

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>services for children and young people (2023) reads: <i>“Some Group B respondents felt that the EHIA could have more thoroughly addressed the potential impact on those with the protected characteristic of sex – particularly the impacts on girls who, as recent statistics showed, were now much more likely to seek treatment from gender dysphoria services than boys. NHS England was encouraged to investigate and publicise the degree to which possible causations such as internalised homophobia, exposure to social media, trauma, bullying, difficulties in navigating bodily changes at puberty, experiencing sexual objectification, familial and social situations and social contagion had played a part in this trend”.</i></p> <p>Separately, the independent report on the analysis of responses to NHS England’s separate public consultation on the policy for Puberty Suppressing (2024) reads that some respondents to public consultation had suggested that the EHIA had not sufficiently reflected on how the withdrawal of GnRHa from the NHS pathway of care would differently and negatively impact natal males going through undesired puberty, for</p>	<p>The policy position has been proposed because there is a lack of sufficient evidence relating to the safety and clinical effectiveness of PSH for children and young people with gender incongruence / dysphoria, including about the benefits, risks and long-term outcomes. It is therefore proposed that adoption of the policy would in itself be a risk mitigation measure. Other forms of specialist clinical support will remain available through the NHS for this patient cohort;</p>

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	example, in the development of an Adam's apple or the deepening of the voice.	the NHS England interim service specification for gender incongruence (June 2023) describes a multi-disciplinary approach to care that focuses on psychosocial and psychological approaches, and psychoeducation.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	NHS England does not hold data on the sexual orientation of individuals who are referred to or seen by the NHS commissioned service. The website of the GIDS at the Tavistock and Portman NHS Foundation Trust describes the challenges in collecting this information from children and it reads: <i>"In our most recent statistics (2015), of the young people seen in our service who were assigned male at birth and for whom we have data, around 30% were attracted to males, 30% to females, and 30% to both males and females (or other genders). The remaining approximately 10% of those for whom we have data described themselves as not being attracted to either males or females, or as asexual. For young people assigned female at birth for whom we have data: over half were attracted to females, a quarter were attracted to males, just under 20% were to both males and females (or other genders), and a small percentage described themselves as asexual or as not being attracted to either males or females"</i> .	NHS England's proposed interim service specification for a new configuration of providers describes the importance of routine and consistent data collection, analysis and reporting. We expect providers to report demographic data for the purpose of continuous service improvement initiatives, including to identify whether any particular groups are experiencing barriers in access to service provision. NHS England's proposed interim service specification also describes the importance of building research capabilities for the purpose of continuous quality improvement initiatives. Working with the new configuration of service providers and academic partners, NHSE will consider how to use the outcome of this research to inform its future approach to the commissioning of these services. The Cass Review has said that in forming further advice to NHS England it is considering further the complex interaction between sexuality and gender identity, and societal responses to both – the Review's Interim Report (2022) cited the example of <i>"young lesbians who felt pressured to identify as transgender male, and conversely transgender</i>

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	<p>A large UK-wide study in 2012 (Trans Mental Health Study) reported the following:</p> <table border="1" data-bbox="625 451 1192 1049"> <thead> <tr> <th>Sexual Orientation</th> <th>N</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Bisexual</td> <td>145</td> <td>27%</td> </tr> <tr> <td>Queer</td> <td>126</td> <td>24%</td> </tr> <tr> <td>Straight or heterosexual</td> <td>104</td> <td>20%</td> </tr> <tr> <td>Pansexual</td> <td>79</td> <td>15%</td> </tr> <tr> <td>BDSM/Kink</td> <td>73</td> <td>14%</td> </tr> <tr> <td>Lesbian</td> <td>69</td> <td>13%</td> </tr> <tr> <td>Not sure or questioning</td> <td>64</td> <td>12%</td> </tr> <tr> <td>Other</td> <td>59</td> <td>11%</td> </tr> <tr> <td>Don't define</td> <td>55</td> <td>10%</td> </tr> <tr> <td>Gay</td> <td>51</td> <td>10%</td> </tr> <tr> <td>Polyamorous</td> <td>46</td> <td>9%</td> </tr> <tr> <td>Asexual</td> <td>41</td> <td>8%</td> </tr> <tr> <td>Total</td> <td>912</td> <td></td> </tr> </tbody> </table> <p>The 2021 census reported that 89.4% of the UK population (16+years) identified as straight or heterosexual, which is a marked variation to the findings of the above survey in 2021 (20%). It is unclear as to the extent to which these data can be extrapolated for the purpose of this EHIA, but it may be reasonable to surmise that there is likely to</p>	Sexual Orientation	N	Percentage	Bisexual	145	27%	Queer	126	24%	Straight or heterosexual	104	20%	Pansexual	79	15%	BDSM/Kink	73	14%	Lesbian	69	13%	Not sure or questioning	64	12%	Other	59	11%	Don't define	55	10%	Gay	51	10%	Polyamorous	46	9%	Asexual	41	8%	Total	912		<p><i>males who felt pressured to come out as lesbian rather than transgender”.</i></p> <p><i>Criteria for enrolment in a clinical study</i></p> <p>Alongside the first proposed study, further engagement is also planned by the National Research Oversight Board to identify the key evidence gaps for children and young people with later-onset gender dysphoria – recognising that there is even greater uncertainty in terms of the supporting clinical evidence base, less established clinical practice and less known about the natural history of gender dysphoria in this group. The clinical study team has yet to define these terms.</p>
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	<p>be a lower percentage of children and young people who are referred to a gender incongruence service who identify / will identify as straight or heterosexual than for the general population.</p> <p>NHS England has concluded that there is insufficient evidence to determine if a particular group or cohort will be disproportionately impacted by the policy.</p> <p>The independent report on the analysis of responses to NHS England's separate public consultation on a proposed interim service specification for gender incongruence services for children and young people (2023) reads that some respondents believed that: <i>"the protected characteristic of sexual orientation had not been sufficiently addressed in the Equalities and Health Inequalities Impact Assessment due to their belief that gender dysphoria services have disproportionately impacted on homosexual or bisexual children and young people in the past"</i>.</p>	

5. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your policy will not impact on patients who experience health inequalities.**

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	There is an over-representation percentage wise (compared to the national percentage) of looked after children seen by services for children and young people with gender incongruence ²⁷ .	<p>NHS England's interim service specification for Children and Young People's Gender Services (2023) recognises that a significant number of children and young people with very complex needs may also be <i>Looked After</i> or may not live with their birth family and may require the active involvement from children's social care and/or expert social work advice alongside support from the specialist service.</p> <p>As a risk mitigation measure, in April 2024 NHS England will have commissioned a rapid assessment service for every child or young person on the waiting list for CYP Gender Services, through local NHS children and young people's mental health services. This will be a directly commissioned service for this cohort over-and-above existing mental health provision.</p>
Carers of patients: unpaid, family members.	Families and carers of the children and young people who are directly affected by the policy, in terms of the impact to their overall wellbeing	In mitigation of any adverse impacts NHSE will ensure clear communications directly to the families and carers and to sign post them to additional support services if this is needed.

²⁶ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

²⁷ Interim report of the Cass Review, 2022

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p>Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.</p>	<p>The charity <i>akt</i> reports that 24% of homeless people identify as “LGBT” but we do not have specific data on the prevalence of children 16 years and under who are homeless and who present with gender incongruence. A decision that GnRHa will not be routinely commissioned by the NHS will not have any specific impact on this group. Separately, if a clinical study is determined to be feasible, it will be for the National Research Oversight Board to define access criteria into such a study and to consider the equalities implications of the access criteria.</p> <p>NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.</p>	
<p>People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.</p>	<p>NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on</p>	

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	reducing health inequalities in accessing services or achieving outcomes for this group.	
People with addictions and/or substance misuse issues	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	
People or families on a low income	Some respondents to consultation invited NHS England to accept that inequity may arise as a consequence of adoption of the policy in that lower-income families will be disadvantaged by not being able to afford to source GnRHa from private clinics. NHS England cannot share that view because it is not able to support the sourcing of GnRHa from any source outside of the NHS because of a lack of sufficient evidence relating to the safety and clinical effectiveness of GnRHa for children and young people with gender incongruence / dysphoria, including about the benefits, risks and long-term outcomes. It is therefore proposed that adoption of the policy would in itself be a	NHS England has commissioned Health Education England to deliver on-line MindEd resources directed at parents and local professionals , and these will provide improved psycho-educational advice to mitigate the need for and will caution about accessing GnRHa from unregulated sources (published in 2023). Greater involvement by and closer working between local secondary health services (CYPMHS and community child health and paediatrics) with specialist service consultation advice and liaison will further mitigate this potential impact.

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>risk mitigation measure. Moreover, NHS England is not aware of any regulated source of GnRHa for children and young people with gender incongruence / dysphoria outside of the NHS, hence NHS England's position being the following, regardless of the socio-economic status of the individual child or young person (source: NHS England's Interim Service Specification for CYP Gender Services, 2023).</p> <p><i>NHS England strongly discourages the sourcing of any medication from unregulated providers and unregulated sources such as the internet.</i></p> <p>NHS England is therefore of the view that the policy does not discriminate against this group.</p>	
<p>People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).</p>	<p>There is evidence that there are lower levels of health literacy in communities that are socially and economically disadvantaged. NHS England is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group. NHS</p>	

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.</p> <p>See also: <i>People or Families on a Low Income</i> (above).</p>	
People living in deprived areas	<p>Some respondents to consultation suggested that children and young people from low-income homes would be discriminated against because they would not be able to utilise treatments from private clinics available to those from more affluent families. NHS England has responded in its consultation report by explaining that were the policy adopted, the NHS would discourage all individuals from sourcing GnRHa from unregulated private clinics.</p> <p>NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing</p>	

Groups who face health inequalities²⁶	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>services or achieving outcomes for this group.</p> <p>See also: <i>People or Families on a Low Income</i> (above).</p>	
People living in remote, rural and island locations	<p>NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.</p>	
Refugees, asylum seekers or those experiencing modern slavery	<p>NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the policy does not discriminate against this group; and that the policy will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.</p>	
Other groups experiencing health inequalities (please describe)		

6. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes	No	Do Not Know
Proposed policy was subject to separate processes of stakeholder engagement and public consultation in 2023; the draft EHIA was published for engagement and consultation.		

7. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	<p>NICE evidence review 2020, and refresh in 2023</p> <p>Various published research, as identified elsewhere in this EHIA</p> <p>Review of evidence identified by respondents to public consultation</p> <p>Review of evidence relied upon by World Professional Association for Transgender Health (Chapter 12, Standards of Care v8, 2023)</p>	<p>The NICE evidence review confirms that there is limited evidence.</p> <p><i>Criteria for enrolment in a clinical study</i></p> <p>Alongside the first proposed study, further engagement is also planned by the National Research Oversight Board to identify the key evidence gaps for children and young people with later-onset gender dysphoria – recognising that there is even greater uncertainty in terms of the supporting clinical evidence base, less established clinical practice and less known about the natural history of gender dysphoria in this group. The clinical study team has yet to define these terms.</p>
Consultation and involvement findings	Outcome of public consultation that was held by NHS England in 2023; review of evidence identified by respondents to public consultation	No material evidence was identified

Evidence Type	Key sources of available evidence	Key gaps in evidence
Research	Interim advice from the Cass Review, 2022 and 2023	Potential benefits, potential risks, intended outcomes and efficacy of GnRHa
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The EHIA responds to points that have been made by members of NHS England's Programme Board for Gender Dysphoria Services	

8. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			
The proposal may support?	X	X	X
Uncertain whether the proposal will support?			

9. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?		X
The proposal may support?	X	
Uncertain if the proposal will support?		

10. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1 Potential benefits, potential risks, intended outcomes and efficacy of GnRHa	In 2022 the independent Cass Review advised that consideration is given to the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for GnRHa into a formal research programme with adequate follow up into adulthood. 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. NHS England has appointed a Clinical Trials Unit to develop the research protocol, including eligibility criteria, overseen by a newly established National Research Oversight Programme Board.
2 Potential benefits, potential risks, intended outcomes and efficacy of Gender Affirming Hormones	The independent Cass Review is expected to deliver final advice in March 2024 which may include advice on GAH.

11. Summary assessment of this EHIA findings

The policy will exclusively impact children and young people who are likely to share the protected characteristics of 'age' and 'gender reassignment'. The fact that a policy is likely to exclusively impact a specific group does not, in itself, render the policy discriminatory. NHS England has concluded that no direct or indirect discrimination arises. The policy is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that there is a lack of sufficient evidence relating to the safety and clinical effectiveness of GnRHa for children and young people with gender incongruence / dysphoria, including about the benefits, risks and long-term outcomes. It is therefore proposed that adoption of the policy would in itself be a risk mitigation measure. NHS England is cognisant of the potential impacts and consequences as detailed in this EHIA and through a process of public consultation it has sought views on the impacts, consequences and proposed mitigations through, and subsequent to, public consultation before making a final decision on whether to enact the policy.

EXHIBIT G





Public Health Evidence Report Following Engagement Activity

URN	1927
Policy title	Draft Interim Clinical Policy: Puberty suppressing hormones (PSH) for children and adolescents who have gender incongruence.
CRG	Gender Dysphoria Clinical Programme
NPOC	Not applicable
Engagement activity	Post public consultation
Date	15 th February 2024

Description of comments during engagement (If studies have been suggested please provide a list of references)	A query was received regarding NHSE's consideration of The World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, Version 8 , during development of the draft Interim Clinical Policy: Puberty suppressing hormones (PSH) for children and adolescents who have gender incongruence.
Action taken by Public Health lead	<p>The suggested references at stakeholder testing and public consultation during policy development and the responses to suggestions were checked for mention of the WPATH SOC Version 8.</p> <p>The WPATH SOC Version 8 was suggested at stakeholder testing and public consultation and a correct response was provided in both evidence reports noting that it does not fall within PICO and search methodology (because it is a guideline).</p> <p>To ensure comprehensive consideration of the WPATH SOC Version 8, the 200 citations within the relevant chapter, i.e. Chapter 12 Hormone Therapy, were further assessed and findings are described below.</p>
Outcome for studies cited in Chapter 12 of WPATH SOC Vn 8	
Citation not identifiable	<p><i>Citation given in short form in Chapter 12 but full details not provided in WPATH SOC Vn8 reference list</i></p> <ol style="list-style-type: none"> 1. Baba, 2007 2. Finkelstein et al 1996 3. Lin et al 2021 4. Stuyver et al 2020 5. Tebbens at al 2021

	6. Toorians et al 2013
Citation does not meet PICO criteria or search methodology of the NICE 2020 evidence review	<p><i>Published prior to the date limits of the literature search:</i></p> <ol style="list-style-type: none"> 1. Comite et al 1981 2. Laron et al 1981 3. van Kesteren et al 1997 <p><i>Published within the date limits of the literature search and either was not identified from the searches performed or was identified but sifted out because of not meeting the PICO criteria based on the title and abstract details:</i></p> <ol style="list-style-type: none"> 1. Adeleye et al, 2018 2. Allen et al, 2019 3. Alzahrani et al, 2019 4. Anai et al, 2001 5. Arcelus et al, 2016 6. Ashley, 2019e 7. Asscheman et al, 2013 8. Barrow & Apostle, 2018 9. Bauer et al, 2015 10. Becerra-Culqui et al, 2018 11. Beek, Kreukels et al 2015 12. Bertelloni et al, 1998 13. Bisson, 2018 14. Bockting et al, 2013 15. Borghei-Razavi, 2014 16. Bouman et al, 2016 17. Bouman et al, 2016 18. Bouman et al, 2017 19. Canonico et al, 2007 20. Carel et al, 2009 21. Klink, Caris et al, 2015 22. Carswell & Roberts, 2017 23. Chan et al 2018 24. Chen, Hidalgo et al, 2016 25. Cheng et al, 2019 26. Colebunders et al, 2017 27. Coleman et al, 2012 28. Colizzi et al, 2014 29. Coolhart et al, 2017 30. Costa et al, 2016 31. Davey et al, 2014 32. Davis & Meier, 2014 33. De Roo et al, 2016 34. De Roo et al, 2017 35. Defreyne et al, 2018 36. Defreyne, Nota et al 2017 37. Dekker et al 2016 38. Delemarre-van de Waal & Cohen-Kettenis 2006

	<p>39. Deutsch, 2016a 40. Deutsch, Bhakri et al 2015 41. Djordjevic et al, 2008 42. Du Bois et al, 2018 43. Eisenberg et al 2017 44. Ethics committee of the American Society of Reproductive Medicine et al 2015 45. Finlayson et al 2016 46. Fisher, Castellini et al 2016 47. Fitzpatrick et al 2000 48. Frey et al 2016 49. Gaither et al 2018 50. Gava et al 2016 51. Gava et al 2018 52. Giltay & Gooren, 2000 53. Giltay et al, 2000 54. Goldstein et al 2019 55. Gomez-Gil et al, 2012 56. Gorin-Lazard et al 2012 57. Gorin-Lazard et al 2013 58. Gower, Rider, Brown et al 2018 59. Grossman & D'Augelli 2006 60. Grynberg et al 2010 61. Hembree et al 2009 62. Hendricks & Testa, 2012 63. Heylens, Elaut et al 2014 64. Horbach at al 2015 65. Irwig, 2017 66. Irwig, 2018 67. Iwamoto, Defreyne et al 2019 68. Iwamoto, T'Sjoen et al 2019 69. Jiang et al 2018 70. Jiang et al 2019 71. Kailas et al 2017 72. Keo-Meier & Ehrensaft, 2018 73. Keo-Meier & Fitzgerald, 2017 74. Keo-Meier et al 2015 75. Kerckhof et al 2019 76. Klink, Bokenkamp et al 2015 77. Kuper, Mathews et al, 2019 78. Kuper, Wright et al 2018 79. Levy et al 2003 80. Light et al 2014 81. Mamoojee et al 2017 82. Mancini et al 2018 83. Manson, 2013 84. Maraka et al 2017 85. Marks et al 2019 86. Mattawanon et al 2018 87. Meier et al 2013</p>
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	<p>88. Merrigiola et al 2008 89. Meyer 2003 90. Millington et al 2019 91. Moody et al 2015 92. Murad et al 2010 93. Nash et al 2018 94. Newfield et al 2006 95. Neyman et al 2019 96. Nguyen et al 2018 97. Nobili et al 2018 98. Nota et al 2018 99. Nota et al 2019 100. O'Bryant et al, 2008 101. Olson-Kennedy, Garofalo et al 2019 102. Olson-kennedy, Rosenthal et al 2018 103. Ott et al 2010 104. Pelusi et al 2014 105. Pflum et al 2015 106. Pradhan & Gomez-Lobo, 2019 107. Pullen Sansfacon et al 2015 108. Rider, McMorris et al 2019 109. Rosen et al 2019 110. Rosenthal 2014 111. Rosenthal et al 2016 112. Rothernberg et al 2019 113. Rowniak et al 2019 114. Ryan 2009 115. Ryan et al 2010 116. Safer & Tangpricha 2019 117. Schagen et al 2016 118. Schechter & Safa, 2018 119. Schneider et al 2015 120. Schwartz et al 2019 121. Seal et al 2012 122. Shumer at al 2016 123. Silverberg et al 2017 124. Smith et al 2014 125. Smith et al 2018 126. Taliaferro et al 2019 127. Tangpricha & den Heijer 2017 128. Ter Wengel et al 2016 129. Tishelman & Neumann-Mascis, 2018 130. Tishelman et al 2015 131. Toorians et al 2003 132. T'Sjoen et al 2005 133. T'Sjoen et al 2019 134. van Caenegem, Verhaeghe et al 2013 135. van Dijk et al 2019 136. Vinogradova et al 2019 137. Vlot et al 2017</p>
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	<p>138. Weinand & Safer 2015 139. White Hughto & Reisner, 2016 140. Wiepjes et al 2019 141. Wierckx et al 2013 142. Wierckx, Mueller et al, 2012 143. Wierckx, van Caenegem et al 2014 144. Wierckx, van de Peer et al, 2014 145. Witcomb et al 2018</p>
Citation identified within the NICE 2020 evidence review	<p><i>Listed as an excluded study in the evidence review:</i></p> <ol style="list-style-type: none"> 1. de Vries et al, 2014 2. Klaver et al 2020 3. Turban, King et al 2020 <p><i>Included in the evidence review:</i></p> <ol style="list-style-type: none"> 1. de Vries, Steensma et al, 2011 2. Klink, Caris et al 2015
Citation identified as part of the literature surveillance report	<p><i>Identified from the literature search but sifted out because of not meeting the PICO criteria based on the title and abstract details:</i></p> <ol style="list-style-type: none"> 1. Angus et al, 2021 2. T'Sjoen et al 2020 <p><i>Identified from the literature search but did not meet the PICO criteria based on reading the full text:</i></p> <ol style="list-style-type: none"> 1. Millington et al 2020 2. Lee, Finlayson et al 2020 3. Rew et al 2020 <p><i>Identified from the literature search, did meet the PICO criteria but did not materially affect the conclusions of the NICE 2020 evidence review:</i></p> <ol style="list-style-type: none"> 1. Schagen et al, 2020
Citation identified as part of stakeholder testing	<p><i>Identified during stakeholder testing but did not meet the PICO criteria:</i></p> <ol style="list-style-type: none"> 1. Hembree et al 2017
Citation identified as part of public consultation	<p><i>Identified during public consultation but did not meet the PICO criteria or search methodology of the NICE 2020 evidence review:</i></p> <ol style="list-style-type: none"> 1. Bangalore Krishna et al, 2019 2. Russell et al 2018 3. Wiepjes et al 2018
New citation that does not fall	<p><i>Not identified from the searches performed for the literature surveillance report, nor during stakeholder testing nor during public consultation:</i></p>

within the search methodology	<ol style="list-style-type: none"> 1. Aldridge et al, 2020 2. Antun et al, 2020 3. Chlebowski, 2020 4. De Blok et al, 2020 5. Defreyne, Elaut et al 2020 6. Eisenberg et al 2020 7. Gava et al 2020 8. Kuper et al 2020 9. Kvist et al 2020 10. Nobili et al 2020 11. Prince & Safer, 2020 12. Sofer et al, 2020 13. Taub et al 2020 14. Van de Grift et al 2020 15. Vereecke et al 2020 16. Wiepjes et al 2020 17. Wilson et al 2020 18. Yeung et al 2020 19. Banks et al, 2021 20. Braun et al, 2021 21. Chantrapanichkul et al, 2021 22. Dy et al 2021 23. Gezer et al 2021 24. Greenwald et al 2021 25. Irwig, 2021 26. Kozato et al 2021 27. Kuijpers et al 2021 28. Kyinn et al 2021 29. Rosenthal 2021 30. Safer, 2021 31. Weill et al 2021
New citation that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review	None
New citation that falls within PICO and search methodology, that does materially affect the conclusions	None

of the NICE 2020 evidence review.	
Updated evidence review to be undertaken (to be agreed with CET)	Not applicable

Completed by:	Public Health Consultant
Date:	21 st February 2024

Peer reviewed and supported by:	Not applicable
Date:	Not applicable

Reference List

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EXHIBIT H





Public Health Evidence Report Following Engagement Activity

This form is to be completed by the Policy Working Group's Public Health Lead if stakeholders identify potential new evidence during policy development engagement activities. The Public Health Lead will assess the evidence raised to against the Population, Intervention, Comparator and Outcome (PICO) criteria and will record the studies in the appropriate boxes in the 'Outcome for studies suggested during engagement activities' section of this form. In cases where newly identified evidence has a material impact, please return the completed form to the Clinical Effectiveness Team (CET).

URN	1927
Policy title:	Draft Interim Clinical Policy: Puberty Suppressing Hormones
CRG:	Gender Dysphoria Clinical Programme
NPOC:	Not applicable
Engagement activity	Public consultation
Date	5 th January 2024

Description of comments during engagement (If studies have been suggested please provide a list of references)	<p>251 URLs related to the public consultation questions:</p> <ul style="list-style-type: none"> • Has all of the relevant evidence been taken into account? • Are there any changes or additions you think need to be made to this policy? <p>Short references were allocated for the information to which each of the URLs linked. 10 URLs linked to 5 duplicate short references, leaving 246 unique short references suggested during consultation.</p>
Action taken by Public Health lead	<p>246 unique references were checked for relevance against the search strategy and PICO used for the evidence review and literature surveillance report and against the references detailed in the evidence review, the literature surveillance report the stakeholder testing Public Health Evidence Report. Where necessary, references were obtained in full text.</p> <p>3 unique references were general website pages from which specific information could not be determined.</p> <ol style="list-style-type: none"> 1. ONS data http://www.nomisweb.co.uk 2. St Louis https://www.stlouischildrens.org/conditions-treatments/transgender-center/puberty-blockers 3. UK Parliament Committees https://committees.parliament.uk/writtenevidence/7947/html/

Outcome for studies suggested during engagement activities	
1. Evidence already identified as part of the evidence review, literature surveillance report or stakeholder testing	<ol style="list-style-type: none"> 1. Achille 2020 https://doi.org/10.1186/s13633-020-00078-2 2. Anacker 2020 https://pubmed.ncbi.nlm.nih.gov/32919399 3. Angus 2020 https://doi.org/10.1111/cen.14329 4. Biggs 2023 https://pubmed.ncbi.nlm.nih.gov/36120756/ 5. Boogers 2022 https://pubmed.ncbi.nlm.nih.gov/35666195/ 6. Carmichael 2021 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0243894 7. Chen 2021 https://doi.org/10.1016/j.jadohealth.2020.07.033 8. Costa 2015 https://pubmed.ncbi.nlm.nih.gov/26556015/ 9. de Vries 2011 https://pubmed.ncbi.nlm.nih.gov/20646177/ 10. de Vries 2014 https://publications.aap.org/pediatrics/article-abstract/134/4/696/32932/Young-Adult-Psychological-Outcome-After-Puberty?autologincheck=redirected 11. Drummond 2008 https://psycnet.apa.org/doiLanding?doi=10.1037%2F0012-1649.44.1.34 12. Giovanardi 2019 https://pubmed.ncbi.nlm.nih.gov/30953318/ 13. Graham 2023 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10063975/ 14. Hembree 2017 https://pubmed.ncbi.nlm.nih.gov/28945902/ 15. Horton 2022 https://doi.org/10.1177/07435584221100591 16. Jensen 2019 https://pubmed.ncbi.nlm.nih.gov/31663037/ 17. Joseph 2019 https://pubmed.ncbi.nlm.nih.gov/31472062/ 18. Khatchadourian 2014 https://pubmed.ncbi.nlm.nih.gov/24315505/ 19. Klink 2015 https://pubmed.ncbi.nlm.nih.gov/25427144/ 20. Kremen 2021 https://pubmed.ncbi.nlm.nih.gov/33883246/ 21. Lee 2020 https://doi.org/10.1210/jendso/bvaa065 22. Nos 2022 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2798002 23. Panagiotakopoulos 2020 https://doi.org/10.1038/s41585-020-0372-2 24. Ramos 2020 https://link.springer.com/article/10.1007/s40618-020-01449-5 25. Rew 2021 https://doi.org/10.1111/camh.12437 26. Schagen 2016 https://pubmed.ncbi.nlm.nih.gov/27318023/ 27. Schagen 2020 https://academic.oup.com/jcem/article/105/12/e4252/5903559?login=false 28. Staphorsius 2015 https://www.sciencedirect.com/science/article/abs/pii/S0306453015000943 29. Steensma 2013 https://doi.org/10.1016/j.yhbeh.2013.02.020 30. Tordoff 2022 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8881768/ 31. Van der Loos 2023 https://pubmed.ncbi.nlm.nih.gov/36763938/

	<p>32. van der Miesen 2020 https://doi.org/10.1016/j.jadohealth.2019.12.018</p> <p>33. Wallien 2008 https://pubmed.ncbi.nlm.nih.gov/18981931/</p> <p>34. Zucker 2010 https://www.tandfonline.com/doi/abs/10.1080/19359705.2011.530574</p>
<p>2. New evidence identified by stakeholders that does not fall within PICO and search methodology</p>	<ol style="list-style-type: none"> 1. AACAP 2020 https://www.aacap.org/AACAP/Families_and_Youth/Facts_for_Families/FFF-Guide/transgender-and-gender-diverse-youth-122.aspx 2. AACE 2022 https://pro.aace.com/recent-news-and-updates/aace-position-statement-transgender-and-gender-diverse-patients 3. AACPP 2019 https://www.aacap.org/AACAP/Latest_News/AACAP_Statement_Responding_to_Efforts_to_ban_Evidence-Based_Care_for_Transgender_and_Gender_Diverse.aspx 4. Abbruzzese 2023 https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2150346 5. Abreu 2022 https://psycnet.apa.org/record/2021-67997-001?doi=1 6. Abreu 2022a https://psycnet.apa.org/record/2022-47098-001 7. ACC 2023 https://www.acc.org/About-ACC/Press-Releases/2023/02/22/20/29/Hormone-Therapy-for-Gender-Dysphoria-May-Raise-Cardiovascular-Risks 8. ACHA https://www.acha.org/ACHA/About/Position_Statements/ACHA/About/Position_Statements.aspx?hkey=ff979452-3284-4993-8cbc-bf4abaa8b430 9. ACNM https://www.midwife.org/acnm/files/acnmldata/uploadfilename/000000000326/ACNM--PS--Care%20for%20TGNB%20People-%20Final_1.pdf 10. ACOG 2021 https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals 11. ACP 2023 https://www.acponline.org/advocacy/state-health-policy/attacks-on-gender-affirming-and-transgender-health-care 12. ACT 2021 https://health.act.gov.au/sites/default/files/2021-11/Guidance%20to%20support%20gender%20affirming%20care%20for%20mental%20health%20FINAL_0.pdf 13. Alegria 2016 https://pubmed.ncbi.nlm.nih.gov/27031444/ 14. AMA 2019 https://www.ama-assn.org/press-center/press-releases/ama-leading-medical-organizations-fight-transgender-americans 15. AMA 2021 https://www.ama-assn.org/press-center/press-releases/ama-states-stop-interfering-health-care-transgender-children

16. ANA 2022 <https://www.nursingworld.org/news/news-releases/2022-news-releases/american-nurses-association-opposes-restrictions-on-transgender-healthcare-and-criminalizing-gender-affirming-care/>
17. Anacker 2021 <https://pubmed.ncbi.nlm.nih.gov/32919399/>
18. APA 2018
<https://www.psychiatry.org/getattachment/3d23f2f4-1497-4537-b4de-fe32fe8761bf/Position-Conversion-Therapy.pdf>
19. APA 2021 <https://www.psychiatry.org/newsroom/news-releases/frontline-physicians-oppose-legislation-that-interferes-in-or-criminalizes-patient-care>
20. Arnold 2023 https://journals.lww.com/co-pediatrics/abstract/2023/08000/transgender_and_gender_diverse_youth_an_update_on.6.aspx
21. Arnoldussen 2022 <https://doi.org/10.1089/lgbt.2020.0494>
22. Arnoldussen 2022a
<https://doi.org/10.1177/13591045221091652>
23. Ashley 2023
<https://www.tandfonline.com/doi/full/10.1080/26895269.2023.2218357>
24. Ashley 2023a <https://psycnet.apa.org/fulltext/2024-16010-001.html>
25. AUA 2022 <https://www.auanet.org/about-us/policy-and-position-statements/transgender-care>
26. AusPath <https://auspath.org.au/standards-of-care/>
27. Azar 2019 <https://www.aapa.org/download/50101/>
28. Bailey 2003 <https://www.amazon.com/Man-Would-Queen-Gender-Bending-Transsexualism/dp/0309084180>
29. Bangalore Krishna 2019
<https://pubmed.ncbi.nlm.nih.gov/31319416/>
30. Barnes 2023 <https://www.bbc.co.uk/news/health-66842352>
31. Barnes 2023a <https://www.amazon.com/Time-Think-Collapse-Tavistocks-Children-ebook/dp/B0BCL1T2XN>
32. Bauer 2022 <https://pubmed.ncbi.nlm.nih.gov/34793826/>
33. Beers 2021 <https://www.aap.org/en/news-room/news-releases/aap/2021/american-academy-of-pediatrics-speaks-out-against-bills-harming-transgender-youth/>
34. Bhatt Murphy solicitors 2023
<https://bhattmurphy.co.uk/files/SRN%20cases/Sophie%20Williams%20Press%20Release%2001.03.23.pdf>
35. Bindmans 2023 <https://www.bindmans.com/knowledge-hub/news/alice-litman-inquest-concludes/>.
36. Blanchard 1989 <https://pubmed.ncbi.nlm.nih.gov/2673136/>
37. Blanchard 2008
https://www.researchgate.net/publication/5420507_Deconstructing_the_Feminine_Essence_Narrative
38. Boerner
2022 <https://www.scientificamerican.com/article/what-the-science-on-gender-affirming-care-for-transgender-kids-really-shows/>

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<p>3.New evidence identified by stakeholders that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review</p>	<p>1. Lavender 2023 https://doi.org/10.1089/lgbt.2022.0201</p> <p>They report a retrospective observational analysis of patients who attended an endocrine clinic. All patients in this study had been treated with puberty suppression and gender-affirming hormone treatment, although results are presented separately for each stage of treatment and thus it is possible to determine outcomes for patients following puberty suppression only.</p> <p>Number of patients in this study is small, with considerable loss to follow up (ie 109 eligible participants but full results only available for 38). Comprehensive assessment at each stage using a range of questionnaires, completed by young people and caregivers.</p> <p>The use of puberty suppressants resulted in statistically significant improvements in the Child Behavior Checklist but no statistically significant differences in the Youth Self Report questionnaire or the Body Image Scale questionnaire or the Utrecht Gender Dysphoria Scale. Improvements were also noted in self harm and suicidality statements following treatment with puberty suppressants.</p>

	<p>2. Ludvigsson 2023 https://doi.org/10.1111/apa.16791</p> <p>This is a systematic review with relevant outcomes. All contributing studies were checked and have been previously identified or are not relevant to the PICO.</p> <p>Note also that the authors state “Evidence to assess the effects of hormone treatment on the above fields [psychosocial and mental health, cognition, body composition, and metabolic markers of hormone treatment in children with gender dysphoria] is insufficient.”</p> <p>3. Kuper 2020 https://doi.org/10.1542/peds.2019-3006</p> <p>In this study a total of 148 participants completed surveys assessing body dissatisfaction, depression and anxiety at initial presentation to their clinic and at follow-up after one year.</p> <p>Most patients in this study were treated with feminising or masculinising hormone therapy but a small number (25/148; 17%) were treated with puberty blocking drugs and the results for this group are reported separately. Note that 90% of all the patients in this study were at a late stage of puberty (Tanner Stage IV or V).</p> <p>There were modest improvements in body dissatisfaction, depressive symptoms and anxiety symptoms in the group of patients treated with puberty suppressants only.</p>
<p>4. New evidence identified by stakeholders that falls within PICO and search methodology, that does materially affect the conclusions of the existing evidence review. Updated evidence review to be undertaken (to be agreed with CET)</p>	<p>None</p>

Completed by:

Consultant in Public Health Medicine, NHS England

Date:	5 th January 2024
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Peer reviewed and supported by:	Not applicable
Date:	Not applicable

EXHIBIT I





Public Health Evidence Report Following Engagement Activity

This form is to be completed by the Policy Working Groups Public Health Lead if stakeholders identify potential new evidence during policy development engagement activities. The Public Health Lead will assess the evidence raised to against the Population, Intervention, Comparator and Outcome (PICO) criteria and will record the studies in the appropriate boxes in the '*Outcome for studies suggested during engagement activities*' section of this form. In cases where newly identified evidence has a material impact please return the completed form to the Clinical Effectiveness Team (CET).

URN	1927
Policy title:	Draft Interim Clinical Policy: Puberty Suppressing Hormones
CRG:	Gender Dysphoria Clinical Programme
NPOC:	Not applicable
Engagement activity	Stakeholder testing
Date	07 July 23

Description of comments during engagement (If studies have been suggested please provide a list of references)	23 responses were received during stakeholder testing. Of these, 8 stakeholders suggested 19 identifiable and unique references that might have been erroneously omitted from the evidence review or literature surveillance report.
Action taken by Public Health lead	All 19 identifiable and unique references were obtained in full text and checked for relevance against the search strategies and PICO details that were used for the evidence review and literature surveillance report.
Outcome for studies suggested during engagement activities	

<p>1. Evidence already identified during the evidence review or literature surveillance report</p>	<ul style="list-style-type: none"> • Angus LM, Nolan BJ, Zajac JD, Cheung AS. A systematic review of antiandrogens and feminization in transgender women. Clin Endocrinol (Oxf). 2021 May;94(5):743-752. doi: 10.1111/cen.14329. Epub 2020 Oct 5. PMID: 32926454. • Chen D, Abrams M, Clark L, Ehrensaft D, Tishelman AC, Chan YM, Garofalo R, Olson-Kennedy J, Rosenthal SM, Hidalgo MA. Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings From the Trans Youth Care Study. J Adolesc Health. 2021 Jun;68(6):1104-1111. doi: 10.1016/j.jadohealth.2020.07.033. Epub 2020 Aug 21. PMID: 32839079; PMCID: PMC7897328. • Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Erratum in: JAMA Netw Open. 2022 Jul 1;5(7):e2229031. PMID: 35212746; PMCID: PMC8881768. • Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. Pediatrics. 2020 Feb;145(2):e20191725. doi: 10.1542/peds.2019-1725. Erratum in: Pediatrics. 2021 Apr;147(4): PMID: 31974216; PMCID: PMC7073269. • de Vries 2014 (see 3 below for details)
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<p>2.New evidence identified by stakeholders that does not fall within PICO and search methodology</p>	<ul style="list-style-type: none"> • Agarwal, Cori A.; Scheefer, Melody F.; Wright, Lindsey N.; Walzer, Norelle K.; Rivera, Andy (2018). Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test. Journal of Plastic, Reconstructive & Aesthetic Surgery, S1748681518300159-. doi:10.1016/j.bjps.2018.01.003 • Becker, Inga; Auer, Matthias; Barkmann, Claus; Fuss, Johannes; Möller, Birgit; Nieder, Timo O.; Fahrenkrug, Saskia; Hildebrandt, Thomas; Richter-Appelt, Hertha (2018). A Cross-Sectional Multicenter Study of Multidimensional Body Image in Adolescents and Adults with Gender Dysphoria Before and After Transition-Related Medical Interventions. Archives of Sexual Behavior, doi:10.1007/s10508-018-1278-4 • Biggs M. The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence. J Sex Marital Ther. 2023;49(4):348-368. doi: 10.1080/0092623X.2022.2121238. Epub 2022 Sep 19. PMID: 36120756 • Bungener SL, de Vries ALC, Popma A, Steensma TD. Sexual Experiences of Young Transgender Persons During and After Gender-Affirmative Treatment. Pediatrics. 2020 Dec;146(6):e20191411. doi: 10.1542/peds.2019-1411. PMID: 33257402. • Drummond KD, Bradley SJ, Peterson-Badali M, Zucker KJ. A follow-up study of girls with gender identity disorder. Dev Psychol. 2008 Jan;44(1):34-45. doi: 10.1037/0012-1649.44.1.34. PMID: 18194003. • Endocrine Society Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: Clinical Practice Guideline: https://academic.oup.com/jcem/article/102/11/3869/4157558#99603252 • Prof Simona Giordano Children and Gender - Ethical issues in clinical management of transgender and gender diverse youth, from early years to late adolescence Issues in Biomedical Ethics ISBN: 9780192895400 • C Heneghan and T Jefferson
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<p>Gender-affirming hormone in children and adolescents BMJ EBM Spotlight Posted on 25th February 2019</p> <ul style="list-style-type: none">• Horton, C. (2022). <p>Experiences of Puberty and Puberty Blockers: Insights From Trans Children, Trans Adolescents, and Their Parents. Journal of Adolescent Research, 0(0).</p> <ul style="list-style-type: none">• Olson-Kennedy, Johanna; Warus, Jonathan; Okonta, Vivian; Belzer, Marvin; Clark, Leslie F. (2018). <p>Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults. JAMA Pediatrics, doi:10.1001/jamapediatrics.2017.5440</p> <ul style="list-style-type: none">• Steensma TD, Kreukels BP, de Vries AL, Cohen-Kettenis PT. <p>Gender identity development in adolescence. Horm Behav. 2013 Jul;64(2):288-97. doi: 10.1016/j.yhbeh.2013.02.020. PMID: 23998673.</p> <ul style="list-style-type: none">• van der Miesen AIR, Steensma TD, de Vries ALC, Bos H, Popma A. <p>Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers. J Adolesc Health. 2020 Jun;66(6):699-704. doi: 10.1016/j.jadohealth.2019.12.018. Epub 2020 Apr 6. PMID: 32273193.</p> <ul style="list-style-type: none">• Wallien MS, Cohen-Kettenis PT. <p>Psychosexual outcome of gender-dysphoric children. J Am Acad Child Adolesc Psychiatry. 2008 Dec;47(12):1413-23. doi: 10.1097/CHI.0b013e31818956b9. PMID: 18981931.</p> <ul style="list-style-type: none">• World Professional Association for Transgender Health - Standards of Care version 8: <p>https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644</p>

<p>3.New evidence identified by stakeholders that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review</p>	<ul style="list-style-type: none"> • de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. <p>Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014 Oct;134(4):696-704. doi: 10.1542/peds.2013-2958. Epub 2014 Sep 8. PMID: 25201798.</p> <p>This study was identified and excluded during preparation of the draft NICE evidence review. It was highlighted for potential inclusion by the Policy Working Group during testing. It remained excluded from the final NICE evidence review as the relevant population and follow-up time points were included in the de Vries et al. (2011) study.</p> <p>The paper was highlighted by 2 stakeholders during stakeholder testing of the policy proposition.</p> <p>It is considered that the paper does fall within PICO details and search methodology. It indicates that use of GnRHa along with other interventions (e.g. multidisciplinary care) improves body image outcomes after gender reassignment surgery. However, this evidence does not materially affect the conclusions of the existing evidence review.</p>
<p>4.New evidence identified by stakeholders that falls within PICO and search methodology, that does materially affect the conclusions of the existing evidence review. Updated evidence review to be undertaken (to be agreed with CET)</p>	<p>Not applicable</p>

Completed by:	Medical Advisor Highly Specialised Service
Date:	07 July 2023

Peer reviewed and supported by:	Not applicable
Date:	Not applicable

EXHIBIT J



NHS England

Interim Clinical Policy: Puberty suppressing hormones (PSH) for children and adolescents who have gender incongruence or dysphoria

Public Consultation Analysis and Summary | January 2024

Version: 1.4

Status: Final Report

Authors: Rory Miller, Katie Lund and Matthew Scott

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TONIC

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Section 1. Executive Summary

Background

As part of its gender incongruence/dysphoria services for children and young people, NHS England is proposing an interim clinical policy on the use of puberty suppressing hormones (PSH). The policy proposition is that puberty suppressing hormones (sometimes referred to as ‘puberty blockers’ or ‘hormone blockers’) are not recommended to be available as a routine commissioning option for the treatment of children and adolescents who have gender incongruence or dysphoria.

Currently, PSH are prescribed through the NHS for children and young people with a diagnosis of persistent gender dysphoria after a certain stage of pubertal development, alongside psychosocial and psychological support, and after review by NHS England’s Multi-Professional Review Group (MPRG). This review includes assurance that child safeguarding and child protection issues have been fully considered, that all necessary steps have been taken, and that all relevant information has been provided to and understood by the young person and their parents/carers.

In January 2020, NHS England commissioned the National Institute for Health and Care Excellence (NICE) to review the published evidence on the use of PSH¹. Nine observational studies were included in the evidence review, with NICE finding that, overall, there was no statistically significant difference in gender incongruence, mental health, body image and psychosocial functioning in children and adolescents treated with PSH. The quality of evidence for all these outcomes was assessed as very low certainty, with limited short-term and long-term safety data available. PSH may, however, reduce the expected increase in lumbar or femoral bone density during puberty.

A follow-up literature surveillance of nine further studies was undertaken by NHS England’s Clinical Effectiveness Team, supported by the Clinical Policy Team, in April 2023². In addition, further evidence was suggested during two weeks of targeted stakeholder consultation, which provided responses from 13 organisations, four clinicians/academics, and six individuals or carers/family members. In addition, the interim recommendations of the Cass Review³ were also considered.

¹ https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf

² https://www.engage.england.nhs.uk/consultation/puberty-suppressing-hormones/user_uploads/literature-surveillance-report-on-gnrh-analogues-for-children-and-adolescents-with-gender-dysphoria-may-2023.pdf

³ <https://cass.independent-review.uk/>

These reviews resulted in NHS England concluding that there is not enough evidence to support the safety or clinical and cost effectiveness of PSH to make the treatment routinely available at this time. NHS England recommends that access to PSH for children and young people with gender incongruence/dysphoria should only be available as part of research.

Public consultation

In order to hear the views of patients, parents and carers, clinicians and service providers, as well as other interested parties, NHS England ran a public consultation between 3rd August and 1st November 2023. The consultation was published on its website alongside seven supporting documents:

- Consultation guide
- Interim clinical policy
- Stakeholder engagement report
- Equalities and health inequalities impact assessment
- Post-engagement evidence report
- Literature surveillance report
- NICE evidence review

The consultation asked three questions of respondents:

Question 1. Has all of the relevant evidence been taken into account?

Question 2. Does the equality and health inequality impact assessment (EHIA) reflect the potential impact that might arise as a result of the proposed changes?

Question 3. Are there any changes or additions you think need to be made to this policy?

A total of 4,040 responses to the consultation were received.

Analysis and report

NHS England commissioned TONIC, a UK-based public consultation and social research specialist organisation (www.tonic.org.uk), to undertake an independent analysis of the consultation responses and to produce a written report of the findings. TONIC analysts read each response and used thematic analysis to make a record of all views. These views and overarching themes are summarised and described in the report that follows.

Respondent demographics

Respondents were asked in which capacity they were participating and whether they were responding on behalf of an organisation. The three largest respondent groups were members of the public (25%), patients (22%), and parents (22%), with a further six groups comprising the remainder.

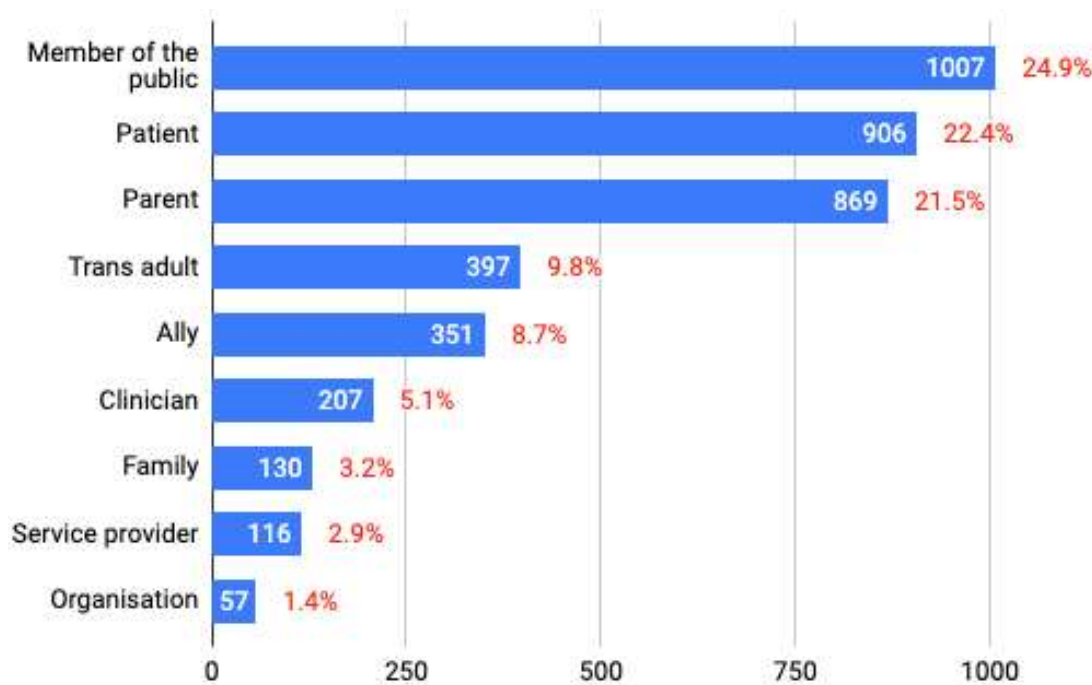


Figure 1. Consultation respondents by respondent type

Summary of quantitative responses

The majority of respondents felt that additional evidence needed to be taken into account when developing the proposals (72%) and believed that the equality and health inequalities impact assessment had failed to reflect the potential impact that might arise as a result of the proposed changes (82%).

Among the different respondent types there was some variation in answers to the two quantitative questions, with parents and clinicians slightly more likely to state agreement overall than other groups (though this was still a minority) and friends/allies and transgender adults much more likely to disagree – particularly in response to question 2.

In addition, those responding on behalf of an organisation were more likely to disagree with question 2 (regarding the EHIA) than any other group, with only 7% saying they agreed. The following table sets out the answers to each of the two quantitative questions by respondent type:

Table 1. Quantitative question results by respondent type

Respondent type	Q1. Has all of the relevant evidence been taken into account?		Q2. Does the equality and health inequality impact assessment reflect the potential impact that might arise as a result of the proposed changes?	
	Yes	No	Yes	No
Member of the public	23.7%	76.3%	14.8%	85.2%
Patient	28.7%	71.3%	16.8%	83.2%
Parent	35.7%	64.3%	28.7%	71.3%
Trans adult	21.5%	78.5%	9.8%	90.2%
Friend / Ally	23.4%	76.6%	9.1%	90.9%
Clinician	36.7%	63.3%	29.0%	71.0%
Family	34.6%	65.4%	20.0%	80.0%
Service provider	28.4%	71.6%	19.8%	80.2%
Organisation	27.3%	72.7%	7.3%	92.7%
Total	28%	72%	18%	82%

Summary of qualitative responses

Differences in viewpoint

Broadly speaking, responses to the three open-ended questions corresponded with one of two viewpoints:

- **Group A:** Those who believed that puberty suppressing hormones have been shown to be harmless and beneficial, and that they should be made available to gender dysphoric children and young people without the requirement to enrol in a research trial. This group made up the majority of responses to the consultation, with 3,492.
- **Group B:** Those who believed that that evidence tended to show that PSH are harmful, unproved, unsuitable or unnecessary, and that therefore, PSH should not be made available to gender dysphoric young people. There were 180 responses from this group.

As a result, it was decided that the most logical way to present respondents' input was in accordance with these overarching viewpoints.

A third category was created for themes and suggestions that were either common to both groups, or from respondents who it was not possible to locate within one of the two groups based on their responses. This contained 368 responses.

In the report that follows, therefore, "Group A respondents" refers to those who stated support for the use of PSH for children and young people (and for gender-affirming care in general), while "Group B respondents" refers to those who were opposed to the use of PSH for children and young people (and who tended to feel that NHS England should direct its avenues of treatment and research towards psychological and psychosocial factors).

Question 1 – Has all the relevant evidence been taken into account?

Over 2,600 respondents provided free text responses explaining why they felt that additional evidence needed to be considered in the proposals.

The most common points put forward by Group A respondents were:

- The experiences, views and outcomes of transgender people, patients, and their families had not been considered as evidence, as well as the views of experts in the field.
- The evidential review had not included enough studies and had strict inclusion criteria, which may have excluded other relevant, good quality studies.
- Studies that rated PSH treatment positively had been ignored, possibly due to unfair bias.
- There has not been an evidential review of the outcomes of transgender children and young people who had been denied PSH.
- Guidance and advice from leading international bodies, such as WPATH, had been ignored.
- Evidence that PSH are used safely for other conditions (such as precocious puberty and prostate cancer) was not included.
- The statement that children and young people treated with PSH do not show a statistically significant difference in mental health and psychosocial functioning misunderstands the intended results of PSH treatment (i.e., that it is the first step in an ongoing treatment plan).

In comparison, Group B respondents tended to express the view that other evidence could have been considered which showed PSH are harmful and unnecessary, stating that:

- The review does not highlight harm caused by PSH or the importance of going through puberty.
- It omits animal studies that have concluded that PSH cause harm.
- The review omits experiential evidence from detransitioners.
- The review fails to use evidence that studies the causes of gender dysphoria.
- There was no review of evidence addressing psychological treatments of gender dysphoria.

Respondents from both groups suggested that the evidence included in the review was unfit for purpose due to small sample sizes, a lack of randomised control trials, and poor quality or inconclusive results. Many respondents from both groups also submitted details of a number of articles, references, papers and studies they felt should have been included in the evidence review.

Question 2 – Does the equality and health inequality impact assessment (EHIA) reflect the potential impact that might arise as a result of the proposed changes?

Just under 2,900 respondents provided details about why they felt the EHIA did not fully reflect the potential impact that may arise due to the proposed changes.

The most commonly raised themes presented by Group A respondents were:

- That the EHIA fails to sufficiently assess the potentially serious impact on the physical, emotional and mental health of transgender children who will be denied PSH treatment.
- That the policy discriminates against transgender children because other NHS treatments do not require a patient to be part of a research protocol and PSH will still be available to non-transgender children and young people.
- The protected characteristic of gender reassignment was insufficiently addressed, with the EHIA misinterpreting the breadth of the characteristic and being at odds with the Equality Act 2010.
- The EHIA fails to acknowledge that children and young people from low-income homes who are unable to afford private care will be discriminated against.
- The EHIA fails to address the future impact of transgender children and young people having developed secondary sexual characteristics.
- It fails to recognise the impact and risk of driving patients to access treatment from unregulated sources.
- It fails to properly address the protected characteristic of disability, given that the policy will disproportionately impact on autistic and neurodivergent children and young people.
- The EHIA does not address the potential impact on those who are currently receiving PSH treatment but who may be forced to stop.
- The EHIA does not address transgender children and young people whose families are unsupportive.

The main themes presented by Group B respondents were:

- The protected characteristic of sexual orientation is insufficiently addressed, with data on sexual orientation of patients lacking and the impact of homophobia not being recognised.
- Regarding the protected characteristic of age, the EHIA does not adequately reflect the potential impact on those considered too young and inexperienced to fully understand their situation and make such important decisions.
- There was no assessment on how others are impacted by 'gender ideology', giving examples such as family members or young females who may have to share intimate physical spaces with biological males.

Respondents from both groups also felt it was not possible for the EHIA to adequately assess potential impact due the scarcity and low quality of the evidence and research that informed it.

Question 3 – Are there any changes or additions you think need to be made to this policy?

3,333 respondents provided views and suggestions regarding changes and additions they believed needed to be made to the policy, as well as other ideas not directly related to the question, but rather to treatment and the subject of gender dysphoria as a whole.

The most commonly raised themes presented by Group A respondents were:

- The requirement to participate in a research trial in order to receive treatment is coercive and unethical.
- The policy does not address the risk of harm it may cause to transgender youth, in terms of driving them to unregulated sources, negative impact on mental wellbeing, and necessitating more drastic medical treatment in order to transition when older.
- Primarily the policy should be informed by the lived experiences of transgender people, or at least by experts in the field. The low number consulted for the draft policy was insufficient.
- There are no definitions for late/early onset gender dysphoria, so these terms should not be included in the policy.
- The research trial is poorly designed and unethical, will lack a randomised control group, and will not provide the desired evidence or results.

- Transgender healthcare should be made available everywhere, not only in specialist clinics.
- The potential harms of being forced to endure an undesired puberty have not been discussed.

Group B respondents said:

- The policy should go further and state that PSH are never made available to gender dysphoric children and young people due to the harms they cause, as well as potential currently unknown future consequences.
- For consistency and clarity, the definition of 'gender incongruence' should align with the ICD-11 definition and the diagnostic framework of the interim service specification.
- The research trial is unethical and violates the 1964 Declaration of Helsinki by not ensuring participants are not harmed in the pursuit of medical knowledge.
- The policy should make support available for detransitioners and children and young people who have been harmed by PSH or other aspects of gender transition.
- There should be no exceptional cases outside of the trial, due to the potential for opening up loopholes.
- The policy should show that aspects of our rapidly changing culture (such as social media, social contagion, and parental influence) have influenced gender dysphoric children and young people.
- The minimum age for the research trial should be 16.
- The research should be classified as a Clinical Trial of an Investigational Medicinal Product (CTIMP) and comply with specific requirements.
- Patients and their families should be educated on the risks of using PSH and should hear the experiences of detransitioners.
- The language used in the policy must be scientifically and medically accurate and not influenced by 'gender ideology'.

In addition, the following viewpoints were put forward by members of both groups:

- More research is required before any final decisions can be made.
- The policy should be closely reviewed and updated following new research outcomes.
- There is not enough available information regarding the specifics of the research trial on which to base an informed opinion.

Campaign and duplicate responses

A number of respondents' submissions were identified as potential 'campaign' or duplicate responses – that is, a set of consultation responses prepared by an organisation and then either copied and pasted in full or reworded and edited slightly before being submitted by others as additional consultation responses. Four such responses were identified and are summarised in the following table along with the number of respondents who submitted these in full (verbatim) or in slightly edited (similar).

Table 2. Campaign responses

Response organisation	Verbatim	Similar	Total
Mermaids	53	77	130
Transgender Trend	27	13	40
What the Trans?!	23	11	34
UCLH Endocrine	6	0	6

Response numbers for the first three organisations are presented as approximate averages across all questions, as not all respondents used the campaign responses for each of their answers – that is, some respondents submitted a combination of exactly copied responses, slightly reworded or edited responses, and responses consisting of their own words.

As there was no basis reason to consider that these campaign and duplicate responses did not accurately represent the views and ideas of the respondents who submitted them, they have been considered in the same way as unique individual responses and included in the question and theme totals as such.

Section 2. Methodology

Disclaimer

This report conveys the key messages arising from the analysis of the consultation responses. The report utilises the language and terminology used by respondents in order to provide the most reliable summary of these responses. We have illustrated some themes identified through the analysis with direct quotations from the response data. It intentionally does not provide challenge or critique on the key messages for example checking of links to published data as part of responses provided. Therefore, the views expressed, and language used in the report, do not represent the views of TONIC nor NHS England but are a faithful analysis of the response data.

Methodology

Analysis methodology

NHS England commissioned TONIC, an independent social research organisation specialising in public consultations, to produce a summary of responses to the consultation. To achieve this, TONIC conducted a quantitative analysis for all responses to the closed (multiple choice) questions and used thematic analysis (Braun and Clarke, 2006) to summarise the written responses to the open (free text) questions.

Thematic analysis is a widely used method for identifying, analysing, and reporting patterns within text data. TONIC chose this approach as it provides a way to summarise themes in a large body of data, highlights similarities and differences across the dataset, and can generate unanticipated insights. The process facilitates the organization and description of the dataset in detail and interprets various aspects of the research topic. Our analysts followed the six steps involved in this process using Quirkos and Excel software to support the process:

1. A detailed reading of the data to become familiar with the text
2. Initial codes are manually ascribed to the data, and organised into meaningful groups relevant to consultation questions
3. Codes conceptually related to one another are grouped together and identified as themes
4. Themes are reviewed to determine whether they are internally coherent and distinct from each other