Te Kāwanatanga o Aotearoa
New Zealand Government

MINISTRY OF HEALTH
MANATŪ HAUORA

Position Statement on the Use of Puberty Blockers in Gender-Affirming Care

November 2024

Purpose

This position statement accompanies the release of an evidence brief which examines the safety and long-term impacts of puberty blockers when used in the context of gender-affirming care[1]. This statement summarises the brief's findings and sets out the Ministry of Health's expectations for their use.

In addition, it outlines our next steps that will ensure young people with gender incongruence and gender dysphoria have access to quality care. It also provides relevant information for health professionals, rainbow communities, and the general public.

Background

In September 2022, the Ministry of Health updated its position on the safety and reversibility of puberty blockers when used for gender-affirming care. This was in light of work underway in other jurisdictions examining the clinical effects of puberty blockers on adolescents. The evidence brief examines the risks and benefits of puberty blockers when used for gender-affirming care.

Reasons for prescription of puberty blockers

Puberty blockers, or gonadotrophin releasing hormone (GnRH) agonists, are used to treat precocious puberty[2] in children. In adults, the same medications can be used to treat endometriosis, breast and prostate cancer, and polycystic ovary syndrome.

Puberty blockers can also be used as part of gender-affirming care to delay the onset of puberty by suppressing oestrogen and testosterone. Clinicians can prescribe them to young people experiencing gender incongruence or gender dysphoria.

Gender incongruence is where an individual's experienced gender and their assigned sex (at birth) persistently do not match.

[1] Gender-affirmative health care can include any single or combination of a number of social, psychological, behavioural, or medical (including hormonal treatment or surgery) interventions designed to support and affirm an individual's gender identity. Source: World Health Organisation. n.d. *Gender Incongruence and Transgender Health in the ICD*. URL: **www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd** (accessed 22 April 2024).

[2] Precocious puberty is defined as the development of pubertal changes, at an age younger than the accepted lower limits for age of onset of puberty, namely, before age 8 years in girls and age 9 years in boys. Source: Cleveland Clinic. 2023. *Precocious Puberty/Early Puberty*. URL: **my.clevelandclinic.org/health/diseases/21064-precocious-early-puberty** (accessed 22 April 2024).

Gender dysphoria is where an individual's gender incongruence has an adverse impact on their health and wellbeing.

The evidence brief examines their use in the context of delaying puberty in adolescents experiencing gender incongruence or gender dysphoria.

Prescription of puberty blockers in New Zealand

In recent years, there has been an increasing awareness of puberty blockers as an option for gender-affirming care. A preliminary review of prescribing data shows a steady increase in the number of young people aged 12 to 17 receiving first-time prescriptions of GnRH agonists between 2010 and 2023. Other countries have observed a similar increase in prescribing of puberty blockers although due the quality of the data, meaningful direct comparison of prescribing rates is not possible.

While these medicines are not approved by Medsafe for the purpose of delaying puberty in gender incongruent or gender dysphoric young people, clinicians can prescribe them 'off label' under section 25 of the Medicines Act, 1981[3]. Use of section 25 is common in clinical practice particularly in paediatric services. Other examples of medications prescribed to young people under section 25 are fluoxetine for depression and melatonin for insomnia.

When authorised prescribers prescribe an unapproved[4] medicine they are expected to be working within their scope of practice. Clinicians need to make sure that the person receiving the medicine knows that the medicine is being used for an unapproved use and have an informed conversation with them about the potential risks and benefits, involving family, whānau, or caregivers where appropriate.

Medical practitioners are expected to meet professional practice and ethical standards and also ensure that they meet the provisions of the Code of Health and Disability Services Consumer Rights.

Guidelines for gender-affirming care have been independently published in New Zealand[5]. These guidelines set out the key considerations for health teams, including the prescribing of puberty blockers. There are also local clinical pathways within primary care and specialist services across New Zealand, but there is not currently a nationally consistent approach.

Clinicians should take a holistic approach and undertake a comprehensive assessment in the provision of gender-affirming care. Puberty blockers are one of a range of options (eg, medical, mental health, and social support) clinicians can discuss with individuals and their families.

[3] Section 25 of the Medicines Act allows an authorised prescriber to 'procure the sale or supply of any medicine' for a patient in their care. This means that prescribers may prescribe any medicine to a patient (within their scope of practice), regardless of whether it is approved or unapproved in New Zealand.

[4] An unapproved medicine is a medicine for which consent, or provisional consent, has not been given by the Minister of Health for sale, distribution or marketing in New Zealand, i.e. it has not been through the Medsafe regulatory process, approval has lapsed, the application was withdrawn or the product available is different in some way to the product that was approved. Unapproved medicines may still be prescribed to patients.

[5] Oliphant J, Veale J, Macdonald J et al. 2018. *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa New Zealand*. Transgender Research Lab: University of Waikato, URL: **patha.nz/Guidelines** (accessed 1 November 2024).

The international context

The World Health Organization (WHO) is in the process of developing a guideline on the health of transgender and gender-diverse people including health policies and legal recognition of self-determined gender identity. While the guideline will not be legally binding, it may influence current or future governance and legal structures.

The UK, Finland, Norway, and Sweden have recently decided to limit the initiation of new prescriptions of puberty blockers for young people seeking gender-affirming care to clinical trials. Young people already initiated on puberty blockers will continue to have access to these medications.

These countries have all expressed concerns about the lack of high-quality evidence on outcomes in the use of puberty blockers for gender incongruence and gender dysphoria. NHS England's independent review[6] also identified gaps in interprofessional approaches and variability in service access by patients. In Sweden[7] there were concerns relating to the consent process, and a lack of data to understand the context in which puberty blockers have been used.

In most Australian states and territories, the prescription of puberty blockers for people aged under 18 years requires consent from the young person, treating clinician and all parties who have parental responsibility for the young person. Prescribing is 'off-label'; the medications are not funded through the Pharmaceutical Benefits Scheme. As a result, prescription is most often through specialist services to enable access to heavily subsidised funding of the medicines through Department of Health and Aged Care investment.

Other countries, such as Canada and the Netherlands, continue to enable the prescription of puberty blockers through clinical processes involving individuals and their families, as part of comprehensive gender-affirming care. However, the Canadian province of Alberta is currently considering banning the use of puberty blockers for young people aged under 16 years, referencing the recent decision made by NHS England.

Evidence brief findings

Scope of the evidence brief

The evidence brief considers national and international peer-reviewed literature, published up until 30 September 2023. It also provides an overview of international regulations, governance structures, and guidelines, which has helped inform our position statement and next steps within the wider context.

Other international analyses and reports have been released since the initial completion of our evidence brief. An addendum to the evidence brief contains a further review of additional publications between October 2023 to May 2024, including the final Cass Report. The addendum

[6] Cass H. 2024. *The Cass Review: Independent review of gender identity services for children and young people: Final report.* URL: **cass.independent-review.uk/home/publications/final-report** (accessed 12 April 2024).

[7] *Gender dysphoria in children and adolescents: an inventory of the literature.* 2019. URL: **www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature** (accessed 22 April 2024).

should be read in conjunction with the evidence brief. Our overall assessment is that the new evidence published since September 2023 does not differ from the earlier evidence that we have included in the evidence brief. Therefore, our conclusions from the evidence brief remain.

Findings

The full evidence brief and addendum are available on the Ministry of Health website. Key findings are as follows:

- There is some evidence that for people treated with puberty blockers, bone density appears to increase at less than the expected rate for individual stage of development.
- Organ systems are often impacted by hormone medication. However, for those on puberty blockers, there is currently no evidence of impact on renal or liver function, the onset of diabetes, or fertility.
- Whilst there are some studies that suggest an improvement in depression, anxiety, and suicidal ideation for individuals treated with puberty blockers, the quality of the evidence is poor.

Overall, the evidence brief found significant limitations in the quality of evidence for either the benefits or risks (or lack thereof) of the use of puberty blockers. This means there is insufficient basis to say that puberty blockers are safe or reversible (or not) for use as an intervention for gender dysphoria in adolescents.

The Ministry of Health's position on the use of puberty blockers

Noting that the Government has signalled an intent to consider regulating puberty blocker prescribing in gender-affirming care, clinicians should exercise caution in prescribing. Clinicians who initiate puberty blockers should be experienced in providing gender-affirming care and be part of an interprofessional team offering a full range of supports to young people presenting with gender-related issues.

The prescription of medication to delay the onset of puberty in young people is a complex issue. The Ministry of Health acknowledges that there are strong and varied views relating to the area of gender-affirming healthcare. In relation to the use of puberty blockers, the Ministry is also aware of a range of experiences and views among young people who have lived experience of gender incongruence or gender dysphoria.[8]

It is the Ministry's role to ensure everyone in New Zealand can access high quality health care that meets their needs. Young people who experience gender incongruence or gender dysphoria have complex needs and require a range of psychological and medical supports. In case where puberty blockers are prescribed patients and their care givers must be fully informed regarding the current state of the evidence regarding their benefits and risks.

[8] Young people have rights under the UN Convention on the Rights of the Child (CRC) to both identity (Article 8) and to health (physical, mental), including equitable access to health care (Article 24). These rights sit among children's wider range of holistic rights under the CRC, which also includes the right and general principle that all decisions made about/or in relation to a child must be made in their best interests (Article 3), and the right and general principle to non-discrimination (Article 2) and to life, survival and development (Article 6).

Given the limitations in the quality of the current evidence, there is a need for high-quality, longitudinal data and research to understand the benefits and risks of puberty blockers when used for treatment of gender-incongruent and gender-dysphoric young people in New Zealand.

Information for health professionals

Under Right 6 of the Code of Health and Disability Services Consumers' Rights Regulations 1996[9], health professions must ensure that people presenting with any condition are given information that explains the options available to them including the expected risks, side effects and benefits of each option.

Clinicians who initiate puberty blockers should be experienced in providing gender-affirming care and be part of an interprofessional team. In their assessment, clinicians need to consider the possible presence of other associated conditions. Young people who experience gender incongruence experience higher rates of anxiety, depression, and suicidal ideation. They should have timely access to therapeutic supports which meet their mental health needs.

The use of puberty blockers in gender-affirming care remains a relatively new area of medicine. Available evidence is predominantly based on clinical experience and patient values and preferences, rather than clinical trials. The Ministry of Health expects healthcare professionals to ensure that clinical conversations about puberty blockers reflect the paucity of high-quality research evidence about the benefits and risks of using these medicines.

Information for young people experiencing issues related to their identity and their family/whānau

It is important to note that gender-affirming care is broader than just the prescription of puberty blockers.

Advice and support are available through primary care providers including your general practice and other community-based services. A range of care options are available and, where appropriate, primary care providers can make a referral to specialist services. It is important to have an individualised care plan that meets your particular needs.

No medical intervention is entirely without risk. Clinicians will continue to provide careful guidance to and follow-up for people and families considering gender-affirming care.

Next steps

The Government has signalled an intention to consider regulating the prescribing of puberty blockers in gender-affirming care. The Ministry of Health will continue to assess the emerging evidence on the safety and long-term impacts of puberty blockers in gender-affirming care, and will provide updates to this position statement as necessary.

[9] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. URL: **hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights** (accessed 1 November 2024)

Young people experiencing gender incongruence or gender dysphoria should have access to comprehensive quality care. To that end the Ministry of Health:

- will work with Health New Zealand – Te Whatu Ora to enhance governance and monitoring of gender-affirming care to ensure the safe and evidence-based delivery of gender-affirming care
- will continue to monitor emerging evidence in the field of gender-affirming care and review the international context in relation to the use of puberty blockers
- will commission New Zealand research to determine the long-term clinical and mental health and wellbeing impacts of puberty blockers in young people with gender incongruence or gender dysphoria
- has established an external advisory group to consider system wide issues and provide advice relating to gender-affirming care.

Health New Zealand is currently developing an updated set of guidance to support clinicians providing gender-affirming care, including the use of puberty blockers. The evidence brief will be available to inform those guidelines.

The Ministry of Health will work closely with Health New Zealand and other partners to ensure young people experiencing gender incongruence or gender dysphoria have access to care which meets their physical and mental health needs and upholds their holistic range of rights as young people.

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