In the interests of time, efficiency and limited pool of NHS clinicians HCW will select and appoint panel members.

The panel will act in an advisory capacity only and strictly in accordance with the commissioning policy.

9.4 Referral Pathway

- The patients GP will initially refer the patient to a local NHS Consultant Psychiatrist
- The local Consultant Psychiatrist will assess the patient, and if appropriate, submit a funding application to HCW for a referral to specialist gender identity disorder services. The application will be reviewed by a panel of clinicians who will advise HCW on the most appropriate care pathway. The panel replaces the usual requirement for two NHS consultant opinions.
- On receipt of funding authorisation the referring clinician will refer to the specialist service provider.
- The specialist service provider will confirm to HCW that it is appropriate for the patient to access treatment and again on completion of a period of Real Life Experience normally a minimum of 24 months
- For patients who wish to proceed to surgery the specialist service provider will inform HCW if the patient is considered appropriate for referral for reassignment surgery.
- HCW authorises referral to an HCW approved NHS Gender Reassignment Surgery (GRS) provider for assessment of suitability for surgery. *It is normal clinical practice for two surgical opinions to be obtained before a patient is accepted for surgery.*
- Patient undergoes appropriate GRS and returns to follow-up with specialist service provider.
- Patient discharged from the specialist services when appropriate and returns to primary care for maintenance hormone therapy and monitoring

10 Access Criteria

All referrals to specialist gender identity services should be made by a Consultant Psychiatrist only after obtaining prior funding approval from HCW. The criteria for referral to specialist services are that the patient should meet the ICD-10 and/or the DSM (IV) criteria for Gender Dysphoria.

10.1 Access criteria/ rationale

This section sets out the criteria that qualify a patient for treatment funded by HCW

10.1.1 Clinical Diagnosis

Diagnosis of Gender Dysphoria in an adult requires four criteria to be met,

- 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; and
- The transsexual identity has been present persistently for at least two years; and
- The disorder is not a symptom of another mental disorder or chromosomal abnormality; and
- The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning;

10.1.2 Readiness for Gender Reassignment Surgery

Gender Reassignment Surgery is one treatment option for extreme cases of Gender Dysphoria and it is to be noted that not all patients choose this treatment pathway. HCW acknowledges the invasive and irreversible nature of genital surgery and its consequences. In light of this, the purpose of this policy is to ensure that surgery is only undertaken on patients who have undergone a clinical assessment for surgery and who will truly benefit from it and are capable of given informed consent. Therefore consideration for funding gender reassignment surgery will only be given to patients who meet the following criteria:

- The patient is at least 18 years old; and
- A minimum of 2 years full time residency in Wales; and
- Has undergone a minimum of 12 months continuous hormone therapy when recommended by a health professional and provided under the supervision of a physician; and
- Has completed a period (normally a minimum of 24 months) of successful continuous real-life experience with no returning to their original gender; including one or more of the following;
- For patients requiring a mastectomy, a minimum of 1 year successful continuous real-life experience will have been completed, with no returning to their original gender.
- Maintain part or full-time employment; or
- Function as a student in an academic setting; or
- Function in a community-based volunteer; and
- Acquire a legal gender-identity appropriate name change; and
- Regular participation in psychotherapy throughout the real-life experience when recommended by a treating medical practitioner; and
- Demonstrable progress in consolidating one's gender identity role.

- Demonstrable progress in dealing with work, family and interpersonal issues resulting in a significantly better state of mental health. This implies satisfactory control of problems such as sociopathy, substance misuse, psychosis, suicidality and self harm.
- Demonstrable knowledge of the required length of hospitalisation, likely complications and post surgical rehabilitation
- Written confirmation that the surgeon is satisfied that the patient meets the above criteria, understands the ramifications and possible complications of surgery, and that the surgeon is of the view that the patient is likely to benefit from surgery.

Note: A bi-lateral mastectomy would normally be provided after 12 months on the pathway unless there are clinical or patient reasons not to proceed.

Gender reassignment surgery is considered not medically necessary when one or more of the criteria above have not been met.

10.1.3 Gender Reassignment Surgery

Male to female core procedures:

- Penectomy
- Orchiectomy
- Vaginoplasty
- Clitoroplasty
- Labiaplasty

Female to male core procedures:

- Mastectomy
- Hysterectomy
- Vaginectomy
- Salpingo-oophorectomy
- Metoidoplasty or phalloplasty
- Urethroplasty
- Scrotoplasty and placement of testicular prostheses
- Phalloplasty

10.2 Exclusions

The following treatments are not considered to be a core part of treatment for Gender Dysphoria and will not be funded by HCW.

- Breast augmentation in trans women
- Reduction Thyroid chondroplasty
- Rhinoplasty / other facial bone reduction
- Blepharoplasty
- Face-lift
- Hair removal / electrolysis other than site preparation for surgery
- Body contouring – e.g. suction-assisted lipoplasty of the waist

- Voice modification surgery
- Procedures to decrease areas of baldness
- Skin resurfacing – e.g. acid peel (a method of removing the upper layer of skin in order to improve skin smoothness)
- Speech and Language Therapy (accessed through primary and secondary service provision)

HCW may consider authorising funding for excluded treatments where there is a clinical recommendation from the specialist service provider.

10.3 Exceptional circumstances

In the rare or exceptional circumstances where a patient or clinician feel that the patient represents a special case then application can be made to Health Commission Wales, where the case will be considered by the Individual Commissioning Panel.

11 Treatment in another Member State

Patients are entitled to go to another Member State for hospital treatment at NHS expense if they face “undue delay” in accessing that treatment on the NHS, if the particular treatment they are seeking is one that is provided by the NHS and the patient meets any criteria set by the commissioner for accessing that treatment. More detailed information on accessing treatment in another Member State may be found on the Department of Health’s website.

<http://www.nhs.uk/Healthcareabroad/Pages/Healthcareabroad.aspx>

There are two possible routes for accessing treatment in another Member State: the E112 route and the Article 49 route. The article 49 route referred to in the guidance on the DoH website, patients would have to pay up front for their treatment and then claim reimbursement. The level of reimbursement under this particular route is capped at what that treatment would cost to provide under the NHS. The rules relating to reimbursement are different if the E112 route is used. Patients are strongly advised to seek advice from HCW and, if necessary, take their own legal advice, before proceeding to arrange treatment in another Member State. If a patient goes to another Member State without prior authority from HCW he or she may subsequently find that they are not entitled to reimbursement.

12 Appeals

Patients who wish to appeal a decision can access The Health Commission Wales Policy for reviewing cases the HCW web site.

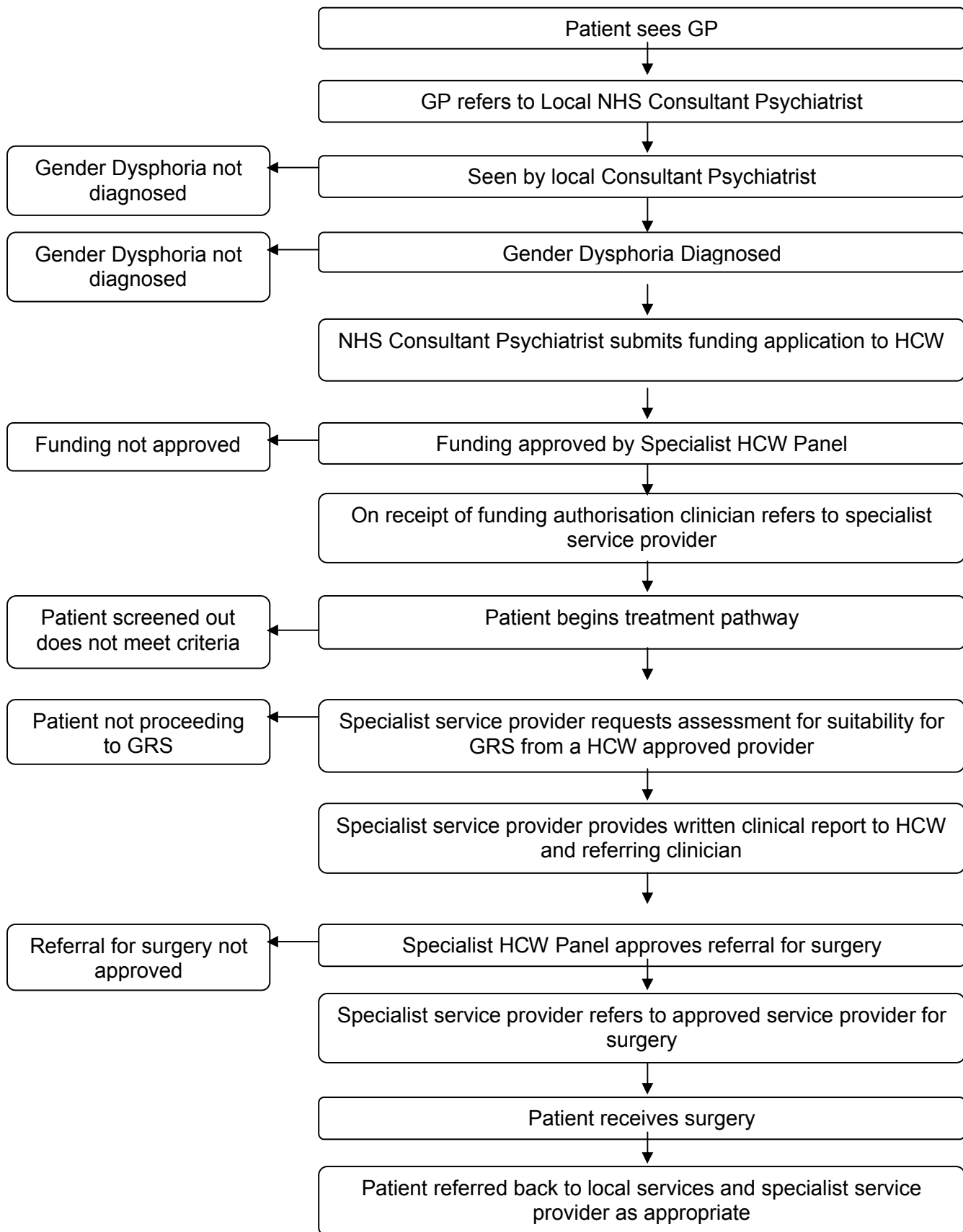
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12 APPENDIX I

References

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- ¹¹ Welsh Health Circular (63) 2003
- ¹² Standards of Care for Gender Identity Disorders. 6th Version. The Harry Benjamin International Gender Dysphoria Association, Inc.(HBIIGDA); 2001
- ¹³ Good Practice Guidelines for the Assessment and Treatment of Gender Dysphoria. RCPsych Intercollegiate SoC Committee Kevan Wylie V8.3b Nov 06

13 APPENDIX II Referral Pathway



14 APPENDIX III Gender Recognition Certificates

Introduction

Some patients wishing to be considered for specialist assessment and treatment under this policy may already have a Gender Recognition Certificate (GRC). This section summarises the key features of the GRC process as they relate to aspects of this policy. The objective of HCW is to ensure that the care pathway takes appropriate account of the stages patients with a GRC may have already completed. The section sets out some of the areas of similarity and potential overlap in the processes.

GRC Process

The process for obtaining a GRC is set out in the Gender Recognition Act 2004. The legal effect of obtaining a GRC is “*Where a GRC is issued to a person, the person’s gender becomes for all purpose the acquired gender*” (Gender Recognition Act 2004 s9(1)).

The Act sets out the determination of applications and the evidence required as per the extract below:

s2 Determination of applications

(1) In the case of an application under section 1(1)(a), the Panel must grant the application if satisfied that the applicant—

- (a) has or has had gender dysphoria,*
- (b) has lived in the acquired gender throughout the period of two years ending with the date on which the application is made,*
- (c) intends to continue to live in the acquired gender until death, and*
- (d) complies with the requirements imposed by and under section 3.*

S3 Evidence

(1) An application under section 1(1)(a) must include either—

- (a) a report made by a registered medical practitioner practising in the field of gender dysphoria and a report made by another registered medical practitioner (who may, but need not, practise in that field), or*
- (b) a report made by a chartered psychologist practising in that field and a report made by a registered medical practitioner (who may, but need not, practise in that field).*

(2) But subsection (1) is not complied with unless a report required by that subsection and made by—

- (a) a registered medical practitioner, or*
 - (b) a chartered psychologist,*
- practising in the field of gender dysphoria includes details of the diagnosis of the applicant’s gender dysphoria.*

(3) And subsection (1) is not complied with in a case where—

- (a) the applicant has undergone or is undergoing treatment for the purpose of modifying sexual characteristics, or*
- (b) treatment for that purpose has been prescribed or planned for the applicant,*

unless at least one of the reports required by that subsection includes details of it.”

The GRC process therefore includes elements of the policy requirement although to a different level of evidence and for a different purpose. The objective of the GRC process is to secure the legal recognition of person's chosen gender.

In contrast the objective of the policy is to ensure that there is a clear care pathway for patients. The policy sets out the level of specialist opinion that is deemed to be required for an individual to proceed all the way through the pathway including surgical options.

Medical Opinion

The GRC process includes the need to have two medical opinions supporting the application, one of which must be a medical practitioner practicing in the field of gender dysphoria.

The policy requires two specialist clinical opinions and confirmation of suitability for surgery from the surgical centre.

HCW would expect that the specialist clinical opinion appropriately takes into account the qualifications and experience of the medical opinion that a person with a GRC has already secured.

Real Life Experience

The GRC requires that the individual "*has lived in the acquired gender throughout the period of two years ending with the date on which the application is made*" (Gender Recognition Act 2004 s2(1)a)

The policy requires that the individual would normally undertake a medically supervised period of two years real life experience (RLE) living in the acquired gender. In some cases the GRC process can be undertaken by a person that has not yet undertaken any medical or surgical treatment. The specialist assessment will need to make a judgement about what period of medical supervision is required given that the individual will have already lived in the acquired gender for two years. In practice, any medical supervision required is likely to be oriented to treatment and medication rather than RLE but this must be a clinical decision.

HCW would expect that the specialist clinical opinion appropriately takes into account the period of real life experience already undertaken by a person with a GRC in determining the length of any period of medical supervision that is required.
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15 APPENDIX IV Abbreviations

HCW – Health Commission Wales

NICE – National Institute for Clinical Excellence

ICD – International Classification of Diseases

DSM – Diagnostic and Statistical Manual of Mental Disorders

GRS – Gender Reassignment Surgery

ARIF – Aggressive Research Intelligence Facility

RCT – Random Controlled Trial

SRS – Sex Reassignment Surgery

WHC – Welsh Health Circular

HBIGDA –Harry Benjamin International Gender Dysphoria Association

RLE – Real Life Experience