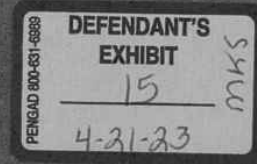


# EXHIBIT 47

# The Cass Review

Independent review  
of gender identity  
services for children  
and young people:  
Interim report

February 2022





# **Independent review of gender identity services for children and young people: Interim report**

February 2022

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# About this report

This interim report represents the work of the independent review of gender identity services for children and young people to date. It reflects a point in time. It does not set out final recommendations; these will be developed over the coming months, informed by our formal research programme.

This Review is forward looking. Its role is to consider how to improve and develop the future clinical approach and service model. However, in order to do this, it is first necessary to understand the current landscape and the reasons why change is needed, so that any future model addresses existing challenges, whilst retaining those features that service users and the professionals supporting them most value.

This report is primarily for the commissioners and providers of services for children and young people needing support around their gender. However, because of the wide interest in this topic, we have included some explanations about how clinical service development routinely takes place in the NHS, which sets the context for some of our interim advice.

The care of this group of children and young people is everyone's business. We therefore encourage the wider clinical community to take note of our work and consider their own roles in providing the best holistic support to this population.

Since the Review began, it has focused on hearing a wide range of perspectives to better understand the challenges within the current system and aspirations for how these could be addressed. This report does not contain all that we have heard during our listening sessions but summarises consistent themes. These conversations will continue throughout the course of the Review and there will be further opportunities for stakeholders to engage and contribute.

It is important to note that the references cited in this report do not constitute a comprehensive literature review and are included only to clarify why specific lines of enquiry are being pursued, and where there are unanswered questions that will be addressed more fully during the life of the Review. A formal literature review is one strand of the Review's commissioned work, and this will be reported in full when complete.



## Independent review of gender identity services for children and young people

### A note about language

There is sometimes no consensus on the best language to use relating to this subject. The language surrounding this area has also changed rapidly and young people have developed varied ways of describing their experiences using different terms and constructs that are relevant to them.

The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately illustrate the complexity of what we are trying to describe and articulate.

The terms we have used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review. A glossary of terms is included.

The Review is cognisant of the broader cultural and societal debates relating to the rights of transgender adults. It is not the role of the Review to take any position on the beliefs that underpin these debates. Rather, this Review is strictly focused on the clinical services provided to children and young people who seek help from the NHS to resolve their gender-related distress.

A letter to children and young people

# A letter to children and young people

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**Children and young people accessing the NHS deserve safe, timely and supportive services, and clinical staff with the training and expertise to meet their healthcare needs.**



**Dr Hilary Cass**

I understand that as you read this letter some of you may be anxious because you are waiting to access support from the NHS around your gender identity. Maybe you have tried to get help from your local services, or from the Gender Identity Development Service (GIDS), and because of the long waiting lists they have not yet been able to see you. I hope that some of you have had help – maybe from a supportive GP, a local Child and Adolescent Mental Health Service (CAMHS), or from GIDS.

I have heard that young service users are particularly worried that I will suggest that services should be reduced or stopped. I want to assure you that this is absolutely not the case – the reverse is true. I think that more services are needed for you, closer to where you live. The GIDS staff are working incredibly hard and doing their very best to see you as quickly as possible but providing supportive care is not something that can be rushed – each young person needs enough time and space for their personal needs to be met. So, with the best will in the world, one service is not going to be able to respond to the growing demand in a timely way.

I am advising that more services are made available to support you. But I must be honest; this is not something that can happen overnight, and I can't come up with a solution that will fix the problems immediately. However, we do need to start now.

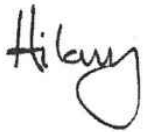
The other topic that I know is worrying some of you is whether I will suggest that hormone treatments should be stopped. On this issue, I have to share my thoughts as a doctor. We know quite a bit about hormone treatments, but there is still a lot we don't know about the long-term effects.

### Independent review of gender identity services for children and young people

Whenever doctors prescribe a treatment, they want to be as certain as possible that the benefits will outweigh any adverse effects so that when you are older you don't end up saying 'Why did no-one tell me that that might happen?' This includes understanding both the risks and benefits of having treatment and not having treatment.

Therefore, what we will be doing over the next few months is trying to make sense of all the information that is available, as well as seeing if we can plug any of the gaps in the research. I am currently emphasising the importance of making decisions about prescribing as safe as possible. This means making sure you have all the information you need – about what we do know and what we don't know.

Finally, some of you may want the chance to talk to me and share your thoughts about how services should look in the future. Over the coming months we will need your help and there will be opportunities to get involved with the Review, so please keep an eye on our website ([www.cass.independent-review.uk](http://www.cass.independent-review.uk)), where we will provide updates on our work.

A handwritten signature in black ink that reads "Hilary". The signature is written in a cursive style with a large, looped 'y'.

**Dr Hilary Cass, OBE**

# Introduction from the Chair

Anyone with an interest in the care of gender-questioning children and young people, as well as those with lived experience, may have wondered what qualifies me to take on this Review, and whether I have a pre-existing position on this subject.

I am a paediatrician who was in clinical practice until 2018, my area of specialism being children and young people with disability. I have also held many management and policy roles throughout my career, most notably as President of the Royal College of Paediatrics and Child Health (RCPCH) from 2012-15.

Children's services are often at a disadvantage in healthcare because health services are usually designed around the needs of adults. As President of RCPCH, a key part of my role was to advocate for services to be planned with children and families at their heart.

I have not worked in gender services during my career, but my strong focus on hearing the voice of service users, supporting vulnerable young people, equity of access, and strong clinical standards applies in this area as much as in my other work.

With this in mind, the aim of the Review is to ensure that children and young people who are experiencing gender incongruence or gender-related distress receive a high standard of NHS care that meets their needs and is safe, holistic and effective.

I have previously set out the principles governing this Review process, namely that:

- The welfare of the child and young person will be paramount in all considerations.
- Children and young people must receive a high standard of care that meets their needs.
- There will be extensive and purposeful stakeholder engagement, including ensuring that children and young people can express their own views through a supportive process.
- The Review will be underpinned by research and evidence, including international models of good practice where available.
- There will be transparency in how the Review is conducted and how recommendations are made.
- There are no pre-determined outcomes with regards to the recommendations the Review will make.

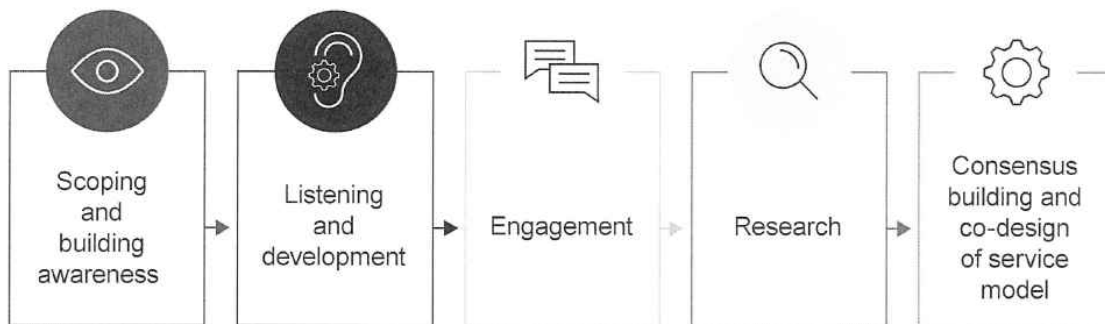
## Independent review of gender identity services for children and young people

The Review's terms of reference (**Appendix 1**) are wide ranging in scope, looking at different aspects of gender identity services across the whole pathway through primary, secondary and specialist services, up to the point of transition to adult services. This includes consideration of referral pathways, assessment, appropriate clinical management and workforce recommendations.

I have also been asked to explore the reasons for the considerable increase in the number of referrals, which have had a significant impact on waiting times, as well as the changing case-mix of gender-questioning children and young people presenting to clinical services.

The Review is taking an investigative approach to understanding what the future service model should look like for children and young people. This means that its outcomes are not being developed in isolation or by committee but rather through an ongoing dialogue aimed at building a shared understanding of the current situation and how it can and should be improved.

### The key aspects of the approach to the Review are:



My starting point has been to hear from a variety of experts with relevant expertise and those with lived experience to understand as many perspectives as possible. To date, this has included hearing directly from those with lived experience, from professionals and support and advocacy groups. This listening process will continue.

We have been very fortunate in the generosity of all those who have been prepared to talk to the Review and share their experiences. In addition to some divergent opinions, there are also some themes and views which seem to be widely shared. The commitment of professionals at all levels is striking and I genuinely believe that with collective effort we can improve services for the children and young people who are at the heart of this Review.

These discussions have been valuable to get an in-depth sense of the current situation and different viewpoints on how it may be improved. However, it is essential that this initial understanding is underpinned by more detailed data and an enhanced evidence base, which is being delivered through the Review's academic research programme.

Providing this evidence base for the Review is going to take some time. I recognise there is a pressing need to enhance the services currently available for children, young people, their

## Introduction from the Chair

parents and carers, some of whom are experiencing considerable distress. Clinicians providing their treatment and care are also under pressure and cannot sustain the current workload. As such, I know the time I am taking to complete this Review and make recommendations will be difficult for some, but it is necessary.

I wrote to NHS England in May 2021 (**Appendix 2**) setting out some more immediate considerations whilst awaiting my full recommendations. This report builds on that letter and looks to provide some further interim advice.

Through our research programme, the Review team will continue to examine the literature and, where possible, will fill gaps in the existing evidence base. However, there will be persisting evidence gaps and areas of uncertainty. We need the engagement of service users, support and advocacy groups, and professionals across the wider workforce to work with us in the coming months in a collaborative and open-minded manner in order to reach a shared understanding of the problems and an agreed way forward that is in the best interests of children and young people.

My measure of success for this Review will be that this group of children and young people receive timely, appropriate and excellent care, not just from specialists but from every healthcare professional they encounter as they take the difficult journey from childhood to adulthood.

# 1. Summary and interim advice



## Summary and interim advice

## Summary

1.1. In recent years, there has been a significant increase in the number of referrals to the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust. This has contributed to long waiting lists and growing concern about how the NHS should most appropriately assess, diagnose and care for this population of children and young people.

1.2. Within the UK, the single specialist service has developed organically, and the clinical approach has not been subjected to some of the usual control measures that are typically applied when new or innovative treatments are introduced. Many of the challenges and knowledge gaps that we face in the UK are echoed internationally,<sup>1</sup> and there are significant gaps in the research and evidence base.

1.3. This Review was commissioned by NHS England to make recommendations on how to improve services provided by the NHS to children and young people who are questioning their gender identity or experiencing gender incongruence and ensure that the best model for safe and effective services is commissioned (**Appendix 1**).

1.4. This interim report represents the Review's work to date. It sets out what we have heard so far and the approach we are taking moving forward. There is still much evidence to be gathered, questions to be answered, and voices to be heard, and our perspective will evolve as more evidence comes to light. However, there is sufficient clarity on several areas for the Review to be able to offer advice at this stage so that action can be taken more quickly.

1.5. The Review is not able to provide definitive advice on the use of puberty blockers and feminising/masculinising hormones at this stage, due to gaps in the evidence base; however, recommendations will be developed as our research programme progresses.

Every gender-questioning child or young person who seeks help from the NHS must receive the support they need to get on the appropriate pathway for them as an individual.

Children and young people with gender incongruence or dysphoria must receive the same standards of clinical care, assessment and treatment as every other child or young person accessing health services.

<sup>1</sup> Vrouwenraets LJ, Fredriks AM, Hannema SE, Cohen-Kettenis PT, de Vries MC (2015). [Early medical treatment of children and adolescents with gender dysphoria: an empirical ethical study](#). *J Adolesc Health* 57(4): 367-73. DOI: 10.1016/.2015.04.004.



## Independent review of gender identity services for children and young people

### **Conceptual understanding and consensus about the meaning of gender dysphoria**

1.6. In clinical practice, a diagnosis of gender dysphoria is currently based on an operational definition, using the criteria set out in DSM-5 (**Appendix 3**). Some of these criteria are seen by some as outdated in the context of current understanding about the flexibility of gender expression.

1.7. At primary, secondary and specialist level, there is a lack of agreement, and in many instances a lack of open discussion, about the extent to which gender incongruence in childhood and adolescence can be an inherent and immutable phenomenon for which transition is the best option for the individual. Professionals' experience and position on this spectrum may determine their clinical approach.

1.8. Children and young people can experience this as a 'clinician lottery', and failure to have an open discussion about this issue is impeding the development of clear guidelines about their care.

### **Service capacity and delivery**

1.9. A rapid change in epidemiology and an increase in referrals means that the number of children seeking help from the NHS is now outstripping the capacity of the single national specialist service, the Gender Identity Development Service (GIDS) at The Tavistock and Portman NHS Foundation Trust.

1.10. The mix of young people presenting to the service is more complex than seen previously, with many being neurodiverse and/or having a wide range of psychosocial and mental health needs. The largest group currently comprises birth-registered females first presenting in adolescence with gender-related distress.

1.11. Until very recently, any local professional, including non-health professionals, could refer to GIDS, which has meant that the quality and appropriateness of referrals lacks consistency, and local service provision has remained patchy and scarce.

1.12. The staff working within the specialist service demonstrate a high level of commitment to the population they serve. However, the waiting list pressure and lack of consensus development on the clinical approach, combined with criticism of the service, have all resulted in rapid turnover of staff and inadequate capacity to deal with the increasing workload. Capacity constraints cannot be addressed through financial investment alone; there are some complex workforce (recruitment; retention; and training) and cultural issues to address.

1.13. Our initial work has indicated that many professionals working at primary and secondary level feel that they have the transferable skills and the commitment to offer more robust support to this group of children and young people, but are nervous about doing so, partly because of the lack of formal clinical guidance, and partly due to the broader societal context.

## Summary and interim advice

1.14. Primary and secondary care staff have told us that they feel under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and diagnosis that they have been trained to undertake in all other clinical encounters.

1.15. Children and young people are waiting lengthy periods to access GIDS, during which time some may be at considerable risk. By the time they are seen, their distress may have worsened, and their mental health may have deteriorated.

1.16. Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be overlooked.

1.17. The current move to adult services at age 17-18 may fall at a critical time in the young person's gender management. In contrast, young people with neurodiversity often remain under children's services until age 19 and some other clinical services continue to mid-20s. Further consideration will be needed regarding the age of transfer to adult services.

## Service standards

1.18. The Multi-Professional Review Group (MPRG), set up by NHS England to ensure that procedures for assessment and for informed consent have been properly followed, has stated that the following areas require consideration:

- From the point of entry to GIDS there appears to be predominantly an affirmative, non-exploratory approach, often driven by child and parent expectations and the extent of social transition that has developed due to the delay in service provision.
- From documentation provided to the MPRG, there does not appear to be a standardised approach to assessment or progression through the process, which leads to potential gaps in necessary evidence and a lack of clarity.
- There is limited evidence of mental health or neurodevelopmental assessments being routinely documented, or of a discipline of formal diagnostic or psychological formulation.
- Of 44 submissions received by the MPRG, 31% were not initially assured due to lack of safeguarding information. And in a number of cases there were specific safeguarding concerns. There do not appear to be consistent processes in place to work with other agencies to identify children and young people and families who may be vulnerable, at risk and require safeguarding.

## Independent review of gender identity services for children and young people

- Appropriate clinical experts need to be involved in informing decision making.

1.19. Many of these issues were also highlighted by the Care Quality Commission (CQC) in 2020.<sup>2</sup>

### International comparisons

1.20. The Netherlands was the first country to provide early endocrine interventions (now known internationally as the Dutch Approach). Although GIDS initially reported its approach to early endocrine intervention as being based on the Dutch Approach,<sup>3</sup> there are significant differences in the NHS approach. Within the Dutch Approach, children and young people with neurodiversity and/or complex mental health problems are routinely given therapeutic support in advance of, or when considered appropriate, instead of early hormone intervention. Whereas criteria to have accessed therapeutic support prior to starting hormone blocking treatment do not appear to be integral to the current NHS process.

1.21. NHS endocrinologists do not systematically attend the multi-disciplinary meetings where the complex cases that may be referred to them are discussed, and until very recently did not routinely have

direct contact with the clinical staff member who had assessed the child or young person. This is not consistent with some international approaches for this group of children and young people, or in other multi-disciplinary models of care across paediatrics and adult medicine where challenging decisions about life-changing interventions are made.<sup>4,5</sup>

1.22. In the NHS, once young people are started on hormone treatment, the frequency of appointments drops off rather than intensifies, and review usually takes place quarterly. Again, this is different to the Dutch Approach.<sup>6</sup> GIDS staff would recommend more frequent contact during this period, but the fall-off in appointments reflects a lack of service capacity, with the aspiration being for more staff time to remedy this situation.

### Existing evidence base

1.23. Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally.

<sup>2</sup> Care Quality Commission (2021). [The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report](#). London: CQC.

<sup>3</sup> de Vries ALC, Cohen-Kettenis PT (2012). [Clinical management of gender dysphoria in children and adolescents: the Dutch approach](#). J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

<sup>4</sup> Ibid.

<sup>5</sup> Kyriakou A, Nicolaidis NC, Skordis N (2020). [Current approach to the clinical care of adolescents with gender dysphoria](#). Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.

<sup>6</sup> de Vries ALC, Cohen-Kettenis PT (2012). [Clinical management of gender dysphoria in children and adolescents: the Dutch approach](#). J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

## Summary and interim advice

1.24. A lack of a conceptual agreement about the meaning of gender dysphoria hampers research, as well as NHS clinical service provision.

1.25. There has not been routine and consistent data collection within GIDS, which means it is not possible to accurately track the outcomes and pathways that children and young people take through the service.

1.26. Internationally as well as nationally, longer-term follow-up data on children and young people who have been seen by gender identity services is limited, including for those who have received physical interventions; who were transferred to adult services and/or accessed private services; or who desisted, experienced regret or detransitioned.

1.27. There has been research on the short-term mental health outcomes and physical side effects of puberty blockers for this cohort, but very limited research on the sexual, cognitive or broader developmental outcomes.<sup>7</sup>

1.28. Much of the existing literature about natural history and treatment outcomes for gender dysphoria in childhood is based on a case-mix of predominantly birth-registered males presenting in early childhood. There is much less data on the more recent case-mix of predominantly

birth-registered females presenting in early teens, particularly in relation to treatment and outcomes.

1.29. Aspects of the literature are open to interpretation in multiple ways, and there is a risk that some authors interpret their data from a particular ideological and/or theoretical standpoint.

### **The mismatch between service user expectations and clinical standards**

1.30. By the time children and young people reach GIDS, they have usually had to experience increasingly long, challenging waits to be seen.<sup>8</sup> Consequently, some feel they want rapid access to physical interventions and find having a detailed assessment distressing.

1.31. Clinical staff are governed by professional, legal and ethical guidance which demands that certain standards are met before a treatment can be provided. Clinicians carry responsibility for their assessment and recommendations, and any harm that might be caused to a patient under their care. This can create a tension between the aspirations of the young person and the responsibilities of the clinician.

<sup>7</sup> National Institute for Health and Care Excellence (2020). [Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria](#).

<sup>8</sup> Care Quality Commission (2021). [The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report](#). London: CQC.

## Independent review of gender identity services for children and young people

### Interim advice

1.32. The Review considers that there are some areas where there is sufficient clarity about the way forward and we are therefore offering some specific observations and interim advice. The Review will work with NHS England, providers and the broader stakeholder community to progress action in these areas.

### Service model

1.33. It has become increasingly clear that a single specialist provider model is not a safe or viable long-term option in view of concerns about lack of peer review and the ability to respond to the increasing demand.

1.34. Additionally, children and young people with gender-related distress have been inadvertently disadvantaged because local services have not felt adequately equipped to see them. It is essential that they can access the same level of psychological and social support as any other child or young person in distress, from their first encounter with the NHS and at every level within the service.

1.35. A fundamentally different service model is needed which is more in line with other paediatric provision, to provide timely and appropriate care for children and young people needing support around their gender identity. This must include support for any other clinical presentations that they may have.

1.36. The Review supports NHS England's plan to establish regional services, and welcomes the move from a single highly specialist service to regional hubs.

1.37. Expanding the number of providers will have the advantages of:

- creating networks within each area to improve early access and support;
- reducing waiting times for specialist care;
- building capacity and training opportunities within the workforce;
- developing a specialist network to ensure peer review and shared standards of care; and
- providing opportunities to establish a more formalised service improvement strategy.

### Service provision

1.38. The primary remit of NHS England's proposed model is for the regional hubs to provide support and advice to referrers and professionals. However, it includes limited provision for direct contact with children and young people and their families.

## Summary and interim advice

**1:** The Review advises that the regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway. The Review team will work with NHS England and stakeholders to further define the proposed model and workforce implications.

**2:** Each regional centre will need to develop links and work collaboratively with a range of local services within their geography to ensure that appropriate clinical, psychological and social support is made available to children and young people who are in early stages of experiencing gender distress.

**3:** Clear criteria will be needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services.

**4:** Regional training programmes should be run for clinical practitioners at all levels, alongside the online training modules developed by Health Education England (HEE). In the longer-term, clearer mapping of the required workforce, and a series of competency frameworks will need to be developed in collaboration with relevant professional organisations.

## Data, audit and research

1.39. A lack of routine and consistent data collection means that it is not possible to accurately track the outcomes and pathways children and young people take through the service. Standardised data collection is required in order to audit service standards and inform understanding of the epidemiology, assessment and treatment of this group. This, alongside a national network which brings providers together, will help build knowledge and improve outcomes through shared clinical standards and systematic data collection. In the longer-term, formalisation of such a network into a learning health system<sup>9</sup> with an academic host would mean that there was systematised use of data to produce a continuing research programme with rapid translation into clinical practice and a focus on training.

<sup>9</sup> Scobie S, Castle-Clarke S (2019). [Implementing learning health systems in the UK NHS: Policy actions to improve collaboration and transparency and support innovation and better use of analytics](#). *Learning Health Systems* 4(1): e10209. DOI:10.1002/lrh2.10209.

## Independent review of gender identity services for children and young people

**5:** The regional services should have regular co-ordinated national provider meetings and operate to shared standards and operating procedures with a view to establishing a formal learning health system.

**6:** Existing and future services should have standardised data collection in order to audit standards and inform understanding of the epidemiology, assessment and treatment of this group of children and young people.

**7:** Prospective consent of children and young people should be sought for their data to be used for continuous service development, to track outcomes, and for research purposes. Within this model, children and young people put on hormone treatment should be formally followed up into adult services, ideally as part of an agreed research protocol, to improve outcome data.

## Clinical approach

### Assessment processes

1.40. We have heard that there are inconsistencies and gaps in the assessment process. Our work to date has also demonstrated that clinical staff have different views about the purpose of assessment and where responsibility lies for different components of the process within the pathway of care. The Review team has commenced discussions with clinical staff across primary, secondary and tertiary care to develop a framework for these processes.

**8:** There needs to be agreement and guidance about the appropriate clinical assessment processes that should take place at primary, secondary and tertiary level.

**9:** Assessments should be respectful of the experience of the child or young person and be developmentally informed. Clinicians should remain open and explore the patient's experience and the range of support and treatment options that may best address their needs, including any specific needs of neurodiverse children and young people.

## Summary and interim advice

## Hormone treatment

1.41. The issues raised by the Multi-Professional Review Group echo several of the problems highlighted by the CQC. It is essential that principles of the General Medical Council's Good Practice in Prescribing and Managing Medicines and Devices<sup>10</sup> are closely followed, particularly given the gaps in the evidence base regarding hormone treatment. Standards for decision making regarding endocrine treatment should also be consistent with international best practice.<sup>11,12,13</sup>

**10:** Any child or young person being considered for hormone treatment should have a formal diagnosis and formulation, which addresses the full range of factors affecting their physical, mental, developmental and psychosocial wellbeing. This formulation should then inform what options for support and intervention might be helpful for that child or young person.

**11:** Currently paediatric endocrinologists have sole responsibility for treatment, but where a life-changing intervention is given there should also be additional medical responsibility for the differential diagnosis leading up to the treatment decision.

1.42. Paediatric endocrinologists develop a wide range of knowledge within their paediatric training, including safeguarding, child mental health, and adolescent development. Being party to the discussions and deliberations that have led up to the decision for medical intervention supports them in carrying out their legal responsibility for consent to treatment and the prescription of hormones.

**12:** Paediatric endocrinologists should become active partners in the decision making process leading up to referral for hormone treatment by participating in the multidisciplinary team meeting where children being considered for hormone treatment are discussed.

<sup>10</sup> General Medical Council (2021). [Good practice in prescribing and managing medicines and devices \(76-78\)](#).

<sup>11</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al (2017). [Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline](#). J Clin Endocrinol Metab 102(11): 3869–903. DOI: 10.1210/jc.2017-01658.

<sup>12</sup> Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). [Treatment of adolescents with gender dysphoria in the Netherlands](#). Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.

<sup>13</sup> Kyriakou A, Nicolaidis NC, Skordis N (2020). [Current approach to the clinical care of adolescents with gender dysphoria](#). Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.



### Independent review of gender identity services for children and young people

1.43. Given the uncertainties regarding puberty blockers, it is particularly important to demonstrate that consent under this circumstance has been fully informed and to follow GMC guidance<sup>14</sup> by keeping an accurate record of the exchange of information leading to a decision in order to inform their future care and to help explain and justify the clinician's decisions and actions.

**13:** Within clinical notes, the stated purpose of puberty blockers as explained to the child or young person and parent should be made clear. There should be clear documentation of what information has been provided to each child or young person on likely outcomes and side effects of all hormone treatment, as well as uncertainties about longer-term outcomes.

**14:** In the immediate term the Multi-Professional Review Group (MPRG) established by NHS England should continue to review cases being referred by GIDS to endocrine services.

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<sup>14</sup> General Medical Council (2020). [Decision making and consent](#).

## 2. Context



## Independent review of gender identity services for children and young people

### Transgender, non-binary and gender fluid adults

2.1. NHS clinical services to support transgender adults with hormone treatment and subsequent surgery began in 1966.

2.2. Services were initially established within a mental health model, in conjunction with endocrinology and surgical services.

2.3. Currently, NHS services for transgender adults do not have adequate capacity to cope with demand.<sup>15</sup> In addition, the broader healthcare needs of this group are not well met. This is important in the context of the current generation of gender-questioning children and young people in that there are now two inflows into adult services – individuals transitioning in adulthood, and those moving through from children's services.

2.4. Legal rights and protections for transgender people lagged behind the provision of medical services, with the Gender Recognition Act 2004 coming into force in April 2005. Over the last few years, broader discussions about transgender issues have been played out in public, with discussions becoming increasingly polarised and adversarial. This polarisation is such that it undermines safe debate and creates difficulties in building consensus.

2.5. It is not the role of this Review to take any position on the cultural and societal debates relating to transgender adults. However, in achieving its objectives there is a need to consider the information and support that children and young people access from whatever source, as well as any pressures that they are subject to, before they access clinical services.

### Terminology and diagnostic frameworks

2.6. The Office for National Statistics defines sex as “referring to the biological aspects of an individual as determined by their anatomy, which is produced by their chromosomes, hormones and their interactions; generally male or female; something that is assigned at birth”.<sup>16</sup>

2.7. The Office for National Statistics defines gender as “a social construction relating to behaviours and attributes based on labels of masculinity and femininity; gender identity is a personal, internal perception of oneself and so the gender category someone identifies with may not match the sex they were assigned at birth”.<sup>17</sup>

2.8. Societal attitudes towards gender roles and gender expression are changing. Children, teenagers and younger adults may more commonly see gender as a fluid, multi-faceted phenomenon which

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<sup>15</sup> Gender Identity Clinic, The Tavistock and Portman NHS Foundation Trust. [Waiting times](#).

<sup>16</sup> Office for National Statistics (2019). [What is the difference between sex and gender?](#)

<sup>17</sup> Ibid.

does not have to be binary, whereas older generations have tended to see gender as binary and fixed. It is not unusual for young people to explore both their sexuality and gender as they go through adolescence and early adulthood before developing a more settled identity. Many achieve this without experiencing significant distress or requiring support from the NHS, but this is not the case for all.

2.9. For those who require support from the NHS, there are two widely used frameworks which provide diagnostic criteria. The International Classification of Diseases (ICD), which is the World Health Organization (WHO) mandated health data standard, and the Diagnostic and Statistical Manual of Mental Disorders (DSM), which is the classification system for mental health disorders produced by the American Psychiatric Association. The current editions of these manuals – ICD-11 and DSM-5 – came into effect in January 2022 and 2013 respectively.

2.10. ICD-11<sup>18</sup> has attempted to depathologise gender diversity, removing the term 'gender identity disorders' from its mental health section and creating a new section for gender incongruence and transgender identities in a chapter on sexual health. These changes are part of a much broader societal drive to remove the stigma previously associated with transgender healthcare. ICD-11

defines gender incongruence as being “characterised by a marked incongruence between an individual's experienced/ expressed gender and the assigned sex.” Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis. The full criteria for gender incongruence of childhood and gender incongruence of adolescence or adulthood are listed in **Appendix 3**.

2.11. DSM-5<sup>19</sup> is currently the framework used to diagnose gender dysphoria. This diagnostic category describes gender dysphoria as “the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender”. A diagnosis of gender dysphoria is usually deemed necessary before a young person can access hormone treatment, and criteria are listed in **Appendix 3**.

## Conceptual understanding of gender incongruence in children and young people

2.12. Children and young people presenting to gender identity services are not a homogeneous group. They vary in their age at presentation, their cultural background, whether they identify as binary, non-binary, or gender fluid, whether they are neurodiverse and in a host of other ways.

<sup>18</sup> World Health Organization (2022). [International Classification of Diseases Eleventh Revision](#).

<sup>19</sup> American Psychiatric Association (2013). [Diagnostic and Statistical Manual of Mental Health Disorders: DSM-5™, 5th ed.](#)

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2.13. Some children and young people may thrive during a period of gender-questioning whilst for others it can be accompanied with a level of distress that can have a significant impact on their functioning and development.

2.14. Alongside these very varied presentations, it is highly unlikely that a single cause for gender incongruence will be found. Many authors view gender expression as a result of a complex interaction between biological, cultural, social and psychological factors.

2.15. Despite a high level of agreement about these points, there are widely divergent and, in some instances, quite polarised views among service users, parents, clinical staff and the wider public about how gender incongruence and gender-related distress in children and young people should be interpreted, and this has a bearing on expectations about clinical management.

2.16. These views will be influenced by how each individual weighs the balance of factors that may lead to gender incongruence, and the distress that may accompany it. Beliefs about whether it might be inherent and/or immutable, whether it might be a transient response to adverse experiences, whether it might be highly fluid and/or likely to change in later adolescence/early adulthood, etc will have

a profound influence on expectations about treatment options.<sup>20</sup>

2.17. All of these views may be overlaid with strongly held concerns about children's and young people's rights, autonomy, and/or protection.

2.18. The disagreement and polarisation is heightened when potentially irreversible treatments are given to children and young people, when the evidence base underlying the treatments is inconclusive, and when there is uncertainty about whether, for any particular child or young person, medical intervention is the best way of resolving gender-related distress.

2.19. As with many other contemporary polarised disagreements, the situation is exacerbated when there is no space to have open, non-judgemental discussions about these differing perspectives. A key aim of this review process will be to encourage such discussions in a safe and respectful manner so that progress can be made in finding solutions.

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<sup>20</sup> Wren B (2019). Notes on a crisis of meaning in the care of gender-diverse children. In: Hertzmann L, Newbiggin J (eds) *Sexuality and Gender Now: Moving Beyond Heteronormativity*. Routledge.

### 3. Current services



## Independent review of gender identity services for children and young people

### Current service model for gender-questioning children and young people

3.1. Currently there are no locally or regionally commissioned services for children and young people who seek help from the NHS in managing their gender-related distress. Within primary and secondary care, some clinical staff have more interest and expertise in initial management of this group of young people, but such individuals are few and far between.

3.2. The pathway for NHS support around gender identity for children and young people is designated as a highly specialised service.<sup>21</sup> The Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust is commissioned by NHS England to provide specialist assessment, support and, where appropriate, hormone intervention for children and young people with gender dysphoria. It is the only NHS provider of specialist gender services for children and young people in England. The Trust runs satellite bases in Leeds and Bristol. Until recently GIDS accepted referrals from multiple sources, for example, GPs, secondary care, social care, schools, and support and advocacy groups, which is unusual for a specialist service.

3.3. Children and young people are assessed by two members of the GIDS team who may be any combination of psychologists, psychotherapists, family therapists, or social workers. If there is uncertainty about the right approach, individual cases may be discussed in a complex case meeting. Those deemed appropriate for physical interventions are referred on to the endocrine team; under the current Standard Operating Procedure (SOP), this decision requires a multi-disciplinary team (MDT) discussion within GIDS. A member of the GIDS team attends new appointments in the endocrine clinic, but they will not routinely be the member of staff who saw the young person for assessment. However, very recently a triage meeting has been piloted to enable endocrinologists to discuss upcoming appointments with the clinician who saw the young person for assessment. The young person then attends an education session prior to their endocrine appointment. The endocrinologist will assess any medical contraindications prior to seeking consent from the patient for any hormone treatments.

3.4. For many years, the GIDS approach was to offer assessment and support, and to only start puberty blockers when children reached sexual maturity at about age 15 (Tanner Stage 5) as the first step in the treatment process to feminise or masculinise the young person, with

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<sup>21</sup> [National Health Service Commissioning Board and Clinical Commissioning Groups \(Responsibilities and Standing Rules\) Regulations 2012.](#)

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oestrogen or testosterone given from age 16. Feminising/masculinising hormones are not given at an earlier stage because of the irreversibility of some of their actions in developing secondary sex characteristics of the acquired gender.<sup>22,23</sup>

3.5. In 1998, a new protocol was published by the Amsterdam gender identity clinic.<sup>24</sup> It was subsequently named the Dutch Approach.<sup>25</sup> This involved giving puberty blockers much earlier, from the time that children showed the early signs of puberty (Tanner Stage 2), to pause further pubertal changes of the sex at birth. This stage of pubertal development was chosen because it was felt that although many younger children experienced gender incongruence as a transient developmental phenomenon, those who expressed early gender incongruence which continued into puberty were unlikely to desist at that stage.

3.6. It was felt that blocking puberty would buy time for children and young people to fully explore their gender identity and help with the distress caused by the development of their secondary sexual characteristics. The Dutch criteria

for treating children with early puberty blockers were: (i) a presence of gender dysphoria from early childhood; (ii) an increase of the gender dysphoria after the first pubertal changes; (iii) an absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; (iv) adequate psychological and social support during treatment; and (v) a demonstration of knowledge and understanding of the effects of gonadotropin-releasing hormones (puberty blockers), feminising/masculinising hormones, surgery, and the social consequences of sex reassignment.<sup>26</sup>

3.7. Under the Dutch Approach, feminising/masculinising hormones were started at age 16 and surgery was permitted to be undertaken from age 18, as in England.

3.8. From 2011, early administration of puberty blockers was started in England under a research protocol, which partially paralleled the Dutch Approach (the Early Intervention Study). From 2014, this protocol was adopted by GIDS as routine clinical practice. Results of the Early Intervention Study were published in December 2021.<sup>27</sup>

<sup>22</sup> Delemarre-van de Wall HA, Cohen-Kettenis PT (2006). Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects. Eur J Endocrinol 155 (Suppl 1): S131–7. DOI: 10.1530/eje.1.02231.

<sup>23</sup> de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

<sup>24</sup> Cohen-Kettenis PT, Van Goozen S (1998). Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. Eur Child Adolesc Psychiatry 7: 246–8. DOI: 10.1007/s007870050073.

<sup>25</sup> de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

<sup>26</sup> Ibid.

<sup>27</sup> Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, et al (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 16(2):e0243894. DOI:10.1371/journal.pone.0243894.



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3.9. However, the Dutch Approach differs from the GIDS approach in having stricter requirements about provision of psychological interventions. For example, under the Dutch Approach, if young people have gender confusion, aversion towards their sexed body parts, psychiatric comorbidities or Autism Spectrum Disorder (ASD) related diagnostic difficulties, they may receive psychological interventions only, or before, or in combination with medical intervention. Of note, in 2011, the Amsterdam team were reporting that up to 10% of their referral base were young people with ASD.<sup>28</sup>

### Changing epidemiology

3.10. In the last few years, there has been a significant change in the numbers and case-mix of children and young people being referred to GIDS.<sup>29</sup> From a baseline of approximately 50 referrals per annum in 2009, there was a steep increase from 2014-15, and at the time of the CQC inspection of the Tavistock and Portman NHS Foundation Trust in October 2020 there were 2,500 children and young people being referred per annum, 4,600 children and young people on the waiting list, and a waiting time of over two years

to first appointment.<sup>30</sup> This has severely impacted on the capacity of the existing service to manage referrals in the safe and responsive way that they aspire to and has led to considerable distress for those on the waiting list.

3.11. This increase in referrals has been accompanied by a change in the case-mix from predominantly birth-registered males presenting with gender incongruence from an early age, to predominantly birth-registered females presenting with later onset of reported gender incongruence in early teen years. In addition, approximately one third of children and young people referred to GIDS have autism or other types of neurodiversity. There is also an over-representation percentage wise (compared to the national percentage) of looked after children.<sup>31</sup>

<sup>28</sup> Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.

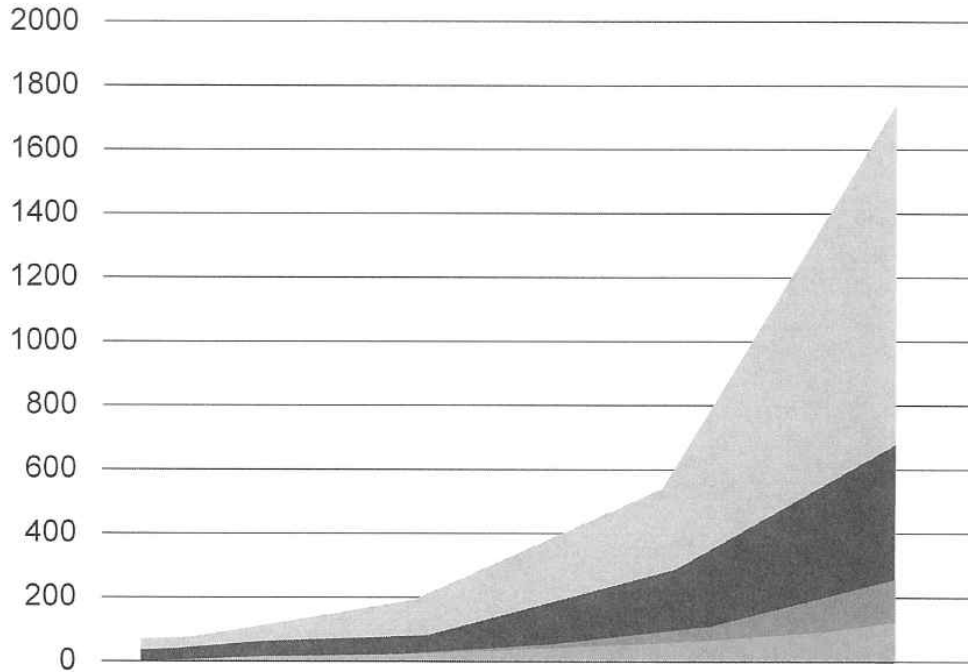
<sup>29</sup> de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). Sex ratio in children and adolescents referred to the gender identity development service in the UK (2009-2016). Arch Sex Behav 47(5): 1301–4.

<sup>30</sup> Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.

<sup>31</sup> Matthews T, Holt V, Sahin S, Taylor A, Griksaitis (2019). Gender Dysphoria in looked-after and adopted young people in a gender identity development service. Clinical Child Psychol Psychiatry 24: 112-128. DOI: 10.1177/1359104518791657.

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Figure 1: Sex ratio in children and adolescents referred to GIDS in the UK (2009-16)



	2009	2010	2011	2012	2013	2014	2015	2016
Adolescents F	15	48*	78*	141*	221*	314*	689*	1071*
Adolescents M	24	44*	41	77*	120*	185*	293*	426*
Children F	2	7	12	17	22	36	77*	138*
Children M	10	19	29	30	31	55*	103*	131

AFAB = assigned female at birth; AMAB = assigned male at birth

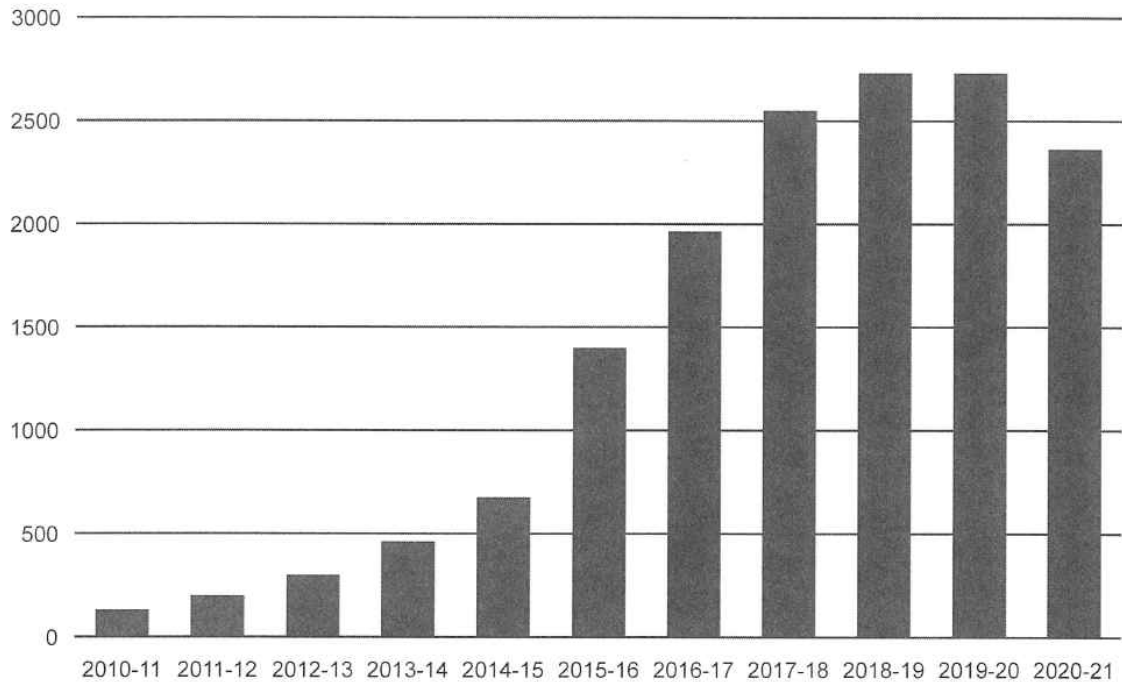
\*Indicates  $p < .05$  which shows a significant increase of referrals compared to the previous year

Source: de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018).<sup>32</sup>

<sup>32</sup> de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). Sex ratio in children and adolescents referred to the gender identity development service in the UK (2009-2016). Arch Sex Behav 47(5): 1301-4.

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**Figure 2: Referrals to GIDS, 2010-11 to 2020-21**



**Source: Gender Identity Development Service.<sup>33</sup>**

3.12. In 2019, GIDS reported that about 200 children and young people from a referral base of 2,500 were referred on to the endocrine pathway. There is no published data on how the other children and young people from this referral baseline were managed, for example if: their gender dysphoria was resolved; they were still being assessed or receiving ongoing psychological support and input; they were not eligible for puberty blockers due to age; they were referred to endocrine services at a later stage; they were transferred to adult services; or they accessed private services.

### Challenges to the service model and clinical approach

3.13. Over a number of years, in parallel with the increasing numbers of referrals, GIDS faced increasing challenges, both internally and externally. There were different views held within the staff group about the appropriate clinical approach, with some more strongly affirmative and some more cautious and concerned about the use of physical intervention. The complexity of the cases had also increased, so clinical decision making had become more difficult. There was also a high staff

<sup>33</sup> Gender Identity Development Service. [Referrals to GIDS, financial years 2010-11 to 2020-21](#).

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turnover, and accounts from staff concerned about the clinical care, which were picked up in both mainstream and social media. This culminated in 2018 with an internal report by a staff governor.

3.14. Following that report, a review was carried out in 2019 by the Trust's medical director. This set out the need for clearer processes for the service's referral management, safeguarding, consent, and clinical approach, and an examination of staff workload and support, and a new Standard Operating Procedure (SOP) was put in place.

## NHS England Policy Working Group

3.15. In January 2020, a Policy Working Group (PWG) was established by NHS England to undertake a review of the published evidence on the use of puberty blockers and feminising/masculinising hormones in children and young people with gender dysphoria to inform a policy position on their future use. Given the increasingly evident polarisation among clinical professionals, Dr Cass was asked to chair the group as a senior clinician with no prior involvement or fixed views in this area. The PWG comprised an expert group including endocrinologists, child and adolescent psychiatrists and paediatricians representing their respective Royal

Colleges, an ethicist, a GP, senior clinicians from the NHS GIDS, a transgender adult and parents of gender-questioning young people. The process was supported by a public health consultant and policy, pharmacy and safeguarding staff from NHS England.

3.16. NHS England uses a standardised protocol for developing clinical policies. The first step of this involves defining the PICO (the Population being treated, the Intervention, a Comparator treatment, and the intended Outcomes). This of itself was challenging, with a particular difficulty being definition of the intended outcomes of puberty blockers, and suitable comparators for both hormone interventions. However, agreement was reached on what should be included in the PICO and subsequently the National Institute for Health and Care Excellence (NICE) was commissioned to review the published evidence,<sup>34,35</sup> again following a standardised protocol which has strict criteria about the quality of studies that can be included.

3.17. Unfortunately, the available evidence was not strong enough to form the basis of a policy position. Some of the challenges and outstanding uncertainties are summarised as follows.

<sup>34</sup> National Institute for Health and Care Excellence (2020). [Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria](#).

<sup>35</sup> National Institute for Health and Care Excellence (2020). [Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria](#).

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### **Feminising/masculinising hormones**

3.18. Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers.

3.19. In young people, consideration also needs to be given to the impact on fertility, with the need for fertility counselling and preservation.

3.20. The additional physical risk of starting these treatments at age 16+ rather than age 18+ is unlikely to add significantly to the total lifetime risk, although data on this will not be available for many years. However, as evidenced by take-up of treatment with feminising/masculinising hormones, where there is a high level of certainty that physical transition is the right option, the child or young person may be more accepting of these risks, which can seem remote from the immediate gender distress.

3.21. The most difficult question in relation to feminising/masculinising hormones therefore is not about long-term physical risk which is tangible and easier to understand. Rather, given the irreversible nature of many of the changes, the greatest difficulty centres on the decision to proceed to physical transition; this relies on the effectiveness of the assessment, support and counselling processes, and ultimately the shared decision making between

clinicians and patients. Decisions need to be informed by long-term data on the range of outcomes, from satisfaction with transition, through a range of positive and negative mental health outcomes, through to regret and/or a decision to detransition. The NICE evidence review demonstrates the poor quality of these data, both nationally and internationally.

3.22. Regardless of the nature of the assessment process, some children and young people will remain fluid in their gender identity up to early to mid-20s, so there is a limit as to how much certainty one can achieve in late teens. This is a risk that needs to be understood during the shared decision making process with the young person.

3.23. It is also important to note that any data that are available do not relate to the current predominant cohort of later-presenting birth-registered female teenagers. This is because the rapid increase in this subgroup only began from around 2014-15. Since young people may not reach a settled gender expression until their mid-20s, it is too early to assess the longer-term outcomes of this group.

## Puberty blockers

3.24. The administration of puberty blockers is arguably more controversial than administration of the feminising/masculinising hormones, because there are more uncertainties associated with their use.

3.25. There has been considerable discussion about whether the treatment is 'experimental'; strictly speaking an experimental treatment is one that is being given as part of a research protocol, and this is not the case with puberty blockers, because the GIDS research protocol was stopped in 2014. At that time, the treatment was experimental and innovative, because the drug was licensed for use in children, but specifically for children with precocious puberty. This was therefore the first time it was used 'off-label' in the UK for children with gender dysphoria. If a drug is used 'off-label' it means it is being used for a condition that is different from the one for which it was licensed. The many uncertainties around the 'off-label' use were recognised, but given that this was not a new drug, it did not need Medicines and Healthcare products Regulatory Agency (MHRA) approval at that time.

3.26. The important question now, as with any treatment, is whether the evidence for the use and safety of the medication is strong enough as judged by reasonable clinical standards.

3.27. One of the challenges that NHS England's PWG faced in considering this question was the lack of clarity about intended outcomes, several of which have been proposed including:

- providing time/space for the young person to make a decision about continuing with transition;
- reducing or preventing worsening of distress;
- improving mental health; and
- stopping potentially irreversible pubertal changes which might later make it difficult for the young person to 'pass' in their intended gender role.

3.28. Proponents for the use of puberty blockers highlight the distress that young people experience through puberty and the risk of self-harm or suicide.<sup>36</sup> However, some clinicians do not feel that distress is actually alleviated until children and young people are able to start feminising/masculinising hormones. The Review will seek to gain a better understanding of suicide data and the impact of puberty blockers through its research programme.

3.29. On the other hand, it has been asserted that starting puberty blockers at an older age provides children and young people with more time to achieve fertility preservation. In the case of birth-registered males, there is an argument that it also

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<sup>36</sup> Turban JL, King D, Carswell JM, et al (2020). [Pubertal suppression for transgender youth and risk of suicidal ideation](#). *Pediatrics* 145 (2): e20191725. DOI: 10.1542/peds.2019-1725.

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allows more time to achieve adequate penile growth for successful vaginoplasty.

3.30. In the short-term, puberty blockers may have a range of side effects such as headaches, hot flushes, weight gain, tiredness, low mood and anxiety, all of which may make day-to-day functioning more difficult for a child or young person who is already experiencing distress. Short-term reduction in bone density is a well-recognised side effect, but data is weak and inconclusive regarding the long-term musculoskeletal impact.<sup>37</sup>

3.31. The most difficult question is whether puberty blockers do indeed provide valuable time for children and young people to consider their options, or whether they effectively 'lock in' children and young people to a treatment pathway which culminates in progression to feminising/masculinising hormones by impeding the usual process of sexual orientation and gender identity development. Data from both the Netherlands<sup>38</sup> and the study conducted by GIDS<sup>39</sup> demonstrated that almost all children and young people who are put on puberty blockers go on to sex hormone treatment (96.5% and 98%

respectively). The reasons for this need to be better understood.

3.32. A closely linked concern is the unknown impacts on development, maturation and cognition if a child or young person is not exposed to the physical, psychological, physiological, neurochemical and sexual changes that accompany adolescent hormone surges. It is known that adolescence is a period of significant changes in brain structure, function and connectivity.<sup>40</sup> During this period, the brain strengthens some connections (myelination) and cuts back on others (synaptic pruning). There is maturation and development of frontal lobe functions which control decision making, emotional regulation, judgement and planning ability. Animal research suggests that this development is partially driven by the pubertal sex hormones, but it is unclear whether the same is true in humans.<sup>41</sup> If pubertal sex hormones are essential to these brain maturation processes, this raises a secondary question of whether there is a critical time window for the processes to take place, or whether catch up is possible when oestrogen or testosterone is introduced later.

<sup>37</sup> National Institute for Health and Care Excellence (2020). [Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria](#).

<sup>38</sup> Brik T, Vrouenraets LJJJ, de Vries MC, Hannema SE (2020). [Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria](#). Arch Sex Behav 49: 2611–8. DOI: 10.1007/s10508-020-01660-8.

<sup>39</sup> Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, et al (2021). [Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK](#). PLoS One. 16(2):e0243894. DOI:10.1371/journal.pone.0243894.

<sup>40</sup> Delevichab K, Klinger M, Nana OJ, Wilbrecht L (2021). [Coming of age in the frontal cortex: The role of puberty in cortical maturation](#). Semin Cell Dev Biol 118: 64–72. DOI: 10.1016/j.semcdb.2021.04.021.

<sup>41</sup> Goddings A-L, Beltz A, Jiska S, Crone EA, Braams BR (2019). [Understanding the role of puberty in structural and functional development of the adolescent brain](#). J Res Adolesc 29(1): 32–53. DOI: 10.1111/jora.12408.

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3.33. An international interdisciplinary panel<sup>42</sup> has highlighted the importance of understanding the neurodevelopmental outcomes of pubertal suppression and defined an appropriate approach for investigating this further. However, this work has not yet been undertaken.

## Initiation of Cass Review

3.34. Dr Cass' own reflections on the PWG process, the available literature, and the issues it highlighted were as follows:

- Firstly, that hormone treatment is just one possible outcome for gender-questioning children and young people. A much better understanding is needed about: the increasing numbers of children and young people with gender-related distress presenting for help; the appropriate clinical pathway for each individual; their support needs; and the full range of potential treatment options.
- Secondly, there is very limited follow-up of the subset of children and young people who receive hormone treatment, which limits our understanding about the long-term outcomes of these treatments and this lack of follow up data should be corrected.

- Thirdly, the assessment process is inconsistent across the published literature. The outcome of hormone treatment is highly influenced by whether the assessment process accurately selects those children and young people most likely to benefit from medical treatment. This makes it difficult to draw conclusions from published studies.

3.35. In light of the above, NHS England commissioned this independent review to make recommendations on how the clinical management and service provision for children and young people who are experiencing gender incongruence or gender-related distress can be improved.

## CQC inspection

3.36. In October and November 2020, the Care Quality Commission (CQC) inspectors carried out an announced, focused inspection of GIDS due to concerns reported to them by healthcare professionals and the Children's Commissioner for England. Concerns related to clinical practice, safeguarding procedures, and assessments of capacity and consent to treatment.

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<sup>42</sup> Chen D, Strang JF, Kolbuck VD, Rosenthal SM, Wallen K, Waber DP, et al (2020). [Consensus parameter: research methodologies to evaluate neurodevelopmental effects of pubertal suppression in transgender youth](#). *Transgender Health* 5(4). DOI: 10.1089/trgh.2020.0006.



## Independent review of gender identity services for children and young people

3.37. The CQC report, published in January 2021,<sup>43</sup> gave the service an overall rating of inadequate. The report noted the high level of commitment and caring approach of the staff but identified a series of issues that needed improvement. In addition to the growing waiting list pressures, the CQC identified problems in several other areas including: the assessment and management of risk; the variations in clinical approach; the lack of clarity and consistency of care plans; the lack of any clear written rationale for decision making in individual cases; and shortfalls in the multidisciplinary mix required for some patient groups. Recording of capacity, competency and consent had improved since the new SOP in January 2020; however, there remained a culture in which staff reported feeling unable to raise concerns.

3.38. The CQC reported that when it inspected GIDS, there did not appear to be a formalised assessment process, or standard questions to explore at each session, and it was not possible to tell from the notes why an individual child might have been referred to endocrinology whilst another had not. Current GIDS data demonstrate that a majority of children and young people seen by the service do not get referred for endocrine treatment, but there is no clear information about what

other diagnoses they receive, and what help or support they might need.

3.39. Since the CQC report, NHS England and The Tavistock and Portman NHS Foundation Trust management team have been working to address the issues raised. However, whilst some problems require a focused Trust response, the waiting list requires a system-wide response. This was noted in the letter from the Review to NHS England in May 2021 (**Appendix 2**).

## Legal background

3.40. This section sets out the chronology of recent case law. In October 2019, a claim for Judicial Review was brought against The Tavistock and Portman NHS Foundation Trust. The claimants' case was summarised by the High Court as follows: "The claimants' case is that children and young persons under 18 are not competent to give consent to the administration of puberty blocking drugs. Further, they contend that the information given to those under 18 by the defendant [GIDS] is misleading and insufficient to ensure such children or young persons are able to give informed consent. They further contend that the absence of procedural safeguards, and the inadequacy of the information provided, results in an infringement of the rights of such children and young persons under Article 8 of the European Convention

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<sup>43</sup> Care Quality Commission (2021). [The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report](#). London: CQC.

## Current services

for the Protection of Human Rights and Fundamental Freedoms.”<sup>44</sup>

3.41. In December 2020, three judges in the High Court of England and Wales handed down judgment in *Bell v Tavistock*.<sup>45</sup> (Most cases in the High Court are heard by a single judge sitting alone, and when a case is heard by more than one judge in the High Court, it is described as the Divisional Court.) The Divisional Court recognised that the Tavistock’s policies and practices as set out in the service specification were not unlawful. However, the Court made a declaration that set out in detail a series of implications of treatment that a child would need to understand to be *Gillick* competent<sup>46</sup> to consent to puberty blockers. Specifically, because most children put on puberty blockers go on to have feminising/ masculinising hormones, the judgment said a child would need to understand not only the full implications of puberty blocking drugs, but also the implications of the full pathway of medical and surgical transition. The judges concluded that it will be “very doubtful” that 14-15 year-olds have such competence, and “highly unlikely” that children aged 13 or under have competence for that decision. Under the Mental Capacity Act 2005, 16-17 year-olds are presumed to have capacity, and they are effectively treated as adults for consent to medical treatment under the Family Law Reform Act 1969 section 8, but the judges

suggested that it would be appropriate for clinicians to involve the court in any case where there were doubts as to whether the proposed treatment would be in the long term best interests of a 16-17 year-old.

3.42. Following the Divisional Court judgment in *Bell v Tavistock*, a claim was brought against the Tavistock in the High Court Family Division by the mother of a child for a declaration that she and the child’s father had the ability in law to consent on behalf of their child to the administration of puberty blockers (*AB v CD*).<sup>47</sup> The Court concluded that “the parents’ right to consent to treatment on behalf of the child continues even when the child is *Gillick* competent to make the decision, save where the parents are seeking to override the decision of the child” [para 114] and that there is no “general rule that puberty blockers should be placed in a special category by which parents are unable in law to give consent” [para 128].

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<sup>44</sup> *Bell v Tavistock*, [2020] EWHC 3274 (Admin).

<sup>45</sup> *Ibid*.

<sup>46</sup> *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112.

<sup>47</sup> *AB v CD & Ors* [2021] EWHC 741.

### Independent review of gender identity services for children and young people

3.43. Subsequently, the Tavistock appealed the Divisional Court's earlier decision in *Bell v Tavistock* and was successful.<sup>48</sup> The Court of Appeal held that it was not appropriate for the Divisional Court to provide the guidance about the likelihood of having *Gillick* competence at particular ages, or about the need for court approval [para 91]. The Court of Appeal went on to say "The Divisional Court concluded that Tavistock's policies and practices (as expressed in the service specification and the SOP) were not unlawful and rejected the legal criticism of its materials. In those circumstances, the claim for judicial review is dismissed." [para 91]. However, clinicians should "take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed" [para 92].

3.44. The Court of Appeal in *Bell v Tavistock* recognised the lawfulness of treating children for gender dysphoria in this jurisdiction. Recognising the divergences in medical opinion, morality and ethics, it indicated that the question of whether treatment should be made available is a matter of policy "for the National Health Service, the medical profession and its regulators and Government and Parliament" [para 3].

3.45. Following the Divisional Court decision in *Bell v Tavistock*, new referrals for puberty blockers were suspended and a requirement was put in place that children currently on puberty blockers were reviewed with a view to court proceedings for a judge to determine the best interests for children in whom these medications were considered essential. This requirement was changed following *AB v CD*, with the reinstatement of the hormone pathway in March 2021. However, an external panel, the Multi Professional Review Group (MPRG), was established to ensure that procedures for assessment and for informed consent had been properly followed. The outcome of the *Bell* appeal has not changed this requirement, which is contingent not just on the legal processes but on the concerns raised by CQC regarding consent, documentation and clarity about decision making within the service.<sup>49</sup>

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<sup>48</sup> [EWCA \[2021\] Civ 1363](#).

<sup>49</sup> Care Quality Commission (2021). [The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report](#). London: CQC.

## The Multi-Professional Review Group

3.46. NHS England has established a Multi-Professional Review Group (MPRG) to review whether the agreed process has been followed for a child to be referred into the endocrinology clinic and to be prescribed treatment. The Review has spoken directly to the MPRG, which has reported its observations of current practice.

3.47. The MPRG has stated that its work has been impeded by delays in the provision of clinical information, the lack of structure in the documentation received, and gaps in the necessary evidence. This means that when reviewing the documents provided it is not always easy to determine if the process for referral for endocrine treatment has been fully or safely followed for a particular child or young person.

3.48. The MPRG indicates that there does not appear to be a standardised approach to assessment. They are particularly concerned about safeguarding shortfalls within the assessment process. There is also limited evidence of systematic, formal mental health or neurodevelopmental assessments being routinely documented, or of a discipline of formal diagnostic formulation in relation to co-occurring mental health difficulties. This issue was also highlighted by the Care Quality Commission (CQC).<sup>50</sup>

3.49. Additionally, there is concern that communications to GPs and parents regarding prescribed treatment with puberty blockers sometimes come from non-medical staff.

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<sup>50</sup> Care Quality Commission (2021). [The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report](#). London: CQC.

## 4. What the review has heard so far



## What the review has heard so far

### Listening sessions

4.1. Since its establishment, the Review has met with an extensive range of stakeholders, including professionals, their respective governing organisations and those with lived experience, both directly and through support and advocacy groups, to understand the broad range of views and experiences surrounding the delivery of gender identity services.

### What we have heard from service users, their families and support and advocacy groups

#### Issues for children and young people

4.2. What we understand most clearly from all we have heard is that at the centre of a difficult and complex debate are children, young people and families in great distress. We have heard concerns about children and young people facing the stress of being on a prolonged waiting list with limited support available from statutory services, lack of certainty about when and if they might reach the top of that list and subsequent impacts on mental health. Also, the particular issues that have followed the *Bell v Tavistock* litigation.

4.3. We have heard about the anxiety that birth-registered males face as they come closer to the point where they will grow facial hair and their voice drops, and the fear that it will make it harder for them to pass as a transgender woman in later life. We have also heard about the distress

experienced by birth-registered females as they reach puberty, including the use of painful, and potentially harmful, binding processes to conceal their breasts.

4.4. When children and young people are able to access the service, there is often a sense of frustration with what several describe as the “gatekeeping” medical model and a “clinician lottery”. This can feel like a series of barriers and hurdles designed to add to, rather than alleviate, distress. Most children and young people seeking help do not see themselves as having a medical condition; yet to achieve their desired intervention they need to engage with clinical services and receive a medical diagnosis of gender dysphoria. By the time they are seen in the GIDS clinic, they may feel very certain of their gender identity and be anxious to start hormone treatment as quickly as possible. However, they can then face a period of what can seem like intrusive, repetitive and unnecessary questioning. Some feel that this undermines their autonomy and right to self-determination.

4.5. We have heard that some young people learn through peers and social media what they should and should not say to therapy staff in order to access hormone treatment; for example, that they are advised not to admit to previous abuse or trauma, or uncertainty about their sexual orientation. We have also heard that many of those seeking NHS support identify as non-binary, gender non-conforming, or gender fluid. We understand that some

## Independent review of gender identity services for children and young people

young people who identify as non-binary feel their needs are not met by clinical services unless they give a binary narrative about their gender preferences.

### Issues for parents

4.6. We have also heard about the distress parents may feel as they try to work out how best to support their children and how tensions and conflict may arise where parents and their children have different views. For example, some parents have highlighted the importance of ensuring that children and young people are able to keep their options fluid until such time as it becomes essential to commit to a hormonal course of action, whilst their children may want more rapid hormone intervention.

4.7. We have heard about families trying to balance the risks of obtaining unregulated and potentially dangerous hormone supplies over the internet or from private providers versus the ongoing trauma of prolonged waits for assessment.

4.8. Parents have also raised concerns about the vulnerability of neurodiverse children and young people and expressed that the communication needs of these children and young people are not adequately reflected during assessment processes or treatment planning.

4.9. GIDS has always required consent/assent from both the child and parents/carers and has sought ways to resolve family conflict, which in the worst-case scenario can lead to family breakdown. It has been highlighted to us that the future

service model should provide more targeted support for parents and carers.

### Service issues

4.10. Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be subsumed by the label of gender dysphoria. This issue is compounded by the waiting list, which means that there can be a significant period of time without appropriate assessment, treatment or care.

4.11. Stakeholders have spoken of the need for appropriate assessment when first accessing NHS services to aid both the exploration of the child or young person's wellbeing and gender distress and any other challenges they may be facing.

### Information

4.12. We have also heard about the lack of access to accurate, balanced information upon which children, young people and their families/carers can inform their decisions.

4.13. We have heard that distress may be exacerbated by pressure to identify with societal stereotyping and concerns over the influence of social media, which can be seen to perpetuate unrealistic images of gender and set unhealthy expectations, especially given how long

## What the review has heard so far

children and young people are waiting to access services.

### Other issues

4.14. Several issues that were raised with us are not explored further in this interim report, but we have taken note of them. These will be considered further during the lifetime of the Review and include:

- The important role of schools and the challenges they face in responding appropriately to gender-questioning children and young people.
- The complex interaction between sexuality and gender identity, and societal responses to both; for example, we have heard from young lesbians who felt pressured to identify as transgender male, and conversely transgender males who felt pressured to come out as gay rather than transgender. We have also heard from adults who identified as transgender through childhood, and then reverted to their birth-registered gender in teen years.
- The issues faced by detransitioners highlight the need for better services and pathways for this group, many of whom are living with irreversible effects of transition but for whom there is no clear access to services as they fall outside the responsibility of NHS gender identity services.
- The age at which adult gender identity clinics can receive referrals, with concerns about the inclusion of 17-year-olds. The service offer in adult services

is perceived to be quite different from that of GIDS, and young people presenting later may therefore not be afforded the same level of therapeutic input under the adult service model. There is also concern about the impact on the young person of changing clinicians at a crucial point in their care. The movement of young people with special educational needs between children's and adult services raises particular concerns.

## What we have heard from healthcare professionals

### Lack of professional consensus

4.15. Clinicians and associated professionals we have spoken to have highlighted the lack of an agreed consensus on the different possible implications of gender-related distress – whether it may be an indication that the child or young person is likely to grow up to be a transgender adult and would benefit from physical intervention, or whether it may be a manifestation of other causes of distress. Following directly from this is a spectrum of opinion about the correct clinical approach, ranging broadly between those who take a more gender-affirmative approach to those who take a more cautious, developmentally-informed approach.



## Independent review of gender identity services for children and young people

4.16. Speaking to current and ex-GIDS staff, we have heard about the pressure on GIDS clinicians, many of whom feel overwhelmed by the numbers of children and young people being referred and who are demoralised by the media coverage of their service. Although the clinical team attempt to manage risk on the waiting list by engaging with local services, there is limited capacity and/or capability to respond appropriately to the needs of this group in primary and secondary care. The Review has already referred to this issue as the most pressing priority in its letter to NHS England (**Appendix 2**), alongside potential risks relating to safeguarding and/or mental health issues, and diagnostic overshadowing.

4.17. With respect to GIDS, we have been told that although there are forums for staff to discuss difficult cases with senior colleagues, it is still difficult for staff to raise concerns about the clinical approach. Also that many individuals who are more cautious and advocate the need for an exploratory approach have left the service.

### Consistency and standards

4.18. GIDS staff have confirmed that judgements are very individual, with some clinicians taking a more gender-affirmative approach and others emphasising the need for caution and for careful exploration of broader issues. The Review has been told that there is considerable variation in the approach taken between the London, Leeds and Bristol teams.

4.19. Speaking to professionals outside GIDS, we have heard widespread concern about the lack of guidance and evidence on how to manage this group of young people.

4.20. Some secondary care providers told us that their training and professional standards dictate that when working with a child or young person they should be taking a mental health approach to formulating a differential diagnosis of the child or young person's problems. However, they are afraid of the consequences of doing so in relation to gender distress because of the pressure to take a purely affirmative approach. Some clinicians feel that they are not supported by their professional body on this matter. Hence the practice of passing referrals straight through to GIDS is not just a reflection of local service capacity problems, but also of professionals' practical concerns about the appropriate clinical management of this group of children and young people.

4.21. GPs have expressed concern about being pressurised to prescribe puberty blockers or feminising/masculinising hormones after these have been initiated by private providers.

4.22. This also links to professional concerns about parents being anxious for hormone treatment to be initiated when the child or young person does not seem ready.

### Other issues

4.23. We have also heard that parents and carers play a huge role and are instrumental in helping young people

## What the review has heard so far

to keep open their developmental opportunities. In discussion with social workers, we heard concerns about how looked after children are supported in getting the help and support they need.

4.24. Therapists who work with detransitioners and people with regret have highlighted a lack of services and pathways and a need for services to support this population. There is also the need for more research to understand what factors contribute to the decision to detransition.

4.25. The importance of broad holistic interventions to help reduce distress has been emphasised to the Review, with therapists and other clinicians advocating the importance of careful developmentally informed assessment and of showing children and young people a range of different narratives, experiences and outcomes.

4.26. Clinicians have raised concerns about children and young people's NHS numbers being changed inconsistently, as there is no specific guidance for GPs and others as to when this should be done for this population and under what consent. This has implications for safeguarding and clinical management of these children and young people and it also makes it difficult to do research exploring long-term outcomes.

4.27. As with the comments made by service users, their families and support and advocacy groups, we have heard similar views from professionals about the

transition from children's to adult services, and the role of schools.

## Structured engagement with primary, secondary and specialist clinicians

4.28. The Review's letter to NHS England (**Appendix 2**) set out some of the immediate issues with the current provision of gender identity services for children and young people and suggested how its work might help with the challenging problem of establishing an infrastructure outside GIDS. This included looking at the capacity, capability and confidence of the wider workforce and how this could be built and sustained, and the establishment of potential assessment frameworks for use in primary and/or secondary care.

## Professional panel – primary and secondary care

4.29. In order to understand the challenges and establish a picture of current competency, capacity and confidence among the workforce outside the specialist gender development service, an online professional panel was established to explore issues around gender identity services for children and young people. The role of the panel was aimed at better comprehending how it looks and feels for clinicians and other professionals working with these young people, as well as any broader thoughts about the work, and to start exploring how the care of these

## Independent review of gender identity services for children and young people

children and young people can be better managed in the future.

4.30. The project was designed to capture a broad mix of professional views and experiences, recruiting from the professional groups that are most likely to have a role in the care pathway – GPs, paediatricians, child psychiatrists, child psychologists and child psychotherapists, nurses and social workers.

4.31. A total of 102 clinicians and other professionals were involved in the panel. The panel represented a balanced professional mix, and participant ages and gender were broadly representative of the overall sector workforce. Participants were self-selecting and were recruited via healthcare professional networks and Royal Colleges.

4.32. Each week the panel was set an independent activity comprised of two or more tasks. Additionally, a sub-set of the panel was invited to participate in focus groups at the midway and endpoint of the project. Activities were designed to capture an understanding of:

- experiences of working with gender-questioning children and young people and panel members' confidence and competence to manage their care;
- changes they may have experienced in the presentation of children and young people with gender-related distress;
- areas where professionals feel they require more information in order to

support gender-questioning children and young people;

- where professionals currently go to find that information;
- the role of different professions in the care pathway;
- the role of professionals in the assessment framework; and
- what participants felt should be included in an assessment framework across the whole service pathway.

### Gender specialist questionnaire

4.33. Having concluded the professional panel exercise, we wanted to triangulate what we had heard with the thoughts and views of professionals working predominantly or exclusively with gender-questioning children and young people.

4.34. To do this in a systematic way, we conducted an online survey which contained some service-specific questions, but also reflected and sought to test some of what we had heard from primary and secondary care professionals.

### Findings

4.35. This structured engagement has yielded valuable insights from clinicians and professionals with experience working with gender-questioning children and young people both within and outside the specialist gender service. It has contributed to the thinking of the Review and informed some of the interim advice set out in this report.

## What the review has heard so far

4.36. There are a number of consistent messages arising from these activities:

- The current long waiting lists that gender-questioning children and young people and their families/carers face are unacceptable for all parties involved, including professionals.
- Many professionals in our sample said that not only are gender-questioning children and young people having to wait a long time before receiving treatment, but they also do not receive appropriate support during this waiting period.
- Another impact of the long wait that clinicians reported is that when a child or young person is seen at GIDS, they may have a more fixed view of what they need and are looking for action to be taken quickly. This reportedly can lead to frustration with the assessment process.
- When considering the more holistic support that children and young people may need, gender specialists further highlighted the difficulties that children and young people face accessing local support, for example, from CAMHS, whilst being seen at GIDS.
- It is clear from the professionals who took part in these activities that there is a strong professional commitment to provide quality care to gender-questioning children and young people and their families/carers. However, this research indicates that levels of confidence and competence do vary

among primary and secondary care professionals in our sample.

- Concerns were expressed by professionals who took part in this research about the lack of consensus among the clinical community on the right clinical approach to take when working with a gender-questioning child or young person and their families/carers.
- In order to support clinicians and professionals more widely, participants felt there is a need for a robust evidence base, consistent legal framework and clinical guidelines, a stronger assessment process and different pathway options that holistically meet the needs of each gender-questioning child or young person and their families/carers.

4.37. There are also several areas where further discussion and consensus is needed:

- There is not a consistent view among the professionals participating in the panel and questionnaire about the nature of gender dysphoria and therefore the role of assessment for children and young people experiencing gender dysphoria.

### Independent review of gender identity services for children and young people

- Some clinicians felt that assessment should be focused on whether medical interventions are an appropriate course of action for the individual. Other clinicians believe that assessment should seek to make a differential diagnosis, ruling out other potential causes of the child or young person's distress.
- There are different perspectives on the roles of primary, secondary and specialist services in the care pathway(s) and what support or action might best be provided at different levels.
- While there was general consensus that diagnostic or psychological formulation needs to form part of the assessment process, there were differing views as to whether a mental state assessment is needed, and should it be, where in the pathway and by whom this should be done.

4.38. It is important to note that the information gathered represents the views and insights of the panel participants and survey respondents at a moment in time and findings should be read in the context of a developing narrative on the subject, where perspectives may evolve. This relates to both the experiences of professionals, but also the extent to which this subject matter is discussed in the public sphere.

4.39. The Review is grateful to all the participants for their time and high level of engagement. The Review will build on the work we have undertaken and, alongside our academic research, will continue with a programme of engagement with professionals, service users and their families, which will help to further develop the evidence base.

The full reports from the professional panel and gender specialist questionnaire are on the Review's website (<https://cass.independent-review.uk/>).

## 5. Principles of evidence based service development



## Independent review of gender identity services for children and young people

### Evidence based service development

5.1. This chapter integrates the information regarding the development of the current service (see Chapter 3) with the views we have heard to date (see Chapter 4) and sets this in the context of how evidence is routinely used to develop and improve services in the NHS.

5.2. Some earlier information is necessarily repeated here, but this is with the intention of providing a more accessible explanation of the standards and processes which govern clinical service development. This is essential to an understanding of the rationale for the Review's recommendations.

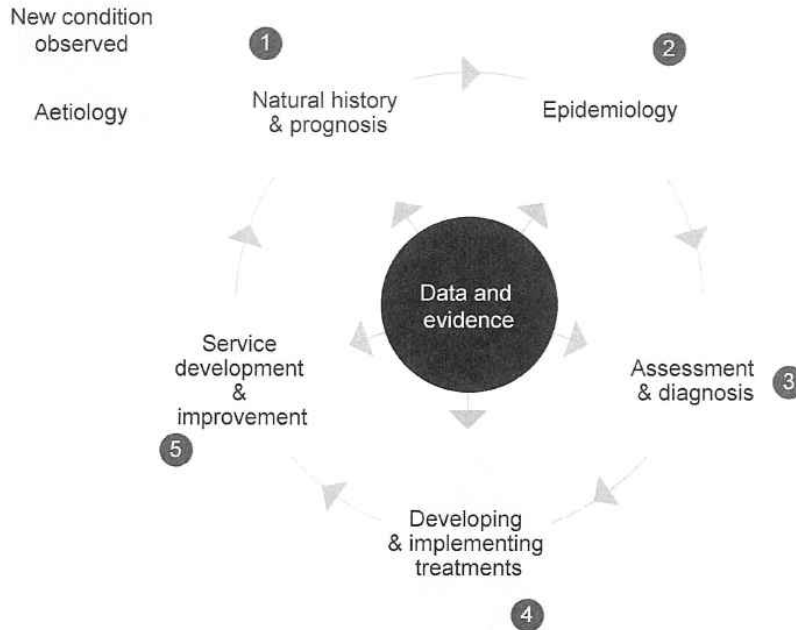
5.3. Because the specialist service has evolved rapidly and organically in response to demand, the clinical approach and overall service design has not been subjected to some of the normal quality controls that are typically applied when new or innovative treatments are introduced. This Review now affords everyone concerned the opportunity to step back and consider from first principles what this cohort of children and young people now need from NHS services, based on the evidence that exists, or additional evidence that the Review hopes to collect.

5.4. In **Appendix 4** we have described the service development process for three different conditions which may help to illustrate what would be expected to happen at each different stage of developing a clinical service. The steps may proceed in a different sequence for different conditions, but each step is important in the development of evidence based care.

5.5. We recognise that for some of those reading this report it may feel wrong to compare gender incongruence or dysphoria to clinical conditions, and indeed this approach would not be justified if individuals presenting with these conditions did not require clinician intervention. However, where a clinical intervention is given, the same ethical, professional and scientific standards have to be applied as to any other clinical condition.

Principles of evidence based service development

## Key stages of service development



**New condition observed:** This often begins with a few case reports and then clinicians begin to recognise a recurring pattern and key clinical features, and to develop fuller descriptions of the condition.

**Aetiology:** Clinicians and scientists try to work out the cause of the condition or the underlying physical or biological basis. Sometimes the answers to this are never found.

**Natural history and prognosis:** It is important to understand how a condition usually evolves over time, with or without treatment. The latter is important if treatment has limited efficacy and the condition is 'self-limiting' (that is, it resolves without treatment), because otherwise there is a risk that treatments create more difficulties than the condition itself.

5.6. The first UK service for gender-questioning children and young people was established in 1989. At that time there were very few children and young people being

seen by medical services internationally. The most common presentation in the early years of the service was of birth-registered



## Independent review of gender identity services for children and young people

boys who had demonstrated gender incongruence from an early age.<sup>51,52,53</sup>

5.7. There is extensive literature discussing the possible aetiology of gender incongruence. Based on the available evidence, many authors would suggest that it is likely that biological, cultural, social and psychological factors all contribute. The examples in **Appendix 4** show that this is not an uncommon situation; many conditions do not have a single clear causation – they are in other words ‘multifactorial’.

5.8. Regardless of aetiology, the more contentious and important question is how fixed or fluid gender incongruence is at different ages and stages of development, and whether, regardless of aetiology, can be an inherent characteristic of the individual concerned. There is a spectrum of academic, clinical and societal opinion on this. At one end are those who believe that gender identity can fluctuate over time and be highly mutable and that, because gender incongruence or gender-related distress may be a response to many psychosocial factors, identity may

sometimes change or the distress may resolve in later adolescence or early adulthood, even in those whose early incongruence or distress was quite marked. At the other end are those who believe that gender incongruence or dysphoria in childhood or adolescence is generally a clear indicator of that child or young person being transgender and question the methodology of some of the desistance studies. Previous literature has indicated that if gender incongruence continues into puberty, desistance is unlikely.<sup>54,55</sup> However, it should be noted that these older studies were not based on the current changed case-mix or the different socio-cultural climate of recent years, which may have led to different outcomes. Having an open discussion about these questions is essential if a shared understanding of how to provide appropriate assessment and treatment is to be reached.

<sup>51</sup> Zucker KJ (2017). [Epidemiology of gender dysphoria and transgender identity](#). *Sex Health* 14(5): 404–11. DOI:10.1071/SH1.

<sup>52</sup> Zucker KJ, Lawrence AA (2009). [Epidemiology of gender identity disorder: recommendations for the Standards of Care of the World Professional Association for Transgender Health](#). *Int J Transgend* 11(1): 8-18. DOI: 10.1080/15532730902799946.

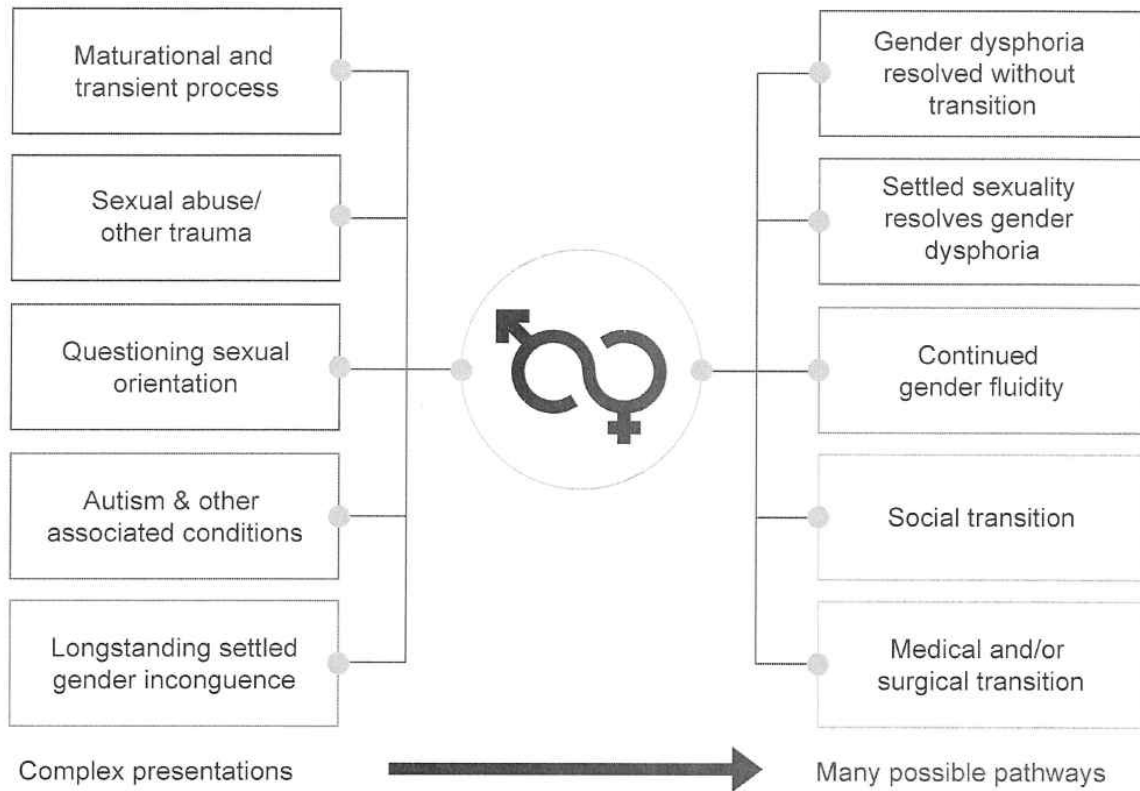
<sup>53</sup> de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). [Sex ratio in children and adolescents referred to the gender identity development service in the UK \(2009-2016\)](#). *Arch Sex Behav* 47(5): 1301–4.

<sup>54</sup> Steensma TD, Biemond R, de Boer F, Cohen-Kettenis PT (2011). [Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study](#). *Clin Child Psychol Psychiatry* 16(4): 485-97. DOI: 10.1177/135910451037803.

<sup>55</sup> Steensma TD, McGuire JK, Kreukels BPC, Beekman AJ, Cohen-Kettenis PT (2013). [Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study](#). *J Am Acad Child Adolesc Psychiatry* 52: 582-590. DOI: 10.1016/j.jaac.2013.03.016.

Principles of evidence based service development

Complex presentations and complex pathways – exemplars, not comprehensive lists



**Epidemiology:** Epidemiologists collect data to find out how common a condition is, who is most likely to be affected, what the age distribution is and so on. This allows health service planners to work out how many services are needed, where they should be established, and what staff are needed.

They also report on changes in who is most affected, which may mean that either the disease is changing, or the susceptibility of the population is changing.

## Independent review of gender identity services for children and young people

5.9. As previously indicated, the epidemiology of gender dysphoria is changing, with an increase in the numbers of birth-registered females presenting in early teens.<sup>56,57</sup> In addition, the majority of children and young people presenting to GIDS have other complex mental health issues and/or neurodiversity.<sup>58</sup> There is also an over-representation of looked after children.<sup>59</sup>

5.10. There are several implications arising from the change in epidemiology:

- Firstly, the speed of change in the numbers presenting means that services have not kept pace with demand.
- Secondly, the cohort that the original Dutch Approach was based on is different from the current more complex NHS cohort, and also from the current case-mix internationally, and therefore it is difficult to extrapolate from older literature to this current group.
- Thirdly, different subgroups may have quite different needs and outcomes, and these must be built into any service design, so that it works for all children and young people.

5.11. At present we have the least information for the largest group of patients – birth-registered females first presenting in early teen years. Since the rapid increase in this group began around 2015, they will not reach late 20s for another 5+ years, which would be the best time to assess longer-term wellbeing.

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<sup>56</sup> Steensma TD, Cohen-Kettenis PT, Zucker KJ (2018). [Evidence for a change in the sex ratio of children referred for gender dysphoria: Data from the Center of Expertise on Gender Dysphoria in Amsterdam \(1988-2016\)](#). *Journal of Sex & Marital Therapy* 44(7): 713–5. DOI: 10.1080/0092623X.2018.1437580.

<sup>57</sup> de Graaf NM, Carmichael P, Steensma TD, Zucker KJ (2018). [Evidence for a change in the sex ratio of children referred for Gender Dysphoria: Data from the Gender Identity Development Service in London \(2000–2017\)](#). *J Sex Med* 15(10): 1381–3. DOI: 10.1016/j.jsxm.2018.08.002.

<sup>58</sup> Van Der Miesen AIR, Hurley H, De Vries ALC (2016). [Gender dysphoria and autism spectrum disorder: A narrative review](#). *Int Rev Psychiatry* 28: 70-80. DOI: 10.3109/09540261.2015.1111199.

<sup>59</sup> Matthews T, Holt V, Sahin S, Taylor A, Griksaitis (2019). [Gender Dysphoria in looked-after and adopted young people in a gender identity development service](#). *Clinical Child Psychol Psychiatry* 24: 112-128. DOI: 10.1177/1359104518791657.

## Principles of evidence based service development

**Assessment and diagnosis:** Clinicians will usually take a history from (that is, of their symptoms) and examine the patient (that is, for signs and symptoms), and where appropriate undertake a series of investigations or tests, to help them reach an accurate diagnosis.

Sometimes the whole process of making a diagnosis through talking to the patient and asking them to complete formal questionnaires, examining them and/or undertaking investigations is called 'clinical assessment'.

As well as diagnosing and ruling out a particular condition, clinicians often need to consider and exclude other, sometimes more serious, conditions that present in a similar way but may need quite different treatment – this process is called 'differential diagnosis'.

5.12. For children and young people with gender-related distress, many people would dispute the notion that 'making a diagnosis' is a meaningful concept, arguing that gender identity is a personal, internal perception of oneself. However, there are several reasons to why a diagnostic framework is used:

- Firstly, the clinician will seek to determine whether the child or young person has a stable transgender identity, or whether there might be other causes for the gender-related distress.
- Secondly, the clinician will determine whether there are other issues or diagnoses that might be having an impact on the young person's mental health. The Dutch Approach suggesting that these should be addressed prior to or alongside initiation of any medical treatments.
- Thirdly, in any situation where life-altering treatments are being administered, the clinician holds the

responsibility for ensuring that they are being administered based on an appropriate decision making process. Therefore, it is usual practice for a diagnosis of gender dysphoria to be made prior to referring for any physical treatments.

5.13. When the word 'diagnosis' is used, people often associate this with the use of blood tests, X-rays, or other laboratory tests. As set out in the **Appendix 4**, the public is very familiar with diagnosis of Covid-19 and understands that there need to be tests that give a high degree of certainty about whether an individual is Covid-19 positive or not. False positive lateral flow tests are rare, but caused problems for schools, while PCR has been treated as the 'gold standard' test for accuracy.

## Independent review of gender identity services for children and young people

5.14. When it comes to gender dysphoria, there are no blood tests or other laboratory tests, so assessment and diagnosis in children and young people with gender-related distress is reliant on the judgements of experienced clinicians. Because medical, and subsequently possibly surgical treatments will follow, it may be argued that a highly sensitive and specific assessment process is required. The assessment should be able to accurately identify those children or young people for whom physical intervention is going to be the best course of action, but it is equally important that it identifies those who need an alternative pathway or treatment.

5.15. The formal criteria for diagnosing gender dysphoria (DSM-5) are listed in **Appendix 3**. However, there are two problems associated with the use of these criteria:

- Firstly, several of the criteria are based on gender stereotyping which may not be deemed relevant in current society, although the core criteria remain valid.
- Secondly, and more importantly, these criteria give a basis on which to make a diagnosis that a young person is clinically distressed by the incongruence between their birth-registered and their experienced gender, but they do not help in determining which factors may have led to this distress and how they might best be resolved.

5.16. At present, the assessment process varies considerably, dependent on the perceptions, experience and beliefs of different clinicians. There are some existing measurement tools, but it is suggested that these have substantial limitations.<sup>60</sup>

5.17. The challenges are similar to the early difficulties in diagnosing autism, as set out in **Appendix 4**. As with autism, the framework for assessment needs to become formalised so there are clearer criteria for diagnosis and treatment pathways which are shared more widely. These should incorporate not just whether the child or young person meets DSM-5 criteria for gender dysphoria, but how a broader psychosocial assessment should be conducted and evaluated, and what other factors need to be considered to gain a holistic understanding of the child or young person's experience. Professional judgement and experience will still be important, but if the frameworks and criteria for assessment and diagnosis were more consistent and reproducible, there would be a greater likelihood that two different people seeing the same child or young person would come to the same conclusion. This would also mean that any research on interventions or long-term outcomes would be more reliable because the criteria on which a diagnosis was made, and hence the patients within the sample, would have the same characteristics.

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<sup>60</sup> Bloom TM, Nguyen TP, Lami F, Pace CC, Poulakis Z, Telfer N (2021). [Measurement tools for gender identity, gender expression, and gender dysphoria in transgender and gender-diverse children and adolescents: a systematic review](#). *Lancet Child Adolescent Health*. 5: 582-588. DOI: 10.1016/s2352-4642(21)00098-5.

## Principles of evidence based service development

5.18. As outlined above, it is standard clinical practice to undertake a process called differential diagnosis. This involves summarising the main points of the clinical assessment, the most likely diagnosis, other possible diagnoses and the reasons for including or excluding them, as well as any further assessments that may be required to clarify the diagnosis and the treatment options and plan. This is important when a medical intervention is being provided on the basis of the assessment, so the process

is robust, explicit and reproducible. These considerations need to be applied to the assessment of children and young people presenting with gender-related distress. In mental health services, practitioners may also undertake a diagnostic or psychological formulation, which is a holistic summary of how the patient is feeling and why, and how to make sense of it, and a plan for moving forward with management or treatment.

**Developing and implementing new treatments:** Clinicians and scientists work on developing treatments. This involves clinical trials and, where there are new treatments, comparing them to any existing treatments. Questions include: What are the intended outcomes or benefits of treatment? What are the complications or side effects? What are the costs? To initiate a new treatment, it must be both safe and effective. Questions of affordability can sometimes become controversial.

The best type of single study is considered to be the randomised controlled trial (RCT), but sometimes this is not feasible. Even where RCTs are not available, it is usual to at least have data on the outcomes of sufficient cases or cohorts to understand the risk/benefit of the treatment under consideration. As demonstrated in Fig. 4, the highest level of evidence is when the results of several different studies are pooled, but this is only useful if the individual studies themselves are of high quality.

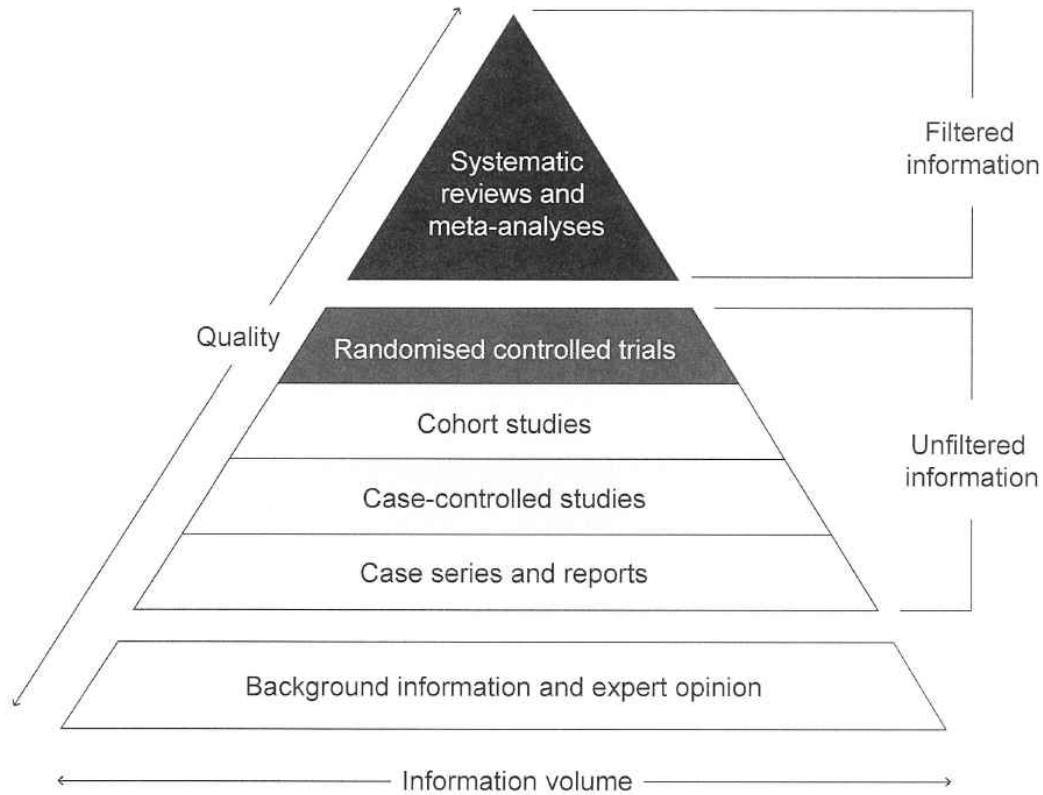
In many instances, evidence is not perfect and difficult decisions have to be made. Where treatments are innovative or life-changing, the whole multi-disciplinary team will usually meet to consider the available options, and how to advise the child or young person and family so that a shared decision can be made. Sometimes an ethics committee is involved. This is one of the most challenging areas of medicine and is underpinned by GMC guidance.<sup>61,62</sup>

<sup>61</sup> General Medical Council (2020). [Decision making and consent](#).

<sup>62</sup> National Institute for Health and Care Excellence (2021). [Shared decision making](#).

Independent review of gender identity services for children and young people

Figure 3: Pyramid of standards of evidence



Source: Levels of evidence pyramid, OpenMD. Reproduced with permission<sup>63</sup>

5.19. There are three types of intervention or treatment for children and young people with gender-related distress, which may be introduced individually or in combination with one another:

- **Social transition** – this may not be thought of as an intervention or treatment, because it is not something

that happens within health services. However, it is important to view it as an active intervention because it may have significant effects on the child or young person in terms of their psychological functioning.<sup>64,65</sup> There are different views on the benefits versus the harms of early social transition. Whatever position one

<sup>63</sup> OpenMD (2021). *New Evidence in Medical Research*.

<sup>64</sup> Sievert EDC, Schweizer K, Barkmann C, Fahrenkrug S, Becker-Hebly I (2020). *Not social transition status, but peer relations and family functioning predict psychological functioning in a German clinical sample of children with Gender Dysphoria*. *Clin Child Psychol Psychiatry* 26(1): 79–95. DOI: 10.1177/1359104520964530

<sup>65</sup> Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Colton K-M (2018). *Prepubertal social gender transitions: What we know, what we can learn—A view from a gender affirmative lens*. *Int J Transgend* 19(2): 251–68. DOI: 10.1080/15532739.2017.1414649.

## Principles of evidence based service development

takes, it is important to acknowledge that it is not a neutral act, and better information is needed about outcomes.

- **Counselling, social or psychological interventions** – these may be offered before, instead of, or alongside physical interventions. Again, they should be viewed as active interventions which require robust evaluation in their own right.
- **Physical treatments** – these comprise puberty blockers and feminising/masculinising hormones (administered by endocrinologists) and surgery. The latter is not considered as part of this Review since it is not available to those under age 18.

5.20. It should also be recognised that 'doing nothing' cannot be considered a neutral act.

5.21. The lack of available high-level evidence was reflected in the recent NICE review into the use of puberty blockers and feminising/masculinising hormones commissioned by NHS England, with the evidence being too inconclusive to form the basis of a policy position.<sup>66,67</sup> Assessing treatments for gender dysphoria has many of the same problems as assessing treatment for children with autism – it can take many years to get a full appreciation of outcomes and there may be other complicating factors in the child or young

person's life during this period. However, this of itself is not an adequate reason for the major gaps in the international literature.

5.22. It is still common that drugs are not specifically licensed for children because the trials have only taken place on adults. This does not preclude their use or make their use inherently unsafe, particularly if they are used very commonly in children. However, where their use is innovative, patients receiving the drug should ideally do so under trial conditions.

5.23. The same considerations apply to 'off-label' drugs, where the drug is used for a condition different to the one for which it was licensed. This is the case for puberty blockers, which are licensed for use in precocious puberty, but not for puberty suppression in gender dysphoria. Again, it is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria.

5.24. As outlined above, in other areas of practice where complex or potentially life-altering treatment is being considered for a child or young person, it is usual for the case to be discussed by an MDT including all professionals involved in their care. In gender services for children and young people in the Netherlands, as well as a number of other countries, there are full

<sup>66</sup> National Institute for Health and Care Excellence (2020). [Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria](#)

<sup>67</sup> National Institute for Health and Care Excellence (2020). [Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria.](#)



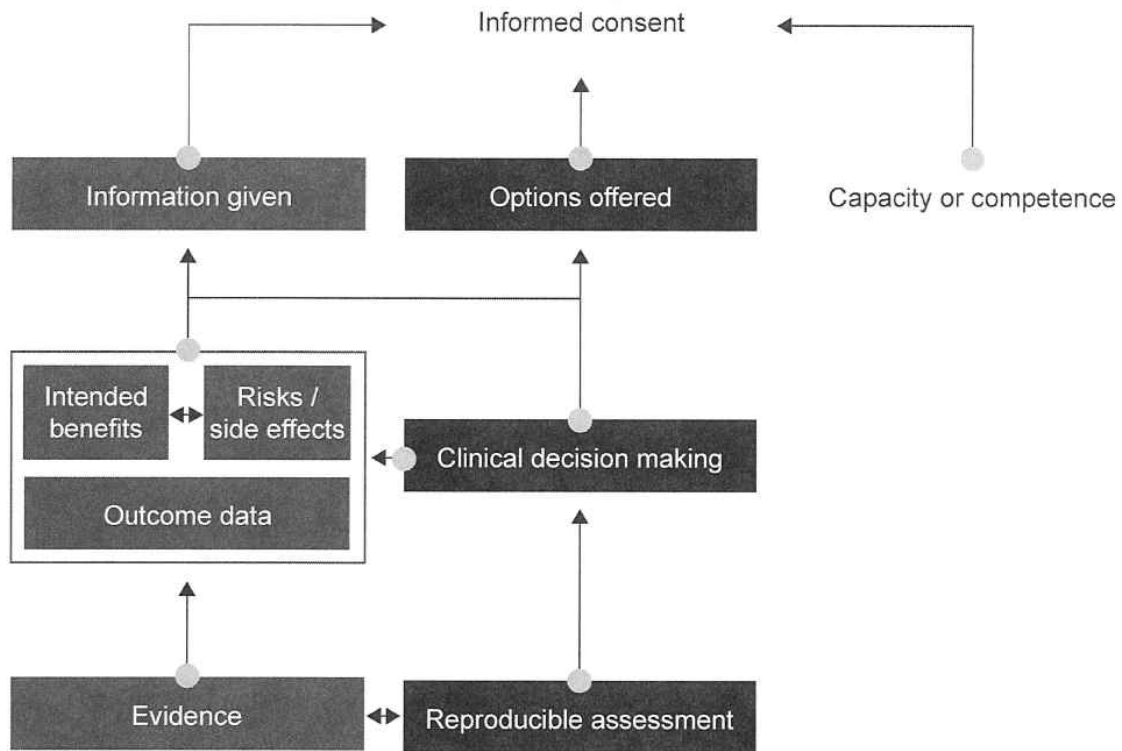
### Independent review of gender identity services for children and young people

MDT meetings, including psychiatrists and endocrinologists, to make decisions about suitability for hormone intervention and to review progress.<sup>68,69</sup>

5.25. Recent legal proceedings have examined the question of the competence and capacity of children and young people to consent to hormone treatment. However, there are some essential components that underpin informed consent; the robustness

of the options offered to the patient, the information provided to them about those options, and their competence and capacity to consider them. The courts have given consideration to competence and capacity, and it is incumbent on this Review to consider the soundness of the decision making which underpins the options offered, and the quality and accuracy of the information provided about those options.

### Elements of informed consent



<sup>68</sup> Kyriakou A, Nicolaides NC, Skordis N (2020). Current approach to the clinical care of adolescents with gender dysphoria. Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.

<sup>69</sup> Cohen-Kettenis PT, Steensma TD, de Vries ALC. Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20. 689–700. 2001. DOI: 10.1016/j.chc.2011.08.001.

## Principles of evidence based service development

**Service development and service improvement:** Central to any service improvement is the systematic and consistent collection of data on outcomes of treatment. There is a process of continuous service improvement as new presentations or variations on the original condition are recognised, diagnosis or screening improves and/or trials on new treatments or variations on existing treatments are ongoing.

There should be consistent treatment protocols or guidelines in place, in order to make sense of variations in outcomes. Where possible, these should be compared between and across multiple different centres.

As time passes, services need to be changed or extended based on patient need, and on what resources are needed to deliver the available treatments. They need to be accessible where the prevalence of the condition is highest. The relevant workforce to deliver the service needs to be recruited and trained, contingent on the type of treatments or therapy that is required.

5.26. When a pioneering treatment or specialist service starts, it is often delivered in a single centre. Thereafter, additional centres take on the work as increasing numbers of patients need to access the treatment. Current provision of NHS specialist gender identity services for children and young people has remained concentrated within a single organisation, but demand has grown dramatically.

5.27. The situation has been exacerbated because there are not many local services seeing gender-questioning children at an earlier stage in their journey, which means that GIDS is carrying an unsustainable workload of increasingly complex young people.

5.28. As a condition evolves, rigorous data collection and quantitative research is an essential prerequisite to refining understanding and treatment. Historically, The Tavistock and Portman NHS

Foundation Trust built its international reputation as the home of psychoanalysis, psychotherapy and family therapy, with a strong track record of publishing qualitative rather than quantitative research; consequently its approach to quantitative data collection about this important group of children and young people has been weak.

5.29. A further anomaly is a public perception that The Tavistock and Portman NHS Foundation Trust is the responsible organisation for leading the management of children receiving hormone treatment for their gender dysphoria. In reality, the hormone treatment is delivered by paediatric services in University College London Hospitals NHS Foundation Trust and The Leeds Teaching Hospitals NHS Trust.

### Independent review of gender identity services for children and young people

5.30. In practice, it is important that for children and young people who need physical intervention, paediatric and mental health services are seen as equal partners, with seamless joint working and shared responsibility. When there were very small numbers of patients, it was easier for this to be achieved, but cross-site working with a very large caseload has made this more difficult to achieve, despite the best intentions of the staff.

5.31. Over the last two years there have been strong efforts on the part of The Tavistock and Portman NHS Foundation Trust to make practice within GIDS more consistent, with tighter procedures for case management, consent, and safeguarding. However, although this has resulted in better documentation, variations and inconsistencies in clinical decision making remain. In responding to a changing legal framework, some processes have become more cumbersome and complex, and the team are working hard to streamline the process.

5.32. Overall, GIDS faces a daunting task as a single provider in managing risk on the waiting list, seeing new referrals, reviewing and supporting those on hormone treatment, undertaking an ongoing transformation programme, recruiting and training new staff and trying to retain existing staff. This suggests that the current model is not sustainable and that another model is needed.

## 6. Interim advice, research programme and next steps



## Independent review of gender identity services for children and young people

### Dealing with uncertainty

6.1. As outlined throughout this report, there are major gaps in the research base underpinning the clinical management of children and young people with gender incongruence and gender dysphoria, including the appropriate approaches to assessment and treatment.

6.2. As with any other area of medicine, where there are gaps in the evidence base and uncertainties about the correct clinical approach, three tasks must be undertaken:

- Clinical services must be run as safely and effectively as possible, within the constraints of current knowledge; treatment options must be weighed carefully; and treatment decisions must be made in partnership between the clinicians and the children, young people and their families and carers, based on our current understanding about outcomes.
- Consistent data must be collected by clinical services, for both audit and research purposes so that knowledge gaps can be filled, alongside an active research programme.
- Where there is not an immediate prospect of filling research gaps, professional consensus should be developed on the correct way to proceed pending clearer research evidence, supported by input from service users.

6.3. The additional problem with the current service model is that safety and access are further compromised by the pace at which referrals have grown and outstripped capacity at tertiary level, and the lack of service availability at local level.

6.4. The Review's approach to these tasks is as follows:

- Our **interim advice** focuses on the issues of capacity, safety, and standards around treatment decisions, as well as data and audit.
- Our **research streams** will provide the Review with an independent collation of published evidence relevant to epidemiology, clinical management, models of care, and outcomes, as well as delivering qualitative and quantitative research relevant to the Terms of Reference of the Review. This offers a real opportunity to contribute to the international evidence base for this service area.
- There will be an ongoing and wide-ranging **programme of engagement** to address areas on which we will not be able to obtain definitive evidence during the lifetime of the Review.

## Interim advice

6.5. The Review considers that there are some areas where there is sufficient clarity about the way forward and we are therefore offering some specific observations and interim advice. The Review will work with NHS England, providers and the broader stakeholder community to progress action in these areas.

### Service model

6.6. It has become increasingly clear that a single specialist provider model is not a safe or viable long-term option in view of concerns about lack of peer review and the ability to respond to the increasing demand.

6.7. Additionally, children and young people with gender-related distress have been inadvertently disadvantaged because local services have not felt adequately equipped to see them. It is essential that they can access the same level of psychological and social support as any other child or young person in distress, from their first encounter with the NHS and at every level within the service.

6.8. A fundamentally different service model is needed which is more in line with other paediatric provision, to provide timely and appropriate care for children and young people needing support around their gender identity. This must include support for any other clinical presentations that they may have.

6.9. The Review supports NHS England's plan to establish regional services, and

## Interim advice, research programme and next steps

welcomes the move from a single highly specialist service to regional hubs.

6.10. Expanding the number of providers will have the advantages of:

- creating networks within each area to improve early access and support;
- reducing waiting times for specialist care;
- building capacity and training opportunities within the workforce;
- developing a specialist network to ensure peer review and shared standards of care; and
- providing opportunities to establish a more formalised service improvement strategy.

### Service provision

6.11. The primary remit of NHS England's proposed model is for the regional hubs to provide support and advice to referrers and professionals. However, it includes limited provision for direct contact with children and young people and their families.

**1:** The Review advises that the regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway. The Review team will work with NHS England and stakeholders to further define the proposed model and workforce implications.

## Independent review of gender identity services for children and young people

**2:** Each regional centre will need to develop links and work collaboratively with a range of local services within their geography to ensure that appropriate clinical, psychological and social support is made available to children and young people who are in early stages of experiencing gender distress.

**3:** Clear criteria will be needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services.

**4:** Regional training programmes should be run for clinical practitioners at all levels, alongside the online training modules developed by Health Education England (HEE). In the longer-term, clearer mapping of the required workforce, and a series of competency frameworks will need to be developed in collaboration with relevant professional organisations.

through the service. Standardised data collection is required in order to audit service standards and inform understanding of the epidemiology, assessment and treatment of this group. This, alongside a national network which brings providers together, will help build knowledge and improve outcomes through shared clinical standards and systematic data collection. In the longer-term, formalisation of such a network into a learning health system<sup>70</sup> with an academic host would mean that there was systematised use of data to produce a continuing research programme with rapid translation into clinical practice and a focus on training.

**5:** The regional services should have regular co-ordinated national provider meetings and operate to shared standards and operating procedures with a view to establishing a formal learning health system.

**6:** Existing and future services should have standardised data collection in order to audit standards and inform understanding of the epidemiology, assessment and treatment of this group of children and young people.

### Data, audit and research

6.12. A lack of routine and consistent data collection means that it is not possible to accurately track the outcomes and pathways children and young people take

<sup>70</sup> Scobie S, Castle-Clarke S (2019). [Implementing learning health systems in the UK NHS: Policy actions to improve collaboration and transparency and support innovation and better use of analytics](#). *Learning Health Systems* 4(1): e10209. DOI:10.1002/lrh2.10209.

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**7:** Prospective consent of children and young people should be sought for their data to be used for continuous service development, to track outcomes, and for research purposes. Within this model, children and young people put on hormone treatment should be formally followed up into adult services, ideally as part of an agreed research protocol, to improve outcome data.

**8:** There needs to be agreement and guidance about the appropriate clinical assessment processes that should take place at primary, secondary and tertiary level.

**9:** Assessments should be respectful of the experience of the child or young person and be developmentally informed. Clinicians should remain open and explore the patient's experience and the range of support and treatment options that may best address their needs, including any specific needs of neurodiverse children and young people.

## Clinical approach

### Assessment processes

6.13. We have heard that there are inconsistencies and gaps in the assessment process. Our work to date has also demonstrated that clinical staff have different views about the purpose of assessment and where responsibility lies for different components of the process within the pathway of care. The Review team has commenced discussions with clinical staff across primary, secondary and tertiary care to develop a framework for these processes.

### Hormone treatment

6.14. The issues raised by the Multi-Professional Review Group echo several of the problems highlighted by the CQC. It is essential that principles of the General Medical Council's Good Practice in Prescribing and Managing Medicines and Devices<sup>71</sup> are closely followed, particularly given the gaps in the evidence base regarding hormone treatment. Standards for decision making regarding endocrine treatment should also be consistent with international best practice.<sup>72,73,74</sup>

<sup>71</sup> General Medical Council (2021). [Good practice in prescribing and managing medicines and devices \(76-78\)](#).

<sup>72</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al (2017). [Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline](#). J Clin Endocrinol Metab 102(11): 3869–903. DOI: 10.1210/jc.2017-01658.

<sup>73</sup> Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). [Treatment of adolescents with gender dysphoria in the Netherlands](#). Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.

<sup>74</sup> Kyriakou A, Nicolaides NC, Skordis N (2020). [Current approach to the clinical care of adolescents with gender dysphoria](#). Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.



## Independent review of gender identity services for children and young people

**10:** Any child or young person being considered for hormone treatment should have a formal diagnosis and formulation, which addresses the full range of factors affecting their physical, mental, developmental and psychosocial wellbeing. This formulation should then inform what options for support and intervention might be helpful for that child or young person.

**11:** Currently paediatric endocrinologists have sole responsibility for treatment, but where a life-changing intervention is given there should also be additional medical responsibility for the differential diagnosis leading up to the treatment decision.

6.15. Paediatric endocrinologists develop a wide range of knowledge within their paediatric training, including safeguarding, child mental health, and adolescent development. Being party to the discussions and deliberations that have led up to the decision for medical intervention supports them in carrying out their legal responsibility for consent to treatment and the prescription of hormones.

**12:** Paediatric endocrinologists should become active partners in the decision making process leading up to referral for hormone treatment by participating in the multidisciplinary team meeting where children being considered for hormone treatment are discussed.

6.16. Given the uncertainties regarding puberty blockers, it is particularly important to demonstrate that consent under this circumstance has been fully informed and to follow GMC guidance<sup>75</sup> by keeping an accurate record of the exchange of information leading to a decision in order to inform their future care and to help explain and justify the clinician's decisions and actions.

**13:** Within clinical notes, the stated purpose of puberty blockers as explained to the child or young person and parent should be made clear. There should be clear documentation of what information has been provided to each child or young person on likely outcomes and side effects of all hormone treatment, as well as uncertainties about longer-term outcomes.

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<sup>75</sup> General Medical Council (2020). [Decision making and consent](#).

**14:** In the immediate term the Multi-Professional Review Group (MPRG) established by NHS England should continue to review cases being referred by GIDS to endocrine services.

## Research programme

6.17. The Review's formal academic research programme, comprising a literature review, quantitative analysis and primary qualitative research, has been based on the identified gaps in the evidence and the feasibility of filling them within the lifetime of the Review.

6.18. Initial work has identified the existing evidence base on epidemiology, natural history, and the treatment and outcomes of children and young people with gender dysphoria/gender-related distress. It has also assessed the feasibility of linking data between local, regional or national datasets in order to assess intermediate and longer-term outcomes.

### Literature review

6.19. A literature review is being undertaken, which will interface with evidence gathering from the professional community (see qualitative research section below). Its aim is to systematically identify, collate and synthesise the existing evidence on the changing epidemiology of gender-related distress in children and young people and the appropriate social, clinical,

### Interim advice, research programme and next steps

psychological and medical management of that distress.

6.20. The literature review will capture primary studies of any design, including experimental, observational, survey and qualitative, and is looking to answer the following questions:

1. How has the population of children and young people presenting with gender dysphoria and/or gender-related distress changed over time?
2. What are the appropriate referral, assessment and treatment pathways for children and young people with gender dysphoria and/or gender-related distress?
3. What are the short-, medium- and long-term outcomes for children and young people with gender dysphoria and/or gender-related distress?
4. How do children and young people and their families negotiate distress, present this distress to services, and what are their expectations, following presentation?
5. How do children, young people and their families/carers experience referral, assessment and treatment? And how are these negotiated among children and young people, parents/carers, families and healthcare professionals?

6.21. A separate synthesis for each question will be undertaken. The systematic review has been registered on PROSPERO [ID:289659].

## Independent review of gender identity services for children and young people

### Quantitative research

6.22. The National Institute for Health and Care Excellence (NICE) recently published two evidence reviews.<sup>76,77</sup> These highlight shortcomings in the follow-up data collected about children and young people, when they are referred to a specialist gender identity service. The quantitative research will therefore focus on the collection and analysis of data to uncover patterns and quantify problems, thereby helping the Review to address some of these shortcomings.

6.23. The aim of the quantitative study is to supplement the material collected by the literature review, further examining the changing epidemiology of gender-related distress in children and young people, in addition to exploring the appropriate social, clinical, psychological and medical management. Its objectives are to:

- a) describe the clinical and demographic characteristics of this population of children and young people and their clinical management in the GIDS service; and

- b) assess the intermediate and longer-term outcomes of this population of children and young people utilising national healthcare data.

6.24. This research will provide an evidence base to facilitate informed decision making among children and young people and their families. It will also provide an evidence base for those responsible for commissioning, delivering and managing services.

### Qualitative research

6.25. The qualitative research will capture a diverse range of trajectories experienced by gender-questioning children and young people, exploring a range of different experiences and outcomes. This will include talking to children and young people and their families/carers who are currently negotiating gender-related distress, young adults who have gone through the process of resolving their distress and care professionals.

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<sup>76</sup> National Institute for Health and Care Excellence (2020). [Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria](#).

<sup>77</sup> National Institute for Health and Care Excellence (2020). [Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria](#).

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**The objectives of the qualitative research are to:****1**

Explore how children and young people understand, respond and negotiate gender-related distress within the context of their social networks, alongside the perspectives of young adults who experienced gender distress as children.

**2**

Examine the perspectives, understandings and responses of parents (or carers), including how they support their child.

**3**

Investigate how children, young people, young adults and their families experience(d) and negotiate(d) referral, assessment and possible treatment and intervention options.

**4**

Understand the role and experiences of care professionals who offer support, including identifying shared and potentially divergent views among care professionals, children and young people, and parents of what constitutes optimal care.

**Progress**

6.26. The literature review is already underway and is identifying relevant studies. Initial meetings have also taken place with voluntary organisations and other researchers working in the area to ensure there is no duplication and in recognition of research fatigue among this population.

6.27. Children and young people and young adults who have experienced gender-related distress are involved in the research programme. Their advice has been, and will continue to be, sought throughout this work, including in relation to the focus of the research and interpretation

of findings and the design and content of dissemination materials.

6.28. Three research protocols have been produced setting out how the research will be undertaken, and the research team is currently gaining the necessary ethical and governance approvals to progress the study. The systematic review is published on the PROSPERO website and will be published on the Review website in due course, along with the qualitative and quantitative research proposals once ethical and governance approvals have been received.

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6.29. The research findings will be subject to peer review through the publication process and various summaries, aimed at different audiences, will be available on the project website and distributed via support organisations. These summaries will also be made available on the Review website.

### Ongoing engagement

6.30. In recognition that not all the published evidence is likely to be of high enough quality to form the sole basis for our recommendations, a consensus development approach will be used to synthesise the published evidence and research outputs of the academic work with stakeholder submissions and expert opinion.

6.31. Over the coming months, the Review will build on its engagement to date and, alongside the academic research programme, will continue informal and structured engagement with service users, their families, support and advocacy groups and professionals to test emerging thinking, provide opportunities for challenge and further develop the evidence base.

6.32. This review is an iterative process and we will share important findings when they become available. For the latest updates, please visit our website: <https://cass.independent-review.uk/>

6.33. We thank those who have participated in the Review to date and welcome engagement with us as work progresses towards final recommendations.

# Glossary



## Independent review of gender identity services for children and young people

### Glossary

There is sometimes no consensus on the best language to use relating to this subject. The language surrounding this area has also changed rapidly and young people have developed varied ways of describing their experiences using different terms and constructs that are relevant to them.

The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately illustrate the complexity of what we are trying to describe and articulate.

The terms we have used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review. The glossary below sets out a description of some of the terms we have used in the Review.

Term	Description
Affirmative model	A model of gender healthcare that originated in the USA <sup>78,79,80,81</sup> which affirms a young person's subjective gender experience while remaining open to fluidity and changes over time. This approach is used in some key child and adolescent clinics across the Western world.
Assent	To agree to or approve of something (idea, plan or request), especially after thoughtful consideration.
Autonomy	Personal autonomy is the ability of a person to make their own decisions. In health this refers specifically to decisions about their care.

<sup>78</sup> Hidalgo MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, et al (2013). [The gender affirmative model: What we know and what we aim to learn](#) [Editorial]. *Human Dev* 56(5): 285–290. DOI:10.1159/000355235.

<sup>79</sup> Chen D, Abrams M, Clark L, Ehrensaft D, Tishelman AC, Chan YM, et al (2021). [Psychosocial characteristics of transgender youth seeking gender-affirming medical treatment: baseline findings from the trans youth care study](#). *J Adol Health* 68(6): 1104–11.

<sup>80</sup> Olson-Kennedy J, Chan YM, Rosenthal S, Hidalgo MA, Chen D, Clark L, et al (2019). [Creating the Trans Youth Research Network: A collaborative research endeavor](#). *Transgend Health* 4(12): 304–12. DOI: 10.1089/trgh.2019.0024.

<sup>81</sup> Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Colton K-M (2018). [Prepubertal social gender transitions: What we know; what we can learn—A view from a gender affirmative lens](#). *Int J Transgend* 19(2): 251–68. DOI: 10.1080/15532739.2017.1414649.

## Glossary

Term		Description
Best interests		<p>Clinicians and the courts seek to act in the best interests of children and young people. For the Mental Capacity Act (MCA) 2005, decisions for someone who cannot decide for themselves must be made in their best interests. Under the Children Act 1989, in any decision of the court about a child (under 18), the welfare of the child must be paramount. For these purposes, there is little or no material difference between the welfare and best interests, and we have used "best interests" throughout the report.</p> <p>Although there is no standard definition of "best interests of the child," the General Medical Council advises that an assessment of best interests will include what is clinically indicated as well as additional factors such as the child or young person's views, the views of parents and others close to the child or young person and cultural, religious and other beliefs and values of the child or young person.<sup>82</sup></p>
		<p>The MCA s4,<sup>83</sup> and extensive Court of Protection case law, deals with the approach to best interests under that legislation. Whether in the Court of Protection or the High Court, when the court is asked to make an assessment of a child or young person's best interests, it will consider their welfare/best interests in the widest sense. This will include not just medical factors but also social and psychological factors.</p>
Case-mix		The mix of patients within a particular group.
Child and adolescent mental health services	CAMHS	NHS children and young people's mental health services. <sup>84</sup>

<sup>82</sup> General Medical Council (2018). 0-18 years – guidance for all doctors.

<sup>83</sup> Mental Health Law Online. MCA 2005 s4.

<sup>84</sup> Young Minds. Guide to CAMHS: a guide for young people.



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Term		Description
Child and/or young person		<p>In law, everyone under 18 years of age is a child (Children Act 1989) but we recognise that it may be more appropriate to refer to those approaching the age of 18 as a young person, and that such young people may not recognise themselves as a “child”.</p> <p>In places, we have referred only to “young person”, or only to “child”, for example where treatment in question is only given towards the later stages of childhood, closer to the age of 18, or in reference to the parent/child relationship, in which they remain the parents’ child, regardless of their age.</p> <p>Otherwise, we have used the phrase “child and/or young person” throughout the report for this reason only, and do not intend there to be a material difference between them other than that.</p>
Cognitive		Relating to, or involving, the process of thinking and reasoning.
Consent		<p>Permission for a clinical intervention (such as an examination, test or treatment) to happen. For consent to be ‘informed’, information must be disclosed to the person about relevant risks, benefits and alternatives (including the option to take no action), and efforts made to ensure that the information is understood.</p> <p>In legal terms, consent is seen as needing:</p> <ol style="list-style-type: none"> <li>1 – capacity (or <i>Gillick</i> competence under 16) to make the relevant decision;</li> <li>2 – to be fully informed (ie the information provided about the available options, the material risks and benefits of each option, and of doing nothing, “material” meaning (per the Montgomery Supreme Court judgment in 2015) what a reasonable patient would want to know, and what this patient actually wants to know, NOT what a reasonable doctor would tell them); and</li> <li>3 – to be freely given (that is, without coercion).</li> </ol>
Contraindications		A condition or circumstance that suggests or indicates that a particular technique or drug should not be used in the case in question.

## Glossary

Term		Description
Court of Appeal		(England and Wales) The Court of Appeal hears appeals against both civil and criminal judgments from the Crown Courts, High Court and County Court. It is second only to the Supreme Court.
Detransition/ detransitioners		Population of individuals who experienced gender dysphoria, chose to undergo medical and/or surgical transition and then detransitioned by discontinuing medications, having surgery to reverse the effects of transition, or both. <sup>85</sup>
Diagnostic and Statistical Manual of Mental Disorders Fifth edition	DSM-5	The American diagnostic manual used to diagnose mental health disorders, and commonly used in UK practice. See <b>Appendix 3</b> .
Diagnostic formulation		The comprehensive assessment that includes a patient's history, results of psychological tests, and diagnosis of mental health difficulties.
Divisional Court		(England and Wales) When the High Court of Justice of England and Wales hears a case with at least two judges sitting, it is referred to as the Divisional Court. This is typically the case for certain judicial review cases (as well as some criminal cases).
Dutch Approach		Protocol published in 1998 by the Amsterdam child and adolescent gender identity clinic. <sup>86</sup>
Endocrine treatment		In relation to this clinical area, this term is used to describe the use of gonadotropin-releasing hormones (see below) and feminising and masculinising hormones (see below).
Endocrinologist		An endocrinologist is a medical doctor specialising in diagnosing and treating disorders relating to problems with the body's hormones.
Endocrinology		The study of hormones.

<sup>85</sup> Littman L (2021). [Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: a survey of 100 detransitioners](#). Arch Sex Abuse 50: 3353–69. DOI: 10.1007/s10508-021-02163-w

<sup>86</sup> de Vries ALC, Cohen-Kettenis PT (2012). [Clinical management of gender dysphoria in children and adolescents: The Dutch approach](#). J Homosex 59: 301-320. DOI: 10.1080/00918369.2012.653300.

## Independent review of gender identity services for children and young people

Term		Description
Epidemiology		Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems. <sup>87</sup>
Exploratory approaches		Therapeutic approaches that acknowledge the young person's subjective gender experience, whilst also engaging in an open, curious, non-directive exploration of the meaning of a range of experiences that may connect to gender and broader self-identity. <sup>88,89,90,91</sup>
Feminising and masculinising hormones (also known as cross-sex hormones, and gender affirming hormones).		Hormones given as part of a medical transition for gender dysphoric individuals, where sex hormones (testosterone for transgender males and oestrogen for transgender females).
Gender dysphoria		Diagnostic term used in DSM-5. <sup>92</sup> Gender dysphoria describes "a marked incongruence between one's experienced/expressed gender and assigned gender of at least 6 months duration" which must be manifested by a number of criterion – see <b>Appendix 3</b> for further detail.
Gender fluid		An experience of gender that is not fixed, but changes between two or more identities.
Gender identity		This term is used to describe an individual's internal sense of being male or female or something else.
Gender identity development		The developmental experience of a child or young person in seeking to understand their gender identity over time.
Gender Identity Development Service	GIDS	The service that NHS England commissions for children and adolescents with gender dysphoria.

<sup>87</sup> Centers for Disease Control and Prevention (2012). [Principles of Epidemiology in Public Health Practice: An introduction to Applied Epidemiology and Biostatistics, 3rd ed.](#)

<sup>88</sup> Di Ceglie D (2009). [Engaging young people with atypical gender identity development in therapeutic work: A developmental approach.](#) J Child Psychother 35(1): 3–12. DOI: 10.1080/00754170902764868.

<sup>89</sup> Spiliadis A (2019). [Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development.](#) Metalogos Systemic Ther J 35: 1–9.

<sup>90</sup> Churcher Clarke A, Spiliadis A (2019). ['Taking the lid off the box': The value of extended clinical assessment for adolescents presenting with gender identity difficulties.](#) Clin Child Psychol Psychiatry 24(2): 338–52. DOI:10.1177/1359104518825288.

<sup>91</sup> Bonfatto M, Crasnow E (2018). [Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service.](#) J Child Psychother 44(1): 29–46. DOI:10.1080/0075417X.2018.1443150.

<sup>92</sup> American Psychiatric Association (2013). [Diagnostic and Statistical Manual of Mental Health Disorders: DSM-5™, 5th ed.](#)

## Glossary

Term		Description
Gender incongruence		Diagnostic term used in ICD-11. <sup>93</sup> Gender incongruence is characterised by “a marked and persistent incongruence between an individual’s experienced gender and the assigned sex”. See <b>Appendix 3</b> for further detail.
Gender-questioning		A broader term that might describe children and young people who are in a process of working out how they want to present in relation to their gender.
Gender-related distress		A way of describing distress that may arise from a broad range of experiences connected to a child or young person’s gender identity development. Often used for young people whereby any formal diagnosis of gender dysphoria has not yet been made.
Gillick competence/ Fraser guidelines		A term derived from <i>Gillick v West Norfolk And Wisbech AHA</i> , 1984 that is used to decide whether a child or young person up to the age of 16 years is able to consent to their own medical treatment, without the need for parental permission or knowledge. A child or young person will be ‘Gillick competent’ for that decision if they have the necessary maturity and understanding to make the decision.
Gonadotropin-releasing hormone analogues (also known as the hormone blocker/s and puberty blocker/s)	GnRH	GnRH analogues competitively block GnRH receptors to prevent the spontaneous release of two gonadotropin hormones, Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland. This arrests the progress of puberty.
General Practitioner	GP	GPs deal with a whole range of health problems and manage the care of their patients, referring onto specialists as appropriate. <sup>94</sup>
High Court		The third highest court in the UK. It deals with all high value and high importance civil law (non-criminal) cases and appeals of decisions made in lower courts. When the High Court sits with more than one judge, as required for certain kinds of cases, it is called the Divisional Court.
International Classification of Diseases, Version 11	ICD-11	ICD-11 <sup>95</sup> is the World Health Organization (WHO) mandated health data standard used for medical diagnosis.

<sup>93</sup> World Health Organization (2022). [International Classification of Diseases Eleventh Revision](#).

<sup>94</sup> NHS. [GP services](#).

<sup>95</sup> World Health Organization (2022). [International Classification of Diseases Eleventh Revision](#).

## Independent review of gender identity services for children and young people

Term		Description
Looked after children		Children who are in the care of their Local Authority who may be living with foster parents or in a residential care setting.
Multi-disciplinary-team	MDT	The identified group of professional staff who provide a clinical service.
Neurodiverse		Displaying or characterised by autistic or other neurologically atypical patterns of thought or behaviour; not neurotypical.
Non-binary		A gender identity that does not fit into the traditional gender binary of male and female. <sup>96</sup>
Paediatrics		The branch of medicine dealing with children and their medical conditions.
Pass/passing		A person's gender being seen and read in the way they identify.
Precocious puberty		This is when a child's body begins changing into that of an adult (puberty) too soon – before age 8 in girls and before age 9 in boys.
Primary care		Primary care includes general practice, community pharmacy, dental and optometry (eye health) services. This tends to be the first point of access to healthcare.
Psychological formulation		A structured approach to understanding the factors underlying distressing states in a way that informs the changes needed and the therapeutic intervention for these changes to occur.
Psychosocial		Describes the psychological and social factors that encompass broader wellbeing.
Puberty blockers		See gonadotropin-releasing hormone above.
Secondary care		Hospital and community health care services that do not provide specialist care and are usually relatively close to the patient. For children this will include Child and Adolescent Mental Health Services (CAMHS), child development and general paediatric services.
Tanner Stage		Classification of puberty by stage of development. This ranges from Stage 1, before physical signs of puberty appear, to Stage 5 at full maturity.

<sup>96</sup> Twist J, de Graaf NM (2019). [Gender diversity and non-binary presentations in young people attending the United Kingdom's National Gender Identity Development Service](#). *Clin Child Psychol Psychiatry* 24(2): 277–90. DOI: 10.1177/1359104518804311.

## Glossary

Term		Description
Tertiary care		Tertiary care is the specialist end of the NHS. These services relate to complex or rare conditions. Services are usually delivered in a number of hospitals/centres.
Transgender	trans	This is an umbrella term that includes a range of people whose gender identity is different from the sex they were registered at birth.
Transition		These are the steps a person may take to live in the gender in which they identify. This may involve different things, such as changing elements of social presentation and role and/or medical intervention for some.

# Appendix 1

Terms of reference



## TERMS OF REFERENCE FOR REVIEW OF GENDER IDENTITY DEVELOPMENT SERVICE FOR CHILDREN AND ADOLESCENTS

### INTRODUCTION

1. NHS England is the responsible commissioner for specialised gender identity services for children and adolescents. The Gender Identity Development Service for children and adolescents is currently managed by the Tavistock and Portman NHS Foundation Trust.
2. In recent years there has been a significant increase in the number of referrals to the Gender Identity Development Service, and this has occurred at a time when the service has moved from a psychosocial and psychotherapeutic model to one that also prescribes medical interventions by way of hormone drugs. This has contributed to growing interest in how the NHS should most appropriately assess, diagnose and care for children and young people who present with gender incongruence and gender identity issues.
3. It is in this context that NHS England and NHS Improvement's Quality and Innovation Committee has asked Dr Hilary Cass to chair an independent review, and to make recommendations on how to improve services for children and young people experiencing issues with their gender identity or gender incongruence, and ensure that the best model/s for safe and effective services are commissioned.

### REVIEW SCOPE

**The independent review, led by Dr Cass, will be wide ranging in scope and will conduct extensive engagement with all interested stakeholders. The review is expected to set out findings and make recommendations in relation to:**

- i. Pathways of care into local services, including clinical management approaches for individuals with less complex expressions of gender incongruence who do not need specialist gender identity services;
- ii. Pathways of care into specialist gender identity services, including referral criteria into a specialist gender identity service; and referral criteria into other appropriate specialist services;
- iii. Clinical models and clinical management approaches at each point of the specialised pathway of care from assessment to discharge, including a description of objectives, expected benefits and expected outcomes for each clinical intervention in the pathway;
- iv. Best clinical approach for individuals with other complex presentations.
- v. The use of gonadotropin-releasing hormone analogues and gender affirming drugs, supported by a review of the available evidence by the National Institute for Health and Care Excellence; any treatment recommendations will include a description of treatment objectives, expected benefits and expected outcomes, and potential risks, harms and effects to the individual;
- vi. Ongoing clinical audit, long term follow-up, data reporting and future research priorities;
- vii. Current and future workforce requirements;
- viii. 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; and,



## Independent review of gender identity services for children and young people

### **TERMS OF REFERENCE FOR REVIEW OF GENDER IDENTITY DEVELOPMENT SERVICE FOR CHILDREN AND ADOLESCENTS**

- ix. Any other relevant matters that arise during the course of the review
  
- 4. In addition, and with support from the Royal College of Paediatrics and Child Health and other relevant professional associations, the Chair will review current clinical practice concerning individuals referred to the specialist endocrine service. It is expected that findings and any recommendations on this aspect of the review will be reported early in 2021 with the review's wider findings and recommendations delivered later in 2021.
  
- 5. The review will not immediately consider issues around informed consent as these are the subject of an ongoing judicial review. However, any implications that might arise from the legal ruling could be considered by the review if appropriate or necessary.

# Appendix 2

Letter to NHS England from  
Dr Cass – May 2021



## Independent review of gender identity services for children and young people



Dr Hilary Cass  
Chair  
Review of GIDS for Children and Young People

John Stewart  
National Director  
Specialised Commissioning  
NHS England and NHS Improvement

Sent by email

10 May 2021

Dear John

### **INDEPENDENT REVIEW INTO GENDER IDENTITY SERVICES FOR CHILDREN AND YOUNG PEOPLE**

I am writing to update you on my current approach to the work of the independent review into gender identity services for children and young people. However, the most pressing issue is how we augment the immediate support for children and young people currently needing assessment and treatment, some of whom have already been waiting for an extended period for an appointment. I will therefore also make some suggestions about interim arrangements and ways in which the review team could help to support and strengthen these.

#### **Commissioned research programme**

As you know, a key principle of the review is that it should be evidence-based, and that final conclusions will be developed through a consensus development process contingent on the synthesised evidence.

I am pleased to see that the National Institute for Health and Care Excellence (NICE) evidence reviews of gonadotrophin releasing hormone analogues and gender affirming hormones for children and adolescents with gender dysphoria have now been published. Although this is a helpful starting point, despite following a standard and robust process the NICE review findings are not conclusive enough to inform policy decisions. As part of my review, I am therefore exploring other methodologies to give increased confidence and clarity about the optimal treatment approaches.

My team is commissioning a broader literature review of the existing evidence base on the epidemiology, management and outcomes of children with gender dysphoria. We are also commissioning qualitative and quantitative research, including considering other approaches which might be employed to understand the intermediate and longer-term outcomes of children with gender dysphoria. We intend to include a review of international models and data in this programme of work.

## Appendix 2

**Addressing the immediate situation**

Recognising that the outcome of the review is going to take some time, I have been reflecting on the recent court rulings on puberty blockers and consent and the Care Quality Commission (CQC) report on the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust. These significant developments have changed the context in which the review is taking place, and further added to the service pressures.

I note the proposal to establish an independent multidisciplinary professional review group to confirm decision-making has followed a robust process, which seems an appropriate interim measure pending further clarification of the legal situation.

I know that everyone concerned with the delivery of services – both commissioners and providers – are worried about the increasing number of children on the waiting list for assessment by the GIDS service and the resulting distress for the children and young people and their families. The difficulty in managing risk for those on the waiting list is exacerbated by the staff vacancies at GIDS, the increasing volume of new referrals, and the fact that the support and engagement from local services is highly variable and, in some cases, very limited.

Having a single provider may have been a logical position when the GIDS service was first set up, given that this is a highly specialised service that was seeing a relatively small number of cases each year. As the epidemiology has changed and there has been an exponential increase in numbers of children with gender incongruence or dysphoria, concentration of expertise within a single service has become unsustainable. At the same time, local services have not developed the skills and competencies to provide support for children on the waiting list and those with lesser degrees of gender incongruence who may not wish to pursue specialist medical intervention, and / or to provide help for children with additional complex needs.

I know from discussions we have had that your team is working hard to find some practical alternative arrangements, and that you have been in discussion with relevant professional bodies to come up with creative interim solutions while awaiting the outcome of my review.

The review team has also been in discussion with CQC, with the Tavistock and Portman NHS Foundation Trust and with colleagues within and external to NHS England and NHS Improvement to consider which aspects of this situation we can help with in the short to medium term, whilst keeping our focus on the longer-term questions of the appropriate clinical management and whole care pathway for these children and young people. In the past months I have also met with many groups and individuals with expertise and lived experience relevant to the review, including charities and support groups, Royal Colleges and healthcare professionals.

**Recommendations to NHS England and NHS Improvement**

I would encourage you to consider the following when developing an interim pathway for children and young people experiencing gender dysphoria:

- **Access and referral:** Children and young people need ready access to services. However, it is unusual for a specialist service to take direct referrals. The risk of having a national service as the first point of access is that assessment and treatment of children and young people who have the greatest need for specialist care is delayed because of the lack of differentiation of those on the waiting list. In addition, many children and

## Independent review of gender identity services for children and young people

young people have complex needs, but once they are identified as having gender dysphoria, other important healthcare issues which would normally be managed by local services can sometimes be overlooked.

- **Assessment and management:** All children and young people who are referred to specialist services should have a competent local multi-disciplinary assessment and should remain under active holistic local management until they are seen at a specialist centre.

I recognise that developing capacity and capability outside of the existing GIDS service to provide such initial assessment and support will be difficult to achieve at speed and will be incremental. This means that there will likely be a range of different models and options around the country, dependent on local resources, with some of the work being delivered through existing secondary service teams, and some being delivered at regional level. The support of wider services is vital.

- **Data:** The lack of systematic data collection is a significant issue. Therefore, when employing interim measures, I would suggest that particular attention is paid to the gathering of good quality data, which can then be used to inform the evidence base and future model of provision.

### Actions for the review team

I would like to suggest how the review team might help with the challenging problem of growing an infrastructure outside of GIDS. From my conversations to date, I believe there are three barriers to the involvement of local services:

- **Capacity** – the staff most appropriately trained to be involved in initial assessment are those who are already most stretched within Child and Adolescent Mental Health Services (CAMHS) and paediatric services, and this situation has been significantly worsened through the impact of the Covid-19 pandemic on children's mental health. However, I know that there is substantial investment in CAMHS services, so close engagement with the relevant national policy teams at NHS England and NHS Improvement and at Health Education England (HEE) will be crucial.
- **Capability and confidence** – clinical teams outside of GIDS do not feel confident in initial assessment and support of children and young people with gender incongruence and dysphoria, in large part because they have not had the necessary training and experience, but also because of the societal polarisation and tensions surrounding the management of this group.
- **Lack of an explicit assessment framework** – currently expertise in assessment of children and young people presenting to GIDS is held in a small body of clinicians and their assessment processes have not been made explicit. The CQC report drew attention to the lack of structured assessment in the GIDS notes, and this is something that the Tavistock and Portman NHS Foundation Trust is already working to address internally. However, it is equally important to develop an initial assessment approach that can be used by first contact professionals, not just those working in the specialist service.

In the first instance, it is important that we test these assumptions with a range of clinical staff and ascertain whether there are other barriers that are preventing local engagement in this work. Then we would plan to prioritise a series of workshops, in collaboration with relevant professional groups, service users and close engagement with HEE. The purpose of these workshops would be to address identified barriers and develop:

Appendix 2

- A framework for initial assessment of children and young people presenting with gender dysphoria.
- An approach to training for professionals at local and regional level.
- Some preliminary workforce recommendations, which will be particularly important in meeting the timelines of the three-year Comprehensive Spending Review.

These workshops will serve multiple purposes – firstly to support NHS England and NHS Improvement in the establishment of local and / or regional teams; secondly as an essential component of the work needed to inform the questions that the review is tackling; and thirdly to form the professional networks that will be needed to underpin future service and research networks.

**Timelines**

As you will recognise, setting up a complex national review is difficult and time consuming at the best of times. It requires a team to support the work and mechanisms for stakeholders to engage safely and with confidence. Starting a review in the midst of a pandemic is even more challenging.

I have committed to a review approach which is participative, consensus-based, evidence-based, transparent, and informed by lived and professional experience. This requires extensive engagement. Pending the appointment of our research team, the review has now launched its website and I have been proactively engaging with the stakeholder community.

It is critical that we get the approach right, particularly the engagement, the evidence review and the quantitative research given the gaps in the evidence highlighted through the NICE review, and this will take time.

My intention is that an interim report will be delivered in the summer, with a report next year setting out my final recommendations.

Yours sincerely



**Dr Hilary Cass**  
**Chair, Independent Review into Gender Identity Services for Children and Young People**

Cc: Care Quality Commission  
Health Education England  
Tavistock and Portman NHS Foundation Trust

# Appendix 3

Diagnostic criteria for  
gender dysphoria



## DSM-5 diagnostic criteria for gender dysphoria

### Gender Dysphoria in Children

**A.** A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.

7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

**B.** The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as congenital adrenal hyperplasia or androgen insensitivity syndrome).

### Gender Dysphoria in Adolescents and Adults

**A.** A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).



### Independent review of gender identity services for children and young people

3. A strong desire for the primary and/ or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

**B.** The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as congenital adrenal hyperplasia or androgen insensitivity syndrome).

Specify if:

Post transition: the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-

sex medical procedure or treatment regimen – namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

### ICD-11: HA60 Gender incongruence of adolescence or adulthood

Gender Incongruence of Adolescence and Adulthood is characterised by 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, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders.

## **ICD-11: HA61 Gender incongruence of childhood**

Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders.

# Appendix 4

The standard approach to  
clinical service development



## The standard approach to clinical service development

The three examples below illustrate the usual process of developing a clinical service: Covid-19 is included because this is a new condition that everyone is familiar with; childhood epilepsy because it is a complex condition with physical manifestations; and autism because it is a condition with neuro-behavioural manifestations.

By comparing these examples of clinical service development, it is possible to demonstrate some of the challenges in developing services for children and young people with gender incongruence or dysphoria, and to identify where there are gaps and questions that need to be addressed for this population, in order to ensure any future service model delivers the highest possible standards of care.

The stages below may proceed in a different sequence for different conditions, but each stage is important in the development of evidence based care.

<b>Stage</b>	<b>Covid-19</b>	<b>Childhood Epilepsy</b>	<b>Autism</b>
<p><b>New condition is observed</b></p> <p>This often begins with a few case reports and then clinicians begin to recognise a recurring pattern and key clinical features, and to develop fuller descriptions of the condition.</p>	<p>Covid-19 is an example of a recent new condition that we all recognise, and this started with a few unusual cases of respiratory illness being described in Wuhan.</p>	<p>Childhood epilepsy has been recognised for centuries, but over the last century there has been growing understanding of the many different subtypes.</p>	<p>Individuals with autism have probably also existed for an indefinite period, but it wasn't until 1943 and 1944 that Leo Kanner and Hans Asperger wrote the first scientific accounts about the condition.</p>

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Stage	Covid-19	Childhood Epilepsy	Autism
<p><b>Aetiology</b></p> <p>Clinicians and scientists try to work out the cause of the condition or the underlying physical or biological basis. Sometimes the answers to this are never found.</p>	<p>The cause of Covid-19 was identified at a very early stage as being due to a novel coronavirus, although it remains unclear where and how this originated.</p>	<p>It is now known that there are numerous different types of epilepsy, with many different causes – for example, epilepsy can be caused by specific epilepsy genes, by birth trauma, by metabolic conditions, by brain tumours and many other mechanisms. Epilepsies due to a change in the brain structure which occur after birth are called ‘symptomatic’ – they are a symptom of something else. Epilepsies for which there is no identified cause are called ‘idiopathic.’</p>	<p>The first theory about the aetiology of autism was that it was caused by so called ‘refrigerator parents’. This was inaccurate and damaging. It has subsequently been shown that there are many complex genetic and physical or chemical brain changes underpinning this condition.</p>
<p><b>Natural history and prognosis</b></p> <p>It is important to understand how a condition usually evolves over time, with or without treatment. The latter is important if treatment has limited efficacy and the condition is ‘self-limiting’ (that is, it resolves without treatment), because otherwise there is a risk that treatments create more difficulties than the condition itself.</p>	<p>Covid-19 is an example of a condition where there are quite polarised views about management based on its prognosis and natural history. A relatively small proportion of people are seriously affected and need treatment, and for the majority the natural history is that it will get better by itself. This has led some people to question the need for lockdowns, vaccinations and other measures which they see as impacting personal freedoms.</p>	<p>In epilepsy the natural history is very important. Some epilepsies get better through puberty and into adulthood, and some can get worse with hormonal changes. This is important to know when monitoring and reviewing drug treatment.</p>	

Appendix 4

<b>Stage</b>	<b>Covid-19</b>	<b>Childhood Epilepsy</b>	<b>Autism</b>
<p><b>Epidemiology</b> Epidemiologists collect data to find out how common a condition is, who is most likely to be affected, what the age distribution is and so on. This allows health service planners to work out how many services are needed, where they should be established, and what staff are needed. They also report on changes in who is most affected, which may mean that either the disease is changing, or the susceptibility of the population is changing.</p>	<p>Epidemiologists have been crucial in supporting the management of Covid-19 because they have extracted and analysed the data on which patients are at greater risk from the virus. This has been fundamental to planning a vaccination strategy and other protective measures.</p>		<p>The epidemiology of autism has changed considerably, with a dramatic increase in the numbers of children diagnosed over the last 20 years. This has had major implications for service provision. There is ongoing debate about the cause of the increase – whether it is because of greater awareness and better diagnosis, or because there are more children with autism. Current opinion favours the first option.</p>

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Stage	Covid-19	Childhood Epilepsy	Autism
<p><b>Assessment and diagnosis</b></p> <p>Clinicians will usually take a history from (that is, of their symptoms) and examine the patient (that is, for signs and symptoms), and where appropriate undertake a series of investigations or tests, to help them reach an accurate diagnosis.</p> <p>Sometimes the whole process of making a diagnosis through talking to the patient and asking them to complete formal questionnaires, examining them and/or undertaking investigations is called 'clinical assessment'.</p> <p>As well as diagnosing and ruling out a particular condition, clinicians often need to consider and exclude other, sometimes more serious, conditions that present in a similar way but may need quite different treatment – this process is called 'differential diagnosis'.</p>	<p>PCR has been used as a 'gold standard' test for diagnosis of Covid-19 since the beginning of the pandemic. Lateral flow testing was developed to provide a quicker and cheaper option, but it demonstrates the limitations of testing: it is 99.68% specific, which is a very high specificity. This means there are only a tiny number of false positives. It has lower sensitivity at 76.8%, which means it will miss about a quarter of all cases, so giving many more false negatives. BUT it will only miss 5% of cases with high viral load.</p>	<p>Epilepsy can only be definitively diagnosed by either getting a really clear description of the events from a parent or carer, or seeing the child or young person having a seizure on a video. An EEG (brain wave tracing) and other tests can provide information about the type of epilepsy, but unless a seizure happens during the recording, it does not demonstrate that they actually have seizures – only that they may be susceptible to seizures.</p>	<p>In autism there are no blood tests or X-rays to make the diagnosis. It is a 'clinical' diagnosis, which means it is dependent on taking a standardised history from the parents, and performing standardised assessments on the child or young person to distinguish between autism and other possible diagnoses (for example, language disorder, social anxiety). In the early days, these standardised measures did not exist: the diagnosis was very dependent on experts who were used to diagnosing autism by making a clinical judgement about each child. This made it difficult to teach new people how to do this without a long apprenticeship, and also made it difficult to know whether two different experts would come to the same conclusion about the same child or young person. Standardisation of the questions and process made diagnosis more reliable and consistent, as did an improved evidence base.</p> <p>At the same time, because children with autism all present differently, the assessment had to be flexible enough to accommodate, for example, non-verbal children with severe learning disability, as well as high-functioning children with strong verbal skills.</p>

Appendix 4

<b>Stage</b>	<b>Covid-19</b>	<b>Childhood Epilepsy</b>	<b>Autism</b>
<p><b>Differential diagnosis</b>                      As well as making a positive diagnosis, clinicians often need to exclude other, sometimes more serious conditions that present in a similar way, but may need quite different treatment.</p>		<p>There are conditions that can be mistaken for epilepsy, so it is important to accurately diagnose whether seizures are happening and exclude other conditions (differential diagnoses) by carrying out relevant tests.</p>	<p>There are many conditions that may be mistaken for autism – for example, children who have language disorders, learning disability, severe social anxiety for other reasons, or ADHD can all appear to have autism. It is important to exclude these other conditions as well as making a positive diagnosis of autism. Sometimes these conditions can exist alongside autism, and management must then be planned to address all the child's difficulties.</p>



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Stage	Covid-19	Childhood Epilepsy	Autism
<p><b>Developing and implementing new treatments</b></p> <p>Clinicians and scientists work on developing treatments. This involves clinical trials and, where there are new treatments, comparing them to any existing treatments. Questions include: What are the intended outcomes or benefits of treatment? What are the complications or side effects? What are the costs? To initiate a new treatment, it must be both safe and effective. Questions of affordability can sometimes become controversial.</p> <p>The best type of single study is considered to be the randomised controlled trial (RCT), but sometimes this is not feasible. Even where RCTs are not available, it is usual to at least have data on the outcomes of sufficient cases or cohorts to understand the risk/benefit of the treatment under consideration. As demonstrated in Fig. 3, the highest level of evidence is when the results of several different studies are pooled, but this is only useful if the individual studies themselves are of high quality.</p>	<p>Developing treatments for Covid-19 has been possible at speed because of the large numbers of patients, and the fact that outcomes can be observed on each patient within a matter of days to weeks. Because Covid-19 was a new condition, clinicians also started in a position of 'equipoise' which means that they did not have reason to believe any one treatment might be more effective than another; this made it ethical to have one group having a treatment and another group having a different treatment or a placebo.</p> <p>There are also really clear outcome measures, such as whether or not patients survive or need hospitalisation. This has facilitated a high level of evidence through randomised controlled trials (see diagram below).</p>	<p>Similar considerations apply to the treatment of epilepsy in that there are 'hard' outcome measures (for example, frequency of seizures), but it can take several months to determine whether a new drug is better than an existing one for any one patient, and some side effects may be longer-term, so trials can take several years. In addition, children with epilepsy may have very different conditions causing their seizures which can also make trials more challenging.</p> <p>In the most severe cases of epilepsy, surgery may be the best option for controlling seizures. This can be very radical in certain cases and have lifelong implications for how they function. These options, which have a cost as well as a benefit to the child, will only be offered after a multi-disciplinary team meeting, including the paediatricians, therapists, neuropsychologists, radiologists, neurophysiologists and neurosurgeons have all discussed whether the benefits will outweigh the costs.</p>	<p>Evaluating interventions for autism is the most difficult of these three examples. This is because it can take many years to see developmental outcomes; it is hard to get uniform groups of children; outcomes are extremely sensitive to the social (and historical) response of others; and many other things happen in children's lives (such as changes of school, other medications, new diets). Isolating the effect of the target treatment is therefore challenging.</p>

Appendix 4

<b>Stage</b>	<b>Covid-19</b>	<b>Childhood Epilepsy</b>	<b>Autism</b>
<p>In many instances, evidence is not perfect and difficult decisions have to be made. Where treatments are innovative or life-changing, the whole multi-disciplinary team will usually meet to consider the available options, and how to advise the child or young person and family so that a shared decision can be made. Sometimes an ethics committee is involved. This is one of the most challenging areas of medicine and is underpinned by GMC guidance.<sup>97, 98</sup></p>	<p>The UK has been internationally recognised for its Recovery Trial, led by Oxford University. This has recruited over 46,000 participants, and resulted in several treatments being approved. A key factor in this success was the willingness of patients to participate in these studies – with over 46,000 being recruited and consented.</p>		

<sup>97</sup> General Medical Council (2020). Decision making and consent.

<sup>98</sup> National Institute for Health and Care Excellence (2021). Shared decision making.

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<b>Stage</b>	<b>Covid-19</b>	<b>Childhood Epilepsy</b>	<b>Autism</b>
<p><b>Service development and service improvement</b></p> <p>Central to any service improvement is the systematic and consistent collection of data on outcomes of treatment. There is a process of continuous service improvement as new presentations or variations on the original condition are recognised, diagnosis or screening improves and/or trials on new treatments or variations on existing treatments are ongoing.</p> <p>There should be consistent treatment protocols or guidelines in place, in order to make sense of variations in outcomes. Where possible, these should be compared between and across multiple different centres.</p> <p>As time passes, services need to be changed or extended based on patient need, and on what resources are needed to deliver the available treatments. They need to be accessible where the prevalence of the condition is highest. The relevant workforce to deliver the service needs to be recruited and trained, contingent on the type of treatments or therapy that is required.</p>	<p>Service development to manage Covid-19 has been on a scale unlike any normal new service development ever experienced. It has also demonstrated how other non-Covid services have had to evolve alongside, including the need for isolation, and/or PCR testing prior to routine clinical appointments, use of remote consultation and an array of other changes across the NHS. Continuous audit and monitoring of outcomes has resulted in major improvements in survival – for example, changing ventilation approach to include ‘proning’ (putting patients on their front while on the ventilator) and delaying fully intubated ventilation by giving mask ventilation for as long as possible.</p>	<p>Paediatric epilepsy is a good example of how a national approach can be taken to service improvement through the Epilepsy 12 programme.<sup>99</sup> This is a nationally co-ordinated audit which collects a standardised dataset, incorporating NICE standards, and is used to drive up standards of care for children and young people with epilepsy.</p>	<p>Improvement in autism services has been driven by the changing epidemiology, NICE standards, extensive training of the workforce and attempts to improve public understanding. Where previously diagnosis was undertaken in a few specialist centres, the rising waiting times and NICE standards on access, assessment and appropriate multi-professional provision have led to almost every community child development service having an autism assessment clinic or team. Services are able to self-assess against national standards to inform local improvement strategies.</p>

<sup>99</sup> Royal College of Paediatrics and Child Health (2021). [Epilepsy 12 – national organisational audit and clinical audit.](#)

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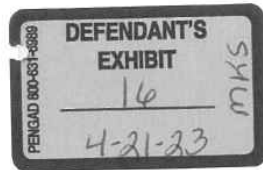
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Journal of Clinical Epidemiology 66 (2013) 151–157

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## GRADE guidelines: 11. Making an overall rating of confidence in effect estimates for a single outcome and for all outcomes

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Accepted 15 January 2012; Published online 27 April 2012

### Abstract

GRADE requires guideline developers to make an overall rating of confidence in estimates of effect (quality of evidence—high, moderate, low, or very low) for each important or critical outcome. GRADE suggests, for each outcome, the initial separate consideration of five domains of reasons for rating down the confidence in effect estimates, thereby allowing systematic review authors and guideline developers to arrive at an outcome-specific rating of confidence. Although this rating system represents discrete steps on an ordinal scale, it is helpful to view confidence in estimates as a continuum, and the final rating of confidence may differ from that suggested by separate consideration of each domain.

An overall rating of confidence in estimates of effect is only relevant in settings when recommendations are being made. In general, it is based on the critical outcome that provides the lowest confidence. © 2013 Elsevier Inc. All rights reserved.

**Keywords:** GRADE; Quality of evidence; Confidence in estimates; Guideline methodology; Systematic review methodology; Values and preferences

The GRADE system has been developed by the GRADE Working Group. The named authors drafted and revised this article. A complete list of contributors to this series can be found on the JCE Web site.

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http://dx.doi.org/10.1016/j.jclinepi.2012.01.006

### 1. Introduction

In prior studies in this series devoted to exploring GRADE's approach to rating confidence in estimates of effect (quality of evidence) and grading strength of recommendations (guidance for practice) we have dealt with issues of framing the question [1]; introduced GRADE's

**What is new?****Key points**

GRADE requires a rating of confidence in effect estimates (quality of evidence) for each outcome.

Rating of confidence of evidence requires a gestalt that simultaneously considers all eight domains (risk of bias, precision, consistency, and so forth)

Guideline developers using GRADE will subsequently make an overall rating of confidence in effect estimates across all outcomes based on those outcomes they consider critical to their recommendation.

Optimal application of GRADE requires making the reasons for key judgments transparent.

conceptual approach to rating the confidence in a body of evidence [2]; and presented five reasons for rating down the confidence in effect estimates (risk of bias [3], imprecision [4], inconsistency [5], indirectness [6], and publication bias [7]) and three reasons for rating up the confidence in effect estimates [8] (a large magnitude of effect, a dose-response gradient, and a situation in which plausible biases, if present, would serve to increase our confidence in the effect estimate), as well as dealing with issues specific to resource use. This 11th article in the series will focus on (1) summarizing the confidence in effect estimates across a single outcome for each important or critical outcome and (2) determining the confidence in effect estimates across all critical outcomes.

## 2. Summarizing the confidence in effect estimates for individual outcomes

GRADE's approach to rating down (or not) with respect to each of five criteria and to rating up (or not) with respect to three others is sometimes straightforward and enhances the transparency of the system. Most commonly, authors will be comfortable with the rating of confidence in estimate of effect that results from considering each criterion separately. Not infrequently, however, if ratings are applied in a blanket or rote fashion without considering context and the relation of one criterion to another, the confidence rating could be problematic. Specifically, ratings of individual domains could result in an overall rating of confidence in effect estimates on a particular outcome that does not correspond well to an integrated assessment or the gestalt of confidence in estimates of effect. In such instances, an adjustment in the final rating based on that gestalt is required.

Consider a systematic review of randomized trials of flavonoids for the treatment of hemorrhoids that produced a pooled estimate of a relative risk of persisting symptoms

(lack of improvement) of 0.42 (95% confidence interval [CI] 0.28–0.61) [9]. Table 1 presents an evidence profile summarizing the evidence regarding two outcomes: persisting symptoms and adverse effects of the intervention. The profile presents the number of studies and patients, considerations related to the five possible reasons for rating down confidence in effect estimates (summarized in the table with expansions in the associated footnotes), and the best estimates and CIs around relative and absolute effects.

Consider now the possible reasons for rating down confidence in effect estimates. In most studies, the published articles left uncertainty whether allocation was concealed (though blinding in most suggests the likelihood of concealment), and all studies used unvalidated measures of symptoms. Given these limitations, one could reasonably argue either for or against rating down for risk of bias.

Fig. 1 presents a forest plot depicting the results of the review. The point estimates from individual studies are quite variable, and some of the CIs overlap little. The test for heterogeneity is highly significant and the  $I^2$  large. All these observations suggest rating down for inconsistency among studies. On the other hand, all point estimates suggest benefit, and one might argue that it is inappropriate to rate down for inconsistency when the only uncertainty appears to be whether the magnitude of the treatment effect is moderate or very large. For instance, if undesirable consequences of an intervention are minimal, even a modest treatment effect may warrant a strong recommendation in favor of that treatment. If, in such a circumstance, the basis of doubt is whether the true effect is modest or large, rating down for inconsistency may well be inappropriate.

All available randomized trials were of small or moderate size (from 40 to 234 patients), and all were industry funded. This is a situation that raises the possibility of publication bias. In addition, one could interpret the funnel plot as suggesting the possibility of publication bias, with three small, very positive studies and no corresponding studies with small or negligible effects (Fig. 2). This line of reasoning would suggest rating down confidence in the estimate for publication bias. On the other hand, the number of studies is insufficient to meet rigorous criteria for creating a funnel plot [10] and one could argue that the case for publication bias is speculative in which case one would not rate down.

Thus, for three of the five domains in which one might rate down confidence in effect estimates (risk of bias, inconsistency, and publication bias) one could reasonably make the case for rating down or for not doing so. The situation is further complicated by the magnitude of effect: the relative risk of persisting symptoms (0.41) is slightly less than 0.5, raising the possibility of rating confidence up for the magnitude of effect. A generous reviewer, who in each case is inclined to view the results favorably, would interpret the body of evidence from these flavonoid studies as high quality (i.e., would not rate down the quality). A less generous reviewer, who decides to rate down the

**Table 1.** GRADE Evidence Profile: flavonoids for patients with symptomatic hemorrhoids (question: flavonoids for patients with symptomatic hemorrhoids?; setting: outpatients)

Quality assessment	Summary of findings										
	No of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	No. of patients	Relative risk (95% CI)	Control rate	Risk difference (95% CI)	Quality
<b>Persisting symptoms/lack of improvement</b>											
Nine (RCT)	Concealment not clear in most studies Outcome measures not validated <sup>a</sup>	No serious inconsistency $I^2$ 70.4 <sup>b</sup>	No serious indirectness	No serious imprecision	All studies industry funded <sup>c</sup>	All studies industry funded <sup>c</sup>	218/384	RR 0.41 (0.27–0.62)	551/1,000	226 fewer per 1,000 (149–342)	Moderate quality because of publication bias <sup>d</sup>
<b>Adverse effects</b>											
13 (RCT)	Lack of concealment and unvalidated questionnaires <sup>a</sup>	No serious inconsistency	No serious indirectness	CI includes reduction to doubling of adverse effects <sup>e</sup>	All studies industry funded <sup>c</sup>	All studies industry funded <sup>c</sup>	20/681	RR 1.22 (0.69–2.15)	60/1,000	Not significant	Low quality because of publication bias and imprecision

**Abbreviations:** CI, confidence interval; RR, relative risk; RCT, randomized controlled trial.  
 The table highlights the three questionable criteria in which reviewers might either rate down or not—study limitations, inconsistency, and publication bias—and how the final judgments could vary if one came to positive judgments on all three (e.g., for persisting symptoms, high-quality evidence) or negative judgments on all three (e.g., for persisting symptoms, very low-quality evidence).  
<sup>a</sup> Allocation concealment unclear in most studies though blinding suggests the likelihood of concealment in most. The outcomes summarized here was failure to improve symptoms and side effects. These were measured by unvalidated questionnaires in each study. The questions, however, were simple and straightforward, final decision was not to rate down for risk of bias.  
<sup>b</sup> Although the  $I^2$  is large and the test for heterogeneity very highly significant, all studies but one suggest benefit, and uncertainty appears to be the magnitude of effect rather than whether there is an effect. Final decision not to rate down for inconsistency.  
<sup>c</sup> Not only are all studies industry funded, but they are all of small or moderate size. Furthermore, the funnel plot (Fig. 2) could be interpreted as suggesting the possibility of publication bias.  
<sup>d</sup> Final decision: rate down for likelihood of publication bias.  
<sup>e</sup> We rated down for publication bias. Although there also was concern about a high risk of bias and inconsistency, we did not further rate down the quality of evidence because not every criterion appeared to justify rating down by one level.  
<sup>f</sup> The lower boundary of the CI would suggest no treatment-induced adverse effects, whereas the upper boundary suggests more than a doubling of adverse effects relative to placebo.

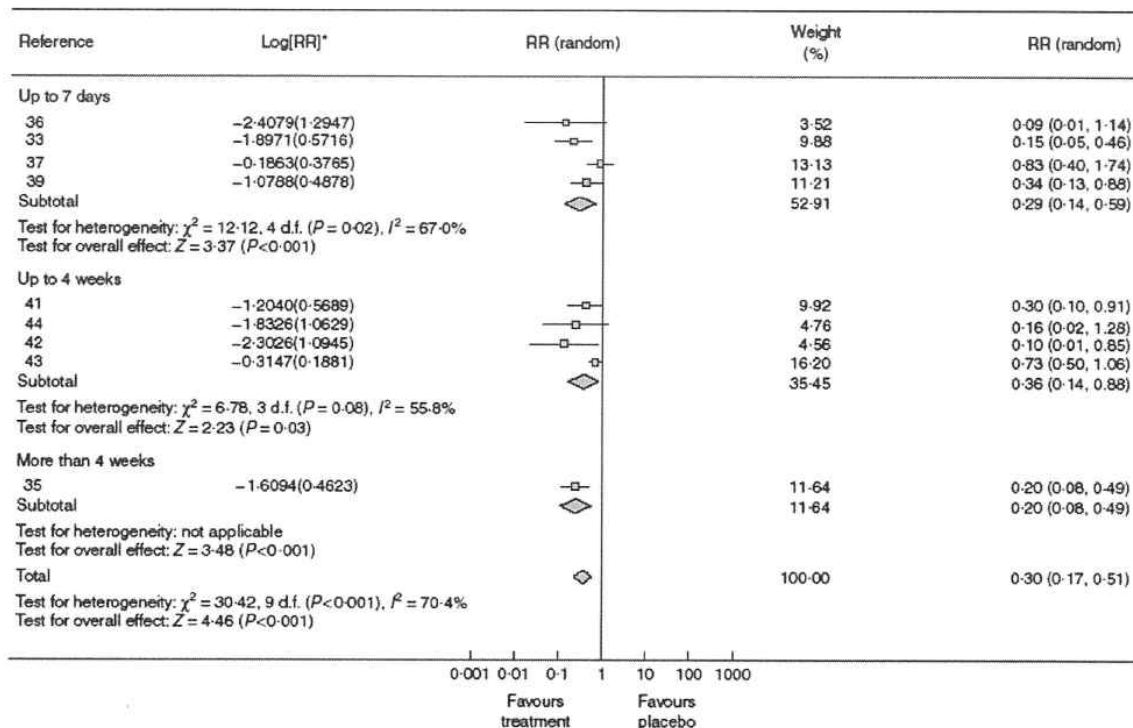


Fig. 1. Forest plot of the results of a systematic review of flavonoids for the treatment of hemorrhoids for the outcome of persisting symptoms or lack of improvement.

evidence in each case and rejects rating up for magnitude of effect, would judge the evidence warranting very low confidence. Both reviewers, having made judgments for individual criteria, might be dismayed that the overall rating (high or very low) does not really capture their confidence in effect estimates.

This example highlights the fact that each criterion for rating quality of evidence up or down reflects not discrete categories but a continuum from minimal limitations to very serious limitations. When the body of evidence is

intermediate with respect to a particular criterion, the decision whether a study falls above or below the threshold for rating confidence up or down (by one or two levels) may be arbitrary. In such instances, it is particularly desirable to describe the rationale for the final decisions.

In the case of flavonoids for hemorrhoids, both reviewers—charitable and harsh with respect to individual domains—may, taking a broad look at the evidence, agree that overall it lies on the border of moderate to low quality evidence (which was the conclusion of the authors of the review) [9]. In that case, reviewers may pick one or two domains (risk of bias, inconsistency, or publication bias) of limitations that would explain their reasoning. For example, the associated explanation could read: “We rated down for publication bias. Although there was also concern about a high risk of bias and inconsistency, we did not further rate down confidence in effect estimates because not every criterion appeared to justify rating down by one level.” This reflects the necessity to take an overall or gestalt view of the body of evidence. In the evidence profile presentation (Table 1), the final decision is that the body of evidence warrants of moderate confidence, and the chosen reason for rating down confidence is likely publication bias.

Having difficulties about placing the evidence in either the moderate or low confidence category emphasizes that

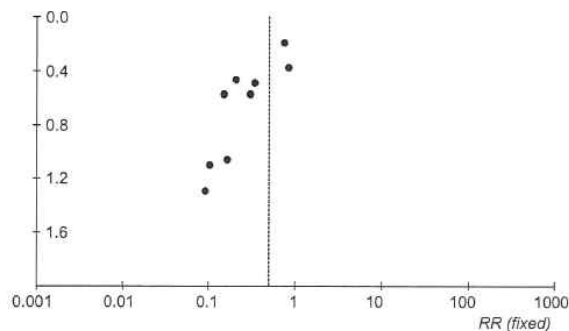


Fig. 2. Funnel plot of studies of flavonoids for ameliorating symptoms in patients with hemorrhoids.

the overall confidence rating also is a continuum, and contextual decisions are necessary when confidence is near the threshold between categories. The authors of the review acknowledged this by suggesting that ratings of either moderate or low confidence would be reasonable.

We encourage review and guideline authors to be explicit when they encounter similar situations, acknowledging borderline decisions in one or more domains. The evidence profile (Table 1) demonstrates such a presentation (note in particular footnote d).

Despite the limitations of breaking continua into discrete categories, treating each domain for rating confidence up or down as a discrete category enhances transparency. Indeed, the example highlights once again that the great merit of GRADE is not that it necessarily ensures reproducible judgments (observers will inevitably differ in close-call situations when rating up or down for individual domains or for the overall confidence per outcome) but that it achieves explicit and transparent judgment. In such close-call situations, apparent disagreement about whether to rate confidence up or down may represent very little disagreement on a continuum if that disagreement occurs near a threshold between categories (i.e., the threshold between rating down and not rating down). Furthermore, when the overall confidence is near a threshold (e.g., moderate or low confidence), systematic reviewers and guideline developers using GRADE may reduce their angst by recognizing that the disagreement, when the confidence rating is viewed as a continuum, is small.

### 3. Determining the confidence in effect estimates across outcomes

GRADE is the first formal system of rating quality of evidence to acknowledge that quality may differ across outcomes and to explicitly address this issue. For systematic reviews that are not associated with recommendations, and therefore do not require an overall confidence rating across outcomes, we suggest presenting confidence ratings for each important outcome and not determining the confidence in effect estimates across outcomes.

Such systematic reviews may, however, subsequently inform guidelines that do require implicit or explicit judgments about the overall confidence in effect estimates. It is better to be explicit, and it is logical that the overall confidence in effect estimates cannot be higher than the lowest confidence in effect estimates for any outcome that is critical for a decision. We therefore suggest applying the lowest confidence rating of the critical outcomes as the overall confidence associated with a recommendation. This requires distinguishing between outcomes that are critical and ones that are important but not critical.

Consider a systematic review of alternative strategies for Whipple resection for pancreatic cancer, one of which preserves the pylorus and the other, the standard approach,

which does not [11]. The evidence in this review for different outcomes varied from moderate to very low confidence in effect estimates (Table 2). In cases such as this, guideline developers must consider whether undesirable consequences of therapy are important but not critical to the decision regarding the optimal management strategy or whether they are critical. If an outcome for which evidence is of lower quality is a critical outcome for decision making, then the rating of overall quality of the evidence must reflect this lower quality evidence. If the outcome for which confidence is lower is an important but not critical outcome, the overall rating will reflect the higher confidence in estimates from the critical outcomes.

Thus, for this example, if those making recommendations felt that gastric emptying problems were critical, the overall rating of the confidence in effect estimates would be very low. If gastric emptying were important but not critical, the overall confidence would be low (on the basis of results from the clearly critical perioperative mortality) despite the presence of moderate confidence regarding 5-year survival.

### 4. Which outcomes are critical may depend on the evidence

The overall confidence in effect estimates may not come from the outcomes judged critical at the beginning of the guideline development process—that is, judgments about what is critical may change when considering the results. For instance, a particular adverse event (e.g., severe nausea and vomiting) may be considered critical at the outset. If it turns out, however, that the event occurs very infrequently—say, less than 3% of patients—the final decision may be that the adverse effect is important but not critical.

Consider, once again, the flavonoids for hemorrhoids review (Table 1) [9]. In addition to the risk of bias (concealment not explicit, questionnaires not validated) and publication bias problems associated with the primary outcome of persisting symptoms, the adverse effect outcome suffers from imprecision. Therefore, whatever judgment of confidence one might make about persisting symptoms, adverse effects would warrant lower confidence. However, even assuming the boundary of the CI associated with the largest increase in adverse effects (an approximate doubling in comparison to placebo) represented the true impact of treatment, the adverse effects would still be relatively infrequent (approximately 6.3%) and minor in nature. Despite these considerations, some might consider the adverse effects critical and thus rate the overall confidence in effect estimates low. Others would not and may therefore rate the overall confidence in effect as moderate.

Consider the choice facing individuals without documented coronary heart disease (CHD) but at high risk (e.g., male smokers over 60 with hypertension, elevated

**Table 2.** GRADE Evidence Profile: different resection strategies for pancreatic carcinoma associated with different evidence quality of different outcomes (question: pylorus-preserving pancreaticoduodenectomy vs. standard Whipple pancreaticoduodenectomy in pancreatic or periampullary cancer?; setting: inpatients)

Quality assessment	Summary of findings										
	No. of patients					Absolute effect					
No of studies (design)	Limitations	Inconsistency	Indirectness	Imprecision	Publication bias	SWPD	PPPD	RR <sup>a</sup> (95% CI)	Control rate	Risk difference (95% CI)	Quality
<b>Mortality at 5 years</b>											
Three (RCT)	Serious limitations <sup>b</sup>	No serious inconsistency	No serious indirectness	No serious imprecision	Undetected	94/114	93/115	RR 0.98 (0.87–1.11)	825/1,000	20 fewer per 1,000 (-120 to +80)	⊕⊕⊕○ Moderate
<b>In-hospital mortality</b>											
Six (RCT)	Serious limitations <sup>b</sup>	No serious inconsistency	No serious indirectness	Serious imprecision <sup>c</sup>	Undetected	12/244	4/246	RR 0.40 (0.14–1.13)	49/1,000	20 fewer per 1,000 (-50 to +10)	⊕⊕○○ Low
<b>Biliary leaks</b>											
Three (RCT)	Serious limitations <sup>b</sup>	No serious inconsistency	No serious indirectness	Serious imprecision <sup>c</sup>	Undetected	0/133	2/135	RR 4.77 (0.23–97.96)	0/1,000	20 more per 1,000 (-20 to +50)	⊕○○○ Low
<b>Delayed gastric emptying</b>											
Five (RCT)	Serious limitations <sup>b</sup>	Serious inconsistency <sup>d</sup>	No serious indirectness	Serious imprecision <sup>c</sup>	Undetected	56/220	66/222	RR 1.52 (0.74–3.14)	255/1,000	110 more per 1,000 (-80 to +290)	⊕○○○ Very low
<b>Blood transfusions (units)<sup>e</sup></b>											
Five (RCT)	Serious limitations <sup>b</sup>	No serious inconsistency	No serious indirectness	No serious imprecision	Undetected	320		— <sup>e</sup>	Best estimate SWPD group 2.45	WMD -0.66 (-1.16 to -0.25)	⊕⊕⊕○ Moderate
<b>Hospital stay (days)<sup>e</sup></b>											
Five(RCT)	Serious limitations <sup>b</sup>	No serious inconsistency	No serious indirectness	Serious imprecision <sup>c</sup>	Undetected	446		— <sup>e</sup>	19.17	WMD -1.45 (-3.28 to +0.38)	⊕⊕○○ Low

Abbreviations: SWPD, standard Whipple pancreaticoduodenectomy; PPPD, Pylorus-preserving pancreaticoduodenectomy; WMD, weighted mean difference.

<sup>a</sup> All data based on random effect models.

<sup>b</sup> Unclear allocation concealment in all studies, patients blinded in only one study, outcome assessors not blinded in any study, >20% loss to follow-up in three studies, not analyzed using intention to treat in one study.

<sup>c</sup> CI includes possible benefit from both surgical approaches.

<sup>d</sup> Unexplained heterogeneity;  $I^2 = 72.6\%$ ,  $P = 0.006$ .

<sup>e</sup> Continuous outcome, therefore no relative effect is given.

cholesterol despite attempts at reduction with diet, diabetes, and a family history of CHD): should they use statins to lower their risk of cardiovascular events? A meta-analysis of rigorous randomized trials in such individuals demonstrated consistent, statistically significant reductions in major CHD events and stroke but nonsignificant reductions in CHD deaths [12]. Serious adverse effects were unusual, and all adverse effects were readily reversible with drug discontinuation [13].

Guideline developers considering a recommendation for or against statins in high-risk individuals are likely to start the process of arriving at a recommendation considering all four outcomes (i.e., death from cardiovascular causes, myocardial infarction, stroke, and adverse effects) as critical. In reviewing the evidence, they find that for three of the four outcomes (myocardial infarction, stroke, and toxicity) the evidence warrants high confidence. For CHD deaths, however, because of imprecision, evidence warrants moderate confidence. Should the overall confidence rating across outcomes be high or moderate?

The judgments made at the beginning of the review process suggest that the answer is “moderate.” Most patients, however, once it is established that their risk of stroke and major coronary events decreases with statins, would find compelling reason to use the medication. Whether CHD mortality decreases is (as long as it is very unlikely it increases) no longer relevant to the decision. Considering this, the overall confidence rating is most appropriately designated as high confidence.

The principle is that if there is higher confidence in some critical outcomes to support a decision in favor of an intervention (i.e., benefits on critical outcomes clearly outweigh undesirable effects of the intervention, for which there also is high-quality evidence) one need not rate down confidence because of lower confidence in other critical outcomes that support the same recommendation. To put it another way: an outcome is no longer critical if, across the range of possible effect of the intervention on that outcome, the recommendation or its strength would remain unchanged. Such judgments require careful consideration and are probably rare.

## 5. Conclusions

GRADE defines criteria for rating the confidence in effect estimates for a given outcome, thereby allowing

systematic review authors and guideline developers to arrive at an outcome-specific confidence in effect estimates rating. Although this rating system represents discrete steps on an ordinal scale, it is helpful to view confidence in effect estimates as a continuum. An overall confidence in effect estimates rating across outcomes is only relevant in settings when recommendations are being made. In general, it is based on the critical outcome that provides the lowest confidence in effect estimates.

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