NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

8 June 2023

1. Name of the proposal: Gender Incongruence Service for Children and Young People: Prescribing Gonadotrophin Releasing Hormone Analogues (Puberty Suppressing Hormones)

2. Brief summary of the proposal in a few sentences

NHS England proposes that Gonadotrophin Releasing Hormone analogues (GnRHa) are not recommended to be available as a routine commissioning option for treatment of children and adolescents who have gender incongruence. GnRHa are commonly referred to as 'puberty blockers' or puberty suppressing hormones.

What is GnRHa?
Administration of GnRHa initially produces an initial phase of stimulation of hormone receptors; continued administration leads to down-regulation of gonadotrophin-releasing hormone receptors, thereby reducing the release of gonadotrophins (follicle stimulating hormone and luteinising hormone) which in turn leads to inhibition of androgen and oestrogen production (NICE: British National Formulary for Children). GnRHa are currently prescribed through the NHS for children and young people with a diagnosis of persistent gender dysphoria from Tanner Stage 2 of pubertal development, alongside psychosocial and psychological support, though no formal clinical commissioning policy is in place.

Who will be impacted by the proposal?
Children and young people aged between around 10 and 17 years – this will be a combination of a prospective cohort (i.e. future referrals to an NHS commissioned specialised gender incongruence service); and those currently in the service and not yet onwardly referred to an endocrine clinic.

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

What may be the impacts of the proposal?

The direct impact will be that for children and young people who are assessed and diagnosed with gender incongruence by an NHS commissioned specialised gender incongruence, GnRHa would no longer be routinely commissioned as a clinical intervention on the NHS-commissioned pathway of care. Some children may be eligible for enrolment in a research framework that would provide access to GnRHa, while some young people may not be eligible (see below). NHS clinicians would no longer prescribe GnRHa for children and young people as a response to gender incongruence or gender dysphoria outside of the research framework. The direct consequence of the proposal is that some children and young people who may otherwise have been prescribed GnRHa and who are not eligible to join the research framework or those who are eligible but who opt to not enrol in the research framework, will proceed with pubertal progression and development of secondary sexual characteristics of the natal sex. Potential consequences of the proposal may be an increase in the number of children and young people who seek GnRHa from unregulated sources; and some stakeholder groups have previously suggested[1] that withholding GnRHa will lead to an increase in emotional and psychological distress, leading to risk-taking behaviour particularly amongst adolescents. Conversely, some stakeholder groups have suggested[2] that GnRHa should be removed from the NHS pathway of care completely in the best interests of children and young people in view of the limited evidence around treatment aims, benefits, risks and outcomes[3].

If the proposal is adopted by NHS England following stakeholder testing and public consultation, it would be appropriate to make a consequential change to the related clinical policy for prescribing cross-sex hormones for young people with gender dysphoria by removing the requirement for a young person to have been receiving puberty supressing hormones for a defined period of time.

Would access to GnRHa still be possible through the NHS regardless of a Non-Routine Commissioning Policy in view of NHS England's public statement that in future access to GnRHa through NHS prescribing would be dependent on the child / young person being enrolled in a formal research framework?

[1] Around 2020/21, when the Tavistock and Portman NHS Foundation Trust took the decision to cease making referrals to endocrine clinics in response to a legal ruling (referrals resumed in 2021 following judgment of the Court of Appeal).

[2] Responses to NHSE public consultation on proposed interim service specification for services for children and young people with gender dysphoria

[3] Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria; National Institute for Health and Care Excellence, 2020

In 2022 the independent Cass Review advised that access to GnRHa through NHS prescribing should be dependent on the child / young person being enrolled in a formal research framework with long-term follow up[4]. 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 now established a new national Children and Young People's Gender Dysphoria Research Oversight Board. Membership includes the National Institute for Health and Care Research, the Medical Research Council, the Royal College of Paediatrics and Child Health and a range of other clinical and academic experts. The Oversight Board has approved the development of a study into the impact of GnRHa on gender dysphoria in children and young people with early-onset gender dysphoria. The study will be taken forward through the National Research Collaboration Programme in place between NHS England and NIHR, with the study team stakeholder engaging with stakeholders in the study design. Subject to the usual ethical and scientific approvals, we anticipate recruitment to the study will open in 2024. Alongside this first study, further engagement is also planned 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 definition of 'early onset' and 'late onset' will be developed by the clinical study team in due course.

In summary, the impacts of the proposed policy in terms of access to GnRHa are likely to be:

- Children and young people will not be able to be referred for consideration of GnRHa until the proposed puberty suppressing hormone study opens to recruitment, unless an individual referral is approved as 'exceptional' by a specially convened multi-disciplinary team
- Once the study opens to recruitment (anticipated 2024), only children presenting with early-onset gender dysphoria, and who meet any other key study entry criteria, will be able to enrol in the study
- Young people with later-onset gender dysphoria will not be eligible for referral for GnRHa unless an individual referral is approved as 'exceptional' by a specially convened multi-disciplinary team. Further consideration is being given to how best to work with a range of stakeholders to identify and articulate the material evidence gaps, and how to gather further evidence, to support future options for young people with later-onset gender dysphoria.

[4] Letter to NHS England, 19 July 2022

Table: Patient Numbers

Patient Cohort	**Number**	**Commentary**
Number of children under 16 years of age who are likely to be directly impacted by the proposal at current referral patterns.	5 per month	Average figure - data from independent Multi-Professional Review Group is that between 10 August 2021 and 21 April 2023 the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS FT referred 96 children under 16 years to an endocrine clinic for assessment of suitability for GnRHa (n=2 in week ending 21 April 2023). However, clinical activity at the GIDS has steadily decreased in recent years due to staff attrition. Up to 2021 the Tavistock reported that around 15 – 20% of children and young people seen by GIDS were referred to an endocrine clinic and that around 2500 patients were referred to GIDS per year between 2017 and 2021. NHS England does not hold data that would differentiate between individuals who present with early-onset gender dysphoria and those who present with late-onset gender dysphoria.
Number of patients under 16 years currently on the waiting list for GIDS	5,999–	There are 5,999 children under 16 years on the waiting list held by AGEM CSU as at 26 April 2023 (source: AGEM CSU). NHS England does not hold data that would differentiate between individuals who present with early-onset gender dysphoria and those who present with late-onset gender dysphoria.

Number of patients aged 16 and 17 years currently on the waiting list for GIDS	1,900	There are circa 1900 young people aged 16 and 17 years on the waiting list held by AGEM CSU as at 26 April 2023 (source: AGEM CSU). *Note: these figures do not reflect the number of young people on the waiting list who will not be seen by GIDS by the time of their 18th birthday and / or who may be referred to an adult Gender Dysphoria Clinic from 17 years of age.* NHS England does not hold data that would differentiate between individuals who present with early-onset gender dysphoria and those who present with late-onset gender dysphoria.
Number of children and young people who may currently being prescribed GnRHa by an NHS endocrine team following a referral by GIDS	378	Source: Data return by Tavistock and Portman NHS Foundation Trust in July 2022. NHS England has requested an updated figure from the Trust. We do not have more detailed data by age or treatment intervention including how many are receiving masculinising / feminising hormones in addition to GnRHa.

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

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
Age: older people; middle years; early years; children and young people.	The impact of the proposal would be that GnRHa may not be routinely available through the NHS (for individuals with gender incongruence) for individuals who share the protected characteristic of 'age' as it would only impact individuals aged between (around) 10 years and 17 years. The proposal is not likely to impact children below the age of 10 years given that recommendations for GnRHa for the purpose	Other forms of specialist clinical support will remain available through the NHS for this patient cohort; the proposed NHS England interim service specification for gender incongruence (June 2023) describes a multi-disciplinary approach to care that focuses on psychoeducation, psychosocial and psychological approaches, and aims to reduce distress and promote wellbeing and functioning. The proposed interim service specification also describes a more coordinated and integrated approach between the specialist service and local

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	of clinical intervention for gender incongruence are not made until the child has reached Tanner Stage 2 of pubertal development. Once the clinical study is established (anticipated 2024) children and young people with later on-set gender dysphoria will not be eligible for the study. The proposal will not impact young people aged over 17 years as the age cut off for the service is the 18th birthday; and as GnRHa would continue to be routinely commissioned for those individuals who are seen in adult Gender Dysphoria Clinics aged 17 years and above and who are prescribed GnRHa alongside gender affirming hormones (endocrine treatment via physiologic doses of oestrogen alone is insufficient to suppress testosterone levels into the normal range for natal females and addition of an anti-androgen such as GnRHa is necessary). The Tavistock and Portman NHSFT has advised that over fifty percent of referrals made by the Tavistock for GnRHa are of children under 16 years of age.	services in the child or young person's best interests. NHS England is leading a national transformation programme that plans to significantly increase clinical capacity in children and young people's gender incongruence services – thereby increasing more timely service provision. *Criteria for enrolment in the clinical study* Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the 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.

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	NHSE has concluded that the fact that the proposals will mainly impact children and young people who may share the protected characteristic of "age" does not result in unlawful discrimination. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that a key limitation to identifying the effectiveness and safety of GnRHa in regard to **children and young people** with gender incongruence is the lack of reliable comparative studies. In other words, the age of the individuals for whom risk and benefits cannot be defined because of the lack of evidence is in itself a contributory reason for taking steps to mitigate clinical risk and safety issues.	
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Various literature suggests that a high proportion of children and young people with gender incongruence will also present with other significant comorbidities, though NHSE does not have specific data from the current commissioned provider nor from the commissioned endocrine clinics. The literature reports that a significant proportion of those presenting with gender dysphoria have a diagnosis of Autistic	Other forms of specialist clinical support will remain available through the NHS for this patient cohort; the proposed 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. The proposed interim service specification also describes a more coordinated and integrated approach between the specialist service and local

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	Spectrum Disorder (ASD). Around 35% of young people referred to the NHS-commissioned children and young people's service present with moderate to severe autistic traits[5]. Individuals with ASD are likely to share the protected characteristic of "disability". Around 70% of people with autism also meet diagnostic criteria for at least one (often unrecognised) psychiatric disorder that further impairs psychosocial functioning, for example, attention deficit hyperactivity disorder or anxiety disorders. Intellectual disability (IQ<70) coexists in approximately 50% of children and young people with autism[6]. There is also an increased prevalence of children and young people presenting to the current service with severe forms of mental health problems which may in some cases constitute a 'disability' for the purpose of the Act. The UK Government's LGBT Survey (2017) reported that 32.5% of respondents from the transgender and non-binary population self-	services in the child or young person's best interests including where the child or young person has complex co-presentations that may form the basis of a 'disability' under the Equality Act including autism, ADHD, other forms of neuro-disability and mental health problems. NHS England is leading a national transformation programme that plans to significantly increase clinical capacity in children and young people's gender incongruence services – thereby increasing more timely service provision and greater integration with and support from local services. The new service offer will be accompanied by improved guidance and *MindEd* psycho-education resources on gender incongruence in childhood and adolescence for local services and professionals that NHS England has commissioned through Health Education England (planned for publication in June 2023). These new support materials will mitigate the potential impact for children and young people becoming more entrenched in their ill health because their expectation of receiving GnRHa has been denied. These resources include specific advice to primary

[5] Assessment and support of children and adolescents with gender dysphoria, Butler et al, 2018
[6] Autism Spectrum Disorder in Under 19s: Support and Management, National Institute for Health and Care Excellence, 2021

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	identified as having a disability (respondents were aged 16 years and above). NHSE may conclude from the information above that the current proposals may have a disproportionate impact on individuals who share this protected characteristic. NHS England has concluded that no direct or indirect discrimination arises. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that a key limitation to identifying the effectiveness and safety of GnRHa in regard to children and young people with gender incongruence is the lack of reliable comparative studies.	and secondary care professionals in respect of co-existing concerns including self-harm. NHS England also proposes to provide specialist consultation advice and liaison for local services and professionals to provide early indirect support for families who are newly identified with gender concerns by local services and professionals. At a local level NHS England, with local commissioners, has improved 24/7 crisis helplines and crisis response services. These are also supported by training resources for crisis practitioners, especially A&E staff which will include specific LGBTQIA+ training resources developed by young people with lived experience. NHS England has also published (April 2023) a new National Framework to Deliver Improved Outcomes in All-Ages Autism Assessment Pathways: Guidance for Integrated Care Boards. This will improve access to assessments and mitigate the impact of undiagnosed autism on some children and young people's experiences.
Gender Reassignment	In January 2023 the High Court agreed that not every child or young person referred to a specialised gender incongruence service will have the protected characteristic of 'gender	Other forms of specialist clinical support will remain available through the NHS for this patient cohort; the proposed NHS England interim service specification for gender incongruence (April 2023)

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	reassignment'[7] . The Court agreed that children and young people who are referred to such a service do not – at the point of referral or while they remain on the waiting list - share the protected characteristic of 'gender reassignment' as a class or cohort of patients. The whole cohort of patients cannot be treated as "proposing to undergo" a process (or part of a process) for the "purpose of reassigning" their sex "by changing physiological or other attributes of sex" as a class or cohort. To apply such a definition to these individuals is to make assumptions upon the aims and intentions of those referred, the certainty of those desires and their outward manifestation, and upon the appropriate treatment that may be offered and accepted in due course. This is particularly likely to be true in the case of very young children. However, as the Court found and as NHS England accepts, many children and young people in this position will, individually, have the protected characteristic at this stage of	describes a multi-disciplinary approach to care that focuses on psychoeducation, psychosocial and psychological approaches. The proposed interim service specification also describes a more coordinated and integrated approach between the specialist service and local services in the child or young person's best interests. NHS England is leading a national transformation programme that plans to significantly increase clinical capacity in children and young people's gender incongruence services – thereby increasing more timely service provision. NHS England proposals will be accompanied by improved guidance and psycho-education resources for local services and professionals which will mitigate the potential impact for children and young people becoming more entrenched in their ill health because their expectation of receiving GnRHa has been denied. These resources include specific advice to primary and secondary care professionals in respect of co-existing concerns including self-harm.

[7] R(AA & Others) v NHS Commissioning Board and Others[2023] EWHC 43 (Admin)

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	the pathway, although determining that will involve a case-specific factual assessment[8]. Additionally, children and young people who are currently under the care of GIDS and who have expressed an intention to undergo a process (or part of a process) of reassigning their sex will share the protected characteristic. Conversely, there are likely to be some children and young people who are currently under the care of GIDS and in regard to whom the protected characteristic cannot be applied where the individual has either not expressed an intention to undergo a process (or part of a process) of reassigning their sex or has expressed an intention to not undergo such a process. NHS England cannot say with certainty whether all children and young people referred for GnRHa have expressed an intention to undergo a process of reassigning their sex because of the conflicting information available to it in this regard – on the one hand the Tavistock and Portman NHS Foundation Trust has described the	NHS England also proposes to provide specialist consultation advice and liaison for local services and professionals to provide early indirect support for families who are newly identified with gender concerns by local services and professionals. At a local level NHS England with local commissioners has improved 24/7 crisis helplines and crisis response services. These are also supported by training resources for crisis practitioners, especially A&E staff which will include specific LGBTQIA+ training resources developed by young people with lived experience.

[8] Ibid

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	purpose of GnRHa as providing time to the child or young person to help determine whether this is their intention, and on the other there is evidence that the vast majority of children and young people who receive GnRHa subsequently receive masculinising / feminising hormones from around age 16 years[9]. In summary, for the purpose of this EHIA and the proposals it addresses, 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. <u>Impacts and Consequences</u> GnRHA would no longer be a routinely commissioned intervention for children and young people who have this protected characteristic. Some children and young people will not be eligible to enrol in the clinical study (those with later-onset gender dysphoria) and some who are eligible (early-onset gender dysphoria) may opt to not enrol or may not the criteria for access that will be	

[9] Bell and Mrs A v Tavistock and Portman NHS Foundation Trust, 2020

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	developed by the clinical study team in due course. The consequences of the proposal may be an increase in the number of children and young people with this protected characteristic who seek GnRHa from unregulated sources; some stakeholder groups suggest that restrictions on gender affirming interventions may lead to an increase in risk-taking behaviour particularly amongst adolescents. Other stakeholders suggest that the proposal will have positive impacts given the limited evidence around aims, benefits, risks and outcomes. NHS England has concluded that no direct discrimination occurs. NHS England has also concluded that no indirect discrimination arises by virtue of the fact that the proposal will exclusively impact individuals who share this protected characteristic. The fact that a proposal will exclusively impact a specific group does not, in itself, render the proposal discriminatory. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that a key limitation to identifying the effectiveness and safety of GnRHa in regard to children and	NHS England strongly discourages children and young people sourcing GnRHa from unregulated sources or on-line providers that are not regulated by UK regulatory bodies. The approach by NHS clinicians to children and young people who source such pharmaceuticals will be described in the interim service specification for gender incongruence services. 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 (planned for publication in June 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. *Criteria for enrolment in the clinical study* Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the Research Oversight Board to identify the key

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	young people with gender incongruence is the lack of reliable comparative studies. <u>Children and Young People with Gender Incongruence who Continue on GnRHa Through an NHS Prescription Within an Existing Agreed Individual Care Plan</u> A consideration as to whether direct or indirect discrimination arises is also necessary in regard to individuals who share this protected characteristic, as GnRHa may continue to be prescribed through NHS protocols for children and young people with a diagnosis of gender incongruence and who at the point that the proposal is implemented, either: - Are receiving the intervention through an existing NHS care plan; or - Who have been referred into an endocrine clinic by the specialist gender incongruence service but have not yet been assessed by a consultant endocrinologist for suitability of GnRHa This group will share the protected characteristic of 'gender reassignment' as a class or cohort.	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.

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	As at July 2022 there were 378 children and young people under the clinical care of the endocrine team at UCLH NHSFT (n=220) or Leeds Teaching Hospitals NHST (n=158) and there were 35 children and young people who had been referred to an endocrine clinic by GIDS and awaiting assessment at the endocrine clinic. NHS England has requested updated information from GIDS including the number of children and young people who are being prescribed (a) GnRHa and (b) GnRHA with masculinising / feminising hormones. NHS England has considered whether the proposal for non-routine commissioning should also apply to children and young people within this group, on the basis that GnRHa should be withheld or withdrawn because of the same concerns about the lack of evidence around aims, benefits, risks and outcomes. However, there are additional ethical and clinical considerations in cases where there is an existing expectation of consideration for treatment / continued	

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	treatment[10]. This is particularly so in regard to the withdrawal of GnRHa in young people who will experience emergence or re-emergence of secondary sexual characteristics of the natal sex and who may have presented in public throughout adolescence with their suppression. On balance, NHS England has concluded that the scope of the proposed Non-Routine Commissioning Policy will not extend to children and young people in this group. In these cases it will be for the child or young person and their family to decide whether, based on the current available information, they wish to continue with administration of GnRHa; if so, it will be for the relevant Consultant Endocrinologist to consider whether it is appropriate to continue with off-label prescribing. NHS England has concluded that no direct discrimination occurs. NHS England has also concluded that no indirect discrimination arises by virtue of the fact that GnRHa will continue to be routinely	

[10] There are similar precedents in the NHS. For example, NICE may exclude patients already being prescribed a drug from the scope of a decision that a drug should no longer be routinely available through the NHS, though these decisions are also influenced by the cost-effectiveness of the drug as assessed by NICE rather than based solely on safety grounds.

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	commissioned for this group. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that a key limitation to identifying the effectiveness and safety of GnRHa in regard to children and young people with gender incongruence is the lack of reliable comparative studies – and there are additional ethical and clinical considerations in regard to individuals in the proposed group who will not be subject to the proposal that are distinct to those relating to individuals who will be directly impacted by the proposal. <u>Comparator Group – Children with Central Precocious Puberty</u> A consideration as to whether direct or indirect discrimination arises is also necessary in regard to individuals who share this protected characteristic, as GnRHa will continue to be routinely available through NHS protocols[11] for children who present with Central Precocious Puberty (CPP)[12].	

[11] NHS England is not the responsible commissioner of clinical interventions for children with a diagnosis of Central Precocious Puberty; this responsibility rests with Integrated Care Boards who form their own clinical commissioning policies in regard to their own populations.
[12] GnRHa is also licensed as a response to various cancers and endometriosis in adults – these patient groups are not regarded as appropriate comparators for the purpose of this EHIA.

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	This is a rare disease[13] caused by premature reactivation of the hypothalamic-pituitary-gonadal axis, resulting in the premature development of pubertal pulsatile secretion of gonadotropins in childhood. GnRHa is standard of care as a response to CPP (where patients meet clinical criteria) and the clinical approach is not contested. The various available agents have been licensed for CPP in the UK[14] and in many other countries for over 25 years following a consideration of the outcome of a number of clinical trials[15]. By contrast, GnRHa is not authorised for use in gender incongruence – they are in use 'off-label' – there is limited evidence on treatment aims, benefits, risks and outcomes;[16] and the clinical approach is contested[17].	

[13] The true epidemiology of CPP is unknown. A US study estimated that CPP in the general population was between 1:5000 to 1:10,000 children; in Europe, a Danish national study reported the prevalence of CPP as 0.2% for girls and less than 0.05% for boys; Spanish and French studies showed different annual incidence of CPP in both sexes; Mucaria, 2021

[14] British National Formulary for Children, National Institute for Health and Care Excellence

[15] A drug will only be licensed for a specific indication if there is good quality evidence around treatment aims, risks, benefits and outcomes.

[16] Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria; National Institute for Health and Care Excellence, 2020

[17] Interim report of the Cass Review, 2022

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	In considering whether discrimination arises, it must be understood that the aetiology and epidemiology of CPP and treatment aims are quite different to that of gender incongruence. CPP is the *early onset* of puberty and secondary sexual characteristics (generally accepted as <8 years in girls and <9 years in boys) and it can range in seriousness from benign to malignant variants. The cause is often unclear but it can be attributable to a number of conditions that may require specialist investigation (Central Nervous System (CNS) tumours; CNS head trauma; genetics; neurofibromatosis type-1; cerebral palsy - *not exhaustive*). GnRHa for this cohort will be considered if the child has rapidly progressing symptoms or if bone age is significantly advanced beyond birth age. The physiological aims of GnRHa as a response to CPP are to halt pubertal progression and progressive physical development and to preserve or reclaim adult height potential. NHS England has concluded that no direct discrimination occurs. NHS England has also concluded that no indirect discrimination arises by virtue of the	

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	fact that GnRHa will continue to be routinely commissioned for this appropriate comparator group. The evidence base that supports the administration of GnRHa as a response to CPP is strong and the clinical approach is not contested; the aetiology and epidemiology of CPP is quite different to that of gender incongruence, though the aetiology of gender incongruence is in itself still largely unidentified[18].	
Marriage & Civil Partnership: people married or in a civil partnership.	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposed interim service specification does not have any significant impact on individuals who may share this protected characteristic.	
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposed interim service specification does not have any significant impact on individuals who may share this protected characteristic.	

[18] Claahsen - van der Grinten, H., Verhaak, C., Steensma, T. *et al.* Gender incongruence and gender dysphoria in childhood and adolescence—current insights in diagnostics, management, and follow-up. *Eur J Pediatr* **180**, 1349–1357 (2021).

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<tr><th>Protected characteristic groups</th><th>Summary explanation of the main potential positive or adverse impact of your proposal</th><th>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</th></tr>
<tr><td>Race and ethnicity[19]</td><td>Table: Children and young people referred to the current commissioned service between July and December 2022[20]
<table><tr><th colspan="3">GIDS: Q2 & Q3 Referred Patient Ethnicities</th></tr><tr><th>Ethnic Group</th><th>Count</th><th>%</th></tr><tr><td>Any Other Ethnicity</td><td>3</td><td>0.6%</td></tr><tr><td>Asian or Asian British – Any Other</td><td>5</td><td>1.0%</td></tr><tr><td>Asian or Asian British – Indian</td><td>1</td><td>0.2%</td></tr><tr><td>Black or Black British – Caribbean</td><td>2</td><td>0.4%</td></tr><tr><td>Mixed – Any Other Background</td><td>15</td><td>3.0%</td></tr><tr><td>Mixed – White & Asian</td><td>1</td><td>0.2%</td></tr><tr><td>Mixed – White & Black Caribbean</td><td>2</td><td>0.4%</td></tr><tr><td>Not Known – Not Requested</td><td>1</td><td>0.2%</td></tr><tr><td>Not Stated – Client Unable to Choose</td><td>152</td><td>30.5%</td></tr><tr><td>Other Ethnic Group – Chinese</td><td>1</td><td>0.2%</td></tr><tr><td>White – Any Other Background</td><td>11</td><td>2.2%</td></tr><tr><td>White – British</td><td>200</td><td>40.2%</td></tr><tr><td>White – Mixed White</td><td>2</td><td>0.4%</td></tr><tr><td>White – Polish</td><td>2</td><td>0.4%</td></tr><tr><td>Blank</td><td>100</td><td>20.1%</td></tr><tr><td>TOTAL</td><td>498</td><td></td></tr></table></td><td>There is evidence that gender diverse individuals from BAME heritage are more likely to face discrimination on the basis of their race and gender and often within their religious community as well.

The reasons for the low numbers of people from BAME communities is not well understood and is likely to include 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.

At a broader level, in 2021 NHS England established the National Healthcare Inequalities Improvement Programme (HiQiP), which works with national programmes and policy areas across NHS England, to address inequalities and ensure equitable access, excellent experience and optimal outcomes. The terms of reference for the</td></tr>
</table>

[19] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc.. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

[20] Source: Data return by Tavistock and Portman NHS Foundation Trust, February 2023

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
	Analysis of ethnicity data from the Tavistock and Portman NHS Foundation Trust remains challenging given the (historically) high number of individuals for whom ethnicity data is not recorded or not available (50.8% of patient records according to the above table). Of the data available, the highest proportion of individuals are "White" which accords with previous NHS analyses of individuals accessing gender dysphoria services. A 2022 publication[21] reported that the majority of young people seen at GIDS self-identified with a white ethnic-background (93.35%) and 6.65% identified as being from ethnic minority heritage. It concluded that service engagement was comparable between the subgroups, while the ethnic minority sub-group was offered and attended more appointments in 2018–2019. Due to the low ethnic minority sub-group numbers, findings need to be interpreted with caution. We may surmise that the proposal will disproportionately impact individuals who are 'White". The proposal does not unfairly discriminate against individuals who share	NHS England National Programme Board for Gender Dysphoria Services (2023 – 2026, to be agreed June 2023) will include a focus on addressing and reducing health inequalities aligned with the HiQiP. *Criteria for enrolment in the clinical study* Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the 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 engagement will include an analysis of the impacts to individuals who may share this protected characteristic.

[21] Manjra II, Russell I, Maninger JK, Masic U. Service user engagement by ethnicity groups at a children's gender identity service in the UK. *Clinical Child Psychology and Psychiatry*. 2022;27(4):1091-1105.

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
	this protected characteristic, but we know from previous data collections that, generally, there is under-representation of people from Black, Asian and Minority Ethnic hertiage accessing gender dysphoria services in England.	
Religion and belief: people with different religions/faiths or beliefs, or none.	There is limited available evidence on the religious attitudes of trans people in the United Kingdom, although The Trans Mental Health Study found that most people who took part stated that they had no religious beliefs (62%). A data collection exercise of adult Gender Dysphoria Clinics undertaken by NHS England in 2016 reaffirmed the findings of this study but it is unclear as to the extent to which the findings may relate to children and young people. NHS England is of the view that the proposal does not significantly impact individuals who share this protected characteristic.	
Sex: men; women	At current referral patterns 69% of referrals to the current commissioned service are of natal females and 31% are of natal males[22].	The terms of reference for the Cass Review include *"exploration of the reasons for the increase in referrals and why the increase has disproportionately been of natal females, and the implications of these matters".*

[22] Source: Data return by Tavistock and Portman NHS Foundation Trust, February 2023

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
	This data accords with figures published by the Cass Review in March 2022 show a trend since 2011 in which the number of natal females is higher than the number of natal males being referred. Prior to that the split in the caseload was roughly even between natal girls and natal boys, but by 2019 the split had changed so that 76% per cent of referrals were natal females. That change in the proportion of natal girls to boys is reflected in the statistics from the Netherlands (Brik et al "*Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria"* 2018). The proposal may disproportionately impact individuals who are natal female based on this data. NHS England has concluded that no direct or indirect discrimination arises. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that a key limitation to identifying the effectiveness and safety of GnRHa in regard to children and young people with gender incongruence is the lack of reliable comparative studies.	NHS England's proposed interim service specification for a new configuration of providers describes the importance of building research capabilities for the purpose of continuous quality improvement initiatives. Also, in 2019 the Government Equalities Office announced that it would commission new research to explore the nature of adolescent gender identity and transitioning to better understand the issues behind the increasing trend of referrals of adolescents to NHS gender dysphoria service. 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. *Criteria for enrolment in the clinical study* Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the 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

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
	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: "*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*".	history of gender dysphoria in this group. The engagement will include an analysis of the impacts to individuals who may share this protected characteristic.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	We do not hold data on the sexual orientation of individuals who are referred to or seen by the NHS commissioned service. A large UK-	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

<table>
<tr><th>Protected characteristic groups</th><th>Summary explanation of the main potential positive or adverse impact of your proposal</th><th>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</th></tr>
<tr><td></td><td>wide study in 2012 (Trans Mental Health Study) reported the following:

<table><tr><th>Sexual Orientation</th><th>N</th><th>Percentage</th></tr><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 colspan="2">912</td></tr></table>
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</td><td>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 “young lesbians who felt pressured to identify as transgender male, and conversely transgender males who felt pressured to come out as lesbian rather than transgender”.

Criteria for enrolment in the clinical study

Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the Research</td></tr>
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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
	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. NHS England has concluded that there is insufficient evidence to determine if a particular group or cohort will be disproportionately impacted by the proposal. 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: "*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*".	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 engagement will include an analysis of the impacts to individuals who may share this protected characteristic.

4. 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 proposal will not impact on patients who experience health inequalities.**

Groups who face health inequalities[23]	**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[24].	NHS England's proposed interim service specification recognises that a significant number of children and young people with very complex needs may also be *Looked After* 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.
Carers of patients: unpaid, family members.	Families and carers of the children and young people who are directly affected by the proposal, 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.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	

[23] Please note many groups who share protected characteristics have also been identified as facing health inequalities.
[24] Interim report of the Cass Review, 2022

Groups who face health inequalities[23]	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
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on 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 proposals do not discriminate against this group; and that the proposals 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	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	

Groups who face health inequalities[23]	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
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	
People living in deprived areas	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	
People living in remote, rural and island locations	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	

Groups who face health inequalities[23]	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
Refugees, asylum seekers or those experiencing modern slavery	NHS England is in receipt of no evidence to suggest otherwise and therefore is of the view that the proposals do not discriminate against this group; and that the proposals will have a neutral impact on reducing health inequalities in accessing services or achieving outcomes for this group.	
Other groups experiencing health inequalities (please describe)		

5. 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 Proposed policy is currently out for stakeholder testing	**No**	**Do Not Know**

6. 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	NICE evidence review, 2020	The evidence review confirms that there is limited evidence. *Criteria for enrolment in the clinical study* Alongside the first study to which children and young people with early on-set gender dysphoria may enrol, further engagement is also planned by the 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 engagement will include an analysis of the impacts to individuals who may share this protected characteristic.
Consultation and involvement findings		
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		

7. 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?			

8. 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?		

9. 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 access to GnRHa through NHS prescribing should be dependent on the child / young person being enrolled in a formal research framework with long-term follow up. NHS England accepted that advice and incorporated wording to that effect in the proposed interim service specification for children and young people's gender incongruence services that was subject to public consultation in 2022. NHS England has appointed a Clinical Trials Unit to develop the research protocol, including eligibility criteria,

		overseen by a newly established Research Oversight Programme Board.
2		
3		

10. Summary assessment of this EHIA findings

The proposal will exclusively impact children and young people who are likely to share the protected characteristics of ‘age’ and ‘gender reassignment’. The fact that a proposal is likely to exclusively impact a specific group does not, in itself, render the proposal discriminatory. NHS England has concluded that no direct or indirect discrimination arises. The proposal is a reasonable, rational and clinically necessary response to the findings of NICE and the Cass Review that there is limited evidence around aims, benefits, risks and outcomes; and that a key limitation to identifying the effectiveness and safety of GnRHa in regard to children and young people with gender incongruence is the lack of reliable comparative studies. NHS England is cognisant of the potential impacts and consequences as detailed in this EHIA and through a process of public consultation it will seek views on the impacts, consequences and proposed mitigations before making a final decision on whether to enact the proposal.