

# **Engagement Report**

## **Topic details**

Title of policy or policy statement: Puberty Suppressing Hormones (PSH)

for children and adolescents who have gender incongruence/dysphoria [URN

1927]

Programme of Care: Gender Services

Service Children and young people's gender services

**URN**: 1927

# 1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. Changes were recommended to the draft document from stakeholder engagement.

# 2. Background

NHS England has carefully considered the evidence review conducted by NICE (2020) to treat children and adolescents who have gender incongruence with PSH and the interim recommendations of the Cass Review. We have concluded that there is not enough evidence to support the safety, clinical effectiveness and cost effectiveness of PSH to make the treatment routinely available at this time. NHS England recommends PSH for children and young people with gender incongruence/dysphoria should only be accessed through a research setting.

# 3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 8<sup>th</sup> June 2023 to 25<sup>th</sup> June 2023. The comments have been reviewed to enable full consideration of

the feedback and to support a decision on whether any changes to the proposition might be recommended.

A 13Q assessment has been completed following stakeholder testing.

Stakeholders were asked the following questions:

- Have you read the draft interim Policy Proposition?
- Please provided comments on the draft interim clinical policy, if any.
- Have you read the NICE Evidence Review?
- Have you read the literature review?
- Do you believe that there is any additional information that should have been considered in the Evidence Review?
- Do you believe that there is any additional information that should have been considered in the Literature Review?
- If yes, provide details of the publication/references.
- Have you read the EHIA?
- Comments on the EHIA, if any.
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.
- Please declare any conflict of interests relating to this document or service area.

The Gender Services Clinical Programme as agreed that the not routinely commissioned position has been concluded based on insufficient evidence of clinical benefit to the patient. A further 90 day public consultation will take place. This decision has been assured by the Patient and Public Voice Assurance Group.

## 4. Engagement Results

23 responses were received in stakeholder engagement. This included 13 representatives from organisations, four from clinicians/academics and six from individuals or carers/family members.

In line with the 13Q assessment it was deemed that further public consultation was required.

#### 5. How has the feedback been considered?

Responses to the engagement process have been reviewed by the Policy Working Group and the Gender Services PoC. The following themes were raised during engagement:

# Keys themes in feedback NHS England Response Impact on patients currently receiving PSH treatment

Three respondents highlighted the requirement for clarity regarding patients currently receiving PSH treatment.

"It is insufficiently clear on the situation for young people who may already be being prescribed puberty blockers by their GPs, for example under a shared care agreement with GIDs, a shared care agreement a private service, or as a continuation of care for a child who has relocated to the UK from elsewhere. (Oddly, this is partly mentioned in the EHIA but not the policy itself). The EHIA clarifies that this policy does not apply to continuation of care for those prescribed by GIDS, but seems to me unclear on the situation for others"

The NHS England commissioning policy is applicable to NHS and not the private sector unless commissioned by the NHS.

Approximately 378 children and young people are currently prescribed PSH by an NHS Endocrine team following a referral to GIDS.

The EHIA which was submitted alongside the policy states the following for patients currently receiving PSH treatment: "it will be for the child or young person and their family to decide whether, based on the current available information, they wish to continue with administration of PSH; if so, it will be for the relevant Consultant Endocrinologist to consider whether it is appropriate to continue with off-label prescribing."

NHS England has noted these comments and has amended the policy proposition to reflect the EHIA for clarification on those who are currently prescribed PSH treatment.

#### International recommendations

Five individuals referred to international practices including the WPATH standards of care, ASIAPATH, EPATH, PATHA and USPATH which include PSH as treatment in this patient cohort.

 "removing the routine prescription of puberty delaying treatment to children and young people removes essential care that is internationally recognised The policy proposition has been developed following a review of peer reviewed published evidence as per NHS England Policy Development Methods. NHS England does not commission based upon guidelines or treatment protocols eg WPATH 8.0 or practices in other countries.

The not for routine commissioning position has been concluded based on

as best practice. WPATH,
ASIAPATH, EPATH, PATHA,
and USPATH all recognise that
the existing research
demonstrates that this care is
associated with positive mental
health benefits in children and
young people, and acts as a
protective factor against risks of
suicidal ideation and self harm"

 "It is not consistent with the practice in most EU countries or with the WPATH standards of care for trans children" insufficient clinical benefit to the patient of which evidence of harm is one aspect.

NHS England has now established a new national Children and Young People's Gender Dysphoria Research Oversight Board. The Oversight Board has approved the development of a study into the impact of PSH on gender dysphoria in children and young people in addition to planned further engagement to identify the key evidence gaps for children and young people with later-onset gender dysphoria.

## **Defining exceptional cases**

Five respondents commented on defining exceptional circumstances, with three concerned that it offers a loophole for a clinic to operate. Two reported concerns that this would act as a barrier to treatment.

NHS England recognises the wish for clarification. Exceptional circumstances will be determined by a specially convened national multidisciplinary team who will have agreed terms of reference. This is currently stipulated in the policy proposition.

## Early- and late-onset gender dysphoria definitions

Five respondents requested clarification on the terms "early-onset" and "late-onset" gender dysphoria which were referred to in the EHIA.

- "We find reference to 'early onset' and 'late onset' gender incongruence confusing and have not come across its use before."
- "Given the diagnostic criteria's reliance on gender nonconformity, enrolling those with "early-onset gender dysphoria" onto the experimental PSH research protocol creates a disproportionate risk and/or adverse impact for homosexual/bisexual CYP."
- "I was confused to see repeated reference to 'early-onset' and 'late-onset' gender incongruence in the equality impact assessment but not the clinical policy."

NHS England has now established a new national Children and Young People's Gender Dysphoria Research Oversight Board. Membership includes the National Institute for Health and Care Research, the Medical Research Council, the Royal College of Paediatrics and Child Health and a range of other clinical and academic experts. The Oversight Board has approved the development of a study into the impact of PSH on gender dysphoria in children and young people with early-onset gender dysphoria. The study will be taken forward through the National Research Collaboration Programme in place between NHS England and NIHR, with the study team stakeholder engaging with stakeholders in the study design.

The Research Oversight Board will determine definitions of early and late-onset gender dysphoria in due course

and will include experts in the subject matter.

#### **Ethics of ongoing research**

Twelve respondents comment on the research study. Eight respondents expressed safety concerns of utilising PSH in children and young people in research. Four respondents expressed concerns that this would amount to coercing patients into research.

- "Treatment should be based on clinical need, and coerced participation in research is unethical"
- "As part of research note that experimenting on children might be acceptable when seeking new treatments for childhood cancer, but when there is nothing physically wrong with a child, experimenting on them is right at the extreme end of unethical."
- "Given that there is an academic interest in establishing a better quality of evidence at what cost damaged children."
- "The fact that these drugs were developed off-label for other purposes is an absolute red flag, suggesting that the prescription of blockers to minors is tantamount to experimentation on children."
- "co-ercing people into research is unethical."
- "It would be unethical to put children and young people through research that was capable of answering important questions of safety and efficacy."

In 2022 the independent Cass Review advised that access to PSH through NHS prescribing should be dependent on the child / young person being enrolled in a formal research framework with long-term follow up. NHS England accepted that advice and incorporated wording to that effect in the proposed interim service specification for children and young people's gender incongruence services that was subject to public consultation in 2022.

The Oversight Board has approved the development of a study into the impact of PSH on gender dysphoria in children and young people with early-onset gender dysphoria. The study will be taken forward through the National Research Collaboration Programme in place between NHS England and NIHR, with the study team stakeholder engaging with stakeholders in the study design.

This study is subject to usual ethical and scientific approval.

The decision to take part in research is an individual choice and the policy proposition does not mandate participation in research.

# 6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

Changes were suggested as part of the engagement response. The viewpoints of the stakeholders were considered, and the following changes were recommended:

## **Policy proposition:**

• Pg 3 paragraph 5, addition of paragraph clarifying proceedings for patients currently prescribed PSH: "For children and young people who, at the point the proposed clinical commissioning policy takes effect, have been referred into an endocrine clinic but have not yet been assessed by a consultant endocrinologist for suitability of PSH, or who are already administering PSH through an NHS prescription, there is an expectation of consideration for treatment that would need to clinically managed. In these cases it would be for the consultant endocrinologist to consider with the child or young person and their family whether to continue with off- label prescribing within the current clinical pathway."

## **Equality and Health Inequalities Impact Assessment:**

- Nil changes required
- 7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

NHS England cannot currently provide definitions for early-onset and late-onset gender dysphoria. The Research Oversight board will determine definitions of early and late-onset gender dysphoria in due course.