

Cass Review – Implications for Scotland

July 2024

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“A compassionate and kind society remembers that there are real children, young people, families, carers and clinicians behind the headlines.”

Cass Review Final Report (10 April 2024)

Introduction

It is recognised and acknowledged that the wider societal debate on gender identity is complex, with a range of opinions and concerns. The Cass Review describes the need to ensure an approach to gender identity healthcare that is more closely aligned with recognised NHS clinical practice, with a multidisciplinary team (MDT) focusing holistically on the needs of the child or young person.

These over-riding priorities are central to how we have developed our recommendations to the Scottish Government in response to the Cass Review. More than that, gender identity healthcare is not confined to services provided by a gender identity clinic. The responsibility for the full range of services in Scotland for children and young people with gender incongruence and dysphoria must extend beyond specialist services.

Background

The Independent Review of Gender Identity Services for Children and Young People, commissioned by NHS England, chaired by Dr Hilary Cass, was established in 2020 to make recommendations on how to improve NHS England commissioned gender identity services for children and young people. Its final report was published on 10 April 2024, accompanied by the publication of several systematic literature reviews conducted to inform the Review and the views of key stakeholders.

Clinical recommendations about the care of people, of any age and developmental stage, should be made carefully, and based on the best evidence available. The development of clinical pathways requires the gathering and interpreting of information, and then integrating it into informed decisions about the overall approach to clinical care. It is underpinned by experience, knowledge, collaboration, and evidence-based practice with the purpose of ensuring care is both effective and safe. This is core to holistic person-centred care, a human rights-based approach and informed decision making.

This approach is rooted in the principles and values of Scotland's 'Getting it right for every child' (GIRFEC). GIRFEC places children and young people, with their families, at the heart of decision making and ensures a single, shared, rights-based

approach to planning for their wellbeing. It also recognises the need for care to be adaptable enough to respect the views of a child or young person, their stage of development and the potential complexity of their life circumstances.

This also echoes the principles set out in the Chief Medical Officer's (CMO) Realistic Medicine strategy. This aims to promote shared decision making between health professionals and individuals and to provide a personalised approach through inclusive communication to reduce harm and promote joined-up care that better meets an individual's needs and preferences.

The foci of this report are the recommendations made by Dr Cass. This report does not seek to undertake a similar review in Scotland nor to provide a critical analysis of the Cass Review and the associated evidence. The intention of this report is to frame the Scottish Government's response to the Cass Review through a clinical lens and from a Scottish NHS context to ensure that the services provided in Scotland have children and young people at their centre.

We have applied a 'systems thinking' methodology to engage with key stakeholders to test and build a shared understanding of the current care pathway for children and young people with gender identity issues to ensure our recommendations are person-centred, coherent, and likely to succeed. This is in recognition of the fact that if one part of the pathway is adapted, we are likely to affect another part of it indirectly or directly. The stakeholders who have provided contextual information and views are detailed in Annexes A and B.

We are conscious that although we have heard from members of the trans community and their families, we have not directly sought lived experience perspectives as the remit of this group was not an open consultation. We have, however, reviewed the results of a range of lived experience consultations that have taken place as part of ongoing national work in Scotland to improve gender identity healthcare.

We would underline that we believe that the development of gender identity services in Scotland in response to this report should be developed with children, young people and their families in an active process of co-production.

We have concentrated on the healthcare provided for children and young people seeking help for gender-related distress. The report also considers how all services provided by the NHS in Scotland are supportive and respectful of children and young people's gender identity.

It is worth highlighting that some of the recommendations in this report are equally applicable to other areas of highly specialist care where the evidence is emergent and where there is a need to ensure appropriate governance is in place to ensure that both those receiving care and those delivering it are fully supported.

It should also be noted that the process of consent in this context is complex and multifaceted and should not be viewed through a more simplistic treatment lens but rather with the support of the MDT and with a more careful approach.

Finally, there has been significant public, media, and political interest in gender identity healthcare provision for children and young people. We recognise that this may detract from the primary issue of providing the best clinical care necessary for them.

In responding to the Cass Review, we have aimed to stay strictly within clinical boundaries whilst recognising that at the centre of all this we have a responsibility to make sure that children and young people in Scotland grow up safe, respected and supported.

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Current Context

This section provides a brief update on Scotland's Young People Gender Services, the current position on the prescribing of puberty-suppressing hormones (also referred to as puberty blockers) and gender-affirming hormones (also referred to as cross-sex hormones) and the research that the Scottish Government has commissioned in this area to date.

Definitions

Gender incongruence is defined as a marked and persistent incongruence (difference) between an individual's experienced gender and their sex recorded at birth. There is a distinction between gender incongruence arising in childhood before the onset of puberty, and where the incongruence has persisted for at least two years, and in adolescence after the onset of puberty. At any developmental stage, gender variant behaviour and preferences alone are not a basis for making the diagnosis.

Gender dysphoria is defined as a clinically significant distress and/or impairment of function associated with gender incongruence.

Gender identity healthcare is used to encompass a range of non-surgical and surgical interventions available via the NHS in Scotland for people seeking medical support to manage distress caused by gender incongruence, and/or gender dysphoria.

Gender Identity Services

Gender identity clinics (GICs) in Scotland offer assessment and access to medical interventions in relation to gender incongruence and/or dysphoria. Currently, the National Gender Identity Clinical Network for Scotland includes four GICs providing clinical assessment, treatment and specialist support to adults in Scotland. These are based within four Health Boards: NHS Grampian, NHS Greater Glasgow and Clyde (GGC), NHS Highland and NHS Lothian.

A separate gender service for children and young people is based within NHS GGC's Gender Service at the Sandyford Clinic and accepts referrals from all Health Boards across Scotland for children and young people up to the age of 18 years old.

There are several different entry routes to Gender Identity Services, such as via a GP, a psychologist, a paediatrician and historically through self-referral.

Sandyford Young People’s Gender Service

The Sandyford Clinic provides integrated specialised sexual health services across NHS GGC, delivering sexual, reproductive and emotional health services. It also provides a Gender Service for those who are uncomfortable or uncertain about their gender identity, and adult transgender and non-binary people considering feminising or masculinising treatment.

Both the Adult Gender Service and the Young People Gender service at the Sandyford Clinic are delivered by a multi-disciplinary team (MDT). The adult service is for anyone over the age of 17 years. The Young People’s Gender Service is for those under the age of 18 years.

Management information provided by NHS GGC indicates that as of February 2024 there were around 1,100 children and young people on the waiting list for the young people gender service at the Sandyford, with typical waiting times of one to three years. Data from Q3 2023 shows that at that time 1253 people were on the waiting list. Approximately 72% of them had been waiting longer than one year and 39% longer than two years with 14% waiting longer than three years. The number of young people seen per year by the Young Persons Service in the last five years is shown in the table below.

	2019	2020	2021	2022	2023	Total
Individuals	303	215	270	148	90	478
Attendances	762	434	865	519	216	2,796

A key challenge for both Adult and Young People’s Gender Services at the Sandyford Clinic has been the recruitment and retention of clinical staff, with the clinic being unable to fill several vacancies in recent years, affecting how many children and young people who can be seen safely. The reasons for this are varied but include the highly specialist nature of the field and the polarised context of the work. These recruitment challenges are mirrored in NHS England, as reflected in the Cass Review.

NHS GGC conducted a clinical review of their waiting list. As part of that process children and young people and their families waiting to be seen were asked a series of questions relating to their current situation. They reported finding the process of clinical waiting list validation helpful. A snapshot of the findings is detailed below:

- 49% of those asked were self-referrals, 30% were referred by their GP and the remainder from other sources.
- 73% of those questioned were natal females with male gender identity.
- 55% of those on the waiting list had a formal diagnosis of a neurodevelopmental condition with a further 15% awaiting a formal diagnosis.

- 35% of those asked had a formal co-existent mental health diagnosis although when asked about a range of symptoms, 58% of those on the waiting list registered scores in the clinical range for symptoms of anxiety, depression and suicidal or self-harm thoughts.

NHS GGC has contracted with a consortium of third sector support for this population to address social isolation, inactivity and mental and emotional wellbeing. The range of support includes physical activity groups, 1:1 coaching and group therapy.

The Young People's Gender Service at Sandyford can refer children to paediatric endocrinology services in either NHS GGC or NHS Lothian for further specialist assessment around pubertal stage, and/or to consider if it may be appropriate to prescribe puberty-suppressing hormones, or gender-affirming hormones for selected young people. Only a minority of young people referred to the young people's service proceed to being referred to paediatric endocrinology services and not all of those will be prescribed puberty-suppressing or gender-affirming hormones.

Puberty-suppressing hormones and gender-affirming hormones

Medicine Regulation

The regulation for the licensing of medicines is reserved to the UK Government. The regulations involved are the Human Medicine Regulations 2012. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK regulator for medicines and medical devices. Before a medicine can be marketed, a pharmaceutical company must be able to demonstrate its safety, quality and efficacy. This is done through a series of rigorous clinical trials, consisting of four phases. Applications to the MHRA for a marketing authorisation, sometimes referred to as a licence, must include data demonstrating the quality, safety and efficacy of the medicine. After detailed assessment and providing the data is satisfactory, a licence may be granted. It is granted to the manufacturer to market the medicine for a specific indication and not to the medicine itself.

Puberty-suppressing hormones

Gonadotrophin-releasing hormone (GnRH) analogues are licensed for use in the UK for precocious puberty in children and several different indications in adults, including the treatment of endometriosis, precocious puberty, infertility, anaemia due to uterine fibroids (together with iron supplementation), breast cancer, prostate cancer and before intra-uterine surgery.

There are no licensed medicines in the UK for the specific indication of suppressing the onset of puberty.

GnRH analogues are currently prescribed off-label (which means outside of the licensed indication) for the purpose of suppressing puberty. Prescribing medicines off-label may be necessary if, for example, there is no suitably licensed medicine to meet the person's need (often the case with children where a medicine is licensed only for adult patients), or the prescribing is part of research. Occasionally, clinicians may prescribe a medicine when the product licence does not cover the indication if they consider there would be significant clinical benefit to an individual, but only in line with local Health Board governance processes and protocols.

Prescribing governance

Prescribers should usually prescribe licensed medicines in accordance with the terms of their marketing authorisation. However, they may prescribe unlicensed medicines or medicines 'off-label' (outside the UK marketing authorisation) where, based on an assessment of the individual person, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of that person.

Prescribers are professionally and clinically responsible for any medicine that they prescribe. The responsibility that falls on them, and on the dispenser of that medicine, when prescribing either a medicine off-label or an unlicensed product is greater than when prescribing a licensed medicine within its licence.

The GMC guidance on *Good Practice when Prescribing and Managing Medicines and Devices* advises that when prescribing in these circumstances: the prescriber must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy; take responsibility for prescribing the medicine and for overseeing the person's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so; and make a clear, accurate and legible record of the reasons for prescribing an unlicensed/off-label medicine.

Taking GnRH analogues stops the progress of puberty by competing with the body's natural gonadotrophin releasing hormone. This competition blocks the release of two gonadotrophin hormones, Follicle Stimulating Hormone (FSH) and Luteinising Hormone (LH), from the pituitary gland. These two hormones play an important part in sexual maturation during puberty.

GnRH analogues have been used in the UK and other countries as a component of gender identity healthcare for several years in a small number of children/young people exhibiting gender dysphoric distress. However, as highlighted in the Cass Review, the evidence base for this indication is weak and the risk of short- or long-term harm remains uncertain. In addition, Dr Cass highlighted that a focus purely on puberty suppressants and belief in their efficacy has meant that other treatment

options, including medicines, have not been studied or developed to support children and young people, which is ultimately a disservice to them.

It is worth noting that the prescribing of puberty-suppressing hormones forms a very small part of the clinical pathway for gender incongruence and/or dysphoria within the NHS in Scotland, which, for those under 16 years of age, consists primarily of talking therapies.

Management data provided by NHS GGC and NHS Lothian, from 2012 to December 2023, show that around 90 to 100 young children and young people have received puberty-suppressing hormones and/or gender-affirming hormones having been referred from the Sandyford Clinic to paediatric endocrinology for further assessment. In April 2024, 21 patients were recorded as attending in NHS GGC and the remaining 22 in NHS Lothian to access puberty-suppressing hormones and/or gender-affirming hormones. It is worth noting that not all children and young people will be on both puberty-suppressing hormones and gender-affirming hormones.

We recognise that this may be an under-representation of those currently on waiting lists to be assessed or those accessing puberty suppressing hormones privately. The numbers of children and young people referred to endocrinology have fallen over the last three years due to slow throughput in the service, exacerbated by staff recruitment challenges.

Gender-Affirming Hormones

Gender-affirming hormones (masculinising or feminising hormones) are sex hormones prescribed as part of a medical transition for gender incongruence and/or dysphoria. Testosterone is prescribed to transgender males (female to male) and oestrogen for transgender females (male to female).

Prescribing of Puberty-Suppressing and Gender-Affirming Hormones

UK Government restrictions on the Prescribing of GnRH Analogues

On the 29 May 2024, the Department of Health and Social Care (DHSC), in response to one of the recommendations in the Cass Review, introduced emergency restrictions through a temporary order (which came into effect from the 3 June 2024) to prevent the sale or supply of GnRH analogues to suppress puberty as part of treating gender incongruence and/or gender dysphoria in children and young people who are under 18 years of age. These restrictions mean it is a criminal offence for a doctor, pharmacist or any other individual to sell or supply a GnRH analogue to child or young person under the age of 18 years other than in the specific circumstances. The restrictions will affect private prescriptions for GnRH analogues authorised by non-UK registered and UK registered prescribers although the way in which they are affected differs depending on whether the prescriber is registered in the UK.

Interim policy setting out the position of NHS England on the prescribing of puberty-suppressing hormones and gender-affirming hormones

In an interim policy published in July 2023, NHS England announced that it would only make puberty-suppressing hormones a treatment option for gender dysphoria available as part of a research study being established by the National Institute of Health and Care Research (NIHR). This study is not expected to go live until December 2024 at the earliest.

On 12 March 2024, NHS England published an updated clinical policy commissioning position, stating that puberty-suppressing hormones were no longer available as a routine commissioned treatment option for the treatment of children and young people who have gender incongruence and/or gender dysphoria. Whilst this had technically been its position since July 2023, in the absence of the establishment of the proposed research study, this updated position means that that there will be no new prescribing of puberty-suppressing hormones as a treatment for gender dysphoria in NHS England until the research study is established.

In England, gender-affirming hormones are available as a routine commissioned treatment option for young people with continuing gender incongruence and/or gender dysphoria from around their 16th birthday subject to individuals meeting the eligibility and readiness criteria set out in a commissioning policy. The policy is restricted to certain age groups as there is insufficient evidence to confirm safety in those age groups not included in the policy.

The position of the NHS in Scotland on the prescribing of puberty-suppressing hormones and gender-affirming hormones

The Medical Directors of NHS GGC and NHS Lothian wrote to the CMO in March 2024 to advise of their Boards' intention to follow NHS England's position to pause new prescriptions for puberty-suppressing hormones.

Based on the latest evidence, the specialists in this field of medicine developed a consensus that is that it is considered no longer safe to continue to prescribe these medicines without further evidence developed within the clinical trial settings that would normally apply to all other medicines. This decision was based on their concerns described in the evidence summary under recommendation 6.

In April 2024 NHS GGC and NHS Lothian issued a joint statement highlighting that both Health Boards would pause any new prescribing of puberty-suppressing hormones and gender-affirming hormones for young people under 18 years of age. Children and young people who were already receiving these medicines were not affected by the pause. This goes further than the most recent NHS England position for gender-affirming hormones. An exercise was undertaken to ensure that all young people in Scotland directly affected by this change were notified prior to the announcement.

Scottish Government commissioned research

The Scottish Government has previously awarded grant funding to the University of Glasgow to administer a wide programme of research on gender identity healthcare, including the long-term health outcomes of people accessing gender identity healthcare.

Following an open call to bid and a recommendation by an independent assessment panel, the University of Glasgow awarded research grants to six projects, each addressing an aspect of long-term health outcomes of people accessing gender identity healthcare. This includes both adults and young people, cardiovascular health, hypertension, sexual health, mental health and longer-term outcomes.

Research projects specific to young people that have been funded include research into the prevalence of hypertension (high blood pressure) in young people with gender dysphoria and research into young people's experiences before and after accessing gender identity healthcare services including their emotional, social and physical wellbeing and development as well as educational or vocational progress.

The outputs of the programme will help to support and drive improvements in service provision and health outcomes for those accessing gender identity healthcare in Scotland.

In addition, the Scottish Government has commissioned Policy Scribe to carry out an independent evaluation of the impact of Scottish Government funding allocated to Health Boards. The overall aim of this work is to understand the potential impact of Scottish Government investment on waiting times and quality of care at each gender identity clinic including the Young Peoples Gender Service. This will include considering supportive factors or impediments to service improvement. This will help to support future development and service improvement work.

Cass Review Summary

The Cass review was commissioned for an NHS England operational setting, but we recognise it comes from an appraisal of the clinical, governance and scientific perspectives and we have accepted them where we feel they should apply in a Scottish context.

No.	CASS REVIEW RECOMMENDATION	MDT RESPONSE	SUMMARY OF THE MDT TEAM'S COMMENTS ON SCOTTISH CONTEXT
1	<p><i>Given the complexity of this population, these services must operate to the same standards as other services seeing children and young people with complex presentations and/or additional risk factors. There should be a nominated medical practitioner (paediatrician/child psychiatrist) who takes overall clinical responsibility for patient safety within the service.</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> Individuals presenting to services will often have complex needs and may require tailored approaches to care. It is key that a lead senior clinician take overall responsibility for the child or young person's care; this could either be a psychiatrist or paediatrician.
2	<p><i>Clinicians should apply the assessment framework developed by the Review's Clinical Expert Group, to ensure children/young people referred to NHS gender services receive a holistic assessment of their needs to inform an individualised care plan. This should include screening for neurodevelopmental conditions, including autism spectrum disorder, and a mental health assessment. The framework should be kept under review and evolve to reflect emerging evidence.</i></p>	<p>PARTIALLY APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> Each child or young person's care plan must include a multidimensional assessment of their needs, considering social, family, welfare, psychological as well as physical needs. In the Scottish context, the most suitable framework for this is the forthcoming National Standards, to be published by Healthcare Improvement Scotland (HIS) in summer 2024.
3	<p><i>Standard evidence-based psychological and psychopharmacological treatment approaches should be used to support the management of the</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> A wide multidimensional assessment, which considers the child or young person's life, education, development,

	<i>associated distress and co-occurring conditions. This should include support for parents/carers and siblings as appropriate.</i>		mental health and medical conditions in parallel, is essential.
4	<i>When families/carers are making decisions about social transition of pre-pubertal children, services should ensure that they can be seen as early as possible by a clinical professional with relevant experience.</i>	PARTIALLY APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • Recognising the anxiety and questions that a family or young person may have; it is important that they and their families feel they have support to ask questions and seek timely help. • There needs to be a balance between creating ready access to services and avoiding a restrictive pathway. • There is evidence that non-binary people felt pressure from gender identity services to do things that they did not want to do, e.g. undergo treatment or change name to access care. Services should be sensitive, attentive and responsive to the needs of those they care for.
5	<i>NHS England, working with DHSC should direct the gender clinics to participate in the data linkage study within the lifetime of the current statutory instrument. NHS England's Research Oversight Board should take responsibility for interpreting the findings of the research.</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • This recommendation refers both to a statutory instrument that it is not relevant in Scotland and a specific situation regarding data sharing between clinics and the Cass Review in NHS England. • Nevertheless, a Scottish dataset, including clinical data, which aligns with that used by NHS England should be developed.

<p>6</p>	<p><i>The evidence base underpinning medical and non-medical interventions in this clinical area must be improved. Following our earlier recommendation to establish a puberty blocker trial, which has been taken forward by NHS England, we further recommend a full programme of research be established. This should look at the characteristics, interventions and outcomes of every young person presenting to the NHS gender services.</i></p> <p><i>The puberty blocker trial should be part of a programme of research which also evaluates outcomes of psychosocial interventions and masculinising/feminising hormones.</i></p> <p><i>Consent should routinely be sought for all children and young people for enrolment in a research study with follow-up into adulthood.</i></p>	<p>PARTIALLY APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • As highlighted in the Cass Review there is inadequate clinical evidence for the use of puberty-suppressing hormones. • While these treatments might be appropriate for some young people, there is insufficient evidence to know who will benefit and understand the risks. • A decision to pause the routine clinical provision of puberty-suppressing hormones has been made by NHS clinicians in Scotland, and to engage with NHS England and NIHR around Scottish participation in their forthcoming research study on this subject. • The call to research is wider than simply a trial of puberty suppressants and there does need to be a wider understanding of the needs and provision of safe and effective treatments for this population.
<p>7</p>	<p><i>Long-standing gender incongruence should be an essential pre-requisite for medical treatment but is only one aspect of deciding whether a medical pathway is the right option for an individual.</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • There should be rigorous entry criteria for medical treatment pathways including longstanding gender incongruence, and this should be clearly documented as part of the multidisciplinary team (MDT) assessment process. • Work is underway in Scotland to ensure this recommendation is met. Discussions between clinicians, children and young

			people about the potential risks and benefits of treatment options will be informed by an individualised care plan.
8	<i>NHS England should review the policy on masculinising/feminising hormones. The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend extreme caution. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • Clinicians in NHS GGC and NHS Lothian have already paused the use of masculinising and feminising hormones for those aged under 18 years in Scotland. • Further UK-wide research into the use of these hormones in children and young people under 18 years is recommended.
9	<i>Every case considered for medical treatment should be discussed at a national MultiDisciplinary Team (MDT) hosted by the National Provider Collaborative replacing the Multi Professional Review Group (MPRG).</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • This recommendation concerns NHS England structures. • As in NHS England the principle of holistic assessment by an MDT with person-centred approaches forms the bedrock of how clinical services are provided by the NHS in Scotland. • This recommendation should form part of the service delivery component of services for children and young people.
10	<i>All children should be offered fertility counselling and preservation prior to going onto a medical pathway.</i>	PARTIALLY APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • Pre-pubertal children are not offered fertility preservation in Scotland in the context of gender identity healthcare, but services will provide these children with information about fertility.

			<ul style="list-style-type: none"> • Young people will only be referred to fertility preservation services in this context once they have reached sexual maturity.
11	<i>NHS England and service providers should work to develop the regional multi-site service networks as soon as possible. This could be based on a lead provider model, where NHS England delegates commissioning responsibility to the regional services to subcontract locally to providers in their region.</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • This recommendation pertains to NHS England's service model. • There are potential opportunities for the NHS in Scotland to expand its capacity through a distributed service model.
12	<i>The National Provider Collaborative should be established without delay.</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • The National Provider Collaborative is specific to NHS England. The service structure and clinical pathways in Scotland will need to reflect NHS arrangements in Scotland.
13	<i>To increase the available workforce and maintain a broader clinical lens, joint contracts should be utilised to support staff to work across the network and across different services.</i>	PARTIALLY APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • While contractual arrangements for NHS England staff are different from those in Scotland, there is a need for adequate staff who must be able to work flexibly and collaboratively across wider services. • Services are currently experiencing workforce recruitment and retention challenges which makes this currently somewhat aspirational. However, a more distributed model of delivery may help deliver this.

14	<p><i>NHS England, through its Workforce Training and Education function, must ensure requirements for this service area are built into overall workforce planning for adolescent services.</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • Work to map training resources and identify gaps has started alongside discussions between NHS Education for Scotland (NES) and NHS England. A report identifying available resources/training and gaps is expected by the end of 2024. • See response to recommendation 15 also.
15	<p><i>NHS England should commission a lead organisation to establish a consortium of relevant professional bodies to:</i></p> <ul style="list-style-type: none"> • <i>develop a competency framework</i> • <i>identify gaps in professional training programmes</i> • <i>develop a suite of training materials to supplement professional competencies, appropriate to their clinical field and level.</i> <ul style="list-style-type: none"> ○ <i>This should include a module on the holistic assessment framework and approach to formulation and care planning.</i> 	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • NES is working on a commission from the Scottish Government to develop a Transgender Care Knowledge and Skills Framework and explore resources and opportunities for training for NHS staff in Scotland in relation to adult services. • The Knowledge and Skills Framework for adult services is expected to be completed in summer 2024 and a specific piece of work on young people's services developed thereafter.
16	<p><i>The National Provider Collaborative should coordinate development of evidence-based information and resources for young people, parents and carers. Consideration should be given as to whether this should be a centrally hosted NHS online resource.</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • While the Scottish NHS context is different, the Scottish Government is currently scoping work to develop additional public-facing resources on the NHS Inform website and Healthcare

			Improvement Scotland's Right Decision Service.
17	<i>A core national data set should be defined for both specialist and designated local specialist services.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • A core national data set should be defined for both specialist and designated local specialist services and this should be done at a UK-wide level. • Agreeing consensus should not hold back data for quality assurance and improvement purposes and should align with any quality indicators which might be used for service evaluation and improvement purposes.
18	<i>The national infrastructure should be put in place to manage data collection and audit and this should be used to drive continuous quality improvement and research in an active learning environment.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • There is a commitment to improve data collection for gender identity healthcare in Scotland and the Scottish Government has already been clear to all Health Boards with gender identity clinics that they are expected to support work to improve data collection. • Public Health Scotland (PHS) has been commissioned by the Scottish Government to develop a quarterly, aggregate data collection for NHS GIC waiting times.
19	<i>NHS England and the National Institute for Health and Care Research (NIHR) should ensure that the academic and administrative infrastructure to support a programme of clinically-based research is embedded into the regional centres.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • The NHS in Scotland is engaging actively with NIHR and NHS England regarding participation in their forthcoming research study on puberty-suppressing hormones.

			<ul style="list-style-type: none"> The Scottish Government has already awarded a grant to the University of Glasgow to administer a programme of research into the long-term outcomes of people accessing gender identity healthcare.
20	<i>A unified research strategy should be established across the Regional Centres, co-ordinated through the National Provider Collaborative and the Research Oversight Group, so that all data collected are utilised to best effect and for sufficient numbers of individuals to be meaningful.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> These objectives in a specialist and low volume service such as gender identity healthcare in children and young people are best achieved via a four nations approach. A UK wide collaboration on addressing the research challenges should be progressed. The Chief Scientists Office (CSO) in Scotland has indicated a willingness to cooperate on projects of national relevance.
21	<i>To ensure that services are operating to the highest standards of evidence the National Institute for Health and Care Research (NIHR) should commission a living systematic review to inform the evolving clinical approach.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> HIS conducted a rapid evidence review in July 2023. A national current and systematic review of the available best evidence should be regularly updated to reflect emerging evidence and best practice.
22	<i>Within each regional network, a separate pathway should be established for pre-pubertal children and their families. Providers should ensure that pre-pubertal children and their parents/carers are prioritised for early discussion with a professional with relevant experience.</i>	PARTIALLY APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> As outlined in relation to recommendation 12, services for initial assessment should be as local as practical. In Scotland the provision of specialist services for children and young people

			<p>must address the needs of the pre-pubertal population and this would form part of a regional specialist service.</p> <ul style="list-style-type: none"> • Consideration will need to be given nationally to the workforce and service capacity to implement these recommendations.
23	<p><i>NHS England should establish follow-through services for 17-25-year-olds at each of the Regional Centres, either by extending the range of the regional children and young people's service or through linked services, to ensure continuity of care and support at a potentially vulnerable stage in their journey. This will also allow clinical, and research follow up data to be collected.</i></p>	<p>PARTIALLY APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • Services in Scotland should review current transfer arrangements to ensure continuity of care and support over this potentially vulnerable period. • This should form part of any children and young people's service.
24	<p><i>Given that the changing demographic presenting to children and young people's services is reflected in a change of presentations to adult services, NHS England should consider bringing forward any planned update of the adult service specification and review the model of care and operating procedures.</i></p>	<p>PARTIALLY APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • There needs to be data collection to better understand the needs of this group that extends into transfer to adult services. • The Scottish Government has commissioned an external provider to evaluate the impact of Scottish Government funding to Health Boards to improve young people's and adults' gender identity healthcare services.
25	<p><i>NHS England should ensure there is provision for people considering detransition, recognising that they may not wish to reengage with the services whose care they were previously under.</i></p>	<p>APPLICABLE TO SCOTLAND</p>	<ul style="list-style-type: none"> • A person's reasons for stopping medical care or seeking its reversal will be highly personal and may be complex and they should be appropriately supported by their NHS clinical team to do so.

			<ul style="list-style-type: none"> Processes should also be in place to facilitate someone who is stopping medical care or seeking its reversal being referred to another Gender Identity Clinic (GIC) for support if they do not wish to reengage with the service whose care they were previously under.
26	<i>The Department of Health and Social Care and NHS England should consider the implications of private healthcare on any future requests to the NHS for treatment, monitoring and/or involvement in research. This needs to be clearly communicated to patients and private providers.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> Private Healthcare in Scotland is regulated by HIS who have already done work in this area, recognising the risks posed by online and international private practice add further complexities to this challenge. No clinician should prescribe outside their competence, nor should GPs be expected to enter a shared care arrangement with a private provider, particularly if that private provider is acting outside NHS guidance.
27	<i>The Department of Health and Social Care should work with the General Pharmaceutical Council to define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> Since the publication of the Cass Review, the UK DHSC has made a temporary Order, having effect for three months, which prevents the sale or supply of GnRH analogues in particular circumstances, and specifically private prescriptions from approved European countries. This applies in Scotland.
28	<i>The NHS and the Department of Health and Social Care needs to review the process and circumstances</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> There are differences between the NHS number in England and the Community Health Index (CHI) in Scotland.

	<i>of changing NHS numbers and find solutions to address the clinical and research implications.</i>		<ul style="list-style-type: none"> • At present the CHI number contains a sex code which represents the individual's sex at birth (male and female). Currently trans people can request that their CHI number is updated by asking their GP practice to update their gender. • The issue with changing NHS England numbers is not applicable in Scotland as when a CHI number is changed, there remains a link between the old and new CHI in the patient's records.
29	<i>NHS England should develop an implementation plan with clear milestones towards the future clinical and service model. This should have board level oversight and be developed collaboratively with those responsible for the health of children and young people more generally to support greater integration to meet the wide-ranging needs of complex adolescents.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • There should be an implementation plan with clear milestones for any future and clinical service model, and this needs to be developed collaboratively across clinical disciplines, as well as with children and young people themselves. • Work to commission and design a regional service for children and young people should begin immediately and in parallel to address the needs of those currently on waiting lists.
30	<i>NHS England should establish robust and comprehensive contract management and audit processes and requirements around the collection of data for the provision of these services. These should be adhered to by the providers responsible for delivering these services for children and young people.</i>	NOT APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • While this recommendation covers NHS England contract management systems, these data gaps exist in Scotland. • PHS has been commissioned by the Scottish Government to develop a

			quarterly, aggregate data collection for NHS GIC waiting times.
31	<i>Professional bodies must come together to provide leadership and guidance on the clinical management of this population taking account of the findings of this report.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • Clinicians must have the support and guidance of national professional leadership bodies and regulators. Ideally, this should be done collaboratively to support multiagency working in practice. • The implications of this recommendation are for UK wide bodies such as the Medical Royal Colleges, the Royal College of Nursing (RCN), the Royal Pharmaceutical Society and others to consider in terms of developing support and guidance based on evidence-based approaches.
32	<i>Wider guidance applicable to all NHS services should be developed to support providers and commissioners to ensure that innovation is encouraged but that there is appropriate scrutiny and clinical governance to avoid incremental creep of practice in the absence of evidence.</i>	APPLICABLE TO SCOTLAND	<ul style="list-style-type: none"> • HIS has been commissioned by the Scottish Government to produce national standards for young people's and adults' services. • Other workstreams like the training scoping exercise being undertaken by NES will also support this.

Cass Review Recommendations

We have listed below the individual recommendations of the Cass review itself, to address in full, the breadth of the review's advice. Clearly the recommendations were commissioned for an NHS England operational setting, but we recognise that many come from an appraisal of the clinical, governance and scientific perspectives. In that light we have sought to match the clinical and scientific concerns in our responses below.

(1) Given the complexity of this population, these services must operate to the same standards as other services seeing children and young people with complex presentations and/or additional risk factors. There should be a nominated medical practitioner (paediatrician/child psychiatrist) who takes overall clinical responsibility for patient safety within the service.

Dr Cass highlights the heterogenous nature of this population and the complex overlaying factors that drive gender dysphoria. Many will have broad ranging presentations often including complex needs that extend beyond gender-related distress. A clinical service must be designed to be responsive, supportive, and person centred, recognising that no two individuals are the same and that meeting their needs requires tailored approaches.

A key governance concern is the need for a lead senior clinician (usually at consultant level) to take responsibility for the care of an individual. This lead role could be either a psychiatrist or paediatrician and in line with standard best practice for specialist services. This individual would be expected to take a lead role in MDT discussions and in the coordination of the care and in the governance and safety of the service.

There are risks for clinicians operating in high complexity, very specialist or potentially vulnerable areas with limited evidence. For this reason board medical directors require to be satisfied that they have strong clinical and professional governance arrangements in place to provide escalation and oversight and help clinicians practice in supported and safe services.

(2) Clinicians should apply the assessment framework developed by the Review's Clinical Expert Group, to ensure children/young people referred to NHS gender services receive a holistic assessment of their needs to inform an individualised care plan. This should include screening for neurodevelopmental conditions, including autism spectrum disorder, and a mental health assessment. The framework should be kept under review and evolve to reflect emerging evidence.

Key to creating a tailored care plan for each child and young person is identifying outcomes that are important to the individual ('What matters to me') as well as taking a multidimensional assessment of their needs as recommended by Dr Cass. This must include the social, family, welfare, psychological as well as physical needs.

This multifaceted approach to assessment would be normal best practice for any complex condition in children and young people as well as adults. Additionally, as is the case for all healthcare, the treating clinician will assess the appropriateness of the treatment for the child or young person as well as the child's capacity to make decisions about treatment and involve parents appropriately.

Creating an individualised care plan as part of the assessment process will require the input of an expert MDT as highlighted by Dr Cass. This team needs to meet and discuss each case to agree the best course of action with the child or young person at the heart of any decision making.

The purpose of this approach is to ensure an individual care plan covers all the MDT dimensions with the aim of supporting the development of the children and young peoples' broader wellbeing and functioning.

Importantly, plans need to be flexible to reflect that the situation may be complex and dynamic, and a child or young person should understand that they can change their mind at any time.

Within the Scottish context, HIS, whose aim is to enable the people of Scotland to experience the best quality of health and social care, is developing new National Standards for Gender Identity Healthcare. A public consultation on the draft standards took place earlier this year and the publication of the final standards is planned for summer 2024.

These standards will link to wider national standards regarding the delivery of care in the NHS. Their purpose is to improve the quality of gender identity healthcare across Scotland.

We expect the standards to make clear that people accessing gender identity healthcare should have holistic, effective and person-centred assessment and care plans.

It will also be important to align with the Child and Adolescent Mental Health Service (CAMHS) National Specification that was published in 2020, as well as the National Neurodevelopmental Specification published in 2021.

(3) Standard evidence-based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and co-occurring conditions. This should include support for parents/carers and siblings as appropriate.

Standardised assessment processes fit with best practice and provide confidence on quality standards and consistency. The need for further rigorous scientific evaluation of psychological assessment and support tools is addressed later.

One of the reasons that a multi-faceted assessment is important for children and young people is to address the risk of diagnostic overshadowing. This is the risk that one diagnosis or concern (e.g. gender incongruence) becomes dominant and other important concerns (e.g. mental illness, neurodiversity or trauma) are missed or not addressed.

This is especially important as it has been recognised that this group of individuals have higher rates of significant psychological distress and potentially undiagnosed concerns. Diagnostic overshadowing can be avoided by wide multidimensional assessment looking at different aspects of the child/young person's life, education, development, mental health and medical conditions in parallel at initial review and if appropriate at follow up visits. It will be important to list all the concerns relevant to child or young person including those non-medical concerns, such as schooling or bullying, and address them on an equal footing as important to the child's welfare. They will need ongoing support for all these issues throughout the stages of their care.

For this reason, we recommend that a comprehensive biopsychosocial assessment forms part of an individual's initial assessment and is complemented by tailored support as their needs progress or change. Given the significant risks to children and young people with gender dysphoria highlighted by the review including distress, trauma, anxiety, depression and suicide risk, such an assessment is important in ensuring that important diagnoses are not missed, and that appropriate treatments and support are provided. More than one challenge may be present at once and all should be addressed in parallel where possible.

Additionally, it should be recognised that psychological input is therapeutic itself and for many will form the mainstay of a child or young person's care as well as an important support, working with the young person, whether or not they progress onto more medical pathways.

As described in the Cass review, trans and non-binary young people are more likely to experience discrimination and bullying at school, sometimes poor family and

caregiver relationships and to have experience of the care system. All these factors may impact on their health and wellbeing.

In a recent LGBT Youth Scotland survey 53% of trans participants described experiencing bullying related to their gender identity/perceived gender. Many participants also reported feeling unsafe on public transport and the impact of discrimination and bullying on their ability to stay in school. Almost 1 in 5 trans participants (19%) described leaving school compared to 6% of cisgender (a person whose sense of personal identity and gender is the same as their birth sex) participants ([lgbtyouth Trans Report 2024](#)).

Other studies indicate that trans young people are disproportionately represented in youth homelessness, with some studies suggesting that young people fear that expressing their identity to family members would lead to eviction ([the LGBTQ+ youth homelessness report](#)) ([LGBTIQ+ Homelessness: A Review of the Literature](#)).

There is evidence of higher rates of mental health issues, adverse childhood events and neurodiversity in this group making holistic assessment and ongoing care planning that considers all relevant medical, social, developmental and other factors to support a young person in their decision-making essential.

We have made significant progress in the NHS in Scotland in embedding a trauma informed approach to service delivery. This approach is important in providing services for children and young people.

(4) When families/carers are making decisions about social transition of pre-pubertal children, services should ensure that they can be seen as early as possible by a clinical professional with relevant experience.

Recognising the anxiety and questions that a family or young person may have it is important that they and their families feel they have support to ask questions and seek timely help. There is a balance to be struck in creating ready access to services for those who need them whilst recognising that for many a formal and overly medicalised pathway can be too restrictive. Creating environments in health and care systems that do not pressurise children or young people whilst remaining accessible is key.

Meanwhile, addressing access and capacity will be an important concern in the configuration of services in Scotland in order to deliver this recommendation. This will be covered again later in in this report in more detail.

Education also has a key role as the main interface between children and young people and their community. Local multi-agency Children's Services Plans, and individual child plans, can provide a framework for ensuring that children and young people and their families have access to appropriate supports.

We need to create the confidence and safety for conversations in non-clinical areas too for young people to open up about difficult subjects (such as body image, thoughts of self-harm, gender etc) and to allow them to feel heard and understood.

Clinicians we have spoken to express the concern that we need to demystify and destigmatise conversations on difficult topics in trusted and safe spaces to avoid the need for children and young people to turn to social media for answers.

Research undertaken by Scottish Trans's in 2016 ([Non-binary-GIC-mini-report.pdf](#) ([scottishtrans.org](#))) into non-binary people's experiences of gender identity services found that only 1 in 4 of non-binary participants had 'always' felt comfortable sharing their non-binary identity when using gender identity services, and that 42% of non-binary participants had felt pressured by gender identity services to do things they did not want to do, such as change their name or undergo a particular treatment. For this reason, it is vital that clinicians are attentive and responsive to the needs of those they care for.

(5) NHS England, working with DHSC should direct the gender clinics to participate in the data linkage study within the lifetime of the current statutory instrument. NHS England's Research Oversight Board should take responsibility for interpreting the findings of the research.

We recognise the concern that gender-incongruent children and young people may be at higher risk of poor outcomes in terms of general healthcare needs and that these needs are not fully researched or understood. Whilst there is a need for a specific research trial of puberty-suppressing hormones as discussed later in this report, we also recognise the need for a wider range of real-world data capturing the experiences and outcomes for those on medical pathways as well as those who are not on medical pathways.

While acknowledging that this recommendation refers both to a statutory instrument that it is not relevant in Scotland and a specific situation regarding data sharing between clinics and the Cass Review in NHS England, we believe that a core dataset, including clinical data, should be developed. This will support a process of continuous service improvement as the evidence base grows and care pathways are evaluated.

It is our impression that due to data governance complexities, sharing a single database with NHS England would be very complex. However, we recommend a data set and collection period for Scottish children and young people that aligns with that used by NHS England and is consistent with outcome measures routinely used in child health services in Scotland. This is not dissimilar to other data sets and data collection arrangements in place in other clinical areas. This would not exclude aggregated data being analysed on a UK basis. It should also be anonymised for research and improvement purposes and include follow up, potentially to the age of 25 years (or for a minimum of 10-15 years).

Scotland has world leading experience with linked data sets and should consider this a priority area. We recognise the need for sensitivity with data collection but would

want to encourage a wider participation in research to understand the longer-term needs of all those referred for specialist pathways irrespective of treatment option. The intent and priorities are ensuring that we can monitor safety and quality and respond to emerging patterns in terms of benefits and risks for the population.

(6) The evidence base underpinning medical and non-medical interventions in this clinical area must be improved. Following our earlier recommendation to establish a puberty blocker trial, which has been taken forward by NHS England, we further recommend a full programme of research be established. This should look at the characteristics, interventions and outcomes of every young person presenting to the NHS gender services.

The puberty blocker trial should be part of a programme of research which also evaluates outcomes of psychosocial interventions and masculinising/feminising hormones.

Consent should routinely be sought for all children and young people for enrolment in a research study with follow-up into adulthood.

The overarching conclusion from the review by Dr Cass and the sum of the evidence presented in the systematic reviews suggests that there is inadequate evidence for the use of puberty-suppressing hormones or regarding the longer-term risks. In addition, whilst gender-affirming hormones may be the right treatment for some young people, we do not have sufficient evidence to know which children or young people will benefit most.

We agree with the review conclusions that, at the present time, there is insufficient evidence to support the benefits of puberty-suppressing hormones and that the risks of harm remain a significant potential concern.

We understand that it is this emerging evidence base that has led to clinicians across the UK deciding, in their professional opinion, that they no longer feel it is clinically appropriate or safe to continue prescribing puberty suppressants for children and young people with new presentations in GICs.

In the situation where there is an insufficient evidence base to support either efficacy or potential harm, it would be clinically and scientifically unsafe to proceed without further clinical trial evidence from properly designed trials. This is not just the case for puberty suppressing hormones but for other medicines too.

Cass Review – evidence summary

There was insufficient/inconsistent evidence about the effects of puberty suppression on psychological or psychosocial wellbeing, cognitive development, cardio-metabolic risk or fertility.

No changes in gender dysphoria or body satisfaction were demonstrated, however bone density is compromised during puberty suppression.

There is no evidence that puberty blockers buy time to think, and some concern that they may change the trajectory of psychosexual and gender identity development.

There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow-up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health. There is suggestive evidence from mainly pre-post studies that hormone treatment may improve psychological health, although robust research with long-term follow-up is needed.

The evidence found in the systematic review did not support the conclusion that Hormone treatment reduces the elevated risk of death by suicide in this population. The percentage of people treated with hormones who subsequently detransition remains unknown due to the lack of long-term follow-up studies, although there is suggestion that numbers are increasing.

We recognise that for many individuals who had significant hopes for medical treatment this message may be difficult to hear. We would stress that this decision reflects clinical and scientific safety concerns that progressing down medical pathways without an adequate and robust evidence base could lead to harm and regret if long term side effects of medical treatments are not known (in terms of physical or psychological harm). This could lead to worse overall outcomes and harm for individuals.

It is essential that clinicians have access to the best possible evidence. It is our view therefore that the decision to move routine clinical provision of puberty-suppressing hormones (acknowledging that decision has already been made by clinicians) into a clinical trial is the more appropriate scientific and clinical response to a position of equipoise – that is where the benefits and harms appear equally balanced or uncertain.

In addition, we note the need for more evidence around the other therapeutic options presented for these children and young people including gender-affirming hormones, psychological therapies and social supports/interventions, including their longer-term outcomes.

We support the recommendation for establishing rigorous clinical trials and have been engaged in conversations with the Chief Scientist's Office (CSO) and with colleagues in the National Institute for Health and Care Research (NIHR) and NHS England about Scotland's participation in a multicentre trial of puberty-blocking hormones.

The proposed Puberty-Suppressing Hormone research project is being progressed through the National Research Collaboration Programme (NRCP). This programme is a collaboration between NHS England and the NIHR. The NRCP commissions high-quality evidence for treatments where research can prove challenging and might otherwise not progress.

(7) Long-standing gender incongruence should be an essential pre-requisite for medical treatment but is only one aspect of deciding whether a medical pathway is the right option for an individual.

Recognising the concern that there are risks with over-medicalising what can be a normal experience for many young people, there should be care around entry criteria to any clinical pathway that starts long-term treatment options for gender incongruence.

This should be reflected in treatment standards and should be clearly documented as part of the MDT assessment process. It should form part of referral criteria for tertiary review.

Work is underway in Scotland which will ensure this recommendation is met. An individualised care plan will be agreed with the child or young person and their parents/carers. This plan will inform discussions between the relevant healthcare professionals in the multidisciplinary team and the child or young person and their parents/carers about possible treatment options and the potential benefits and risks.

Shared decision making and honest and open conversations are central to the CMO's Realistic Medicine principles that should underpin all clinical encounters including the range of options open to a child or young person and their parents/carers.

It should also be recognised that the process of consent can be complex and dynamic, and that children and young people should have their views sought constantly and sensitively allowing them to continue, pause or reverse any decision without judgement or exclusion from care pathways.

(8) NHS England should review the policy on masculinising/feminising hormones. The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend extreme caution. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18.

In Scotland, clinicians in NHS GGC and NHS Lothian have already identified concerns about the use of gender-affirming hormones in those under 18 years of age due to rising levels of concern around the short- and long-term use of these medicines in this age group. For this reason, they have paused the use of these medicines in those aged under 18 years in Scotland.

We are of a view that, as part of an individualised approach to care, there should be caution and a clear rationale for providing gender-affirming hormones for individuals aged under 18 years and where this happens it should be part of a shared decision-making conversation and be recorded. We would also suggest that further UK-wide research should evaluate the use of gender-affirming hormones in young people aged under 18 years which is linked to the wider aspirations of recommendation 8.

Medical Directors and Directors of Pharmacy should assure themselves that they are content that they have clear governance processes in place that include treatment protocols, multi-disciplinary peer support to clinicians prescribing in this area and clear professional line management and support.

(9) Every case considered for medical treatment should be discussed at a national MultiDisciplinary Team (MDT) hosted by the National Provider Collaborative replacing the Multi Professional Review Group (MPRG).

Although differences exist between the organisation of services in NHS England and the NHS in Scotland, the principle of holistic assessment by an MDT with person-centred approaches form the bedrock of how complex clinical services are provided. This recommendation should form part of services designed for children and young people. This is important as a support to clinicians working in complex and clinically isolated settings but also to provide appropriate clinical governance for the services provided to a child or young person.

(10) All children should be offered fertility counselling and preservation prior to going onto a medical pathway.

The treatment for the protection of fertility in post-pubertal young people involves the collection and storage of gametes (oocytes and sperm) which are currently stored within the four NHS Assisted Conception Centres in Scotland in Aberdeen, Dundee, Edinburgh and Glasgow but will, in the future, be stored at the National Gametes Storage Centre at the Scottish National Blood Transfusion Service (SNBTS). Procedures to remove oocytes require anaesthesia and issues of consent to be considered sensitively in young people.

No pre-pubertal children are given fertility preservation in Scotland for Gender Identity reasons. They will have conversations about fertility at a Gender Identity Clinic (GIC) but must wait for sexual maturity before being referred by a GIC for fertility preservation. This is because fertility preservation requires the initial stages of puberty to have commenced to allow the maturation necessary for procedures to be successful. This means coming off puberty-suppressing hormones for long enough to allow some exposure to natal hormones.

Currently, for pre-pubertal children, GICs will provide information about fertility with a referral for fertility preservation being made, where appropriate, for young people after the onset of puberty.

The service for young people and adults is carried out in Assisted Conception Units. The procedures for preservation of fertility involve a process of appointments, investigations and procedures and are potentially traumatic. There should be great sensitivity when discussing complex long-term issues including discussing fertility preservation with children and young people.

The preservation and use of these gametes is a reserved subject-matter under the Human Fertilisation and Embryology Act 1990.

(11) NHS England and service providers should work to develop the regional multi-site service networks as soon as possible. This could be based on a lead provider model, where NHS England delegates commissioning responsibility to the regional services to subcontract locally to providers in their region.

This recommendation covers commissioning and potential subcontracting by NHS England services. For the Scottish context there are some opportunities to expand capacity through a distributed service model, based in paediatric services and with strong links between secondary and specialist services.

Up until this point NHS GGC has provided a service for several years that has grown organically offering support to children and young people with gender incongruence. Over time the demand for this service has grown almost exponentially while capacity, resources and staffing have not grown to keep pace with demand. In addition, because other services have not grown elsewhere the current service has become the default option.

As a result, children and young people wait a significant period to be seen compounding significant psychological challenges. Many of these individuals have significant comorbidities in terms of mental health, neurodiversity or psychological concerns. The risk at present as highlighted by Dr Cass is that waiting for treatment of their gender incongruence leaves them vulnerable with unmet needs.

We recommend that the service model in Scotland should reflect the principles and priorities highlighted in the Cass Review and be developed in the same way as other specialist services for children and young people.

Access to services should be by referral from a General Practitioner after an initial assessment as would be the case for a referral to any other child or adolescent specialist service. This assessment should cover the minimum criteria for referral to the service and include assessment of any other identified healthcare needs or safeguarding concerns. This means that self-referral would not be available as is also the case with other specialist services.

Management data suggests that at its peak around 300 children and young people were referred annually to the gender service in Glasgow with over 1,000 currently on a waiting list. These numbers are significantly more than could be supported by a single national centre, suggesting that a distributed model based in individual Health Boards or regional services are the appropriate service model. We suggest that the current service planning mechanisms in the NHS in Scotland are used to assess potential service models and make recommendations to Health Board Chief Executives on potential service and staffing models.

(12) The National Provider Collaborative should be established without delay.

The National Provider Collaborative is specific to NHS England. The service structure and clinical pathways in Scotland will need to reflect arrangements specific to the NHS in Scotland. We recommend these are based on the principle of "*as local as possible and as national as necessary*" which should apply to the provision of these services as it does for other NHS service planning, recognising that the best care can usually be delivered close to home by local universal and specialist services with prompt access to expert input where necessary.

Standardisation of this specialist area of healthcare within existing NHS structures is wholly consistent with the Scottish Government's Strategic Action Framework for NHS Gender Identity Services. In the 2021 Strategic Action Framework, the Scottish Government committed to developing national standards of care for adult and young people's gender identity services.

Ideally this would be through a single referral route where physical, social and psychological needs can be addressed in a single setting such as a combined MDT clinic aligned with recommendations 1, 2 and 3. Only after initial multifaceted assessment with the MDT addressing medical, social, psychological and safeguarding needs should an individualised plan of care be agreed with the individual and/or their family as appropriate. In addition, we recommend that this first assessment is face-to-face.

Where follow up support and needs are identified (such as CAMHS or psychological services) this can then be delivered locally via local services to provide ongoing support closer to home.

This may have implications for the capacity currently available within the system and this will need to be addressed. We agree that much of the provision of this care should be normalised within the existing paediatric services with existing staff expertise (e.g. in neurodiversity, speech and language therapy, safeguarding etc.) supplemented by training and specialist staff.

Services should evidence the wider MDT discussion, bringing in the full range of specialists input but should also reflect the necessity to allow children and young people to 'step down' or 'step up' their care pathway as necessary. Shared decision-making must be careful, considered and not pressurised.

Strong professional networks for peer review and governance will be necessary and consideration of pharmacological measures should be part of a national MDT discussion. Clinical criteria for treatment must be clearly met and clinical trials as discussed elsewhere should be accessible through this route.

A combination of service planning, national workforce planning, national standards, quality indicators and assurance across a network of services will create an equivalence to the collaborative described by Dr Cass and facilitate ethical oversight, MDT discussion, staff training and professional development, data collection, audit and quality improvement.

The aim must be for accessible, high-quality care for children and young people anywhere in Scotland and to address their needs simultaneously to avoid additional queuing and avoidable distress offering care based on MDT working with expertise in child and adolescent development, medical paediatrics and endocrinology, child and adolescent mental health, neurodiversity, safeguarding and child protection.

In making the transition between existing service provision and newer distributed models, there needs to be some care to maintain service continuity and address the current capacity and demand challenges. This might mean expanding the existing staff pool as well as including a wider range of admin and support staff to address non specialist tasks. We also recognise the efforts GGC have made to address and support those awaiting care through third sector approaches and recognise that the needs of those awaiting care are significant and concerning.

Principles of NHS clinical care for those under 18 years with gender-related distress:

PRINCIPLE	ACTION
Reducing health inequalities	Equal access to quality health services across Scotland
	Freedom from gender discrimination in all health care in Scotland
Improve mental, physical and social wellbeing	Initial consultation with a general practitioner or other primary healthcare professional
	Holistic assessment and intervention to support all aspects of children and young people's healthy mental and physical development
Safe, effective treatment	Access to and use of high-quality evidence and data
Be included	Children and young people and families/carers provided with accessible information
	Supported to make informed decisions
Right place, as close to home as possible	Access to face-to-face appointments in comfortable and more local clinical settings
Support & services appropriate to risks and needs	Stepped, matched care, with clear pathways to and from specialist services
	Access to universal and targeted community children's services, including social work, education and third sector
Right time	Initial assessment & intervention within 18 weeks from first referral, or more urgently if clinical risk
Right person	Assessment and treatment will be provided by suitably trained clinicians within multidisciplinary teams and with support from specialists as required
Transitions	Support transition across services and pathways, taking account of children and young people's wishes and developmental needs

Other work is also taking place across Scotland to improve gender identity healthcare services. This includes HIS developing standards for gender identity healthcare and NHS Education for Scotland developing a Knowledge and Skills framework. These programmes must also consider the needs of children and young people.

(13) To increase the available workforce and maintain a broader clinical lens, joint contracts should be utilised to support staff to work across the network and across different services.

Although NHS England contractual arrangements for staff are different, we recognise and agree with the need for adequate staff who must be able to work in flexible ways to network and collaborate in the delivery of a distributive networked national service.

We recognise from clinicians in Scottish services that this is a highly challenging, complex and emotive area in which to work.

The recommendations from the Cass Review for representation at service level of a broad range of multidisciplinary professionals is welcome. The list recommended includes psychiatrists, paediatricians, psychologists, psychotherapists, clinical nurse specialists, social workers, specialists in autism and other neurodiverse presentations, speech and language therapists, occupational health specialists and, for the subgroup for whom medical treatment may be considered appropriate, endocrinologists and fertility specialists and pharmacists. Though achieving representation from the entirety of this list may feel aspirational given the current workforce challenges in the NHS in Scotland, we recognise that to meet the complex needs of a diverse population with a significant burden of comorbidities, we need the right skills and competencies in order to provide the optimal support and care.

Social work should also be embedded within services to provide expertise in safeguarding and support for care-experienced children and those who have experienced trauma. This should form part of the considerations of service planning and assurance.

We also recommend staff training to address skill gaps and the inclusion of trauma informed approaches, training on inclusive communications as part of support for children and young people with mental illness, intellectual disabilities, autism and neurodiversity, in addition to regular updates in safeguarding as routine in this area of clinical practice. In smaller teams roles overlap, and close collaboration can bolster team skills and enhance the quality of service delivery.

As part of good professional governance, we welcome the recommendation for clinicians to have professional supervision and support to explore the range of emotions arising from their work that they may experience along with arrangement for peer review of clinical cases. Such arrangements are already routine in several professions and clinical services and should be embedded in routine practice for gender identity healthcare services to provide a mechanism for mutual emotional and professional support. This should include a learning culture where staff can access safe processes for raising concerns.

(14) NHS England, through its Workforce Training and Education function, must ensure requirements for this service area are built into overall workforce planning for adolescent services.

(15) NHS England should commission a lead organisation to establish a consortium of relevant professional bodies to:

develop a competency framework

identify gaps in professional training programmes

develop a suite of training materials to supplement professional competencies, appropriate to their clinical field and level. This should include a module on the holistic assessment framework and approach to formulation and care planning.

NHS Education for Scotland (NES) is working on a commission from the Scottish Government to develop a Transgender Care Knowledge and Skills Framework and explore resources and opportunities for training for NHS staff in Scotland in relation to adult services. In doing so NES has engaged with a range of stakeholders including people with lived experience of accessing or waiting to access gender identity services and the NHS in Scotland, as well as professional bodies, and third sector groups.

Development of this work began in summer 2023 and the framework is expected to be completed/published in Summer 2024.

Work to map training resources and identify gaps has started alongside discussions between NES and NHS England. A report identifying available resources/training and gaps is expected by the end of 2024.

We note and welcome the fact that NES intends to follow this commission with a specific piece of work for children and young people's services recognising that the complexity and diversity that is not reflected in adult training.

This should include as suggested a breadth of skills and competency to reflect not simply the medical and psychological skills and knowledge required from a paediatric and developmental perspective, but the skills in safeguarding and trauma informed approaches.

Clinicians we have spoken to highlight the gaps in adolescent health services as a distinct specialty for a range of challenges that affect this age group including eating disorders, functional conditions, gender incongruence, developmental conditions and transitions to adult services from complex childhood conditions. It may be that greater national focus needs to be considered for the wider needs of this age group, in which context gender identity services would form a significant part of the array of supports for this age group.

(16) The National Provider Collaborative should coordinate development of evidence-based information and resources for young people, parents and carers. Consideration should be given as to whether this should be a centrally hosted NHS online resource.

Although the context is different, we agree with the principles of providing a range of clear, inclusive, supportive and accessible information for children and young people and their families is important. We understand that work is being scoped to be hosted on Right Decision Right Time and NHS Inform for children and young people and clinicians. This should be available on public facing websites such as NHS Inform to help families and children and young people to access a range of trusted and accessible sources of information and support.

(17) A core national data set should be defined for both specialist and designated local specialist services.

We agree with this recommendation and believe that it will need to be defined at a UK basis, however, agreeing consensus should not hold back data for quality assurance and improvement purposes and should align with any quality indicators which might be used for service evaluation and improvement purposes.

(18) The national infrastructure should be put in place to manage data collection and audit and this should be used to drive continuous quality improvement and research in an active learning environment.

We agree with this recommendation. There is a commitment to improve data collection for gender identity healthcare in Scotland and the Scottish Government has already been clear to all Health Boards with gender identity clinics that they are expected to support work to improve data collection.

As part of that Public Health Scotland (PHS) was commissioned by the Scottish Government to develop a quarterly, aggregate data collection for NHS GIC waiting times, focussing on number of new referrals and length of wait from initial referral to first outpatient consultation with a specialist.

In November 2022, PHS conducted a pilot data collection exercise with all four NHS GICs in Scotland ahead of implementation of quarterly data collection (from 1st April 2023) with a view to publication of quarterly data on the PHS website in the future.

Whilst this is a technical commission, the detail of which is being worked through by PHS and territorial Health Boards, we expect this to feature data specifically for children and young people's services.

(19) NHS England and the National Institute for Health and Care Research (NIHR) should ensure that the academic and administrative infrastructure to support a programme of clinically-based research is embedded into the regional centres.

The Scottish Government has awarded a grant to the University of Glasgow to administer a programme of research into the long-term outcomes of people accessing gender identity healthcare. The outputs of the programme will support Ministers, policy makers and healthcare professionals to drive improvements in service provision and health outcomes for people accessing gender identity healthcare in Scotland.

In addition, Scotland is in discussion regarding participation in the NIHR evaluation of Puberty Suppressants.

Whilst progress in this area has been promising there is a need for considerable additional research, and we support the development of a research infrastructure recognising that this may be best suited to a collaborative approach across all four nations.

(20) A unified research strategy should be established across the Regional Centres, co-ordinated through the National Provider Collaborative and the Research Oversight Group, so that all data collected are utilised to best effect and for sufficient numbers of individuals to be meaningful.

We believe these objectives in a specialist and low volume service such as gender identity healthcare in children and young people are best achieved via a four nations approach. We would hope to see UK wide collaboration on addressing the research challenges. The CSO office in Scotland has indicated a willingness to cooperate on projects of national relevance.

(21) To ensure that services are operating to the highest standards of evidence the National Institute for Health and Care Research (NIHR) should commission a living systematic review to inform the evolving clinical approach.

Healthcare Improvement Scotland conducted a rapid evidence review in July 2023.

[Rapid Response - Evidence synthesis: puberty blockers for children and young people with gender dysphoria: July 2023 \(healthcareimprovementscotland.scot\)](https://www.healthcareimprovementscotland.scot.nhs.uk/rapid-response-evidence-synthesis-puberty-blockers-for-children-and-young-people-with-gender-dysphoria-july-2023)

Subsequently the Cass review has included a wider evidence review as part of its Final Report.

We agree that a current and systematic review of the available best evidence should be regularly updated to reflect emerging evidence and best practice.

(22) Within each regional network, a separate pathway should be established for pre-pubertal children and their families. Providers should ensure that pre-pubertal children and their parents/carers are prioritised for early discussion with a professional with relevant experience.

As outlined in relation to recommendation 12, we believe that services for initial assessment should be as local as practically possible. We recognise that safeguarding and risk assessment for extremely vulnerable groups should be addressed early particularly to identify those most at risk who will need early and proactive support.

We recommend that these specialist services are not provided in an adult sexual health setting (such as the Sandyford Clinic) but are provided within paediatric clinical settings as with other age-appropriate services for children and young people.

In Scotland the provision of specialist services for children and young people must address the needs of the pre pubertal population and this would form part of a regional specialist service.

There should also be quality indicators in a specialist service for children and young people addressing access and experience. This is in line with advice issued to Health Board Chief Executives highlighting that GICs should be managed in line with November 2023 National Waiting Times Guidance.

Consideration will need to be given nationally to the workforce and service capacity to implement these recommendations.

(23) NHS England should establish follow-through services for 17-25-year-olds at each of the Regional Centres, either by extending the range of the regional children and young people's service or through linked services, to ensure continuity of care and support at a potentially vulnerable stage in their journey. This will also allow clinical, and research follow up data to be collected.

We recognise there is a need for a seamless transfer for vulnerable patients to receive specialist support and follow up. Examples already exist, such as the Scottish Government 'Principles of Transition' to support care planning from CAMHS to adult Mental Health Services.

This recommendation also mirrors the recommendation in LGBT Youth Scotland 2023 Health report based on the experience of young people in Scotland that "Young people must be supported to choose when they transition from young people's services to adult services (within a reasonable timeframe), bringing an end to automatic transition *[between young people's and adult services]* at the age of 18". [Health Report 2023 digital \(lgbtyouth.org.uk\)](https://www.lgbtyouth.org.uk/health-report-2023-digital)

We recommend that services review current transfer arrangements to ensure continuity of care and support over this potentially vulnerable period.

This should mean that for a young person moving to adult services the process is seamless and fully documented. In some cases, a period of shared care may be necessary to ensure a safe transfer. It will require information to be shared safely and fully across service boundaries. This means that goals of care and transfer into adults' services will need to be planned with the young person well ahead of any changes.

We would like to see this requirement reflected in adult service specifications to facilitate the move from children's services to adult services.

Currently it is possible that some young people by virtue of their long waiting times to be seen may inevitably be referred to adult gender identity services without having been seen in children and young people's services. We believe that children or young people transferring under these circumstances should have access to a full MDT assessment recognising many of the challenges that they face may have been exacerbated by not being addressed in their care pathway while experiencing longer waits for care.

(24) Given that the changing demographic presenting to children and young people's services is reflected in a change of presentations to adult services, NHS England should consider bringing forward any planned update of the adult service specification and review the model of care and operating procedures.

We agree that there needs to be data collection to better understand the needs of this group that extends into the transfer into adult services.

The Scottish Government has commissioned an external provider, Policy Scribe, to conduct an independent evaluation of the impact of Scottish Government funding to Health Boards for work to improve access to and deliver of, gender identity services, identifying good practice and challenges to progression. This evaluation will consider the impact of funding provided to both gender identity clinics for adults and the Young People's Gender Service. It will include considering supportive factors and impediments to service improvement.

(25) NHS England should ensure there is provision for people considering de-transition, recognising that they may not wish to reengage with the services whose care they were previously under.

Dr Cass highlighted that this recommendation applied to those who are transitioning, de-transitioning or re-transitioning. The Report also highlighted that those who de-transition should be carefully monitored in a supportive setting, particularly when coming off hormone treatments. This was based on hearing from people

experiencing regret who may be hesitant to engage with the gender services that supported them through their initial transition.

A person's reasons for stopping medical care or seeking its reversal will be highly personal and may be complex and they should be appropriately supported by their NHS clinical team to do so.

This care will need to be highly personalised to the individual and the nature of medical treatments they have accessed. It will also need to be carefully managed on a case-by-case basis in consultation with the GIC clinical team. Processes should also be in place to facilitate someone stopping medical care or seeking its reversal being referred to another GIC for support if they do not wish to reengage with the service whose care they were previously under during their previous care.

(26) The Department of Health and Social Care and NHS England should consider the implications of private healthcare on any future requests to the NHS for treatment, monitoring and/or involvement in research. This needs to be clearly communicated to patients and private providers.

The Cass Review highlighted concerns about the use of unregulated medicines and of healthcare providers that are not regulated within the UK and any associated implications for the NHS.

We agree with this recommendation. No clinician should prescribe outside their competence, nor should GPs be expected to enter a shared care arrangement with a private provider, particularly if that private provider is acting outside NHS guidance.

Some aspects of the private healthcare provision have been addressed by the DHSC emergency restrictions on the prescribing of GnRH analogues, especially from non-UK registered private prescribers. This is covered in more detail in our response to recommendation 27.

The Royal College of General Practitioners (RCGP) recognises that some GPs have expertise, or an extended role, in transgender care and supports them to act in their patient's best interests, within the limits of their competence. The guidance also sets out that for most GPs, without this expertise or extended role, the role of the GP does not include prescribing puberty-suppressing or gender-affirming hormones, carrying out any blood tests or monitoring or sharing care with the private sector.

In addition, the Scottish Government has provided universal advice when people present in general practice having been treated abroad without first advising their GP of their intentions. The advice states that in these circumstances, the Scottish Government would not expect GPs to be obliged to provide routine associated management required such as scans, blood tests, follow-up treatments or arrangements to deal with complications as required but should always provide care based upon their own judgement, and in keeping with the GMC's guidance on [Good Medical Practice](#), local health board policies, procedures and pathways.

UK based private healthcare in Scotland is regulated by HIS and they have already done work in this area recognising the risks posed by online and international private practice add further complexities to this challenge.

We agree on the need for further information that makes this clearer for children and young people, their families and private prescribers.

(27) The Department of Health and Social Care should work with the General Pharmaceutical Council to define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing.

We agree with this recommendation. As highlighted earlier in our report, in response to this recommendation, the DHSC has introduced emergency restrictions through a temporary Order, having effect for three months from 3 June 2024, which prevents the sale or supply of GnRH analogues to suppress puberty as part of treating gender incongruence and/or gender dysphoria in children and young people who are under 18 years of age.

The emergency restrictions mean it is a criminal offence for a doctor, pharmacist or any other individual to sell or supply a GnRH analogue to child or young person under the age of 18 years other than in the specific circumstances. The restrictions will affect private prescriptions for GnRH analogues authorised by non-UK registered and UK registered prescribers although the way in which they are affected differs depending on whether the prescriber is registered in the UK.

The most significant impact will be on children and young people who are under the age of 18 years and are currently receiving a private prescription for a GnRH analogue for any reason from a prescriber who is in the European Economic Area (EEA) or Switzerland, but who is not UK registered. Community pharmacies in Great Britain will no longer be able to dispense new private prescriptions, dated on or after 3 June 2024 for GnRH analogues from the EEA or Switzerland for anyone under 18 years of age. Many children and young people who began their treatment before the emergency restrictions came into effect will be able to continue to receive their prescriptions.

The General Pharmaceutical Council has also published [a resource for pharmacy professionals](#) in response to this recommendation to support them in providing information, support and services to children and young people with gender incongruence and/or gender dysphoria.

(28) The NHS and the Department of Health and Social Care needs to review the process and circumstances of changing NHS numbers and find solutions to address the clinical and research implications.

There are differences between the NHS number in England and the Community Health Index (CHI) in Scotland.

Our understanding is that in NHS England if you change your NHS number your previous record is disposed of, and systems are no longer able to access it – this could have a range of clinical and research implications. This is not the case in Scotland where there remains a link between a new and old CHI and a person's records.

At present the CHI number contains an indicator of the person's sex at birth (male and female). Currently trans people can request that their CHI number is updated by asking their GP practice to update their gender.

Within the commitments set out in the Scottish Government's Non-Binary Equality Action Plan 2023-28, published in November 2023, there are considerations being given to how the CHI number can better reflect people's protected characteristics, including gender identity in the context of Scotland's Data Strategy for Health and Social Care.

Given the ubiquity of CHI across Scotland's numerous health and social care systems it is important that the implications of any potential changes to CHI are thoroughly considered. Any action taken must be safe and appropriate. For example, regardless of a person's self-identified gender, there is a need to ensure that no-one risks missing important information such as screening appointments, diagnosis, referral or other clinical support that may be appropriate to their biological sex and/or previous medical history.

All screening programmes in Scotland identify eligible participants through their CHI number. The screening services that an individual is called for align with their biological sex, if the CHI number was changed after 14 June 2015. As it is not always possible to identify people who have transitioned prior to 14 June 2015, a person in this category is not automatically called for screening and must self-refer. There is already published information on how to do so on NHS inform ([Transgender screening in Scotland at nhsinform.scot](https://www.nhs.uk/infomanagement/articles/transgender-screening-in-scotland-at-nhsinform.scot)).

(29) NHS England should develop an implementation plan with clear milestones towards the future clinical and service model. This should have board level oversight and be developed collaboratively with those responsible for the health of children and young people more generally to support greater integration to meet the wide-ranging needs of complex adolescents.

We agree with the principle of having an implementation plan with clear milestones for any future clinical and service model, with the appropriate oversight. We also agree with the need for this to be developed collaboratively, not only with those responsible for the health of children and young people, but also co-designed with children and young people themselves.

Access to high-quality and equitable healthcare is an essential part of improving the health and wellbeing of society. The barriers that people experience in accessing gender identity services contributes to inequalities and inequity.

Health Boards and Integration Joint Boards (IJBs) have a statutory duty to involve people and communities in the planning and development of care services, and in decisions that will significantly affect how services are run.

As emphasised in *Planning with People*, it is vital individuals and communities are involved in decision making that affects them, and in the development of the health and social care services they use. Development of new services and improvement of current services must include active engagement with people using services in both their development and evaluation. Ongoing meaningful engagement with children and young people using these services and their families will be essential to the delivery improvement of these services.

We acknowledge that developing and implementing these recommendations will take time. The Cass Review describes this process taking several years before a fully operational model is implemented. Whilst we recognise and need to reinforce the realism of this statement, we do however want to acknowledge the distress and considerable delays that have been experienced by some people already within the system.

We therefore recommend that work on planning services for children and young people across Scotland begins as soon as possible and in parallel to address the needs of those currently on waiting lists. We note the current pressure on CAMHS services and in that context many of the children and young people on the current waiting lists for gender identity services have unmet needs that are symptomatic of general service pressures. Given the potential risk that these peoples face, we think access to services as soon as possible is vital.

(30) NHS England should establish robust and comprehensive contract management and audit processes and requirements around the collection of data for the provision of these services. These should be adhered to by the providers responsible for delivering these services for children and young people.

This recommendation covers NHS England contract management and reflects the challenges in obtaining data from services for evaluation as well as quality improvement.

In compiling this report, we at times struggled to get access to the data that would help us to understand current service provision. We therefore agree that the provision of service level data is a quality indicator and should form part of the necessary infrastructure of a regionally provided network of services.

As highlighted previously, PHS has been commissioned by the Scottish Government to develop a quarterly, aggregate data collection for NHS GIC waiting times, focussing on the number of new referrals and length of wait from initial referral to first outpatient consultation with a specialist. However, as highlighted in recommendations 5, 17, 18, and 20 additional data is required, including a wider range of real-world data capturing the experiences and outcomes for those on medical pathways as well as those who are not on medical pathways.

We envisage both service providers, Health Boards and HIS having a role in this.

(31) Professional bodies must come together to provide leadership and guidance on the clinical management of this population taking account of the findings of this report.

Dr Cass advised that healthcare professionals needed support and guidance from their professional bodies to apply the evidence-based approaches described in her report.

We endorse and agree with the call for clinicians to have the support and guidance of national professional leadership bodies and regulators. Ideally, this should be done collaboratively to support multiagency working in practice.

The implications of this recommendation are for UK wide bodies such as the Medical Royal Colleges, the Royal College of Nursing (RCN), the Royal Pharmaceutical Society and others to consider in terms of developing support and guidance based on evidence-based approaches.

We believe there is also a role for UK regulatory bodies including the General Medical Council (GMC), the General Pharmaceutical Council (GPhC), the Nursing and Midwifery Council, the Health and Care Professions Council (HCPC) and others to consider the implications of the Cass Review for the professions they regulate in a supportive manner.

We are also thoughtful as to whether further development of adolescent health services as a subspecialty of paediatric medicine needs to be considered and developed by the Royal Colleges of Paediatrics and the Royal College of Psychiatrists in conjunction with NES.

In addition, Dr Cass recommended the consortium in England brought together to develop training resources should be a vehicle for agreeing professional guidance for their respective clinical groups. We agree and envisage NES having a key role in continuing to develop and provide training resources to support additional professional guidance for the respective clinical groups and that this should provide additional materials to support clinicians in their roles in delivering services to both adults and children and young people.

(32) Wider guidance applicable to all NHS services should be developed to support providers and commissioners to ensure that innovation is encouraged but that there is appropriate scrutiny and clinical governance to avoid incremental creep of practice in the absence of evidence.

As detailed under the responses to recommendations 1 and 8, areas of clinical practice generally that deliver treatment for highly specialist care where the evidence is emergent, need to have clear governance and support in place.

Ideally this should be provided both nationally and locally. Nationally through standards, treatment protocols, guidelines and professional support networks. Locally through clear lines of reporting and escalation as well as via governance arrangements. This should mitigate some of the vulnerabilities that clinicians describe in practice and provide stable safe care.

The Scottish Government's Strategic Action Framework committed to developing national standards of care for adult and young people's gender identity services to support service delivery and ensure a balance between service improvement, innovation, scrutiny and governance.

As noted in the response to recommendation 2, HIS has been commissioned to develop these standards for both adult and children and young people services. The overall aim of these standards is to support the best outcomes and experiences for adult and children and young people accessing gender identity services. We recommend these standards are followed by measures to evaluate clinical service performance and/or other measures, such as quality indicators for services in Scotland to assure quality delivery.

In addition, the NES training resources, once extended to include children and young people, will help to support healthcare professionals and other working in Scotland.

With the work underway in Scotland for children and young people in this complex and sensitive area, we recognise the significant capacity challenges that exist but at the same time are optimistic that it should be possible to see a future where fewer

children and young people are waiting with distress at a vulnerable point in their lives.

ANNEX A: Policy and Clinical Stakeholder Engagement

In constructing this response to the Cass Review, we have sought a range of contextual information and views from relevant experts, commissioners and clinicians. This review does not necessarily represent their views fully but was shaped by their input. This included but was not limited to;

- Scottish Government Chief Scientist Office
- Scottish Government Directorate for Chief Nursing Officer
- Directorate for Chief Operating Officer, NHS Scotland – Scottish Government
- Directorate for Population Health, Scottish Government
- Directorate for Health and Social Care Finance, Digital and Governance
Scottish Government
- Directorate for Mental Health, Scottish Government - Children, Young People, Relationships and Families
- Scottish Government Directorate for Children and Families
 - Improving Health and Wellbeing Division - Maternal and Infant Health, Supporting Maternal and Child Wellbeing, Supporting Disabled Children and Young People
 - Office of the Chief Social Work Adviser
 - Children's Rights, Protection and Justice Division
 - Care Experience and Whole Family Wellbeing Division
- The University of Glasgow, School of Cardiovascular and Metabolic Health
- Healthcare Improvement Scotland
- NHS Education for Scotland
- NHS National Services Scotland
- NHS Greater Glasgow and Clyde and NHS Lothian Health Boards
- The Royal College of Paediatric and Child Health
- The Directorate for Learning, Scottish Government
- Service clinicians including psychologists, psychiatrists and paediatricians.
- The National Gender Identity Healthcare Reference Group

ANNEX B: The National Gender Identity Healthcare Reference Group / Stakeholder Engagement

The Scottish Government is committed to listening to and involving those people who have experience of accessing specialist gender identity healthcare in its policymaking decision process.

National Gender Identity Healthcare Reference Group

Established in early 2022, the National Gender Identity Healthcare Reference Group advises on the ongoing implementation of actions outlined in our 2021 Framework.

The Reference Group includes Health Board representation, LGBT organisations, clinicians, academics and people with lived experience of using gender identity healthcare.

This reference group is not a clinical oversight forum.

It brings together a wide range of stakeholders for the collective aim of improving provision of gender identity healthcare.

It is right that the specific recommendations from the Cass Review are considered by senior clinicians and not by the Reference Group.

Engagement with Lived Experience

Engagement with people who have experience of accessing, or waiting to access, these services is embedded through our national work to improve gender identity healthcare.

We have also put in place a Lived Experience Coordinator for this work to support engagement with people with lived experience across Scotland.

We will continue with this approach.

Engagement with LGBT Stakeholders

Engagement with stakeholders, including those that could be impacted by service or policy change, is standard practice in the public sector.

Health Boards and Integration Joint Boards have a statutory duty to involve people and communities in the planning and development of care services, and in decisions that will significantly affect how services are run.

ANNEX C: Prescribing Regulations, Policy and Guidance

Regulation of medicines

The regulation for the licensing of medicines is reserved to the UK Government. The regulations involved are the Human Medicine Regulations 2012. Parts 3-5 cover the regulations relating to licensing. They outline the approach to the authorisation (licensing) of products; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance (the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems associated with pharmaceutical products).

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK regulator for medicines and medical devices.

Before a medicine can be marketed, a pharmaceutical company must be able to demonstrate its safety, quality and efficacy. This is done through a series of rigorous clinical trials, consisting of four phases.

Pharmaceutical Clinical trials for drugs to achieve licencing requirements

Each phase of a clinical trial varies in size, character and focus:

Phase 1 primarily determines how a medicine works in humans and helps to predict the dosage range for the medicine, and involves healthy volunteers;

Phase 2 tests efficacy as well as safety among a small group of patients (100-300) with the condition for which the medicine has been developed;

Phase 3 involves a much larger group (1000-5000) of these patients which will help determine if the medicine can be considered both safe and effective; and

Phase 4 trials are conducted after a medicine has been granted a licence and involves real world evidence to develop new treatment uses for the medicine, compare with other treatments for the condition and determine the clinical effectiveness of the medicine in a much wider variety of patient types in conditions of "real life". Safety is a major part of phase 4 trials, which often involve several thousand patients so that more rare side effects, if any, may be detected.

Applications to the MHRA for a marketing authorisation must include data demonstrating the quality, safety and efficacy of the medicine. After detailed assessment and providing the data is satisfactory, a marketing authorisation (sometimes called a licence) may be granted.

A marketing authorisation is granted to the manufacturer to market the medicine for a specific indication and **not** to the medicine itself.

All licensed medicines are required to have a Summary of Product Characteristics (SPC) and a Patient Information Leaflet (PIL). These contain information on what a medicine is used for, how it should be used and what risks may be associated with the medicine. The SPC is available to prescribers and the PIL is specifically written for patients.

The MHRA tries to ensure that all known side effects of licensed medicines are documented so that patients and clinicians are informed about them. However, it is not possible to predict which individuals may be at risk or when side effects may occur.

Pharmacovigilance – managing the risks and benefits of medicines

Despite the extensive research in clinical trials for a specific medicine, some adverse drug reactions (ADRs) may not be seen until a very large number of people have received the medicine. Therefore, it is vital that the safety of all medicines is monitored throughout their marketed life - this is known as pharmacovigilance.

Pharmacovigilance involves monitoring the use of medicines in everyday practice to identify previously unrecognised adverse effects or changes in the patterns of adverse effects, assessing the risks and benefits of medicines to determine what action, if any, is necessary to improve their safe use, providing information to healthcare professionals and patients to optimise safe and effective use of medicines, and monitoring the impact of any action taken.

For a medicine to be considered safe, its expected benefits should be greater than any associated risks of harmful reactions. All medicines can cause reactions; however, most people take medicines without suffering any serious side effects. Healthcare professionals should be able to discuss such information with patients, parents and carers, be vigilant in the detection of suspected ADRs and prompt in reporting them via an MHRA process called the Yellow Card Scheme.

Information from many sources is used for pharmacovigilance. These include spontaneous adverse drug reaction (ADR) reporting schemes, for example, the Yellow Card Scheme; clinical and epidemiological studies; worldwide published medical literature; pharmaceutical companies; worldwide regulatory authorities; and morbidity and mortality databases.

Prescribing of medicines

The decision to prescribe a medicine for a person, and which medicine to prescribe, is entirely for the clinician in charge of their care, having considered the person's clinical condition and any relevant clinical guidance.

As part of the medical responsibility of doctors their primary imperative under General Medical Council (GMC) regulation and accountability is to 'first do no harm'; in other words a doctor is accountable for the care they provide, or fail to provide, to the person they treat and to the regulator and to their own employers through clinical governance pathways and not to any other party.

Clinicians should usually prescribe licensed medicines in accordance with the terms of their marketing authorisation. However, they may prescribe unlicensed medicines or medicines 'off-label' (outside the UK marketing authorisation) where, based on an assessment of the individual person, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of that person.

Prescribing unlicensed medicines or medicines off-label may be necessary if, for example, there is no suitably licensed medicine to meet the person's need (this is often the case with children where a medicine is licensed only for adult patients), a licensed medicine is not available because of a temporary shortage in supply, or the prescribing is part of research. Occasionally, clinicians may prescribe a medicine when the product licence does not cover the indication if they consider there would be significant clinical benefit to the patient and in line with local Health Board governance processes and protocols.

A clinician is professionally and clinically responsible for any medicine that they prescribe. The responsibility that falls on them, and on the dispenser of that medicine, when prescribing either a medicines off-label or an unlicensed product is greater than when prescribing a licensed medicine within its licence.

The GMC guidance on *Good Practice when Prescribing and Managing Medicines and Devices* advises that clinicians must, when prescribing in these circumstances: be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy; take responsibility for prescribing the medicine and for overseeing the person's care, monitoring and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so; and make a clear, accurate and legible record of the reasons for prescribing an unlicensed/off-label medicine.

Clinicians must give patients, or their parents or carers, sufficient information about the medicines they propose to prescribe, to allow them to make an informed

decision. It is more difficult to capture pharmacovigilance data when medicines are prescribed off-label.

Off-label Prescribing of puberty-suppressing hormones Suppressors

There are no licensed medicines to suppress the onset of puberty.

The National Institute for Health and Care Excellence (NICE) completed an evidence review on this subject in 2020 which included nine observational studies. The quality of evidence for the identified critical outcomes for decision making, gender dysphoria and mental health, was assessed at the time as very low certainty. There was no statistically significant difference in measurements compared with baseline. No evidence was found for quality of life. The quality of evidence reported for important outcomes was also assessed as very low certainty.

A re-run of the search was undertaken by NHS England (NHSE) in April 2023 to capture literature published after the NICE evidence review in 2020. Nine further studies were identified.

Subsequent trials in other contexts have shown that the use of puberty-suppressing hormones may be associated with significant harm in some, as well as benefit in others. The mounting evidence suggests that these medicines are certainly not harmless and are not as safe to use as had been initially thought.

In addition, this evidence base does not provide adequate data to address questions about the longer-term benefits or harms in relation to mental health, bone health, fertility or other yet unknown risks at a very critical stage in child growth and development.

NHSE concluded, in March 2024, that there was not enough evidence to support the safety or clinical effectiveness of puberty blocking medicines to make the treatment routinely available currently.

Off-label Prescribing of puberty-suppressing hormones – the Clinical Perspective

Based on the latest evidence, clinicians who are specialists in this field have developed a consensus that it is no longer safe to continue to prescribe these medicines without further evidence developed within the rigorous clinical trials that apply to all other medicines. It is their concern around the welfare and health of the children in their care that has brought clinicians to this decision.

In April 2024 NHS Greater Glasgow and Clyde (GGC) and NHS Lothian issued a joint statement highlighting that both Health Boards would pause any new prescribing of GnRH analogues via their Paediatric Endocrinology teams to children

and young people under 18 years of age for the purpose of suppressing puberty. Existing children and young people who were receiving these medicines were not affected by the pause. An exercise was undertaken to ensure that all children and young people directly affected by this change were notified prior to the announcement.



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