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Advice on the use of puberty suppressants in the care of trans and gender diverse people aged under 18

For public consultation

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Definitions

For the purposes of this *Advice on the use of puberty suppressants in the care of trans and gender diverse people aged under 18* (Advice on Puberty Suppressants), **young person** refers to a child or adolescent aged under 18.

Many definitions in this Advice on Puberty Suppressants are consistent with definitions published by the Australian Government, including the Australian Bureau of Statistics' Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables and the NHMRC Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research. We acknowledge the terminology used in this Advice on Puberty Suppressants may not reflect the identities and preferences of all trans and gender diverse people.

The list of definitions in Table 1 is not intended to be exhaustive and reflects the use of key terms in this Advice on Puberty Suppressants.

Table 1. Definitions

Term	Definition
Care	A broad term used in these guidelines to describe the interactions between healthcare professionals and young people, alongside their parents or carers. Care is multifaceted and tailored to each young person's needs. Care can include psychosocial support and medical interventions such as the use of GnRH agonists and/or hormones.
Cisgender	A cisgender person is someone whose gender is the same as their sex recorded at birth. Cis is a Latin term meaning on the same side as.[1,2]
Embodiment goals	Personal goals relating to how a body looks, feels, and behaves.[3]
Family/families	A general term that (depending on its use) can include a diverse range of people important to the young person beyond their parents or carers, such as siblings, grandparents, extended family, and social family or community.
Gender	Gender is a social and cultural concept and is not defined by biological or physical differences.[4] Gender refers to the social characteristics – including expected norms, behaviours, relationships and roles – associated with particular identities.[5] Concepts of gender vary across cultures and can change over time.[1,2] Gender includes the following concepts: - Gender identity is about who a person feels and knows themself to be - Gender expression is the way a person presents their gender. A person's gender expression may also vary depending on the context, for instance expressing different genders at school and home

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Term	Definition
	- Gender experience describes a person's alignment with the gender presumed for them at birth, i.e. a cis experience or a trans experience.[1,2]
Gender dysphoria	A clinical term describing the significant distress that can arise from gender incongruence. Gender dysphoria is defined in the American Psychiatric Association DSM-5-TR, with the definition reproduced online. See **Gender dysphoria**.
Gender incongruence	A clinical term describing the inconsistency between an individual's gender and their sex recorded at birth. Gender incongruence is a health-related condition defined in the World Health Organization ICD-11, for children [HA61], and for adolescents and adults [HA60]. See **Gender incongruence**.
Gonadotropin-releasing hormone (GnRH) agonists	A class of medication used to suppress puberty in the care of trans and gender diverse young people in Australia. See **Gonadotropin-releasing hormone (GnRH) agonists as puberty suppressants**.
Minority stress	The excess exposure to social stress faced by minority populations (including gender and sexual minority populations) due to their stigmatised social status, which puts them at greater risk of negative health outcomes.[6]
Non-binary	An umbrella term describing gender identities that are not exclusively male or female. Included in the term gender diverse.[1,2]
Preferred pronouns	A person may prefer and request that certain personal pronouns are used when referring to them in conversation and in documentation. Personal pronouns are words that take the place of a person's name in a sentence. Personal pronouns exist in the first person (I, me, we, us), second person (you), and third person (she, her, he, him, they, them).
Sex	A person's sex is based upon their sex characteristics, such as their chromosomes, hormones and reproductive organs.[1,2]
Sex characteristics	A person's physical sex features, such as their chromosomes, hormones and reproductive organs, often designated as representing the male or female sex.[1,2] Some people will have variations of sex characteristics (see below).
Sex recorded at birth	A person's sex as determined by sex characteristics observed at birth or in infancy.[1,2]
Social transition	The process by which a person outwardly affirms their gender expression to better align with their gender identity.

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Term	Definition
Tanner staging	A scale of sexual maturation used by healthcare professionals to track a child's physical development during puberty. Tanner stage 2 is the time from which physical signs of puberty will emerge, including breast bud development, sparse pubic hair, increase in testicular volume, and increase in height.
Trans and gender diverse	A trans and gender diverse person is someone whose gender is different to their sex recorded at birth.[1,2]
Variations of sex characteristics	A wide spectrum of variations of innate genetic, hormonal, or physical sex characteristics that do not conform to medical norms for female or male bodies, including variations to genitals, hormones, chromosomes and/or reproductive organs. [1,2]
Young person	A child or adolescent aged under 18.

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1 Executive summary

The National Health and Medical Research Council (NHMRC) is developing clinical practice guidelines for the care of trans and gender diverse people aged under 18, at the request of the Minister for Health and Ageing, the Hon Mark Butler MP. The Minister asked NHMRC to prioritise advice on the use of puberty suppressants.

The NHMRC *Advice on the use of puberty suppressants in the care of trans and gender diverse people aged under 18* (Advice on Puberty Suppressants) is now available for public consultation. Submissions received as part of public consultation will be considered by the Gender Guidelines Development Committee as they continue to develop the full guidelines. Advice on the use of puberty suppressants post public consultation will be presented as part of the full guidelines. The full guidelines are expected to be released for public consultation by early 2028 and will also include advice on the use of hormones and psychosocial support.

The Advice on Puberty Suppressants was developed with advice from the multidisciplinary Gender Guidelines Development Committee and is supported by a systematic review of the evidence, in line with NHMRC's Standards for Guidelines and Guidelines for Guidelines, and the internationally recognised GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to guideline development. As part of this approach, only critical and important outcomes relevant to the decisions of young people seeking care for gender incongruence and their parents or carers were prioritised for the evidence review.

The supporting systematic review for the Advice on Puberty Suppressants: *Effects of puberty suppression medications in young people (under 18) experiencing gender incongruence or dysphoria: systematic review and meta-analysis* (Evidence Evaluation Report)[7] is also available to view.

The input of people with lived experience of accessing care for gender incongruence is a feature of this guideline development process. The Gender Guidelines Development Committee includes people who accessed care as a young person (when under the age of 18) or as a parent or carer supporting a young person accessing care. The Gender Guidelines Development Committee sought additional input from the Gender Guidelines Reference Panel, which included feedback from people with lived experience, and clinicians and researchers who work with trans and gender diverse young people and their parents or carers. A range of views were expressed and considered.

Applying the GRADE Evidence-to-Decision framework, the Gender Guidelines Development Committee has determined a **conditional recommendation for the use of puberty suppressants (specifically, gonadotropin-releasing hormone (GnRH) agonists) in the care of young people with gender incongruence**. This recommendation and several Good Practice Statements relevant to clinical practice are summarised below and are described in detail in the Advice on Puberty Suppressants.

Conditional recommendations are more common than strong recommendations in clinical practice guidelines. A conditional recommendation is made in cases where shared decision-making is essential because different options may be appropriate for different individuals and they might make different choices, or where the overall certainty of available evidence is low. Both are the

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case here. Low certainty evidence does not lessen the importance of making a recommendation to a guideline's end users.

Once published, the full guidelines will be an important resource for healthcare professionals, and for trans and gender diverse young people and their families.

Summary of the Recommendation and Good Practice Statements

Good Practice Statements: Principles of providing care

Best interests and wellbeing of the young person

i. Healthcare professionals should prioritise the best interests and wellbeing of the young person and provide care that respects their autonomy. This includes discussing the young person's goals, preferences, and experiences, and allowing them to participate in decisions about their care.

Human rights and anti-discrimination

ii. Healthcare professionals and health services should provide care to trans and gender diverse people without discrimination, consistent with human rights principles and respect for the young person's inherent dignity, gender, and unique experiences.

Informed consent

iii. Healthcare professionals should obtain informed consent to medical treatments, while respecting the young person's capacity to be involved in decisions to agree to their own care, and where possible, to consent to their care.

Privacy and confidentiality

iv. Health services and all staff supporting a young person's access to care should protect the young person's privacy and confidentiality, and healthcare professionals should involve the young person in decisions about if and how private information (including preferred name and pronouns) is documented and shared with others.

Culturally safe, accessible and inclusive care

v. Healthcare professionals should provide culturally safe, accessible and inclusive care that supports the young person's health and wellbeing.

Conditional recommendation for the use of GnRH agonists to suppress puberty

The Gender Guidelines Development Committee suggests that, based on a shared decision between the young person, parents or carers and clinicians, gonadotropin-releasing hormone (GnRH) agonists can be considered for a young person who wants puberty suppression and who meets the following criteria:

- Tanner stage 2 or later

- Gender incongruence with or without distress (assessed according to ICD-11 gender incongruence in childhood – HA61, or gender incongruence in adolescence or adulthood – HA60)

- Assessed as suitable for treatment with GnRH agonists in collaboration with appropriate clinicians including multidisciplinary input tailored to the needs of the young person.

The wording of the recommendation, particularly the word "suggests", reflects the GRADE language for a conditional recommendation. GRADE advises that groups making recommendations should make every effort to provide guidance even when the certainty of evidence is low.

Good Practice Statements: Clinical considerations when using GnRH agonists

Providing information as part of shared decision-making

vi. Healthcare professionals should provide the young person and their parents or carers with the information necessary to make an informed decision on the use of GnRH agonists as part of shared decision-making.

Health assessment prior to commencing GnRH agonists

vii. Healthcare professionals should conduct a comprehensive health assessment before prescribing GnRH agonists to suppress puberty in a trans and gender diverse young person.

Multidisciplinary input

viii. Healthcare professionals should tailor multidisciplinary input to the needs of the young person, to assist with the assessment and monitoring of a young person on GnRH agonists.

Regular monitoring of a young person on GnRH agonists

ix. While a young person is receiving GnRH agonists for puberty suppression, healthcare professionals should conduct appropriate monitoring of their health and wellbeing.

Evidence on the use of gonadotropin-releasing hormone (GnRH) agonists

Multiple evidence reviews, both nationally and internationally, have examined the effects of puberty suppressants in young people with gender incongruence or gender dysphoria. The conclusions of any single review, and the strength of those conclusions, will depend on the exact question, the sorts of studies and outcomes included in the review, and the methods used for combining data. Reviews are always limited to the data that is available in primary studies.

Randomised controlled trials (RCTs) are considered the strongest study design for showing causality. However, there are many areas of medicine where ethical and equity concerns preclude the use of RCTs. Evidence on the use of GnRH agonists comes from non-randomised studies of the intervention (NRSI). Stronger conclusions can be drawn from NRSI studies which compare a group of people who received the intervention (in this case, GnRH agonists) to a group who did not, ideally where both groups are similar. In contrast, studies which compare people before and after an intervention may inadvertently include effects like social or family factors, or changes which would have occurred anyway, making it much harder to draw conclusions about the effects of the intervention. For example, attributing any change in mental health outcomes during adolescence to the use of GnRH agonists would be problematic in the absence of a comparator group that does not receive GnRH agonists, because adolescence is associated with the onset of common mental disorders (e.g. depression or anxiety) resulting from multiple biological and social factors.[8,9]

Outcomes included in reviews

The outcomes chosen for a review will affect the conclusions that can be drawn. As with many medications, the use of GnRH agonists in the care of young people with gender incongruence may affect physical, metabolic, psychological, social, or quality of life outcomes. GRADE recommends focusing on outcomes that are critical or important to key interest holders and keeping the number of outcomes manageable. Including too many outcomes makes it difficult to weigh up the desirable and undesirable effects to make decisions. The key interest holders relevant to developing this Advice on Puberty Suppressants are trans and gender diverse young people, their parents or carers, healthcare professionals and services providing care to trans and gender diverse young people.

Most reviews of puberty suppressants do not contain information about outcome prioritisation or the relevance of outcomes to interest holders, and many include a large number of outcomes. Evaluations of instruments that measure outcomes commonly used in studies involving trans and gender diverse young people indicate that existing measures do not adequately represent (and sometimes misrepresent) the perspectives of people with lived experience.[10,11,12]

Considering the impact of puberty suppression in isolation is also difficult for many outcomes, particularly long-term or rare outcomes for which data is often difficult to collect. Individuals' lives and behaviours can also vary considerably and in ways that could also affect the outcomes. For example, measuring bone health requires evidence until peak bone mass is reached (from adolescence into early adulthood). By that time, individuals who have received GnRH agonists will also have been exposed to interventions and lifestyle factors that may affect bone health and peak bone mass. Despite these challenges, outcomes in guidelines are prioritised according to their relevance to decision making rather than the availability of evidence.

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2 Introduction

NHMRC is developing clinical practice guidelines for the care of trans and gender diverse people aged under 18.

A trans and gender diverse person is someone whose gender is different to their sex recorded at birth. The clinical term to describe this inconsistency is gender incongruence. Gender diversity is a natural part of human diversity. Some people question their gender or realise and articulate that they are trans and gender diverse from a young age, while others come to understand this about themselves in adolescence or adulthood.

Health services in Australia, where possible, provide multidisciplinary care for trans and gender diverse young people (aged under 18). Care is multifaceted and tailored to each young person's needs. Care can include psychosocial support and medical interventions such as the use of puberty suppressants and/or hormones.

This Advice on Puberty Suppressants focuses only on the use of puberty suppressants in the care of young people with gender incongruence. The full guidelines will also include advice on psychosocial support and the use of hormones.

This Advice on Puberty Suppressants includes one recommendation regarding the use of puberty suppressants, and several Good Practice Statements relevant to clinical practice. This advice was developed by the multidisciplinary Gender Guidelines Development Committee and is supported by a systematic review of the evidence, in line with NHMRC's Standards for Guidelines and Guidelines for Guidelines, and the internationally recognised GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to guideline development.

The guidelines are intended for use by healthcare professionals providing care for young people with gender incongruence. The guidelines may also be a resource for trans and gender diverse young people and their families. The guidelines will not make recommendations for the care of trans and gender diverse adults (people aged over 18).

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3 Healthcare for trans and gender diverse young people in Australia

3.1 Gender diversity

Gender is a social and cultural concept and is not defined by biological or physical differences.[4] Gender refers to the social characteristics – including expected norms, behaviours, relationships and roles – associated with particular identities.[5] Gender can be non-binary. Concepts of gender vary across cultures and can change over time.[4,5] Gender includes the following concepts:

- Gender identity is about who a person feels and knows themself to be.
- Gender expression is the way a person presents their gender. A person's gender expression may also vary depending on the context, for instance expressing different genders at school and home.
- Gender experience describes a person's alignment with the gender presumed for them at birth, i.e. a cis experience or a trans experience. [1,2]

Every person's gender and sex are separate components of who they are and how they exist in the world. For many people, their gender aligns with their sex recorded at birth; this is a cisgender experience of gender. [1,2]

A trans and gender diverse person is someone whose gender is different to their sex recorded at birth. [1,2] Some people question their gender or realise and articulate that they are trans and gender diverse from a young age, while others come to understand this about themselves in adolescence or adulthood.

Gender diversity is a natural part of human diversity. However, trans and gender diverse people in Australia and around the world continue to be marginalised and commonly experience the pathologisation of their identity, harassment and abuse, transphobia, prejudice, stigmatisation, and discrimination. These experiences affect all aspects of their lives, including their health and wellbeing, education, employment, housing, safety, and access to public spaces and services.[13] Family support is an important protective factor in the lives of trans and gender diverse young people, in addition to having strong peer networks, trusted adults and social support, individual self-esteem, problem solving and self-advocacy skills, community visibility or participation and access to resources.[14]

A lack of these protective factors, fear of stigma, discrimination, cost, negative messaging and past negative experiences can all deter young trans and gender diverse people from accessing safe and appropriate healthcare, both in relation to gender and for other health conditions.[13,15,16,17] These and other barriers to care contribute to avoidable, ongoing health disparities for trans and gender diverse people, such as higher rates of depression and anxiety, suicidality and self-harm, substance abuse, exposure to violence, sexually transmitted infections, and the effects of accessing high-risk and unsafe medical interventions when they cannot access quality care.[13,15,18,19]

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3.2 Gender incongruence

Gender incongruence is the clinical term to describe an inconsistency between a person's gender and their sex recorded at birth. Gender incongruence, and being trans and gender diverse, is not a mental health disorder.

Gender incongruence is a health-related condition defined in the World Health Organization ICD-11, for pre-pubertal children [HA61]:

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

and for adolescents and adults [HA60]:

> Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Gender incongruence can be assessed by qualified healthcare professionals, including general practitioners, paediatricians, psychologists and psychiatrists, as part of an informed and shared decision about care made by the young person, their parents or carers, and their clinicians.

Some people will experience distress in relation to gender incongruence that negatively impacts aspects of their personal and professional life. This may result in a diagnosis of gender dysphoria.

3.3 Gender dysphoria

Gender dysphoria is the clinical term to describe the significant distress that can arise from gender incongruence. Gender dysphoria is defined in the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR), with the definitions reproduced online as follows:

Gender dysphoria is defined for children as:

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

    1. A strong desire to be the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).

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2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

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

And for adolescents and adults:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in the case of young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

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

Gender dysphoria can be assessed by qualified healthcare professionals, including clinical psychologists and psychiatrists. Gender dysphoria is different to mental health conditions

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associated with body dissatisfaction that are not specific to gender, such as Body Dysmorphic Disorder.

3.4 When to seek care

Families can seek information and care in relation to a young person's gender at any time.

It is not necessary to wait until a young person is distressed before seeking care.

While the presence of distress will often warrant additional measures to support the young person's health and wellbeing, some well-supported young people may not be experiencing distress when they and their family contact health services.

3.5 How care is provided

NHMRC consulted with paediatric gender services around Australia to explore their models of care, which vary based on the size and location of the service.

A young person's general practitioner or mental health professional (including school counsellors) is likely to be the first point of contact for the young person and their family to discuss the young person's gender and possible gender incongruence, and to provide support and referrals.

Most Australian states and territories operate paediatric gender services as part of their public health and hospital systems, though some services are limited in the care they can provide.[20]

Most paediatric gender services provide psychosocial and medical care and are staffed by multidisciplinary teams. Depending on the size and location of the service, teams can include endocrinologists, child and adolescent psychologists, child and adolescent psychiatrists, paediatricians, nurses, social workers, allied health professionals, and other specialists as needed.

Once a referral is made, paediatric gender services typically undertake an initial assessment that helps to triage people onto waiting lists. Young people can be on waiting lists for months to years.

The young person and their parents or carers attend multiple clinical appointments with members of the multidisciplinary team to discuss the young person's goals, receive information and psychosocial support, and complete health assessments, often over months to years before giving informed consent to the use of puberty suppressants and/or hormones.

The use of puberty suppressants allows a young person with gender incongruence to pause or prevent the development of sex characteristics that do not align with their gender. For a young person who is questioning their gender, or in cases where parents or carers are uncertain about the young person affirming their gender, puberty suppression may provide breathing space for discussion and decision making, allowing the young person time to clarify their embodiment goals. Withholding care to 'wait and see' as puberty progresses may not improve distress and can affect the young person's physical and mental health, wellbeing, and ability to function.[21]

Young people receiving care from gender services often remain engaged with those services for years and are regularly monitored. Psychosocial care and medical care are also provided by private specialists with training and experience in transgender health. Some general practitioners and nurses provide care to young people living in regional and remote areas via shared arrangements with gender services, to reduce the burden on families travelling to capital cities.

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Trans and gender diverse young people also continue to see their general practitioner for the management of illnesses or other health conditions, and for ongoing support in relation to gender incongruence, including while they are on waiting lists for gender services.

3.6 What care is provided and who is accessing this care

Audit data is not available for every state and territory paediatric gender service. However, published data indicates only a small number of young Australians are accessing this care.

The Royal Children's Hospital Gender Service (RCHGS) in Melbourne, Victoria is Australia's largest paediatric gender service.[22] In the 8 years from 2017-2024, 1,391 young people were discharged from the service.[22] While 577 of those young people (41.5%) went on to access multidisciplinary care, 814 young people (58.5%) were discharged with no ongoing multidisciplinary care.[22] This figure includes young people who were discharged after an initial triage appointment, those who declined or did not attend additional appointments, and those who were managed through an 'Under 8 pathway' without progression to multidisciplinary care.[22]

The median age of young people at their first appointment was 15.5 years, and the median age at discharge was 17.3 years.[22] The service saw a higher number of young people whose sex assigned at birth was female (70.2%) than male (29.8%).[22] Most young people identified as transgender (66.9%) or non-binary (22.6%) at their first appointment.[22] Most young people were born in Australia (93.6%) and spoke English at home (96.4%).[22] Approximately 2.7% of young people identified as Aboriginal or Torres Strait Islander.[22]

Of the 577 young people who accessed multidisciplinary care, 353 young people (25.4% of the total cohort) started a medical intervention.[22] This included 64 young people who commenced puberty suppressants (4.6% of the total cohort and 11.1% of those who accessed multidisciplinary care) and 341 young people who commenced hormones (24.5% of the total cohort and 59.1% of those who accessed multidisciplinary care).[22] The lower rate of young people commencing puberty suppressants may be due to a range of reasons, including age at presentation, personal choice, family factors, and barriers to care.[23] However, most young people who commenced puberty suppressants (52 young people; 81.3%) also commenced hormones to affirm their gender.[22]

For those young people who received puberty suppressants or hormones at RCHGS, the median time and number of sessions from first appointment until commencing medication was 530 days and 9 sessions.[22] Data on gender identity at discharge was available for 98% of these young people, and re-identification with sex assigned at birth was rare, with 7 young people re-identifying during the 8-year period (1.2% of those who accessed multidisciplinary care).[22] This included 4 young people who received puberty suppressants (6.6% of those starting puberty suppressants) and 3 young people who received hormones (0.9% of those starting hormones).[22] One young person expressed regret, after 1 month on estrogen.[22]

In a similar study in Western Australia, the Child and Adolescent Health Service Gender Diversity Service at Perth Children's Hospital received 995 referrals over a 7-year period (2014-2020).[24] The service also saw a higher number of young people registered female at birth than male at birth (65.6% and 34.4% of total referrals, respectively).[24] Before the end of 2020, 196 patients had commenced treatment, including 163 who initiated the use of puberty suppressants and 132 who initiated the use of hormones (99 young people used both).[24] Of the 552 referrals that were closed over the audit period, a reason for closure was not identified in 4 cases, and 29 young people of the remaining 548 closed referrals (5.3%) had re-identified with their sex recorded at birth.[24] The

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majority of people who re-identified with their sex recorded at birth (27 people) did so while waiting for initial assessment or during the assessment process, before initiating any medical intervention.[24] Two people (1% of the 196 people who commenced medical interventions) ended their care after receiving puberty suppressants or hormones.[24]

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4 Good Practice Statements – Principles of providing care

4.1 Best interests and wellbeing of the young person

Good Practice Statement

i. Healthcare professionals should prioritise the best interests and wellbeing of the young person and provide care that respects their autonomy. This includes discussing the young person's goals, preferences, and experiences, and allowing them to participate in decisions about their care.

Remarks:

As with all healthcare decisions, care should be in the young person's best interests and tailored to their individual needs.[25,26] Trans and gender diverse young people will have varied values, identities, preferences, lived experiences, and embodiment goals. Not all young people will want or need the same intervention at the same time or age, and care that is in one young person's best interests may not suit another.[16] It is important to listen to the young person and treat them with respect and dignity.

Young people and their families can make decisions about the best interests and wellbeing of the young person when they are supported by healthcare professionals and health services. Factors to discuss with the young person and their parents or carers include the child's physical health and development, psychological health, social and emotional wellbeing, family relationships, the young person's views and values, their developmental, environmental, cultural, and spiritual needs, and any other relevant factors based on the young person's unique circumstances.[27,28,29]

Every young person's autonomy evolves over time and is shaped by their relationships with parents or carers, family, and communities.[28,30,31] Healthcare professionals and families should support and empower young people to acquire the knowledge, skills, and self-confidence to increasingly participate in decisions about their care as part of shared decision-making.[30,32,33]

4.2 Human rights and anti-discrimination

Good Practice Statement

ii. Healthcare professionals and health services should provide care to trans and gender diverse people without discrimination, consistent with human rights principles and respect for the young person's inherent dignity, gender, and unique experiences.

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Remarks:

Trans and gender diverse young people have the same rights as other young people in Australia.[34] Every young person has a right to freedom of thought and expression,[35] and a right to the highest attainable standard of physical and mental health.[36] Healthcare professionals and health services must comply with legislation protecting trans and gender diverse young people from discrimination.[37]

Healthcare professionals should recognise the diversity of trans and gender diverse identities as valid, including non-binary and gender fluid identities. Gender diversity is not inherently pathological or negative. It is important to recognise the young person's inherent dignity and worth, and to avoid undermining or pathologising their gender identity or experiences.[13]

At the time of drafting this Advice on Puberty Suppressants, practices that attempt to change or suppress a person's gender identity to be more aligned with their sex recorded at birth are illegal in Queensland, New South Wales, South Australia, Victoria, and the Australian Capital Territory.

4.3 Informed consent

Good Practice Statement

iii. Healthcare professionals should obtain informed consent to medical treatments, while respecting the young person's capacity to be involved in decisions to agree to their own care, and where possible, to consent to their care.

Remarks:

Healthcare professionals are generally required to obtain consent before medical care is provided. Consent must be provided by a person who is legally permitted to consent, either for themselves or on behalf of another person. For consent to be valid, healthcare professionals must be satisfied:

- the person providing consent has capacity
- consent is free and voluntary
- consent covers the proposed treatment.[38]

Failing to appropriately obtain valid consent may give rise to civil and criminal liability. Additionally, healthcare professionals have a duty of care to provide information on all material risks of the proposed treatment.[39] See Providing information as part of shared decision-making. Failing to discharge this duty may lead to a civil action in negligence.

When providing care to a person aged under 18, the parents or guardians of the young person are generally responsible for providing consent.[28] However, a parent's right to make those decisions diminishes as the young person grows and becomes capable of making their own informed choices as a mature minor.[28,41] Also known as Gillick competence, the mature minor doctrine recognises that some young people will possess sufficient maturity and understanding to be capable of consenting to (or refusing to consent to) healthcare decisions.[40,28,41]

Determining a young person's capacity to consent is not based on age alone, and involves assessing the young person's understanding of and ability to weigh the medical advice provided,

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the nature of the treatment, benefits, risks and side effects, alternatives to the treatment, the potential consequences of treatment (including impact on social function, family relationships, and long-term emotional impact), and the impact of not having the treatment or doing nothing.[13,28,29,42]

It is not unusual for a young person to be assessed as competent to make decisions about their own health care. The cognitive capacity required to make autonomous medical decisions (the ability to reason and consider alternative courses of action) increases steeply from age 10 and typically reaches adult levels around age 16.[43] Many young people can make informed decisions regarding medical care like the use of puberty suppressants, especially as decisions are made in the context of shared decision-making alongside parents or carers and clinicians, often over multiple appointments and extended periods of time.[22,43,44,45]

When parents or guardians remain legally required to consent, healthcare professionals should obtain the young person's agreement with the decision, also known as obtaining informed assent. To do this, the young person should be provided with age and developmentally appropriate information about the treatment in ways they can understand. They should be involved in the decision to the greatest extent possible, consistent with respect for their autonomy.

Legal requirements for consenting to medical care for trans and gender diverse young people may change over time and differ between Australian states and territories, but shared decision-making remains a critical part of the process. Currently, informed consent is generally required from both parents or guardians, and an application to the Family Court of Australia may be made if there is a dispute as to the Gillick competence of the young person, a diagnosis of gender dysphoria, or the proposed intervention.[29] Recent cases in Queensland and Victoria suggest the consent of only one parent or guardian may be permitted where the other parent is absent or estranged.

4.4 Privacy and confidentiality

Good Practice Statement

iv. Health services and all staff supporting a young person's access to care should protect the young person's privacy and confidentiality, and healthcare professionals should involve the young person in decisions about if and how private information (including preferred name and pronouns) is documented and shared with others.

Remarks:

Every person's gender identity is personal and deserving of privacy. As the young person's autonomy and capacity evolve, healthcare professionals can see the young person separately from parents or carers for parts of their appointments, which affords them a greater degree of privacy.

Protecting the privacy and confidentiality of trans and gender diverse young people includes all staff taking steps to prevent the non-consensual public disclosure ('outing') of the young person's gender. Breaches of privacy and confidentiality can cause trans and gender diverse young people to avoid seeking care and can lead to harassment and other significant harms, regardless of whether the disclosure is intentional or accidental.[13,15,16,46]

Involving the young person in decisions about if and how their private information is documented and shared with others respects the young person's autonomy. Decisions about the use of

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preferred names and pronouns in a variety of contexts should be respected, including when making appointments, when being called in waiting rooms, when attending one-on-one appointments with clinicians, and when attending appointments alongside parents or carers.

4.5 Culturally safe, accessible and inclusive care

Good Practice Statement

v. Healthcare professionals should provide culturally safe, accessible and inclusive care that supports the young person's health and wellbeing.

Remarks:

Australia is a diverse, multicultural nation, and providing culturally safe, accessible, and inclusive care is important for all young people and their families.

Cultural safety requires healthcare professionals to respect the cultures, identities and beliefs of others, and to provide care free from racism or bias.[33] Healthcare professionals should understand how their own culture, values, beliefs and biases influence interactions with patients, families, and colleagues.[33] Providing culturally safe care to Aboriginal and Torres Strait Islander people also includes acknowledging the ongoing impacts of colonisation, racism, and bias on Aboriginal and Torres Strait Islander health, which includes social and emotional wellbeing.[33,47,48,49] Community input into the design and delivery of culturally safe health services for trans and gender diverse young people and their families should include members of Aboriginal and Torres Strait Islander communities,[50] and trans and gender diverse people from migrant communities or those with varied cultural and language needs.

Healthcare professionals should take a positive, inclusive approach to working with trans and gender diverse young people that respects each young person's unique strengths, capabilities, and connection to culture.[33,51,52] This includes accommodating accessibility needs, such as those relating to disability, neurodivergence, health literacy, or remoteness (e.g. telehealth options).

Information should be provided in accessible ways that the young person and their parents or carers can access and understand,[53] including in person (e.g. use of visual aids, access to interpreters), in writing (e.g. plain language and multilingual information about services and treatment options), via telehealth, and online. The wellbeing of trans and gender diverse young people can be further supported by a diverse and multicultural workforce that reflects the diversity of the Australian community,[53] including Aboriginal Health Workers and trans and gender diverse peer workers.

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5 Use of puberty suppressants for a young person with gender incongruence

5.1 Key question for puberty suppression addressed in developing the Advice on Puberty Suppressants

Should puberty suppressants versus no puberty suppressants be used for young people experiencing gender incongruence with or without dysphoria?

5.2 Gonadotropin-releasing hormone (GnRH) agonists as puberty suppressants

5.2.1 How puberty suppressants work

Gonadotropin-releasing hormone (GnRH) agonists are the most common medications used to suppress puberty as part of care for trans and gender diverse young people in Australia.[54]

Continuous use of GnRH agonists inhibits the production of endogenous sex hormones from the testicles and ovaries. GnRH agonists do this by desensitising cell receptors in the pituitary gland, which reduces the pituitary gland's production of luteinizing hormone (LH) and follicle stimulating hormone (FSH). This then reduces gonadal hormone production of testosterone and estrogen.

Because GnRH agonists bind to receptors to activate a response (they are an 'on' switch), there will be an initial increase in hormone production, but shortly after the first injection, levels of LH and FSH will be reduced and the production of testosterone and estrogen will be suppressed.[54]

For young people in puberty, GnRH agonists suppress the progression of puberty and the development of sex characteristics associated with increasing levels of these hormones (e.g. breast development, menstruation, genital development, Adam's apple development, facial masculinisation, voice changes).[54] The suppression of hormones is generally achieved within the first few weeks of treatment.

GnRH agonists do not trigger the development of physical changes that may be better aligned with the young person's gender; this requires the introduction of exogenous estrogen or testosterone.

The effect of puberty suppressants on hormone production is reversible when treatment is stopped, and pubertal development will resume.[54]

GnRH agonists have been used to pause and delay pubertal development in children with central precocious puberty since the 1980s.[55] Central precocious puberty is when pubertal development begins in girls aged under 8 years and boys aged under 9 years.[55]

GnRH agonists are not the only medications that suppress puberty. Other classes of medication include progestins and steroidal and non-steroidal antiandrogens. These medications are more

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commonly used for a range of purposes outside of caring for trans and gender diverse young people and were excluded from the systematic evidence review underpinning this Advice on Puberty Suppressants.[7]

5.2.2 GnRH agonists available to suppress puberty

GnRH agonists can be prescribed by authorised healthcare professionals, including doctors registered with the Medical Board of Australia.[56] For trans and gender diverse young people wanting to suppress puberty, prescribing of GnRH agonists in Australia is currently off-label. Off-label means using a product for a reason not listed as one of the indications for use in the Australian Register of Therapeutic Goods (ARTG).[57] Product information often does not include paediatric dosing information, and clinical trials in children may be considered unethical, unprofitable, or impractical (e.g. due to challenges with recruitment and sample sizes).[58,59,60,61] Consequently, off-label prescribing is very common in paediatric medicine and can be warranted based on clinical indication and shared decision-making involving parents or carers.[62,63,64]

Commonly prescribed GnRH agonists include:

- Goserelin
- Leuprorelin
- Triptorelin.

Depending on the medication, administration is typically via injection or implant.

There are few contraindications for the use of GnRH agonists. These include pregnancy and allergies to the active ingredients or any components of the medications.

5.2.3 Effects of using GnRH agonists on critical and important outcomes

For the systematic evidence review underpinning this Advice on Puberty Suppressants, 11 outcomes were prioritised as critical or important to the decisions of young people seeking care for gender incongruence and their parents or carers. The outcome prioritisation process is described in the Technical Report.

Critical outcomes for decision making

1. Pubertal development (during treatment; after discontinuation of puberty suppressants)
2. Gender dysphoria (during treatment; end of treatment period)
3. Body image (during treatment; end of treatment period)
4. Serious adverse events (any serious untoward outcome that occurs during or after the use of puberty suppressants, but not necessarily caused by puberty suppressants; short- and longer-term follow-up after treatment if effects can be isolated from subsequent medical care)

Important outcomes for decision making but not critical

5. Quality of life and wellbeing (end of treatment period)

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6. Functioning: social, family; any context (end of treatment period)
7. Satisfaction with care (end of treatment period)
8. Mental health: depression symptoms, anxiety symptoms, suicidal thoughts and behaviours (end of treatment period)
9. Mental health: death by suicide (end of treatment period)
10. Adverse events of special interest: bone health - fractures (during treatment; after cessation of treatment if effects can be isolated from other exposures, including subsequent treatment)
11. Adverse events of special interest: fertility - reproductive potential (end of treatment period)

After a screening and selection process, 15 non-randomised studies that examined the effects of puberty suppression on critical or important outcomes were included in this review.[65-79] Critical outcomes were eligible from studies of any design, whereas important outcomes were only included from studies that had an independent comparator group (prospective and retrospective cohorts). The length of follow-up varied; most studies reported results between 6 months and 2 years from commencing puberty suppressants. There was limited data available on the long-term effects of using GnRH agonists, which is consistent with other guidelines.[21,55] The included studies reported data from 12,756 people. None of the included studies were conducted in Australia, so there is no representation of Aboriginal or Torres Strait Islander peoples.

Appendix A provides the Summary of Findings table from the Evidence Evaluation Report,[7] which outlines the population, setting, intervention and comparison of the included studies. Each outcome is listed with details about the measures, the number of studies and participants, the size of effects, the certainty of the evidence using GRADE, and the plain language interpretation (the "what happens" column). Further information about the evidence assessment process is outlined in the Evidence Evaluation Report.[7]

Pubertal development

Pausing pubertal development is the reason trans and gender diverse people may desire to use GnRH agonists. The available evidence indicates that using GnRH agonists:

- will suppress pubertal development (menstruation) compared to no puberty suppression. Effects were very large in all 4 studies.[65,66,67,68]
- will likely suppress pubertal development (shorter penile length) compared to no puberty suppression. Effects were larger among those who received puberty suppressants at Tanner stage 2/3.[69]
- may suppress breast growth compared to no puberty suppression. Effects were larger among those who received puberty suppression at Tanner stage 2/3.[69]
- probably results in less invasive mastectomy for those undergoing future gender-affirming surgery (i.e. a large reduction in the amount of breast tissue removed or resected in future surgeries). Effects were larger among those who received puberty suppressants at Tanner stage 2/3.[69]

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Gender dysphoria and body image and satisfaction

The available evidence indicates that using GnRH agonists:

- may have little to no change in gender dysphoria between commencing puberty suppressants and follow-up, but the evidence is very uncertain.[65, 70,71]
- may have little to no change in body image and satisfaction between commencing puberty suppressants and follow-up, but the evidence is very uncertain.[65,70,71]

Serious adverse events

No evidence was found of serious adverse events with GnRH agonists, noting that follow-up was short-term. Two studies examined serious adverse events commonly evaluated for drugs to identify safety concerns. The available evidence indicates that using GnRH agonists:

- may have little to no effect on the incidence of idiopathic intracranial hypertension (a serious but rare adverse outcome) compared to no puberty suppressants.[72]
- may have little to no effect on QTc interval (which, if prolonged, is a risk factor for serious heart rhythm abnormalities) but the evidence is very uncertain.[73]

Although the available evidence indicates that serious adverse events are rare, a young person using GnRH agonists should be monitored for signs or symptoms that may warrant additional investigations and management. See Regular monitoring of a young person on GnRH agonists.

Quality of life

The evidence is very uncertain about the effect of puberty suppressants on quality of life and wellbeing.[74]

Functioning

The available evidence indicates that using GnRH agonists may improve functioning (overall psychosocial/social functioning). [74,75,76,77]

Satisfaction with care

The evidence review did not find any eligible studies that reported on satisfaction with care.

Mental health

The available evidence indicates that using GnRH agonists:

- may improve psychological functioning.[74,76,77,78]
- may reduce suicidality behaviours, but the evidence is very uncertain.[79]

Mental health (death by suicide)

The evidence review did not find any eligible studies that reported on death by suicide.

Adverse events of special interest

The evidence review did not find any eligible studies that reported on adverse events relating to fertility (reproductive potential).

The evidence review did not find any eligible studies that reported on adverse events relating to bone health (fractures).

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5.3 Conditional recommendation for the use of GnRH agonists to suppress puberty

The Gender Guidelines Development Committee suggests that, based on a shared decision between the young person, parents or carers and clinicians, gonadotropin-releasing hormone (GnRH) agonists can be considered for a young person who wants puberty suppression and who meets the following criteria:

- Tanner stage 2 or later

- Gender incongruence with or without distress (assessed according to ICD-11 gender incongruence in childhood – HA61, or gender incongruence in adolescence or adulthood – HA60)

- Assessed as suitable for treatment with GnRH agonists in collaboration with appropriate clinicians including multidisciplinary input tailored to the needs of the young person.

Additional information

- This recommendation should be read in conjunction with the Good Practice Statements included in this Advice on Puberty Suppressants.
- The Gender Guidelines Development Committee considered it would be problematic if the recommendation applied only to young people with gender distress, because some well-supported young people may not be experiencing distress when they and their family contact health services for information and care, and making them wait until they are distressed would be unethical.
- The Gender Guidelines Development Committee noted that GnRH agonists should not be used indefinitely without the introduction or return of hormones.

The Recommendation was developed following the Gender Guidelines Development Committee's consideration of the evidence and contextual factors outlined in the GRADE Evidence-to-Decision Framework. The full Evidence-to-Decision Framework is in the Technical Report: Appendix A.

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6 Good Practice Statements – Clinical considerations when using GnRH agonists

6.1 Providing information as part of shared decision-making

Good Practice Statement

vi. Healthcare professionals should provide the young person and their parents or carers with the information necessary to make an informed decision on the use of GnRH agonists as part of shared decision-making.

Remarks:

Healthcare professionals have a duty of care to provide information on all material risks of the proposed treatment.[39] See Informed consent.

Working with the young person and their parents or carers to make a shared decision on the use of GnRH agonists includes providing information to them on:

- the aims of using GnRH agonists as part of care for the young person
- stages of developing sex characteristics through puberty from Tanner stage 2 onwards (e.g. breast development, menstruation, genital development, Adam's apple development, facial masculinisation, voice changes), which the use of GnRH agonists will pause
- implications of delaying puberty, including on future treatment options (e.g. reducing the need for or extent of top surgery, or limiting later choices in the type of genital surgery available)
- available treatment options, including any reasonable alternatives to GnRH agonists and the option of no treatment
- potential benefits, risks and side effects of the available treatment options
- other relevant information on GnRH agonist medications, including administration and timing
- length of time the young person may be on GnRH agonists before further pubertal development, either by the introduction of gender-affirming hormones or by ceasing the medication
- ongoing support in relation to gender that is available to the young person on GnRH agonists, including how to seek help if or when they experience distress
- the importance of taking a comprehensive history and baseline assessments to determine suitability for GnRH agonists (e.g. baseline hormonal assessment)
- monitoring requirements while receiving GnRH agonists, and the importance of openly discussing any changes to health and wellbeing, so additional care can be arranged as needed

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- possible implications on fertility and options for fertility preservation
- legal requirements for parent or guardian consent under state or territory laws
- the importance of the young person continuing relationships with other healthcare professionals (e.g. their general practitioner) for management of any co-existing conditions and as a source of ongoing support between appointments with gender specialists.

This information can be provided by more than one healthcare professional working together to support the young person and their parents or carers.

This information can be provided and discussed at a pace suitable for the young person and their parents or carers, including before, as part of, or after various elements of the health assessment.

Information should be communicated in a way that accommodates the needs of the young person and their parents or carers, including consideration of neurodivergence, disability, cultural and linguistic diversity, and health literacy. Healthcare professionals can offer additional appointments to discuss information and answer questions, individually or as a family. This may be important when one or more of the young person's parents or carers are uncertain or do not support the young person's desire to access care, as shared decision-making may mitigate the need for court involvement.

Healthcare professionals should refer the young person and their parents or carers to appropriate clinicians or health services if they cannot provide this information.

There is a prolonged uncertainty that accompanies delayed referrals and being placed on waiting lists to access care.[17] Health services should ensure young people and their families have timely access to referrals, information, and care. Providing information about services, wait times, and treatment options prior to health service access and during waiting periods can help foster trust and allow the young person and their family to make informed decisions about accessing care.[80]

6.2 Health assessment prior to commencing GnRH agonists

Good Practice Statement

vii. Healthcare professionals should conduct a comprehensive health assessment before prescribing GnRH agonists to suppress puberty in a trans and gender diverse young person.

Remarks:

Undergoing a health assessment prior to commencing medication is a standard part of medical practice and informs the shared decision made by patients and clinicians about using the medication. For a trans and gender diverse young person wanting to commence GnRH agonists to suppress puberty, the health assessment will include appointments with medical specialists and additional tests (e.g. blood tests).

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The health assessment should be accommodating of neurodivergence, cultural and linguistic diversity, and disability, and should consider:

- The young person's goals, including embodiment goals and other goals beyond medical care, such as exploring gender, obtaining psychosocial support, or support with social transition.
- Information relevant to the young person's gender, to determine whether they meet the criteria for gender incongruence (assessed according to ICD-11 gender incongruence in childhood – HA61, and gender incongruence in adolescence or adulthood – HA60).
- Assessment of pubertal development and Tanner staging. There are no set ages at which puberty begins, progresses, and ends for every child. With respect to Tanner staging, physical examinations should only be conducted with the young person's consent, and refusal of consent should not prevent the young person from accessing GnRH agonists where the history and hormonal assessment indicate the young person is in puberty.
- The young person's medical history, including any co-existing physical or mental health conditions and the management of those conditions, current medications, allergies, any contraindications for GnRH agonists and, where possible, a family medical history. The diagnosis of any condition or illness on its own should not prevent the young person from accessing GnRH agonists, but possible interactions between GnRH agonists and other medications should be considered.
- Baseline assessment of general physical health (e.g. blood tests). The use of Dual Energy X-ray Absorptiometry (DEXA) scanning to assess bone mineral density can be considered.
- Baseline assessments of mental health and wellbeing, including a mental health history and exposure to bullying, stigma or discrimination that could contribute to minority stress.[81,82]
- The young person's social history, including family relationships and community context. This may include considering factors relevant to providing culturally safe care. This may also include discussing aspects of social transition with the young person and their parents or carers, but there is no requirement for the child to be socially transitioning prior to being prescribed GnRH agonists.

Safety concerns raised as part of the initial assessment or regular monitoring (e.g. reports of worsening distress or suicidal ideation) should be addressed with the young person, their parents or carers, and by timely referral to relevant specialists and community support. Experiencing distress or suicidal ideation, or the management of other health conditions, may not prevent access to care but may necessitate additional care and multidisciplinary input.

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6.3 Multidisciplinary input

Good Practice Statement

viii. Healthcare professionals should tailor multidisciplinary input to the needs of the young person, to assist with the assessment and monitoring of a young person on GnRH agonists.

Remarks:

Multidisciplinary input should be determined on a case-by-case basis to carry out the health assessment, provide information as part of shared decision-making, and undertake the monitoring requirements for each young person's care. The need for, timing, and scope of multidisciplinary input will vary based on the needs of the young person and the experience and expertise of the healthcare professional.

Some young people will require multidisciplinary input throughout their care, while others will not require as much input before being able to make an informed decision about the use of GnRH agonists alongside their parents or carers. For example, in one case, a paediatrician seeing a young person and coordinating their care may consult with an endocrinologist for clinical advice and may refer the young person to a psychologist for psychosocial support. In another case, a young person may also need to regularly see a psychiatrist and social worker as part of their care. The full guidelines will include a section expanding on recommendations for psychosocial support.

Multidisciplinary input may ultimately include endocrinologists, child and adolescent psychologists, child and adolescent psychiatrists, paediatricians, general practitioners, nurses, social workers, speech pathologists, fertility specialists, peer support workers, or any other healthcare professional. However, the lack of availability of multidisciplinary services should not be used as a barrier to delay or prevent access to care. Paediatric gender services in Australia include multidisciplinary input as part of their models of care, and input can include telehealth and healthcare professionals who are not linked to a single service.

The nature of the multidisciplinary input that is required (and the reasons why it is required) should be clear to the young person and their parents or carers. Arrangements should be made for coordination and continuity of care, acknowledging that managing multidisciplinary input can be challenging for young people and their parents or carers, who may need to advocate for referrals and appointments across specialties (particularly in the private sector), navigate waiting lists, and provide information ahead of and during appointments to inform healthcare professionals and support the young person.[17]

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6.4 Regular monitoring of a young person on GnRH agonists

Good Practice Statement

ix. While a young person is receiving GnRH agonists for puberty suppression, healthcare professionals should conduct appropriate monitoring of their health and wellbeing.

Remarks:

Regular monitoring is important to assess the health and wellbeing of the young person over time, including whether the use of GnRH agonists is successfully suppressing puberty and whether there are any indications that GnRH agonists are no longer suitable for that person.

Regular monitoring includes clinical appointments with the young person to discuss their goals, their satisfaction with care, their experience in receiving GnRH agonists, and their desire to continue treatment.

A young person should be monitored for side effects and signs of rare but serious adverse events, including those detailed in the medication's product information. This includes monitoring for any injection-site reactions, headaches, and/or other symptoms that may warrant additional investigations and management.

Additionally, repeating initial baseline tests that are part of the health assessment enables decisions on injection frequency, optimising physical health, and detecting and managing health impacts. This includes monitoring bone mineral density as well as levels of LH and FSH, estrogen or testosterone.

Any changes to the young person's health and wellbeing while receiving GnRH agonists should be discussed with the young person and with their parents or carers, with arrangements made for appropriate additional care as needed.

Importantly, not all matters identified through regular monitoring will be due to the use of GnRH agonists. Where test results indicate a separate concern (e.g. a current infection), the young person should be informed and referred for additional care. Where the patient or family reports concerns that are not directly related to the use of GnRH agonists as part of regular monitoring (e.g. continued or worsening distress and related impacts to their quality of life) these should also be discussed, with arrangements made for appropriate additional care as needed.

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7 What comes next

Advice on Puberty Suppressants was prioritised as part of the guideline development process, but the use of GnRH agonists to suppress puberty does not represent the full scope of care that can be provided to young people with gender incongruence. The full clinical practice guidelines will also include advice on the use of hormones and psychosocial support.

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Appendix A. Summary of findings

Summary of findings: effects of puberty suppressants on critical and important outcomes

Puberty suppressants compared to no puberty suppressants for young people experiencing gender incongruence or dysphoria

Patient or population: young people experiencing gender incongruence or dysphoria who commenced puberty suppression at <18 years of age

Setting: Any care setting was eligible. Care was provided in specialist gender clinics in 12 of 15 studies, paediatric hospitals (Emergency Department (ED) or inpatient admissions) in one study, and not reported in 2 studies (studies using national population data). Countries: 5 Netherlands, 3 UK, 3 USA, 1 Germany, 1 Israel, 1 Italy, 1 Sweden.

Intervention: puberty suppressants (gonadotropin-releasing hormone agonists, GnRH agonists). We included studies in which some participants had received gender-affirming hormones (GAH) if effects of puberty suppressants could be isolated. We included results from one study where participants had also received GAH and gender-affirming surgery because the study examined potentially serious Adverse Effects (AEs) for those who underwent future gender-affirming surgery and compared outcomes for people who had received puberty suppressants with those who had not.

Comparison: no puberty suppressants. Gender-affirming care (GAC) was provided to both groups in 12 of the 15 studies with results in this table. Three of the 15 studies did not report whether GAC was provided. In two of these studies, data were from a national population sample (one study from the USA that contributed data on mental health; one study from Sweden on idiopathic intracranial hypertension). The third was a multi-centre study using data from paediatric hospitals (a study in the USA on suicidality diagnoses).

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		no puberty suppressants	**puberty suppressants**	**Difference**		
CRITICAL OUTCOMES						
Pubertal development (AMAB): penile length (cm) follow-up: range 4 to 5 years № of participants: 103 (1 non-randomised study)	-	The mean penile length without puberty suppressants was **12.8** cm	-	MD **3.26 cm shorter** (3.44 shorter to 3.09 shorter)	⊕⊕⊕◯ Moderate[a,b]	Puberty suppressants (GnRH agonists) likely suppress pubertal development importantly (shorter penile length) compared to no puberty suppression. Effects were larger among those who received puberty suppressants at Tanner stage 2/3 (MD 4.90 cm shorter, 95% CI: 4.63 to 5.17 cm shorter). [c]
Pubertal development (AFAB): menstruating follow-up: range 3 to 12 months № of participants: 143 (4 non-randomised studies)	In all four studies, none of the young people who were at menarche before puberty suppressants (baseline: 15/19, 20/22, 49/65, 35/37) had menses after puberty suppressants (follow-up: 12, 3, 12 and 12 months respectively). Proportion menstruating at follow-up: 0.00 (95% CI: 0.00 to 0.01)				⊕⊕⊕⊕ High[d]	Puberty suppressants (GnRH agonists) suppress pubertal development (menstruation) importantly compared to no puberty suppression. The effects were very large in all four studies.

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		no puberty suppressants	**puberty suppressants**	**Difference**		
Pubertal development (AFAB): breast cup size B or larger follow-up: range 4 to 5 years № of participants: 126 (1 non-randomised study)	RD 47 fewer per 100 had a breast cup size of B or larger (95% CI: 32 fewer to 62 fewer)				⨁⨁◯◯ Low[a,e]	Puberty suppressants (GnRH agonists) may suppress breast growth importantly compared to no puberty suppression. Effects were larger among those who received puberty suppression at Tanner stage 2/3.
Gender dysphoria assessed with: Utrecht gender dysphoria scale (lower is better) follow-up: range 12 to 24 months № of participants: 100 (3 non-randomised studies)	-	-	-	SMD **0.06 SD lower** (0.25 lower to 0.13 higher)	⨁◯◯◯ Very low[f,g]	The evidence suggests that there may be little to no change in gender dysphoria between commencing puberty suppressants and follow-up, but the evidence is very uncertain. [h]
Body image and satisfaction assessed with: Body image scale (overall or secondary sex characteristics, lower is better) follow-up: range 12 to 24 months № of participants: 118 (3 non-randomised studies)	-	-	-	SMD **0.15 SD higher** (0.03 lower to 0.33 higher)	⨁◯◯◯ Very low[f,i]	The evidence suggests that there may be little to no change in body image and satisfaction between commencing puberty suppressants and follow-up, but the evidence is very uncertain.[h]
SAE: idiopathic intracranial hypertension (IIH) assessed with: ICD10 code during inpatient visit or specialist outpatient care № of participants: 4230 (1 non-randomised study)	Incidence rate difference: 15.7 fewer IIH events per 100,000 person-years among those receiving PS (95% CI: 37.4 fewer to 6.1 more per 100,000 person-years) [j] No cases of IIH were identified among individuals receiving GnRH agonists (410 people, median follow-up 1.4 years)				⨁⨁◯◯ Low[k,l]	Puberty suppressants may have little to no effect on the incidence of idiopathic intracranial hypertension (a serious but rare adverse outcome) compared to no puberty suppressants.

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		no puberty suppressants	puberty suppressants	Difference		
SAE: QTc interval assessed with: ECG follow-up: range 2 to 3 months № of participants: 16 (1 non-randomised study)	Trans women: MD 20.5 ms longer (95% CI: 4.3 longer to 36.7 longer) Trans men: MD 12.5 ms longer (95% CI: 8 shorter to 33 longer)				⊕◯◯◯ Very low[m,n]	Puberty suppressants may have little to no effect on QTc interval (which, if prolonged, is a risk factor for serious heart rhythm abnormalities) but the evidence is very uncertain.
Amount of breast tissue resected (grams) in future surgeries (SAE: invasive mastectomy) follow-up: range 4 to 5 years № of participants: 174 (1 non-randomised study)	-	The mean amount of breast tissue resected in future surgeries (SAE: invasive mastectomy) without puberty suppressants was **684** grams	-	MD **248 grams lower** (270 lower to 226 lower)	⊕⊕⊕◯ Moderate[a]	For those undergoing future gender-affirming surgery, puberty suppressants probably result in less invasive mastectomy (i.e. a large reduction in the amount of breast tissue removed or resected). Effects were larger among those who received puberty suppressants at Tanner stage 2/3 (MD 540 grams less tissue resected, 95% CI: 605 lower to 475 lower).
IMPORTANT OUTCOMES						
Satisfaction with care (gender-affirming prior to receipt of GAH) - not reported	-	-	-	-	-	
Quality of life and wellbeing assessed with: Kidscreen-27 or SF-8 (higher is better) follow-up: range 18 to 24 months № of participants: 32 (1 non-randomised study)	-	-	-	SMD **0.77 SD higher** (0.03 higher to 1.5 higher)	⊕◯◯◯ Very low[o,p]	The evidence is very uncertain about the effect of puberty suppressants on quality of life and wellbeing (due to the extremely wide confidence interval).

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		no puberty suppressants	puberty suppressants	Difference		
Functioning (socially; family) assessed with: Youth self-report (YSR - social problems scale); Child Global Assessment Scale (CGAS) (lower is better) follow-up: range 18 to 24 months № of participants: 991 (4 non-randomised studies)	-	-	-	SMD **0.3 SD lower** (0.45 lower to 0.15 lower)	⨁⨁◯◯ Low[q,r]	Puberty suppressants may improve functioning (overall psychosocial, social) importantly.
Mental health - symptoms (psychological functioning) assessed with: Youth self-report (overall, internalising) (lower is better) follow-up: range 18 to 24 months № of participants: 4414 (4 non-randomised studies)	-	-	-	SMD **0.39 SD lower** (0.68 lower to 0.11 lower)	⨁⨁◯◯ Low[s,t]	Puberty suppressants may improve psychological functioning importantly.
Mental health - suicidality (attempts or thoughts, as diagnosed at ED or inpatient visit) assessed from electronic health records at 5 paediatric hospitals follow-up: mean 2 years № of participants: 3321 (1 non-randomised study)	**HR 0.79** (0.47 to 1.31)	**Moderate risk** 16.0%	**13.0%** (8 to 20)	**3.0% fewer** (8.0% fewer to 4.0% more)	⨁◯◯◯ Very low[u,v]	Puberty suppressants may reduce suicidality diagnoses, but the evidence is very uncertain. Using the baseline risk for suicide attempts reported in Trans Pathways (an Australian national survey of young TGD people), puberty suppressants may lead to 3 fewer diagnoses of suicidality in an ED/inpatient setting per 100 people over 12 months.
Mental health - death by suicide - not reported	-	-	-	-	-	
AE: bone fracture - not reported	-	-	-	-	-	

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		no puberty suppressants	puberty suppressants	Difference		
AE: fertility - not reported	-	-	-	-	-	

The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **HR:** hazard ratio; **MD:** mean difference; **SMD:** standardised mean difference; **RD:** risk difference; **AMAB**: assigned male at birth; **AFAB**: assigned female at birth; **PS** = puberty suppression; **GnRH agonists** = gonadotropin-releasing hormone agonists, **GAC** = gender-affirming care, **GAH** = gender-affirming hormones, **GAS** = gender-affirming surgery, **ED** = emergency department, **AE** = adverse event, **SAE** = serious adverse event, **cm** = centimetres, **ms** = milliseconds
Thresholds. The thresholds for an important effect (benefit or harm) were agreed prior to the GDC seeing results. These thresholds were used for interpreting point estimates and assessing certainty of the evidence and were as follows.

- Pubertal development – penile length: 10% difference in length (in centimetres). Shorter penile length indicates pubertal suppression.
- Pubertal development – menstruating: 10 fewer [or more] people menstruating per 100. Fewer people menstruating indicates pubertal suppression.
- Pubertal development – breast cup size B or above: 10 fewer [or more] people with a breast cup size of B or above per 100 people. Fewer people with a breast cup size of B or above indicates pubertal suppression.
- Gender dysphoria, body image and satisfaction, quality of life and wellbeing, functioning, mental health symptoms – psychological functioning: SMD of 0.2. A lower score (i.e. SMD of -0.2 or below) is better for all outcomes (i.e. less dysphoria, less body dissatisfaction, fewer problems with psychosocial functioning, fewer problems with psychological functioning) except quality of life (SMD of 0.2 or above is better).
- Serious adverse events – idiopathic intracranial hypertension (IIH): 20 more with incident IIH per 100,000 person years. Fewer people with IIH is better. The threshold is set low because this is a rare adverse event (not an outcome that is a goal of treatment). Left undetected, IIH can have serious undesirable consequences.
- Serious adverse events – QTc interval: change from baseline of ≥30 ms. Based on ICH E14 / FDA guidance where an increase of ≥30 ms signals a potential concern (>500 ms or of >60 ms over baseline are commonly used as thresholds for potential discontinuation)
- Serious adverse events – breast resection volume for those undergoing future gender-affirming surgeries: 10% difference in volume resected. A reduction in the amount of breast tissue removed or resected indicates less invasive surgery.
- Mental health symptoms – suicidality: 1 fewer [or more] person with a diagnosis of suicidality per 100 people over 12 months.

No eligible studies reported on satisfaction with care, mental health – death by suicide, adverse events – bone fracture or other functional measures of bone health, adverse events – fertility potential
Control group risk. The baseline risks for 'attempted suicide in the last 12 months' was from Trans-pathways 2017, a large Australian survey of trans and gender diverse young people. https://www.thekids.org.au/projects/past/trans-pathways/

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Serious risk of bias (-1)/large effect (+1): study with 100% of weight in the analysis rated at moderate risk of bias. This effect is large (both the point estimate and either end of the 95% CI indicate large effects relative to the threshold, with the direction of effect reversed from usual pubertal development), offsetting concerns about risk of bias and justifying an upgrade for a large effect (+1).
b. Serious indirectness (-1): Tanner stage provides a more direct measure of pubertal development than penile length.
c. Compared to no puberty suppression, for those who commenced puberty suppression at Tanner stage 4/5 penile length was MD 2.10 cm shorter (95% CI: 1.87 to 2.33 cm shorter).
d. Very serious risk of bias (-2)/very large effect (+2): all four studies used an uncontrolled before-after design, but the effect is unlikely to be explained by bias alone. The effect is very large (the point estimate and both ends of the 95% CI indicate very large effects relative to the threshold, with the direction of effect reversed from usual pubertal development), so the evidence was upgraded for a very large effect (+2).
e. Very serious indirectness (-2): breast cup size is an indirect measure of pubertal development.
f. Extremely serious risk of bias (-3): all three studies use an uncontrolled before-after design and were rated at critical risk of bias for this outcome.
g. Serious imprecision (-1): the 95% CI crosses a threshold for an important effect (SMD=0.2) such that the result is compatible with important benefit (SMD= -0.25) and little to no change (SMD=0.13).
h. This finding is consistent with the hypothesis pre-specified in the protocol that puberty suppressants may prevent deterioration in gender dysphoria and body image and satisfaction, rather than improve these outcomes. See Figure 1 in the pre-specified protocol for

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this systematic review, which shows the underpinning logic for how these outcomes relate to the primary and secondary goals of treatment and the predicted effects.
i. Serious imprecision (-1): the 95% CI crosses a threshold for an important effect (SMD=0.2) such that the result is compatible with little to no change (SMD= -0.03) and slight, but important worsening (SMD=0.33).
j. The threshold for this outcome is set low because while this is a rare event, left undetected it can have serious consequences.
k. Serious risk of bias (-1): the single study is at moderate risk of bias due to confounding
l. Serious imprecision (-1): the 95% CI crosses a threshold for an important effect (20 events per 100,000 person years), so the result is compatible with important benefit (37 fewer cases of incident IIH) and little to no difference (6 more cases). Although the result is imprecise, there is no indication of important harm (i.e. no indication of an increase in the incidence of IIH above the threshold).
m. Extremely serious risk of bias (-3): single study that uses an uncontrolled before-after design.
n. Serious imprecision (-1): Using a threshold for change of 30ms, the 95% confidence interval slightly crosses the threshold such that the result is compatible with little or no difference and important harm. This is most likely due to the small sample size.
o. Extremely serious risk of bias (-3): single cohort study rated at critical risk of bias due to missing outcome data (follow-up data available for 75/204, intervention status ascertained at follow-up, so missingness may be due to intervention and outcome).
p. Extremely serious imprecision (-3): the 95% CI crosses a threshold for an important effect (SMD=0.2), but the result is compatible with very large benefit (SMD=1.5) and little to no difference (SMD=0.03), which is extremely imprecise.
q. Very serious risk of bias (-2): two studies at serious risk of bias, and one at moderate risk of bias. One study at critical risk of bias due to missing outcome data (showing a large effect) but this study has negligible influence on the analysis (weight 4%).
r. No serious imprecision: although the CI crosses the threshold for a small benefit, the effects favour puberty suppression and the upper bound of the CI (SMD=-0.15) is close to the threshold (SMD=-0.2).
s. Very serious risk of bias (-2): Most of the included studies are at serious risk of bias, including the study with 43% of the weight in the analysis.
t. No serious imprecision: although the CI crosses the threshold for a small benefit, the effect favours puberty suppression and the upper bound of the CI (SMD=-0.11) is close to the threshold (SMD=-0.2).
u. Very serious risk of bias (-2): study with 100% of weight in the analysis rated at serious risk of bias.
v. Very serious imprecision (-2): Using a 1% threshold for an important effect, the 95% CI crosses both thresholds such that the result is compatible with important benefit and important harm.

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