CYP Interim Services

Puberty Suppressing Hormones Policy

Trans Learning Partnership Consultation Response

Has all the relevant evidence been taken into account?

No.

We do not believe this policy has taken all the available evidence into consideration. When engaging with this policy at stakeholder testing, we listed the below studies as having been excluded. These studies have still not been included, despite their wealth of context, evidence, and significance.

Significantly, there is a core flaw in NHS England's approach to the evidence, in a seeming lack of understanding as to how data on gender affirming care can be ethically gathered. Randomised Controlled Trials are not appropriate or possible for the majority of research into gender affirming care, and particularly so for puberty suppressing hormones. This medication is often needed in a very short window of time while the young person is experiencing distress: it is very unlikely that recruitment from this group would be possible or appropriate, particularly as some will receive a placebo, and therefore not the life-saving treatment they were seeking. Furthermore, a blinded trial, where neither party knows who has the real or placebo drug, is impossible with GnRHas: it will become evident very quickly who has been given which drug, as we know that GnRHas effectively pause puberty. The NHS, based on NICE's evidence review, has ruled that the evidence is low quality as a result of this. However, this creates a fallacy that evidence of RCT-quality can be ethically gathered for GnRHas. This is not the case: instead, the evidence should be understood within this context and its value acknowledged.

Further, we note that there is no reference to the WPATH Standards of Care 8 or previous versions, which seems to be a major oversight.

Drummond, K. D., Bradley, S. J., Peterson-Badali, M., & Zucker, K. J., 'A follow-up study of girls with gender identity disorder,' *Developmental Psychology* 44 (1) (2008) 34-45. https://doi.org/10.1037/0012-1649.44.1.34.

Steensma, T. D., Kreukels, B. P., de Vries, A. L., & Cohen-Kettenis, P. T., 'Gender identity development in adolescence,' *Hormones and Behaviour* 64 (2013) 288-297. https://doi.org/10.1016/j.yhbeh.2013.02.020.

Wallien, M. S. C., & Cohen-Kettenis, P. T., 'Psychosexual outcome of gender-dysphoric children,' *Journal of the American Academy of Child & Adolescent Psychiatry* 47 (12) (2008) 1412-1423. https://doi.org/10.1097/CHI.0b013e31818956b9.

Bungener, S. L., de Vries, A. L. C., Popma, A. & Steensma, T. D., 'Sexual experiences of young transgender persons during and after gender-affirmative treatment,' *Pediatrics* 146 (6) (2020). https://doi.org/10.1542/peds.2019-1411.

Angus, L. M., Nolan, B. J., Zajac, J. D., & Cheung, A. S., 'A systematic review of antiandrogens and feminization in transgender women,' *Clinical Endocrinology* 94 (5) (2020) 743-752. https://doi.org/10.1111/cen.14329.

Chen, D., et al, 'Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings from the Trans Youth Care Study,' *Journal of Adolescent Health* 68 (6) (2020) 1104-1111. https://doi.org/10.1016/j.jadohealth.2020.07.033.

Van der Miesen, A.I.R., et al, 'Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers,' *Journal of Adolescent Health* 66 (6) (2020) 699-704. https://doi.org/10.1016/j.jadohealth.2019.12.018.

Turban, J., et al, 'Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation,' *Pediatrics* 145 (2) (2020) https://doi.org/10.1542%2Fpeds.2019-1725.

Tordoff, D. M., et al, 'Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care,' *JAMA Netw Open* 5 (2) (2022) doi:10.1001/jamanetworkopen.2022.0978.

De Vries, A. L. C., et al, 'Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment,' *Pediatrics* 134 (4) (2014) https://doi.org/10.1542/peds.2013-2958.

Horton, C., 'Experiences of Puberty and Puberty Blockers: Insights from Trans Children, Trans Adolescents, and Their Parents,' *Journal of Adolescent Research* (2022) https://doi.org/10.1177/07435584221100591.

Does the equalities and health inequalities impact assessment reflect the potential impact that might arise as a result of the proposed changes?

No.

We are extremely concerned about the use of the terms 'early onset gender dysphoria' and 'late onset gender dysphoria' within the EHIA. We recognise that NHS England intends to define these terms in due course, but we believe it is inappropriate to request input on such a policy when such key elements are undefined and therefore unknowable quantities.

Furthermore, we are concerned about NHS England's decision to create this new clinical terminology that does not exist elsewhere in the medical literature, with the closest-existing term being 'Rapid Onset Gender Dysphoria (ROGD)': a concept that has no scientific or clinical weight. All articles on the topic have either been retracted, or stated by the authors that this cannot be used as a real diagnosis. Alongside this, 'ROGD' has consistently been proven to be a pseudo-scientific concept that reflects how safe children feel talking to their parents more than anything else. We hope that NHS England does not intend on leaning on this anti-scientific concept which prioritises a parent's comfort over children and young people's clinical needs.

We understand that an alternative genesis to this concept follows from the trend of younger trans feminine people and older adolescent trans masculine people forming the two core groups seen by gender clinics. If this were the case, we anticipate the distinction between early and late onset gender dysphoria to be defined by Tanner stage. We are concerned about the extent to which this would create a discriminatory situation based on age, which fails to be addressed in the EHIA.

Furthermore, routine HRT prescription for trans feminine people often includes the use of GnRHa to block testosterone; the policy fails to address whether this would still be the case for individuals accessing this form of treatment. Again, if this element of the treatment protocol will no longer be available to trans feminine people, this could

amount to discrimination, as these trans feminine people would be delivered poorer care than their trans masculine counterparts.

Due to these terms not yet being defined, many areas of the EHIA have not been fully considered, and therefore we are unable to provide a full response.

The EHIA recognises that many children and young people waiting to be seen by the Service will hold the protected characteristic of gender reassignment; and also recognises that many children and young people who would otherwise be eligible for puberty suppressing medication will have this care routinely withheld. This could amount to discrimination. We are concerned about the damaging impact this will have on individual trans people and the community at large.

We are also deeply troubled by the NHS' admission that people of colour are more likely to experience discrimination, yet there are no proposals as to how NHS England will mitigate this.

We would suggest that within the recommendations for supporting Looked After children and young people, there is also signposting to organisations such as Gendered Intelligence and Mermaids in order for young people to access peer-to-peer support.

Are there any changes or additions you think need to be made to this policy?

We firmly disagree with the policy, and believe it is out of line with international law and research ethics, and is not in the best interest of trans young people. 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. This harm reductionist approach is particularly vital given the current political environment and the damaging impact it is having on the mental health of trans children and young people.

We welcome an approach that embraces research alongside routine prescription, as we believe that further research into puberty suppressing hormones will continue to improve the healthcare experiences of trans people. However, access to this

medication through research only will lead to young people feeling coerced into consenting to research to receive vital medication, meaning that their consent will not be freely given. This would invalidate the data, and risk the validity of the entire research project. If this were to happen, it could be devastating for the NHS' gender services' reputation, the landscape of research into and delivery of gender affirming care, and the wellbeing of the children and young people who took part in the research.

Furthermore, GIDS carried out research protocols into this area until 2014: any research must identify where the gaps in this previous research are, and why GIDS failed to gather this information at the time.

We are concerned that this policy does not appear to have been created with the needs and voices of trans children and young people taken into account. TONIC's report on the consultation responses found patients largely disagreed with the proposals put forth by NHS England. That NHS England has pursued the route of withholding care, it appears that patient voices have not been valued here. Clinician responses also highlighted that many children and young people turn to unregulated sources for hormones and puberty suppression due to the extensive waiting times: with this care being withheld, this will undoubtedly drive more children and young people to consider this route. We are concerned that this policy will do significantly more harm than good.

While we recognise and welcome the clause allowing for exceptional prescribing outside of the research protocol, we are concerned that this clause will rarely be used, if at all, and will not be accessible for any young people. It must be made clear what these exceptional circumstances are, how a young person would apply for this, and how they would demonstrate this need.

Various policies, research, and international laws establish the unethical nature of the proposed approach.

In 6.16 of her Interim Report, Dr Cass states that full informed consent must be ascertained before prescribing puberty suppressing hormones, referencing 'Decision making and consent' by the GMC, with 13d of this document stating that patients must have the right to refuse participation in teaching and research. By making this

medication accessible only through research, this consent is not fully informed, and patients will not feel able to refuse participation.

This is in direct contradiction to published recommendations around ethical research into trans healthcare, which advises that 'any provision of transgender healthcare is also available in a manner that is explicitly independent of research participation,' as informed consent must be 'without coercion or undue influence.'[1] It follows that, as access to GnRHa will only be available if a service user consents to the study, this consent cannot be freely given without coercion or undue influence: the threat of denial of care will mean that children and young people will not have an option to truly consent.

There is also precedent from international law that draws the legality and morality of this approach into question. The first principle of the Nuremberg Code is that 'the voluntary consent of the human subject is absolutely essential'. Again, how voluntary this consent would be is questionable and could certainly be challenged in a court of law. Alongside this, the Helsinki Declaration - the cornerstone document regarding human research ethics - states 'when seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress'. Individuals seek puberty suppressing hormones due to their distress, with some children and young people seeing this as the only hope for their wellbeing. As such, this may be considered to be 'consent under duress', and again could face challenge in a court of law. This proposal could also engage Regulation (EU) No 536/2014 of the European Parliament and of the Council Chapter V, stating that 'no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial.' Once again, this proposal may be experienced as undue, coercive influence by children and young people.

Most importantly, the first and most fundamental principle of research ethics is 'respect for the person,' meaning that their autonomy is paramount.[2] This includes ensuring individuals are not coerced or experience undue influence when recruited into

[1] Adams, N., Pearce, R., Veale, J., Radix, A., Castro, D., Sarkar, A., Thom, K. C., 'Guidance and Ethical Consideration for Undertaking Transgender Health Research and Institutional Review Boards Adjudicating this Research,' *Transgender Health* 2 (1) (2017) p. 170. DOI: 10.1089/trgh.2017.0012.
[2] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

research studies. Furthermore, informed consent requires that an individual is given information about the research, in a comprehensible way, and '*without duress or inappropriate inducement*.' Once again, this proposal will amount to inappropriate inducement, and therefore means that informed consent will not be possible for this research protocol.

Once again, we firmly support the inclusion of a research protocol *alongside* routine prescription of puberty suppressing hormones. However, we cannot support the current proposal due to its high risk of endangering the wellbeing and autonomy of vulnerable trans children and young people, and its clear violation of fundamental research ethics.

Finally, we are troubled by the references to 'natal sex' throughout this document. This language is inaccurate, disrespectful, and unnecessary. We strongly recommend NHS England change this wording to 'trans masculine people' and 'trans feminine people,' or, where absolutely necessary, 'people assigned male/female at birth.'