National Gender Identity Clinical Network for Scotland (NGICNS)

Endocrine Management of Adult Transgender Patients
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The group 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

For further detail, please refer to NGICNS Scottish Gender Protocol Explanatory Notes on NGICNS website (http://www.ngicns.scot.nhs.uk/).

Adult patients (18+) presenting with Gender Dysphoria ¹ / Transsexualism ² are initially seen and assessed at their local Gender Identity Clinic (GIC). This usually includes a detailed history and mental health assessment. Most patients will be followed up regularly by the GIC until a stable medication regimen and surgeries (if required) are concluded.

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;
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.

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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 characteristic). 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.
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 refer:

http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf

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 a treatment 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.

**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 can be referred for an endocrinological opinion at a local service. Co-location of endocrine services in a GIC can be helpful.
- 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.

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. 1mg oral oestradiol increased 2-3 monthly by 1mg 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 in conjunction with feminising hormonal treatment unless there are specific contraindications or patient refusal.

Typical medication regime may include

- Oral Oestradiol 1mgs to 6mgs daily
  OR
Transdermal oestradiol patches (initially 40-50mcg changed twice weekly but increase to up to 160-200mcg changed twice weekly) more commonly used in patients over 40 and in patients with Cardiovascular risk factors, liver disease or patient preference.

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 are not recommended

Androgen suppression

- Cyproterone Acetate (50-100 mg daily)
  OR
- Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 12 weekly
  OR
- Leuprolelin/Triptorelin 3.75mg 4 weekly or 11.25mg 12 weekly by IM injection.

- Finasteride 5mg daily and Spironolactone (50 -100mg daily) are much less effective in androgen suppression but may help with hirsutism, 
  NB: ensure normal renal function with spironolactone and monitor for possible hyperkalaemia

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

Orchidectomy, Penectomy, Vaginoplasty, Clitoroplasty, Labiaplasty
Breast augmentation, Facial feminisation surgery, and Laryngoplasty

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.
- 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

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. Patients will not be routinely included in the National Cervical Screening programme.
- 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)

1. **Consider use of GnRH Analogues for cessation of menses (these should be stopped once patient is established on testosterone typically after 6 months)**
   - Goserelein 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

2. **Gradual introduction of androgens**
   - Sustanon or testosterone enantate 250mg 6 weekly for 3 months, increase to 250mg monthly if tolerated  
   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.

**Maintenance treatments**

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

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

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

Contributors
Dr Sarah Kennedy, Consultant Psychiatrist
Dr Gordon McKenna, Consultant GUM Physician
Dr John Ewan, Associate Specialist
Mr James Morton, Scottish Transgender Alliance
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.

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
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): ______________________________