Population, Intervention, Comparator and Outcomes (PICO) template

1. Topic details

Intervention: Feminising medicines comprising oestrogen monotherapy

Indication: Children and young people with gender incongruence who identify as non-binary and wish partial physical feminisation

Programme of Care: Gender Services Clinical Programme

Clinical Reference Group: Gender Services Clinical Programme

Unique Reference Number (URN): 2417i

2. Background

In the ICD-11 (WHO, 2025), under conditions related to sexual health, gender incongruence is split into that identified in childhood (Gender incongruence of childhood – HA61) and that identified in adolescents and adults (Gender incongruence in adolescents and adults – HA60).

Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years (WHO, 2025). Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Gender incongruence of adolescence and adulthood is defined as a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

This PICO refers specifically to children and adolescents up to their 18th birthday.

The reason why some people experience gender incongruence is not fully understood and it is likely that the development of gender identity is multifactorial and influenced by both biological and social factors. Gender variant behaviours may start between ages 3 and 5, the same age at which most typically developing children begin showing gendered behaviours and interests (Fast et al, 2018).

Gender atypical behaviour is common among young children and may be part of normal development (Young et al, 2019).

Previously, feminising medicines for CYP comprised of oestrogen, preceded by puberty suppressing hormones (PSH). PSH, which is gonadotrophin releasing hormone analogue (GnRHa) for the indication of puberty suppression, are no longer available as a routine commissioning treatment option for treatment of CYP who have gender incongruence because there is not enough evidence of safety and clinical effectiveness. NHS England and the National Institute of Health and Care Research (NIHR) are working together to set up a study into the potential benefits and harms of PSH as a treatment option for CYP with gender incongruence. PSH are not covered by this PICO.

Population and Indication

Gender incongruence 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 had either gone through part of a process to change from the sex they were assigned at birth to the gender they identified with, or they intended to do so.

Estimates for the proportion children and young people (CYP) with gender incongruence vary considerably. This reflects a number of factors such as: variable data reporting by providers; differences in diagnostic thresholds applied and inconsistent terminology; the methodology and diagnostic classification used – population surveys give a much higher estimate than numbers based on service use; and the year and country in which the studies took place. Additionally, a significant proportion of referred CYP have co-occurring conditions such as autism spectrum disorder or mental health difficulties (Stynes et al. 2021).

At current referral patterns 69% of referrals to the current commissioned service are of natal females and 31% are of natal males[1]. This data accords with figures published by the Cass Review in March 2022, which show a trend since 2011 in which the number of natal females is increasingly higher than the number of natal males being referred. That change in the proportion of birth assigned females to males is reflected in the statistics from the Netherlands (Brik et al. 2020).

The number of referrals into the CYP Gender Incongruence Service is currently likely to be around 1 per 2000 population per year. The current referral profile suggests that the majority of referrals will be of adolescents following the onset of puberty. Data from January 2025, shows the current CYP waiting list as 6,246[2].

Intervention

The endocrine medicines used for gender incongruence in CYP are feminising medicines including oestrogen and GnRHa (not for the indication of puberty suppression). Endocrine medicines may influence central nervous system function and cognition (thoughts and feelings) as well as sex-specific physical characteristics. They may augment physical interventions intended to modify secondary sex characteristics. They may mitigate the unwanted endocrine and metabolic effects of hypogonadism, which follow gonadectomy or the suppression of sex hormones produced by the body.

When deciding what medicines are appropriate for a non-binary trans feminine person it is important that the degree of fluidity of the person's current gender expression is assessed; a clear formulation of the mix of masculine, feminine and

[1] Data return by Tavistock and Portman NHS Foundation Trust, February 2023.
[2] Data return by NHS Arden and GEM, January 2025.

neutral physical features is made. This is often based on the context of a multidisciplinary team so that the social psychological and physical implications of medical therapy can be adequately explored.

Feminising medicines (referred to as 'gender affirming hormones' in previously published NHS England clinical commissioning policy) may be considered for some individuals who have gender incongruence and who may wish to proceed with gender reassignment in later life. The medicines are consistent with the individual's experienced gender as compared to their gender assigned at birth. Feminising medicines include oestrogen which is one of the main female sex hormones. There are three types of oestrogen: oestradiol, oestriol and oestrone. Oestradiol is the main, and strongest type, which can result in feminisation (development of a more typical female body type) and can also reduce some male aspects of the body. This is a medicine that will need to taken regularly to cause feminising physical changes.

Oestradiol is usually given as a tablet, gel or patch. Feminising medicines are generally given lifelong and can used as monotherapy or alongside GnRHa. This PICO will focus on individuals receiving oestrogen monotherapy only. A patch is typically used first line and a tablet as second line management.

Feminising medicines are currently available as a routine commissioning treatment option for young people with continuing gender incongruence/gender dysphoria from around their 16th birthday subject to individuals meeting the eligibility criteria outlined in the NHS England clinical commissioning policy.

Current Standard Treatment(s)

NHS England commissions a specialist multi-disciplinary gender incongruence service for CYP up to their 18th birthday.

The current service provides:

- Treatment options for gender incongruence following an initial process of assessment and diagnosis, focus on psychosocial, psychological and psychoeducational support. The aim of psychosocial interventions is to alleviate gender-related distress and any co-occurring difficulties (Taylor et al, 2024).
- From around the age of 16, young people with a diagnosis of gender incongruence or gender dysphoria who meet various clinical criteria may be given feminising medicines alongside psychosocial and psychological support.
- PSHs are not currently available to CYP for gender incongruence or gender dysphoria because there is not enough evidence of safety and clinical effectiveness. NHS England and the National Institute of Health and Care Research (NIHR) are working together to set up a study into the potential benefits and harms of PSH as a treatment option for CYP with gender incongruence.
- A move to the final step of irreversible sex reassignment surgery (gender affirmation surgery) may follow a few years later, typically at an age greater than 18 years and is delivered by adult gender dysphoria services.

Clinical Problem

CYP with gender incongruence experience discomfort or distress because there is a mismatch between their assigned sex at birth and the gender with which they identify. Feminising medicines aim to reduce endogenous sex hormone levels and achieve and maintain a sex hormone profile that is consistent with the attainment of the individual's gender identity and developmental goals. The aim of treatment is to reduce the incongruence between the person's physical expression of gender and their internal sense of gender identity.

NICE guidance: There is no NICE guidance that specifically refers to the pharmacological treatment of gender incongruence.

Current commissioning policy:

Prescribing of Gender Affirming Hormones (masculinising or feminising hormones) as part of the Children and Young People's Gender Service

Clinical policy: puberty suppressing hormones (PSH) for children and young people who have gender incongruence/gender dysphoria

Interim service specification for specialist gender incongruence services for children and young people

Objective: The purpose of the evidence review is to determine the clinical effectiveness, safety and cost-effectiveness of oestrogen monotherapy for CYP with gender incongruence who identify as non-binary and wish partial physical feminisation.

Research Questions

1. For CYP with gender incongruence who identify as non-binary and wish partial physical feminisation, what is the clinical effectiveness of treatment with oestrogen monotherapy with or without psychological and psychosocial support compared with one or a combination of psychological support or social transitioning to the desired non-binary gender or with no intervention?
2. For CYP with gender incongruence who identify as non-binary and wish partial physical feminisation, what is the short-term and long-term safety of oestrogen monotherapy with or without psychological and psychosocial support compared with one or a combination of psychological support or social transitioning to the desired non-binary gender or with no intervention?
3. For CYP with gender incongruence who identify as non-binary and wish partial physical feminisation, what is the cost-effectiveness of oestrogen monotherapy with or without psychological and psychosocial support compared to one or a combination of psychological support or social transitioning to the desired non-binary gender or with no intervention?
4. From the evidence selected, are there particular sub-groups of CYP with gender incongruence who identify as non-binary and wish partial physical feminisation that may benefit more from treatment with oestrogen monotherapy than the wider population?
5. From the evidence selected:

a) What were the criteria used by the research studies to define gender incongruence?

a) What were the starting criteria, formulation, duration and dose of oestrogen monotherapy for those aged 16 years up to their 18th birthday?
b) Did any children aged 15 years or younger receive oestrogen monotherapy for gender transition? If so, in what circumstances?
c) What monitoring was in place for CYP with gender incongruence who identify as non-binary and wish partial physical feminisation receiving oestrogen monotherapy?
d) What were the exclusion criteria in the studies?

3. PICO Table

P –Population and Indication	Children and young people (up to their 18th birthday) who have gender incongruence as defined by the study and identify as non-binary and wish partial physical feminisation. [Some terms used to describe this population include, but are not limited to, agender, gender fluid, non-binary transfeminine, transfem, genderqueer, polygender, gender diverse, gender non conforming, non-gender, transperson, transgender, transgendered, transexual, trans-sex, trans*, cross-gender, gender non conforming non binary (GNNB), trans-sex or cross-sex (alternate spellings may be considered). The term gender incongruence may also be referred to as, but is not limited to, gender dysphoria, gender identity disorder, gender dysfunction, gender diverse, gender questioning or transsexualism. 'Gender incongruence of childhood' is a diagnostic term used by health professionals, found in the WHO International Classification of Diseases ICD-11 characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years (WHO, 2025). Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis. 'Gender incongruence of adolescence or adulthood' is a diagnostic term used by health professionals, found in the WHO International Classification of Diseases ICD-11. Gender incongruence is characterised by "a marked and persistent incongruence between an individual's experienced gender and the assigned sex". It is important to note that it has been moved out of the "Mental and behavioural disorders" chapter and into the "Conditions related to

	sexual health" chapter so that it is not perceived as a mental health disorder. It does not include references to dysphoria or dysfunction. Gender dysphoria, within the section of gender identity disorders, is the term used in Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) (American Psychiatric Association, 2022). In the DSM-5-TR definition, gender dysphoria has to be associated with clinically significant distress or impairment of function. Gender dysphoria is the more commonly used term clinically and among research papers. It is also most likely to be familiar to the lay public since it has been used widely in mainstream and social media. It is a label that is used colloquially to describe feelings, as well as being a formal diagnosis.] The following subgroups of CYP with gender incongruence are of interest: • Peri-pubertal vs post-pubertal • The stated duration of gender incongruence is either less than 6 months, 6-24 months or more than 24 months at time of assessment and/or treatment • The age of onset of gender incongruence • The age of onset of puberty • The age/ Tanner stage at which treatment was initiated with oestrogen monotherapy • CYP with gender incongruence who have a preexisting diagnosis of neurodiversity • CYP with gender incongruence who have a preexisting diagnosis of a learning disability • CYP with gender incongruence with a history of severe enduring mental disorder including anxiety, depression (with or without a history of self-harm and suicidality), psychosis, personality disorder, and eating disorders.
I – Intervention	Feminising medicines comprising oestrogen monotherapy. Individuals taking feminising medicines may also be receiving psychological or psychosocial support. [Feminising medicines may be referred to as gender affirming hormones, cross sex hormones, sex reassignment, sex change, sex transformation, sex hormones, gender reassignment, gender change, gender transformation or gender hormones. Oestrogen can be given as a patch, gel, spray, injection or a tablet. Examples include: oral oestradiol and its salts including valerate and hemihydrate (Zumenon, Progynova, Elleste Solo, Bedol, Delestrogen); oestrogen gel (Sandrena, Oestrogel); oestradiol patch (Evorel, Estradot, Estraderm, Progynova TS patch, FemSeven patch); oestradiol spray (Lenzetto); injectable oestrogens (Depo-Estradiol, Delestrogen). Oestrogen may also be referred to as estrogen, oestradiol, estradiol, 17beta-estradiol, E2, E3, estriol, oestriol and ethinylestradiol. This list is not exhaustive.

	Individuals may also have experienced a period of time or process known as 'real-life experience' (RLE), sometimes historically called 'real-life test' (RLT) where they have lived full-time in their identified gender role in order to be eligible for feminising medicines. This PICO excludes individuals who are receiving or have received GnRH analogues for the indication of puberty suppression or gender affirmation.]
C – Comparator(s)	One or a combination of: 1. Psychological and psychosocial support 2. Social transitioning to the gender with which the individual identifies **OR** 3. No intervention [Psychological and psychosocial support include cognitive behavioural therapy (CBT), Psychoanalytic and Psychodynamic therapies, Humanistic and Existential Therapies, Interpersonal and Relational Therapies, Trauma-Focused Therapies, Arts and Expressive Therapies, mindfulness and self-compassion, attachment-based family therapy, attachment therapy, psychoeducation, gender exploratory therapy, exploratory therapy. • Examples of Cognitive and Behavioural Therapies include: Cognitive Behavioural Therapy (CBT), Dialectical Behaviour Therapy (DBT), Acceptance and Commitment Therapy (ACT), Exposure Therapy, Behaviour Therapy Examples of Psychoanalytic and Psychodynamic Therapies include: Psychoanalysis, Psychodynamic Therapy, Intensive short-term dynamic psychotherapy (ISTDP), sensorimotor psychotherapy • Examples of Humanistic and Existential Therapies include: Person-Centered Therapy (Carl Rogers), Gestalt Therapy, Existential Therapy • Examples of Interpersonal, Relational and Systemic Therapies include: Interpersonal Therapy (IPT), Couples Therapy, Family Therapy, Group Therapy, Narrative Therapy, Mentalisation-based Therapy, Dyadic Developmental Psychotherapy (DDP), Narrative exposure therapy • Examples of Trauma-Focused Therapies include: Eye Movement Desensitization and Reprocessing (EMDR), Trauma-Focused CBT (TF-CBT) • Examples of Mindfulness-Based Therapies include: Mindfulness-Based Stress Reduction (MBSR), Mindfulness-Based Cognitive Therapy (MBCT) • Examples of Arts and Expressive Therapies include: Art Therapy, Music Therapy, Drama Therapy, Play-based Therapy, Theraplay • Examples of Integrative and Holistic Therapies include: Integrative Therapy

	• Examples of Specialised Therapies include: Compassion-Focused Therapy (CFT), Schema Therapy, Solution-Focused Brief Therapy (SFBT). Psychosocial support also includes: assessment, extended assessment, therapeutic assessment. These longer assessments allow exploration at a deeper level to seek understanding. Interventions can be delivered by psychological practitioners including Clinical and Counselling Psychologists, Psychotherapists, other healthcare professionals with additional training and supervision (e.g., specialist nurse or therapeutic social worker), trained facilitators or counsellors. Interventions can be delivered face to face or online, individually or in groups. Duration of intervention can range from a single session to having no fixed duration or number of sessions. No intervention may include individuals who actively choose not to take any interventions.]
O – Outcomes	**<u>Clinical Effectiveness</u>** *There are no known minimal clinically important differences and there are no preferred timepoints for the outcome measures selected.* *<u>Critical to decision-making:</u>* • **Impact on gender incongruence** *This outcome is important to patients because gender incongruence is associated with significant distress and problems functioning.* [This outcome may be measured using the Utrecht Gender Dysphoria Scale (UGDS), Gender Dysphoria Questionnaire, Gender Identity Interview for Adolescents and Adults, Gender Identity Interview for Children, Gender Distress Scale (TYC-GDS), Self-reported satisfaction. Other measures (including self-reported) may be used as an alternative to the stated measures.] • **Impact on mental health** *This outcome is important to patients because gender incongruence is associated with psychological distress which can lead to the development of mental health problems.* [Examples of mental health problems include self-harm, thoughts of suicide, suicide attempts, suicide, eating disorders, depression/low mood, anxiety, psychotic symptoms/psychosis, substance abuse, minority stress and trauma. This outcome may be measured using Child Behaviour Checklist (CBCL), Youth Self Report (YSR), Childhood Global Assessment Scale (CGAS), Revised Children's Anxiety and

	Depression Scale (and Subscales) (RCADS), The Child and Adolescent Psychiatric Assessment (CAPA), ED-15-Y eating disorder measure, Depression Anxiety Stress Scales (DASS-Y), Patient health questionnaire (PHQ-9) Modified for Teens, Beck Depression Inventory for Youth (BDI-Y), Beck Depression Inventory-II (BDI-II), Quick Inventory of Depressive Symptoms [QIDS], Generalised Anxiety Disorder Questionnaire (GAD-7), Hospital Anxiety and Depression Scale (HADS), Screen for Child Anxiety Related Emotional Disorders (SCARED), Ask Suicide Screening Questions (ASQ), Suicide Ideation Questionnaire Junior, Children's Rosenberg Self-Esteem Scale (CRSES), Clinical Outcomes in Routine Evaluation (CORE), Child Revised Impact of Events Scale 8 or 13 (CRIES 8 or 13), Dissociative Experiences Scale (DES), Assessment Checklist for Adolescents (ACA), Assessment Checklist for Children (ACC). Other measures (including self-reported) may be used as an alternative to the stated measures.] • **Impact on Quality of Life** *This outcome is important to patients because gender incongruence may be associated with a significant reduction in health-related quality of life.* [Quality of life can be measured using a recognised quality of life score for example KINDL questionnaire, Kidscreen 10/27/52, Pediatric Quality of Life Inventory (PedsQL), EuroQuality of Life Five Dimensions Youth (EQ-5D-Y/EQ-5D-3L/EQ-5D-5L), Satisfaction with Life Scale for Children (SWLS-C), Quality of Life Enjoyment and Satisfaction Questionnaire (QLES-Q-SF), General Well-Being Scale (GWBS). Other measures (including self-reported) may be used as an alternative to the stated measures.] <u>*Important to decision making:*</u> • **Feminising physical changes** *This outcome is important because most patients with gender incongruence wish to take steps to suppress features of their physical appearance associated with their sex assigned at birth or accentuate physical features of their experienced gender.* [Feminising physical changes can include: facial/body/head hair, breast growth, body fat and muscle distribution, erectile dysfunction, testicular size and function and voice change. Measures can include The Children's Body Image Scale (CBIS), Body Image Scale for Children (BISC), Body Dysmorphia scale YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BD D-YBO CS). Other measures (including self-reported) may be used as an alternative to the stated measures.] • **Psychosocial impact** *This outcome is important to patients because gender incongruence is associated with internalising and externalising*

	behaviours and emotional and behavioural problems which may impact on social and occupational functioning. [Examples of psychosocial impact are coping mechanisms (such as substance misuse) which may impact on family relationships; peer relationships, living arrangements, educational attendance, work participation, romantic involvement, prosocial skills. Measures that may be used are The Work and Social Adjustment Scale – Youth versions (WSAS-Y), Strengths and Difficulties Questionnaire (SDQ), Multidimensional Scale of Perceived Social Support (MSPSS), Inventory of Interpersonal Problems (IIP32), Family Adaptability, Partnership, Growth, Affection and Resolve test. Other measures (including self-reported) may be used as an alternative to the stated measures.] • **Fertility** *This outcome is important to patients because feminising medicines can reduce fertility. Prior to commencing feminising medicines patients should be counselled on the impact of treatment on their fertility and offered fertility preservation options.* [Examples of fertility outcomes include presence, number and quality of mature spermatozoa. Alternative measures may be used as reported in studies.] • **Feasibility of feminising genital surgery** *This outcome is important to patients because feminising medicines can have an impact on surgical outcomes as treatment may alter the amount of genital tissue available for vaginoplasty, clitoroplasty and/or vulvoplasty.* • **Cognitive outcomes** *This outcome is important to patients because feminising medicines can negatively impact cognitive processes such as concentration, memory, and executive function.* [Observations and cognitive testing are performed by a trained professional which may include a key worker, support worker, social care, social worker or through school observations. This might include assessment of visuospatial ability, verbal memory, verbal fluency, verbal reasoning, verbal comprehension, visual memory, working memory, processing speed, computation, motor coordination, executive functioning, timed task completion or cognitive flexibility. Measures can include Wechsler Intelligence Scale for Children (WISC), Wechsler Adult Intelligence Scale (WAIS), Adaptive Behaviours Assessment System (ABAS) or Wechsler Preschool and Primary Scale of Intelligence (WPPSI).]. • **Detransition after receipt of feminising medicines** *Medical detransition is a complex experience encompassing medical, psychological, social implications and is important to*

	patients because they may choose to discontinue treatment. The decision to detransition may or may not be associated with regret. [Detransitioning is a concept that has evolved over time. Older studies may incorporate terminology relating to retransition. Relevant terms in the literature may include: detransitioner, desistence, discontinuation, cessation, termination, reversion, reversal, disidentification, reidentification.] • **Regret after receipt of feminising medicines** *This outcome is important to patients because some patients who choose to take feminising medicines may regret this decision. Regret may or may not be associated with detransition.* [This may be expressed as a proportion of the study population or other measures such as documentation of regret or semi-structured interviews.] **<u>Safety</u>** *It is important to assess whether treatment causes acute side effects that may lead to withdrawing the treatment or long-term effects that may impact on decisions for transitioning.* • Aspects to be reported could include: o Of most importance: Thromboembolic disease, cardiovascular disease, pre-diabetes (glycosylated haemoglobin (HbA1c) 42mmol/mol – 47mmol/mol, 6% vs 6.4%) or diabetes (HbA1c ≥48mmol/mol, ≥6.5%). o Breast cancer, impaired liver function, severe acne, gallstones, nausea, skin reactions and for those with diabetes, worsening control e.g. increase in HbA1c despite treatment or as defined in study. **<u>Cost effectiveness</u>**
Inclusion criteria	
Study design	Systematic reviews, randomised controlled trials, controlled clinical trials, cohort studies. If no higher level quality evidence is found, case series can be considered.
Language	English only
Patients	Human studies only
Age	Up to 18 years
Date limits	2005-2025

Exclusion criteria	
Publication type	Conference abstracts, non-systematic reviews, narrative reviews, commentaries, letters, editorials, pre-prints and guidelines
Study design	Case reports, resource utilisation studies

4. References submitted with Preliminary Policy Proposal

There is no preliminary policy proposal for this policy.

5. References

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6. Document sign-off

Clinical lead: Derek Glidden	**Dated:** 10th May 2025
Public health lead: Robert Wilson	**Dated:** 6th May 2025
Policy team Clinical Director: Anthony Kessel.	**Dated:** 9th May 2025