Guidance for doctors treating transgender and non-binary patients

This guidance covers adults as well as children and adolescents from around their 16th birthday. Children may transfer into adult services from their 17th birthday.

The <u>first report of the House of Commons Women and Equalities Committee</u> (pdf)¹ highlighted significant concerns about doctors' lack of awareness and consideration in treating transgender patients. In March 2016 the GMC produced guidance for doctors highlighting how the principles of Good Medical Practice apply in relation to trans patients and to explain duties under the Equality Act 2010. This guidance can be found at the following link: http://www.gmc-uk.org/guidance/ethical guidance/28851.asp2 This guidance explains the legal protection against discrimination and harassment given to trans people by The Equality Act 2010 and Gender Recognition Act 2004. At this link there are also details of **free e-learning resources to aid continuing professional development**.

There have been two Specialised Services Circulars around Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Transgender and Non-Binary Adults: SSC 1417³ and SSC 1620⁴.

In recent cases some General Practitioners have declined to accept the advice of the specialist Gender Identity Clinic (GIC) and have refused to prescribe and monitor drug treatments for the treatment of gender dysphoria in people with gender incongruence and trans and non-binary identity. The Royal College of Psychiatrists' <u>Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria</u> ⁵ describes how an increasing number of trans people are self-medicating using hormones and hormone-blockers available via the internet, as a consequence of the difficulties they experience in accessing appropriate primary care services. GMC guidance says:

"You must co-operate with Gender Identity Clinics and gender specialists in the same way that you would co-operate with other specialists, collaborating with them to provide effective and timely treatment for trans and non-binary people. This includes: prescribing medicines recommended by a gender specialist for the treatment of gender dysphoria; following recommendations for safety and treatment monitoring; making referrals to NHS services that have been recommended by a specialist.

Once the patient has been discharged by a Gender Identity Clinic or gender specialist, the prescribing and monitoring of hormone therapy can be carried out successfully in primary care without further specialist input. From the patient's perspective, management in primary care is far easier, and there is no specific expertise necessary to prescribe for and monitor patients on hormone therapy.

It is not necessary to refer trans people back to their gender specialist before referring them to other secondary or tertiary providers, for matters unrelated to their gender history.

If you feel you lack knowledge about the healthcare needs of trans people, you should, in the short term, ask for advice from a gender specialist. In the longer term, you should address your learning need as a part of your continuing professional development which will enable you to provide treatment to meet your patients' needs. E-learning is freely available on the Royal College of General Practitioners' website and carries CPD points".²

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Prescribing cross sex hormones

Prescribing by GPs of cross sex hormones covers post patients' attendance at GICs.

Most of the medicines used for treatment of gender dysphoria are not licensed for this specific indication. GPs are allowed to prescribe 'off-license' where this is necessary to meet the specific needs of the patient, and where there is no suitably licensed medicine that will meet the patient's needs; this would cover gender dysphoria. GMC guidance says:

"Prescribing unlicensed medicines may be necessary where there is no suitably licensed medicine that will meet the patient's need, for example, where:

- There is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
- A medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
- The dosage specified for a licensed medicine would not meet the patient's need; or
- The patient needs a medicine in a formulation that is not specified in an applicable license."8

When prescribing an unlicensed medicine doctors must:

- 1. Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- 2. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- 3. Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.8

Co-operating with GICs is shared care but may not be under a Shared Care Guideline/ Agreement. GPs are advised to ask the GIC if they have a Shared Care or Prescribing Guideline. However once the patient has been discharged by a GIC or gender specialist, the prescribing and monitoring of hormone therapy can be carried out successfully in primary care without further specialist input. From the patient's perspective, management in primary care is far easier, and there is no specific expertise necessary to prescribe for and monitor patients on hormone therapy".²

With regard to prescribing drugs for the treatment of gender dysphoria, as described above:

- The gender specialist physician takes responsibility to assess the capacity of the patient to give meaningful informed
 consent to use such treatment, to explain its potential risks, benefits and limitations, to explain that the treatment is not
 approved for this indication and the implications thereof, and to obtain and document consent before making a
 recommendation to a General Practitioner to prescribe treatment for their patient
- The gender specialist physician takes responsibility for overseeing the patient's care in collaboration with the patient's General Practitioner, and for their recommendation that the General Practitioners prescribe and monitor treatment
- The gender specialist physician will provide the patient's General Practitioner with the clear written guidance on prescribing and monitoring, be available to provide additional information on request, and answer questions regarding treatment and monitoring at reasonable notice.
- General Practitioners should co-operate with the specialist GIC and prescribe hormone therapy (feminising or virilising endocrine therapy) recommended for their patients by the GIC. The specialists at the GIC make recommendations for the prescription and monitoring of these therapies but they do not directly prescribe them, or provide physical and laboratory monitoring procedures for patients.
- The decision on whether or not to provide long-term feminising or virilising endocrine therapy requires the skills of a gender specialist physician, usually working within a GIC.

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- Typical drugs recommended by GICs include oestradiol preparations (e.g. transdermal oestradiol gels and patches, and oral oestradiol preparations), testosterone preparations (e.g. gels, and Sustanon® and Nebido® injection), gonadotropin releasing hormone analogues and depilatory agents (e.g. Vaniqa®); this list is not exhaustive. Apart from Sustanon®, there are no licensed products with an approved indication for the treatment of gender dysphoria. There is, however, extensive clinical experience of the use of these products in the treatment of gender dysphoria over decades, which provides evidence of tolerability and safety comparable with their use for approved indications.
- Lancashire does not recommend the prescribing of depilatory agents (eg. Vaniqa®) as stated in the public health
 commissioning policies. This BLACK status will also apply to transgender patients, who will be expected to buy
 these products off prescription.
- General Practitioners should collaborate with GICs in the initiation and on-going prescribing of hormone therapy, and for
 organising blood and other diagnostic tests as recommended by the GIC.
- General Practitioners are also expected to co-operate with GICs in patient safety monitoring, by providing basic physical
 examinations (within the competence of General Practitioners) and blood tests and diagnostic tests recommended by the
 GIC. Hormone therapy should be monitored at least 6 monthly in the first 3 years and yearly thereafter, dependent on
 clinical need.
- The GIC is expected to assist General Practitioners by providing relevant information and support, including the provision of guidance regarding the interpretation of blood test results.⁴

Prescribing Bridging hormones

It should be noted that people accessing gender identity services have a legal right under the NHS constitution to be seen within 18 weeks of referral; historically waits may have been longer and this is being addressed by a letter from NHS England.⁶ At the time of writing this advice sheet, the predicted waiting times for patients in Lancashire was an average of 98 weeks, based on patients attending either Leeds, London, Nottingham or Sheffield clinics⁷. This long wait can be very distressing and mental health may suffer as a consequence. The risk of self-harm and suicide for trans people is much greater than in the general population, and delay in accessing medical care substantially increases these risks. If your patient is distressed, or you believe them to be at risk from self-harm, you should offer them support and consider the need for referral to local mental health services.

Sometimes GPs may need to consider prescribing 'bridging prescriptions' of hormone blockers while patients wait for their first appointment, this is usually to reduce the risk of harm, such as from products being brought on-line from unregulated sources, and further information can be found at the link above to the GMC website guidance.

The harm reduction approach is recommended, and endorsed by the <u>UK Good Practice Guidelines For The Assessment And Treatment Of Adults With Gender Dysphoria</u>⁵ These guidelines state "...the GP or other medical practitioner involved in the patient's care may prescribe 'bridging' endocrine treatments as part of a holding and harm reduction strategy while the patient awaits specialised endocrinology or other gender identity treatment and/or confirmation of hormone prescription elsewhere or from patient records" (page 25) and, "A bridging prescription may be appropriate, and blood tests and health checks are undertaken to screen for contraindications" (page 28).

After assessing the risk and screening for medical contraindications to hormone therapy use, GPs should seek advice from a GIC or gender specialist to find a hormone therapy regimen that has the lowest risk for their patient. Advice regarding a standard regimen is available in the RCGP-GIRES Gender variance e-learning module. Particular care is needed with patients who are already self-medicating and who have experienced improvement in their gender dysphoria. In these circumstances, sudden discontinuation of established hormone use may have unpredictable psychological consequences, and is not recommended.

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In summary, a GP should only consider issuing a bridging prescription in cases where all the following criteria are met:

- 1. the patient is already self-prescribing with hormones obtained from an unregulated source (over the internet or otherwise on the black market)
- 2. the bridging prescription is intended to mitigate a risk of self-harm or suicide
- 3. the doctor has sought the advice of a gender specialist, and prescribes the lowest acceptable dose in the circumstances.

Summary

Transgender and non-binary people will spend a relatively short time under the care of a specialist Gender Identity Clinic. General Practitioners therefore have an important role in the ongoing care of patients when they no longer have a need for specialised gender identity services. The prescribing and monitoring of hormone therapy can be carried out safely in primary care without specialist input, though Gender Identity Clinics are encouraged to provide support to individual General Practitioners when this is requested.

For further information please contact: Steve Hamer, Accountable Commissioner for Gender Identity Services, NHS England Steve.Hamer1@nhs.net

Commissioning of Gender Identity Clinics

NHS England is the responsible commissioner for the specialised element of the gender dysphoria pathway, which in England is delivered through seven specialist Gender Identity Clinics (GIC). Commissioning information can be found on NHS England's website: https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-c/c05/

A list of GICs from which England commission can be found on NHS choices: http://www.nhs.uk/Livewell/Transhealth/Pages/local-gender-identity-clinics.aspx

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