NHS England

Consultation report for the interim service specification for specialist gender incongruence services for children and young people

9 June 2023

Contents

1. Background

In September 2020, NHS England commissioned an independent and wide-ranging expert review of gender identity services for children and young people. The Independent Review, which is ongoing, is being led by Dr Hilary Cass, past president of the Royal College of Paediatrics and Child Health. It was established in response to a complex and diverse range of issues including:

1. **A significant and sharp rise in referrals**
   In 2021/22 there were over 5,000 referrals into the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust. This compares to just under 250 referrals in 2011/12.

2. **Marked changes in the types of patients being referred which are not well understood**
   There has been a dramatic change in the case-mix of referrals from predominantly natal males to predominantly natal females presenting with gender incongruence in early teen years. Additionally, a significant number of children are also presenting with neurodiversity and other mental health needs and risky behaviours which requires careful consideration and needs to be better understood.

3. **Scarce and inconclusive international evidence to support clinical decision making**
   This has led to a lack of clinical consensus and polarised opinion on what the best model of care for children and young people experiencing gender incongruence and dysphoria should be; and a lack of evidence to support families in making informed decisions about interventions that may have life-long consequences.

4. **Long waiting times for initial assessment and significant external scrutiny and challenge surrounding the clinical approach and operational capacity at GIDS**
   This has all contributed to the service provided by the Tavistock and Portman NHS Foundation Trust being unable to meet the scale of rising demand and provide the level of appropriate care.

Next steps

In February 2022, the Independent Review published an interim report in which she set out initial findings and advice from her Review. She emphasised the need to move away from the current model of a sole provider and to establish regional services that work to a new clinical model that can better meet the holistic needs of a vulnerable group of children

and young people. She began to describe the need for these new services to work as networked centres that connected with other local services including children and young people's mental health services and primary care to support all a patient's clinical needs.

In July 2022, the Independent Review sent further advice on the core components of this model. You can read the advice in full here.

In summary, she said:

- 'Regional centres should be led by experienced providers of tertiary paediatric care to ensure a focus on child health and development, with strong links to mental health services. These will generally be specialist children's hospitals.
- 'They should have established academic and education functions to ensure that ongoing research and training is embedded within the service delivery model'.
- 'The services should have an appropriate multi-professional workforce to enable them to provide an integrated model of care that manages the holistic needs of this population'.
- 'Staff should maintain a broad clinical perspective to embed the care of children and young people with gender uncertainty within a broader child and adolescent health context'.

Establishing Phase 1 service providers

Following the further advice the Independent Review provided in July 2022, NHS England set out plans for how it would start building a more resilient service by expanding provision and enhancing the focus on quality in terms of clinical effectiveness, safety, and patient experience. These plans were welcomed and supported by the Tavistock and Portman NHS Foundation Trust.

The first phase in these plans is to establish two new nationally networked services which, consistent with advice from the Independent Review, will be led by specialist children's hospitals.

These Phase 1 service providers will take over clinical responsibility for seeing children and young people on the national waiting list as well as providing continuity of care for the GIDS open caseload at the point of transfer. The Tavistock GIDS service itself will be decommissioned as part of a managed transition of the service to the new Phase 1 service providers.

One service – The Southern Hub – is being formed through a partnership between Great Ormond Street Hospital, Evelina London Children's Hospital (part of Guy's and St Thomas' NHS Foundation Trust) and South London and Maudsley NHS Foundation Trust.

The other service – The Northern Hub – is being formed through a partnership between Alder Hey Children's NHS Foundation Trust and the Royal Manchester Children's Hospital (part of Manchester University NHS Foundation Trust).

These new services will be commissioned against a new, interim service specification. The draft specification- which is the subject of this consultation- was developed by a clinically led Specification Working Group chaired by the NHS National Medical Director for Specialised Services and comprised of senior clinicians with expertise in gender incongruence, mental health and neurodiversity in children and young people, safeguarding and paediatric medicine.

2. How we consulted

The public consultation on this draft interim service specification ran on the NHS England consultation website for 45 days from 20 October to 4 December 2022. It received 5,183 responses in total. NHS England thanks all those individuals and organisations who submitted responses to consultation.

NHS England commissioned TONIC - an independent organisation specialising in public consultation, social research and evaluation - to conduct analysis on all responses and report back on these findings. Their detailed analysis of the responses can be found on the consultation page.

During the consultation period, NHS England actively engaged with individuals, organisations and services who were most likely to be directly affected by the proposed changes, including patient groups, Royal Colleges, professional bodies, as well as some of the current patients and parents of patients within the GIDS. These groups were invited to virtual meetings and discussion groups throughout the course of the consultation period with the aims of:

1. increasing awareness about the constitution,
2. clarifying our proposals,
3. listening to the early thoughts and feedback and
4. encouraging a formal, written response.

3. How has feedback at consultation been considered?

The Specification Working Group considered the report of the independent analysis of consultation responses.

The consultation asked the following questions:

- To what extent do you agree with the four substantive changes to the service specification?
    - Composition of the clinical team
    - Clinical leadership
    - Collaboration with referrers and local services
    - Referral sources
- To what extent do you agree that the interim service specification provides sufficient clarity about approaches towards social transition?
- To what extent do you agree with the approach to the management of patients accessing prescriptions from un-regulated sources?
- Are there any other changes or additions to the interim service specification that should be considered in order to support Phase 1 services to effectively deliver this service?
- To what extent do you agree that the Equality and Health Inequalities Impact Assessment reflects the potential impact on health inequalities which might arise as a result of the proposed changes?

The following sections outline how our consideration of consultation feedback has informed the final version of the interim service specification.

Composition of the clinical team

The current service specification for the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust describes a service that is delivered through a specialist multidisciplinary team with contributions from specialist social workers, family therapists, psychiatrists, psychologists, psychotherapists, paediatric and adolescent endocrinologists and clinical nurse practitioners. The new interim service specification proposed to extend the clinical team so that it is a more integrated multi-disciplinary team that, in addition to gender dysphoria specialists, will include experts in paediatric medicine, autism, neurodisability and mental health.

The majority of respondents (53%) agreed or partially agreed with this proposal, while 38% disagreed or partially disagreed. A large portion of the objections to this proposal suggested that it would further increase waiting times.

The purpose of the proposed change is to improve the timely provision of appropriate integrated support for children and young people with co-presentations, while addressing concerns expressed by the Care Quality Commission in 2021 that the current service does not always include the full range of clinical specialists to meet the individual needs of patients. NHS England has therefore retained this change to the final version of the interim service specification.

Clinical leadership

The current service specification for GIDS does not describe criteria for the clinical lead for the service. The new interim service specification proposed that the clinical lead for the service will be a consultant medical doctor.

A narrow majority (49%) of respondents agreed or partially agreed with this proposal, while 41% disagreed or partially disagreed. Most comments on this proposal highlighted the need to ensure that the clinical lead should be an experienced expert in gender dysphoria. Many respondents also said that this proposed change pathologises gender dysphoria.

NHS England views this change as being consistent with the recommendations of the Independent Review, particularly in the context of these services being hosted by tertiary paediatric units (specialist children's hospitals), in that it brings this service in line with other multi-disciplinary models of care across paediatric medicine. However, NHS England acknowledges that an alternative view has been expressed during the public consultation, namely that it is not only medical doctors who are suitably qualified to oversee integrated clinical teams with a broad range of clinical disciplines. Therefore, while NHS England will retain this change in the interim service specification at present, we will keep this position under review and the experience and learning from the Phase 1 providers will inform whether there is a need to retain the requirement for a medical professional to lead the service in the longer-term substantive service specification that will be developed once the Independent Review has delivered its final advice to NHS England later in 2023/24.

Collaboration with referrers and local services

The current service specification for GIDS describes a tiered approach for progression through the clinical pathway: the first tier involves meetings between the GIDS team and local professionals involved in the care of the child or young person and the second tier involves the child or young person accessing local services for mental health needs with GIDS offering advice to local services. There are numerous references in the current GIDS service specification to joint working between GIDS and local services including through consultation and liaison. However, GIDS has struggled to provide this support to local services in a consistent way.

The new interim service specification proposed to retain this tiered approach to progression through the pathway and describes a more structured approach for collaboration with local services in the interests of the child and young person. It described that a referral to The Service will require a consultation meeting between the Phase 1 provider and the relevant local secondary healthcare team and / or the GP. The interim service specification proposed that where the outcome of the initial professional consultation between the Service and the referrer is that the patient does not meet the access criteria for The Service, the child or young person will not be added to the waiting list, but the family and professional network will be assisted to develop their formulation of the child or young person's needs and a local care plan and will be advised of other resources for support that are appropriate for individual needs.

There were significantly mixed views on this proposal, but a narrow majority (47%) of respondents disagreed or partially disagreed with the proposed changes. Many respondents viewed this change as "gatekeeping" and expressed concerns around increasing waiting times for the service. As a result of the feedback received, NHS England has decided to form a separate service specification that will describe the process for making referrals onto the national waiting list that will be held by NHS Arden & GEM Commissioning Support Unit (until the new regional services are established), including the relationship with referrers and local professionals at the point of referral. NHS England will begin the engagement process on this draft service specification and its associated Equality and Health Inequalities Impact Assessment later this summer (2023).

Referral sources

The current service specification for GIDS states that referrals can be made by staff in health and social services, schools, colleges of further education and by voluntary organisations. The new interim service proposed that referrals may be made by GPs and NHS professionals only. The reason for the proposal was to ensure that children and young people are already engaged with the local health system before a referral is

considered by a local health professional into the highly specialist gender dysphoria service, including for the reason that a proposed core feature of the new pathway is a consultation meeting between the specialist service and local health professionals before the referral is made to the specialist service. Around 65% of referrals into GIDS are currently made by GPs and around 30% are made by NHS professionals.

The majority of respondents (57%) disagreed or partially disagreed with this proposed change. Several respondents felt that insufficient information had been included in the interim service specification to be able to make an informed decision, and to understand exactly how the new referral procedure would work.

As a result of this feedback, NHS England has decided to form a separate service specification that will describe in greater detail the process for making referrals onto the national waiting list that will be held by NHS Arden & GEM Commissioning Support Unit (until the new regional services are established), including referral sources. NHS England will begin the engagement process on this draft service specification and its associated Equality and Health Inequalities Impact Assessment later this summer (2023).

Clarity on approaches towards social transition

The new interim service specification proposed greater clarity on the clinical approach to social transition. It stated that the clinical approach to pre-pubertal children will reflect evidence that in most cases gender incongruence does not persist into adolescence; and that for adolescents the provision of approaches for social transition should only be considered where the approach is necessary for the alleviation of, or prevention of, clinically significant distress or significant impairment in social functioning and the young person is able to fully comprehend the implications of affirming a social transition.

The majority of respondents (67%) did not agree that the draft interim service specification provided sufficient clarity about approaches towards social transition and / or disagreed with the proposed position. Various issues were raised including the reference to the previous version of WPTAH's standards of care which were updated shortly before the consultation launch, the need for a definition of social transition and describing exactly what the role of the NHS service should be in decision-making around social transition.

Evidence

Several respondents suggested that NHS England had relied on out-of-date evidence to form the conclusion that in most cases gender incongruence or gender variance that presents in pre-pubertal children does not persist in adolescence. At the time of drafting the interim service specification, this conclusion was shared by various bodies in their

published guidelines, including the Endocrine Society's Clinical Practice Guidelines and the World Professional Association for Transgender Health (WPATH) standards of care (Version 7) which said that "*in most children, gender dysphoria will disappear before or early in puberty".* NHS England's position was therefore consistent at the time with various professional societies. Since the interim service specification was drafted, some bodies including WPATH have refined their position on this issue. The WPATH standards of care were updated to version 8 in September 2022. While WPATH agrees that gender incongruence will be transient and will not persist into adolescence for some children, it no longer quantifies whether this will occur in the majority or minority of such children.

NHS England has re-framed this section of the final version of the interim service specification to reflect the advice set out in the consultation response received from the Independent Review. The Review's submission agreed that pre-pubertal children have different needs to older adolescents, and advised NHS England that the detail of the approaches for the different pathways will need to develop as the new services evolve and an evidence base is built.

On the issue of building the evidence base, some respondents suggested that clinical recommendations for the support of pre-pubescent children in particular may need to be developed independently for natal boys and for natal girls, as the presentation of gender incongruence is different and different factors are predictive for the persistence of gender incongruence. Of the evidence that does exist, evidence relating to children and young people who present with a non-binary presentation is lacking. Respondents advised NHS England that young people, their parents and health professionals involved in their care should be informed about the nature and limitations of the evidence base.

<u>What is meant by 'social transition'?</u>

Many respondents objected to what they perceived to be attempts to prevent a child or young person's approach to social transition and questioned how this could be achieved in practice. In response to these views, we have amended the final version of the interim service specification to clarify that the reference to 'social transition' is intended to refer to an active form of support offered by NHS clinicians to children, young people and their families who have decided that the child or young person will fully present in public with a gender identity different to that of their natal sex in all forms and aspects of their daily lives – rather than less profound forms of gender diverse expressions, behaviours or interests such as engaging in activities or presentations socially defined and typically associated with another gender presentation. We have also added clarification that while the ability to express individuality – and to change and adapt that expression over time - can be important to a child or young person's development of the self and to their overall

wellbeing, it is important to view social transition as an active intervention when it forms part of a managed individual care plan because it may have significant effects on the child or young person in terms of their social and psychological functioning. While there are different views on the benefits versus the harms of early social transition, it is important to acknowledge that it is not a neutral act - and that better information is needed about outcomes. Decisions will be individual, and the agency to make the decision will ultimately rest with the young person, along with their family.

Management of patients accessing prescriptions from un-regulated sources

The draft interim service specification clarified the position in regard to children and young people who source prescriptions or drugs from unregulated sources or unregulated providers. It stated that children, young people and their families are strongly discouraged from sourcing GnRHa and masculinising / feminising hormones from unregulated sources or from on-line providers that are not regulated by UK regulatory bodies. It was proposed that in such cases The Service would make the child or young person and their family aware of the risks, contraindications and any irreversible or partly reversible effects and would advise the GP to initiate local safeguarding protocols.

The majority of respondents (63%) disagreed or partially disagreed with these proposed changes. Many respondents argued that people use unregulated drugs because waiting times are so long, and that the proposed changes run contrary to the NHS' overarching duty of care to patients and are potentially coercive and punitive.

NHS England has retained its position on the risks and dangers of sourcing GnRHa and hormones from unregulated sources, but in response to feedback we have amended the final version of the interim service specification to;

1. set out criteria that will be applied by the Service (jointly with the endocrine team) to consider whether it is clinically appropriate to assume clinical responsibility under NHS protocols for children and young people in this situation; and
2. refined the proposed approach for initiation of safeguarding protocols, using language proposed by the Royal College of General Practitioners in its response to public consultation.

Other changes or additions

Revised diagnostic framework

Some respondents objected to the references in the draft interim service specification of the need for the child or young person to demonstrate 'clinically significant distress' in order to be eligible for the NHS pathway of care. This was not a new approach that was being proposed – the requirement reflected the diagnostic framework of the Diagnostic and Statistical Manual of Mental Disorders Version 5, which is the diagnostic framework that is referenced in the published service specification for the Gender Identity Development Service (2016). In the final version of the interim service specification we have applied the diagnostic framework of the International Classification of Diseases (ICD-11) which describes a clinical diagnosis of 'gender incongruence … that must have persisted for about two years" in pre-pubertal children, and for adolescents "a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender".

Future commissioning arrangements for GnRH (puberty suppressing hormones)

The draft interim service specification made clear that, consistent with advice from the Independent Review highlighting the uncertainties surrounding the use of hormone treatments, NHS England would in future only commission GnRH analogues in the context of a formal research protocol. This commitment generated considerable feedback and NHS England is now in a position to update on next steps.

NHS England has established a new national Children and Young People's Gender Dysphoria Research Oversight Board, which is chaired by Professor Sir Simon Wessely. Membership includes the National Institute for Health and Care Research (NIHR), the Medical Research Council (MRC), the Royal College of Paediatrics and Child Health (RCPCH), Dr Hilary Cass and a range of other clinical and academic experts. The role of the Board is to maintain an overview of emerging national and international clinical evidence and ensure it informs front line clinical practice; to identify and articulate remaining evidence gaps to research funders, including potentially commissioning new studies; to build and support research activity, academic expertise and continuous quality improvement in commissioned centres; and, to establish the core data to be collected to support both current and future care.

The Oversight Board has now given the green light for the development of a study into the impact of puberty suppressing hormones ('puberty blockers') 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 engaging with stakeholders on the study design. Subject to the usual ethical and scientific approvals, we anticipate recruitment to the study will open in 2024.

For those children and young people with later-onset gender dysphoria, the Oversight Board asked that further engagement with stakeholders be undertaken to identify the key evidence gaps, 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.

In line with NHS England's published methods, a draft interim clinical commissioning policy relating to the routine use of puberty suppressing hormones has now begun a focused and targeted period of stakeholder testing. After this period of stakeholder testing, our Patient & Public Voice Assurance Group will consider and advise on the appropriateness of NHS England's plans for formal and broader public consultation.

The draft interim clinical commissioning policy proposes that puberty supressing hormones (GnRH analogues) are 'not routinely commissioned' as there is not enough evidence to support their safety or clinical effectiveness as a routinely available treatment and that they should only be accessed as part of research. The draft interim clinical commissioning policy also states that on an exceptional, case by case basis any clinical recommendation to prescribe puberty supressing hormones outside of research, and in contradiction of the clinical commissioning policy, must be considered and approved by a national multidisciplinary team.

Public consultation on the draft interim clinical commissioning policy will follow stakeholder testing and consideration by NHS England's Patient and Public Voice Assurance Group.

It is recognised that if this draft clinical commissioning policy is adopted 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.

Minimum Population Size

In response to feedback, the number of referrals to the service has been expressed as a proportion of children aged 3-17 rather than as a proportion of the whole population.

Equality and Health Inequalities Impact Assessment

An updated EHIA has been published alongside this consultation report. The updated EHIA refers to submissions made during public consultation and provides a response to those submissions.

Most of the submissions that were made in regard to the EHIA were critical of NHS England's approach to the interpretation and application of the protected characteristic of 'Gender Reassignment'. However, the updated EHIA provides reassurance that in January 2023, the High Court agreed with the conclusions that NHS England had reached in the previous EHIA that not every child or young person referred to a specialised gender incongruence service will have the protected characteristic of gender reassignment, though some, as NHS England has always accepted, will have it.