National Gender Identity Clinical Network for Scotland (NGICNS)

Endocrine Management of Adult Transgender Patients
Revised 7th July 2016 (First published 11 August 2015)


The groups convened by NGICNS (Appendix A) took into account all relevant guidelines, published evidence and clinical experience in formulating this guidance. It was accepted by the group that there is limited evidence in this area of practice and a wide variation in practice exists across services. The aims of this guidance are to set standards of endocrine care for transgender patients across Scotland thus enabling all clinicians who encounter this patient group to provide acceptable, safe and effective treatment.

Outline assessment process


Adult patients (18+) presenting with Gender Dysphoria\(^1\)/ Transsexualism\(^2\) are initially seen and assessed at their local Gender Identity Clinic (GIC). This assessment includes a detailed history and a physical and mental health assessment prior to the initiation of hormonal treatment if required. Most patients will be followed up regularly by the GIC until a stable medication regimen is established at which point primary care should continue the monitoring requirements.

Where significant medical co-morbidities exist, patients should be referred to local Endocrinology services for assessment and treatment by the GIC. Co-location of endocrine services in a GIC is recommended.

Adult patients already on established hormonal treatment (i.e. treatment elsewhere, self medicating) should be made aware of this guidance should they wish to change or amend their prescription.

Patients are assessed according to the World Professional Association of Transgender Health (WPATH) Standards of Care, 2011 Criteria for the initiation of hormonal treatment as follows:

1. Persistent, well-documented gender dysphoria;\(^3\)
2. Capacity to make a fully informed decision and to consent for treatment;

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\(^1\) The term 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 characteristics). This includes situations where a person has a non-binary gender identity and describes themselves as other than a man or a woman.

\(^2\) The term Transsexualism is more specific than the term Gender Dysphoria and refers to 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.

\(^3\) It is not necessary for a patient to change their name or the gender role in which they live prior to starting hormone treatment.
3. Age of majority\(^4\) (If the patient is under 18, follow the Child and Adolescent Endocrine Management guidance).

4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

In selected circumstances, it can be acceptable practice to provide hormones to patients who have not fulfilled these criteria. Examples include facilitating the provision of monitored therapy using hormones of known quality as an alternative to illicit or unsupervised hormone use or to patients who have already established themselves in their affirmed gender and who have a history of prior hormone use. For further information about managing such circumstances refer to NGICNS Scottish Gender Protocol Explanatory Notes.

Patients are encouraged to stop smoking, take regular exercise, have a good balanced diet, maintaining a healthy body weight, and consume no more than 14 units of alcohol per week.

Informed consent is essential and all prescribers should ensure that this has been documented. The impact of endocrine treatment on fertility should be discussed with the patient. For further information about fertility preservation options refer to NGICNS Scottish Gender Protocol Explanatory Notes.

**Consent forms**

Consent forms are found in Appendix B.

The forms can usefully be combined with detailed information contained within WPATH Standards of Care; pages 36 to 40:


A further source of information is A Guide to Hormone Therapy for Trans People produced by the NHS Department of Health:


**Individualised treatment**

Treatment is individualised according to patient presentation and preference. Non-binary identifying patients, in particular, will require an individualised treatment package agreed with an experienced clinician. Once an individualised treatment plan has been agreed with the patient, the GIC will write to the patient’s GP to issue the prescription. Initial monitoring is undertaken by the GIC until the patient is well established on treatment after approximately 6 months. Monitoring should continue in primary care once the patient is discharged. However, GIC’s will always be available to discuss any issues arising through ongoing monitoring.

\(^4\) Age of legal majority in Scotland is 16 years
Endocrine treatment

The individual Feminising and Masculinising Endocrine Treatments are outlined below.

FEMINISING ENDOCRINE TREATMENT

This section relates to patients originally assigned male at birth.

Baseline assessment (GIC)

- Medical, family and sexual histories; particular concerns are hypertension, thromboembolic disease, migraine, breast disease, liver disease and prostate disease. Patients with significant co-morbidities should be referred for an endocrinological opinion at a local service.
- Assess cardiovascular risk status (BNF or http://www.qrisk.org/).
- Glucose and lipid profile (preferably fasting).
- Prolactin.
- Consider PSA if age is greater than 50yrs or symptomatic.
- Consider HIV, Hepatitis B core Antibody, Hepatitis C Antibody, and sexual health screen. Consider Hepatitis A and B vaccination if sexual history indicates higher risk.
- BMI of ideally less than 35 is recommended and the patient should be counselled regarding risks. Transdermal Oestradiol preparations are recommended for patients with high BMI.

Monitoring of patients on established hormonal therapy (GIC or Primary Care)

- On a 3-4 monthly basis for the first year (this would usually be undertaken by GIC until patient is on a stable medication regime) and 12 monthly thereafter.
- Monitor Cardiovascular risk if risk factors present.
- LFT yearly.
- U+E pre-treatment
  - If on spironolactone U+E yearly.
- Oestradiol (aiming for levels up to 600pmol/L; if greater than 600pmol/L seek advice from GIC).
- Prolactin (if greater than 1000mU/L seek advice from endocrinology).
- Maintain awareness of prostatic disease and institute appropriate investigations should lower urinary tract symptoms occur. PSA monitoring is not required.
- Breast cancer screening as for natal female guidelines.
- Osteoporosis screening if high risk for osteoporotic fracture or prolonged periods of hypogonadism. DEXA scanning recommended for patients not taking a sex steroid for more than 12 months.

Medication

Patients will usually attend regular GIC appointments for review while hormone dosages are adjusted. The GIC will liaise closely with the patient’s Primary Care Provider until a stable hormonal regimen is established. Oestrogen doses are gradually increased e.g. 1-2mg oral oestradiol increased monthly by 1-2 mg increments until therapeutic range and clinical efficacy appropriate.

- Monitor oestradiol level at clinic visits (3-4 monthly during first year, then annually) and increase dose of oestradiol aiming to achieve oestradiol levels in range 200-600pmol/L.
- Androgen suppression is recommended for all patients who do not suppress androgen levels with oestrogen alone. This occurs in approximately 1 in 3 patients after 3-6 months.
- Should androgen suppression not occur, antiandrogen therapy should be offered.
**Typical medication regimes may include**

- Transdermal oestradiol patches (initially 40-50mcg changed twice weekly but increase to up to 160-200mcg changed twice weekly) recommended for use in patients over 40 and in patients with Cardiovascular risk factors, high BMI, liver disease or patient preference
  
  OR

- Oral Oestradiol 1mgs to 6mgs daily

  OR

- Oestradiol gel 1-3mg daily

- Oestradiol level in the range 200-600pmol/L is appropriate.

**PROGESTERONE (or synthetic progestogens) is of no proven benefit in this patient group and is not recommended**

**Androgen suppression**

- Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 12 weekly*
  
  OR

- Leuprorelin/Triptorelin 3.75mg 4 weekly or 11.25mg 12 weekly by IM injection*
  
  OR

- Cyproterone Acetate (25-100 mg daily)

- **Finasteride 5mg daily and Spironolactone (50 - 100mg daily) are not recommended as they are less effective in androgen suppression although may help with hirsutism (**NB: ensure normal renal function with spironolactone and monitor for possible hyperkalaemia**).**

- *If prescribing GnRH analogues a short term prescription of Cyproterone Acetate 100mg daily for 10 days only is required at the time of GnRH administration to prevent a surge in androgen levels.

**Surgery**

Hormones should be ceased 4 weeks prior to surgery, and resumed 4 weeks after surgery if there are no complications. The surgeon will usually communicate directly with GPs before and after surgery. Anti-androgens are not required after orchidectomy.

**Surgery could include**


**Post operative care**

The oestrogen dose should continue to be monitored post operatively with circulating oestradiol levels maintained below 600pmol/L.
MASculinising Endocrine Treatment

This section relates to patients originally assigned female at birth.

**Baseline Assessment (GIC)**

- Medical, family, sexual histories and menstrual histories are taken; particular concerns are hypertension, breast disease, dysfunctional uterine bleeding and haematological disease. Patients with significant co-morbidities should be referred for an endocrinological opinion at a local service.
- Assess cardiovascular risk (BNF or http://www.qrisk.org/).
- FBC, LFT, Glucose and lipid profile (preferably fasting).
- Consider hormonal profile if irregular menstrual history.
- Consider HIV, Hepatitis B core Antibody, Hepatitis C Antibody, and sexual health screen.
- Consider Hepatitis A and B vaccination if sexual history indicates higher risk.
- BMI recommended less than 35. Patients will not be able to access chest reconstruction surgery unless BMI less than 30 therefore high BMI poses not only medical risks but psychological risks. Psychological distress can be amplified by patients becoming heavily masculinised without being able to access treatment to remove breast tissue.

**Monitoring (GIC or Primary Care)**

On a 3-4 monthly basis for the first year and 12 monthly thereafter.

- Cardiovascular risk assessment.
- FBC (Hb and haematocrit).
- For parenteral treatment monitor Testosterone trough level (Ideal in lower 3rd of normal male range, if more than 20nmol / discuss with GIC).
- For transdermal preparations monitor testosterone level (should be within normal male range)
- Cervical screening should continue as for female guidelines if cervical tissue is present, however, sensitive discussion of this should take into account the patient’s dysphoria.
- Breast screening should also follow female guidelines if mastectomy has not been performed.
- Monitoring for osteoporosis if high risk for osteoporotic fracture or prolonged periods of hypogonadism. DEXA scanning recommended for patients not taking a sex steroid for more than 12 months.

**Medication**

Patients will usually attend regular GIC appointments for review while hormone dosages are adjusted. The GIC will liaise closely with the patient’s Primary Care Provider until a stable hormonal regimen is established. Androgens are introduced gradually and slowly titrated to avoid adverse reactions e.g. headache and affective changes amongst others.

**Initiation Phase (GIC)**

**Gradual Introduction of Androgens**

- Sustanon or testosterone enantate, 125mg three weekly for 2-3 months, increase to 250mg 3 weekly if well tolerated and testosterone levels subtherapeutic
  OR
- Transdermal testosterone 50mg on alternate days for 2 months, increasing to 50mg-100mg daily thereafter
- After 6 months patients either continue on the treatment they are on or can be offered the maintenance treatments below.
GnRH Analogues can be prescribed for cessation of menses (these should be stopped once patient is established on testosterone typically after 6 months)

- Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 12 weekly
- Leuprolelin/Triptorelin 3.75mg 4 weekly or 11.25mg 12 weekly by IM injection.

**Maintenance treatments**

- Testosterone undecanoate (Nebido) 1000mg intramuscular injections 10-14 weekly
- Testosterone (Sustanon or Enantate) intramuscular injections 125-250 mg 2-3 weekly
- Transdermal testosterone (Testogel, Testim, Tostran) 50-100mg daily.

**Testosterone oral preparations are not recommended**
Appendix A

Endocrine Management Group Membership (2015)

Dr David Gerber, Consultant Psychiatrist
Prof Alastair McLellan, Consultant Endocrinologist
Prof Richard Anderson, Consultant in Reproductive Medicine
Dr Guftar Shaikh, Consultant Paediatric Endocrinologist

Additional Contributors (2015)

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Dr Marie Freel, Consultant Endocrinologist
Dr Colin Perry, Clinical Lead and Consultant Endocrinologist
Dr Chris Schofield, Physician in Diabetes and Endocrinology/Acute Medicine
INFORMED CONSENT

FOR FEMINISING ENDOCRINE TREATMENT

This form refers to the use of oestrogen and other medications by persons who wish to become more feminised as part of a gender transitioning process.

<table>
<thead>
<tr>
<th>Patient details (or pre-printed label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's surname / family name: ________________________________</td>
</tr>
<tr>
<td>Patient's first name: ________________________________</td>
</tr>
<tr>
<td>Date of birth: ________________________________</td>
</tr>
</tbody>
</table>

To be retained in patient's notes
Name of proposed course of treatment
Feminising Endocrine Treatment

Statement of health professional

I have explained the treatment to the patient. In particular, I have explained:

The intended feminising benefits which may be permanent

- Breast development
- Redistribution of body fat
- Mood/Affective changes
- Decrease in sex drive
- Erectile dysfunction

Serious or frequently occurring risks

- Deep vein thrombosis & pulmonary embolism (that can be fatal)
- Infertility
- Hypertension
- Weight gain
- Migraines
- Benign intracranial hypertension
- Myocardial infarction (‘heart attack’) (that can be fatal)
- Stroke (that can lead to permanent disability or be fatal)
- Breast cancer

☐ The following leaflet has been provided:

Signed: ___________________________________________ Date: ____________________________

Name (PRINT): ___________________________________________

Job title: ____________________________________________
Statement of patient

I agree to the course of treatment described on this form and understand the risks associated therewith.

I have had sufficient opportunity to discuss my condition and treatment with my medical provider and all of my questions have been answered to my satisfaction.

I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy.

Patient’s signature: ___________________________ Date: ___________________________

Name (PRINT): ___________________________
INFORMED CONSENT

FOR MASCULINISING ENDOCRINE TREATMENT

This form refers to the use of androgens by persons who wish to become more masculinised as part of a gender transitioning process

Patient details (or pre-printed label)

- Patient’s surname / family name: __________________________________________________________
- Patient’s first name: _________________________________________________________________
- Date of birth: _______________________________________________________________________

To be retained in patient’s notes
Name of proposed course of treatment
Masculinising Endocrine Treatment

Statement of health professional
I have explained the treatment to the patient. In particular, I have explained:

The intended masculinising benefits which are irreversible
- Growth of facial and body hair
- Clitoromegaly
- Deepening of the voice
- Hair loss/balding

And the following reversible effects
- Increased muscle mass
- Increased sex drive
- Weight gain
- Amenorrhoea
- Infertility
- Mood / Affective symptoms and aggression
- Vaginal atrophy

Serious or frequently occurring risks
- Increased cardiovascular risk
- ‘Benign intracranial hypertension’
- Myocardial infarction (‘heart attack’) (that can be fatal)
- Increased red blood cells (polycythaemia)
- Liver damage
- Acne
- Diabetes
- Teratogenic risk to fetus (discuss contraception)

☐ The following leaflet has been provided:

______________________________________________________________________________________

Signed: _______________________________       Date: ________________________________

Name (PRINT): ________________________________

Job title: ________________________________
Statement of patient

I agree to the course of treatment described on this form and understand the risks associated therewith.

I have had sufficient opportunity to discuss my condition and treatment with my medical provider and all of my questions have been answered to my satisfaction.

I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy.

Patient’s signature: ___________________________  Date: ___________________________

Name (PRINT): ___________________________