Puberty Suppressing Hormone: Interim Clinical Policy - Mermaids' Stakeholder Response

What is the remit of Mermaids?
Mermaids is a UK charity (registered charity number 1160575) helping transgender, non-binary and gender-diverse young people and their families since 1995. Our mission is to create a world where trans young people can be themselves and thrive.

Have you read the draft interim clinical policy proposition?
https://dmscdn.vuelio.co.uk/publicitem/5b08926e-4b5e-4bc1-a6d4-dabff1a681d0

Comments on the draft interim clinical policy, if any. You can submit up to 500 words later in the survey if you wish.

Causes of Gender Incongruence
We do not believe it is relevant to this policy to understand the causes of gender incongruence. Such claims that one might identify a cause, either social or biological for trans identity, lends to the argument that there is something broken or fixable about transgender individuals. This approach may create a flawed dynamic whereby a clinician can assess the accuracy of a person's claim to gender incongruence or justify their transgender identity. We support a move away from a pathologising approach to gender incongruence, toward a supportive and holistic view which listens to and centres the needs of individuals.

Diagnostic Approaches
On Page 12 of the *Consultation report for the interim service specification for specialist gender incongruence services for children and young people,* it is stated that 'the final version of the interim service specification we have applied the diagnostic framework of the International Classification of Diseases (ICD-11)' yet the Interim Clinical Policy references diagnostic approaches from the Diagnostic and Statistical Manual of Mental Disorders, Version 5. We would object both to this inconsistency and to the fact that by requiring 'clinically significant distress' to access NHS care, transgender young people are pathologised creating an assumption that being trans or experiencing gender incongruence equates to mental ill health

Mandatory Research

The specification states puberty blockers will only be prescribed to children who consent to participate in a medical research protocol. Treatment should be based on clinical need, and coerced participation in research is unethical. At present, no information has been provided regarding the ethics approval process undertaken by the Oversight Board.

WPATH, ASIAPATH, EPATH, PATHA, and USPATH have collectively emphasised the increasing evidence that access to reversible puberty blockers, and later gender-affirming hormone treatment if wished, is associated with positive mental health and social well-being in adolescents with gender incongruence and that adolescents are satisfied with these treatments and perceive them as essential and lifesaving.

In light of this, we would argue that it is right to follow The NHS Health Research Authority which states in its Joint Statement on the Application of Good Clinical Practice to Training for Researchers that “the rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.” In this sense, the needs of the individual should be placed above future benefits of generating further evidence. We agree that further research on puberty blockers should be undertaken however, it must be *meaningfully voluntary* and should not impact access to treatment.

We finally note that the requiring research to access puberty blockers falls short of Yogyakarta Principle 17, Relating to the Right to the Highest Attainable Standard of Health as it does not “ensure access to the highest attainable standard of gender-affirming healthcare, on the basis of an individual’s free, prior and informed consent.”

We would like to finally to highlight that those restricted from accessing puberty blockers through this policy will be supported through psychoeducational and psychosocial approaches. No evidence has been provided for the clinical effectiveness of this approach in improving outcomes for gender-incongruent young people and we would encourage the weighing up of the harms and benefits of both approaches be considered, rather than only considering the evidence for the use puberty blockers.

Have you read the NICE Evidence Review? Yes
https://dmscdn.vuelio.co.uk/publicitem/8b3246cc-cae0-4110-88f9-a816812fe50a

Have you read the Literature Review? Yes
https://dmscdn.vuelio.co.uk/publicitem/d062dd7c-9c30-44ea-91fe-daee98ca3862

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

Research to add

Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings From the Trans Youth Care Study: https://www.sciencedirect.com/science/article/abs/pii/S1054139X20304535

Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers: https://www.jahonline.org/article/S1054-139X(20)30027-6/fulltext

Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269/ (This study was excluded from the NICE but we cannot understand why.)

Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423

Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment: https://publications.aap.org/pediatrics/article-abstract/134/4/696/32932/Young-Adult-Psychological-Outcome-After-Puberty?redirectedFrom=fulltext (This study was omitted from NICE review because there was an earlier study with the same cohort included, however this newer paper includes a longer term evaluation of the safety and effectiveness of GnRHa, and as such this seems a strange omission considering the scope of the review.)

Experiences of Puberty and Puberty Blockers: Insights From Trans Children, Trans Adolescents, and Their Parents: https://journals.sagepub.com/doi/full/10.1177/07435584221100591

Have you read the Equality and Health Inequalities Impact Assessment (EHIA)?
Yes

Comments on the EHIA, if any

- It states that “Subject to the usual ethical and scientific approvals, we anticipate recruitment to the study will open in 2024.” Does this mean that no

ethical approvals have so far been sought for the research protocol? Given the Southern Hub will open in late 2023, are you confident that the study will be open by the point a decision has been made regarding the suitability for puberty blockers for the initial tranche of patients?

- It states that "The definition of 'early onset' and 'late onset' will be developed by the clinical study team in due course." How can Oversight Board limit puberty blockers to those with "early-onset" gender dysphoria without having first given a clear definition of early-onset gender dysphoria?
- We agree with the statement that "NHS England has proceeded on the basis that the majority of individuals who will be impacted by the proposals are likely to have the protected characteristic of gender reassignment." We would again note the increasing evidence to suggest that puberty blockers are associated with positive outcomes for young people with gender incongruence and that the decision to make them no longer routinely, and not to those experiencing 'later-onset gender dysphoria' will discriminate against those under the protected characteristic of gender reassignment. Our experiences of working with trans and non-binary young people and their families show that many will seek treatments from other sources, often at great expense to themselves. The interim service specification states that where a person taking blockers/hormones privately is not deemed suitable by the Service, a GP or local health professional should consider what safeguarding protocols may be appropriate. This may lead to families that seek puberty blockers from private providers being unwilling to engage with their GP or local health professionals which will increase the risk of harm. As such, we would argue that the clinical policy may result in discrimination against those with the protected characteristic gender reassignment

Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.

Early Onset Gender Dysphoria

- We remain unclear on the meaning of the term 'early-onset gender dysphoria' and how they will be distinguished from those experiencing 'later-onset gender dysphoria.' and again highlight how this can be used as a criterion while the terms have not been clearly developed by the NHS, Oversight Board or Cass Review.
- We are concerned that evidence has not been provided to demonstrate the lack of benefits or possible harms associated with the use of blockers among those who come to terms with their trans identity later in life, and if/how the existing studies included in the evidence review distinguish between early and later onset gender dysphoria.
- We note that it can take trans people different lengths of time to come to terms with their identity and desire to transition and this can be for a range of

reasons, including the level of social acceptance in a young person's life - yet there is a wealth of evidence to show that supporting them with medical transition brings significant benefits to an individual (WPATH SoC 8). This is particularly concerning for those aged over 16, who are Gillick competent and may not fall into the category of 'early-onset gender dysphoria' who will nonetheless be barred from accessing puberty blockers under this policy.

Private Care

- We would also highlight our concerns about the restrictive criteria laid out in the Interim Service Specification for a young person who has already been started on puberty-suppressing hormones and now accessing masculinising/feminising hormones through a private provider. We feel the criteria are excessively restrictive for the ongoing prescription of treatments given our understanding that some young people are prescribed masculinising/feminising hormones earlier than 16 years of age. Such young people often have sought our private care owing to the desperation created by long waiting lists for GIDS and should be able to access timely care through the NHS. .
- We also note that many young people accessing private care would be unwilling to seek NHS care because they would be asked to stop puberty blockers for a brief period, with no guarantee they would be allowed to continue taking them after assessment without a possible safeguarding referral.
- Some GPs prescribe puberty blockers through shared care agreements with private providers. We are concerned that the specification encourages GPs to be reported to a UK professional body if they are prescribing outside NHS protocols (for example to a young person who has not been enlisted in mandatory research).