ACT Government

Summary of information session on Variations in Sex Characteristics care reforms

24 January 2023

Chief Minister, Treasury and Economic Development Directorate

Summary of information session on Variations in Sex Characteristics care reforms

This document is a summary of an information session delivered by Dr Hannah Holland on 24 January 2023 on the ACT government's Variation in Sex Characteristics reforms.

What this information session covered

- Overview of why the reform is taking place, and the goal of the changes.
- Overview of the reform proposal, including the government's budget commitments announced in 2022.
- Forthcoming legislation including an explanation of the differences between the current draft of the Bill, and the draft that was put out for consultation in 2022.
- Next steps in the process and how to get in touch with the project team

The session reflected policy decisions made up to January 2023. However, as with any complex reforms, there are still processes to be worked through within government before the Bill is finalised, as well as parliamentary processes that may impact the final form or timing of the Bill. The information shared during this session represented the project team's best understanding of what the final legislation will involve, although there may be further changes between 24 January 2023 and when the legislation is released to the public or passed by the Assembly.

Why this reform

People who are intersex, or have variations in sex characteristics, are born with sex characteristics (such as genitals, gonads or chromosome patterns) that do not fit typical binary notions of male or female. Today I will use both terms, but recognise that not everyone uses either term, with some preferring to refer to the individual variation they have, or to refer to these variations as DSDs. The government's project treats all these terms as interchangeable and as being about bodily diversity. They are not used to refer to a person's identity.

To ensure that the bodies of intersex people, particularly children, are respected, and that they receive the best available care and support, the ACT government is looking at ways to manage permanent medical interventions that are different to some past and current practice.

International published research indicates that the circumstances around contemporary medical care for intersex people present ongoing challenges including the risk of violation of the human rights of intersex children.

From consultation with healthcare consumers and healthcare practitioners in Australia, we know that:

- some people with variations in sex characteristics are insufficiently involved in decision-making about their bodies in which they have the capacity to engage;
- families are not always offered sufficient information that respects the human rights of the child, and sometimes do not have access to adequate support and expertise; and

- In the largest survey of people with variations in sex characteristics in Australia, the majority reported not being told about risks related to the interventions, or about their right to not have these often life-changing treatments, or other related information, with participants also reporting various physical, mental or psychological impacts from treatments.

United Nations committee reports on Australia, as well as an in-depth examination by the Australian Human Rights Commission, have all called for Australian jurisdictions to legislate to prevent deferrable medical interventions on intersex children.

The government's intended outcome

That Canberrans who have variations in sex characteristics have access to high-quality healthcare that respects their bodily integrity and upholds their right to make their own decisions about medical intervention.

The reform process

These reforms have been built on an extensive process of research, consultation, input from experts in the field and people with lived experience, and analysis of available evidence.

There have been three major phases of open stakeholder consultation. After each phase, the government published a listening report summarising all stakeholder feedback. All of these are available on our webpage.

In December 2020, the government released a discussion paper. In April 2021, the government commissioned a legal issues workshop to better understand the legal factors that may be relevant in designing the regulation of deferrable medical interventions on intersex people. A report summarising workshop discussions, prepared by Equality Australia, was published.

There were three major policy conclusions reached as a result of these early phases of work. These were:

- The need for additional psychosocial and peer supports to be provided to people with variations in sex characteristics and their families, particularly if there was to be regulatory oversight.
- A decision not to seek to prohibit outright any medical interventions.
- The necessity for legislative action in order to meet the policy's goals.

In June-July 2021, the government released an options paper for stakeholder feedback. Whereas the first paper sought input on issues generally, this second sought responses around implementation options.

Based on all of the sources of information, including community consultations, legal advice, research and expert input, the government prepared draft legislation and released it for community consultation in May-July 2022. Many of you were involved in responding to that draft, and we thank you for your contributions. The public consultation gathered more than 70 written submissions. Four dedicated workshops were held for human rights and legal experts, intersex advocates and people with lived experience, local clinical and healthcare workers, and medical colleges and professional associations.

A listening report summarising the feedback and perspectives received during the consultation has been published.

Brief description of reform

This proposed approach has two core components. Firstly, improvements to services to increase the availability and quality of care for intersex people and their families, especially when making healthcare decisions. Secondly, a regulatory framework that will ensure people with intersex variations are subject to a requirement for the intervention to be the least restrictive of the person's freedom to make any future decisions about their variation in sex characteristics. This will include professional oversight of medical decisions in situations where a person is too young or unable to provide their own informed consent.

Care will look different in several ways:

- People with variations in sex characteristics and their families will gain access to the psychosocial support and care coordination services of a new Variations in Sex Characteristics Psychosocial Support Unit (VPSU);
- People with variations in sex characteristics and their families will be referred, and have access to, peer support services, which received additional funding from the ACT government's budget; and
- If a person does not have the capacity to give legal consent to a medical intervention that will have permanent effects on their sex characteristics, their treatment decisions will gain additional oversight from the committee established under the new Act.

Budget initiatives

This is a significant reform for the ACT government, which recognised that it would need to be resourced. In the 2022-23 Budget, the government committed to:

- $1.24 million over three years for the establishment and operation of the new statutory body.
- $170,000 over three years from 2023-24 to boost funding for peer support services.
- $1.12 million over four years for the establishment of a Variations in Sex Characteristics (VSC) Unit and to develop training packages for health professionals.
- $30,000 to fund a community education and awareness campaign.

The ACT is a small jurisdiction of less than half a million people. To give you an idea of the scale of this reform, if we applied the announced ACT funding per head of population to a jurisdiction with a population of 6.5 million, the budget of the Variations in Sex Characteristics (VSC) Unit and training would be $16 million.

The legislation

We are now in the process of finalising revised legislation, taking into account all of the feedback and advice we have received. Once government is satisfied with the final bill, we expect it to be introduced into the Assembly this quarter.

Key features

The legislation will establish a new process when medical treatment for people with variations in sex characteristics is being considered. It will authorise these interventions where conditions are met, which are set out in the Bill.

What is a variation in sex characteristics? The bill is expected to defines variations as “a congenital condition that involves atypical sex characteristics”. Sex characteristics, are defined as:

> (a) a person’s chromosomal, gonadal or anatomical sex; and
>
> (b) includes— (i) the person’s hormones that are related to sex; and (ii) the sexual and reproductive parts of the person’s anatomy; and
>
> (iii) the person’s secondary physical features emerging as a result of puberty.

This definition has drawn on definitions used elsewhere and is designed to provide legal clarity.

To provide further certainty about what the law covers, the definition will support creation of a list of named variations that are examples of what the term includes. The regulations will also include a list of variations that the authorisation process in the bill will not apply to. I will talk about what is in those two lists later in this session. For now, the key point is that the legislation will apply to all variations in sex characteristics, regardless of the formal diagnosis, with a small number of conditions being exempted from the bill’s authorisation processes. The approach in the bill applies human rights already recognised in ACT law to important decisions. These include the rights not to receive medical treatment without consent, and the right of children to special protection, free of discrimination.

The legislation’s scope will be limited. It will allow medical treatment where:

- The medical procedure is emergency treatment for the health of the person; or
- The treatment will not permanently change the person’s sex characteristics; or
- The treatment does not affect their sex characteristics; or
- The person has capacity to consent to the medical procedure for themselves.

If a medical treatment proposed for a person with variations in sex characteristics does not meet any of those conditions, then it will be a restricted medical treatment. What kinds of treatments are we regulating? Things like labiaplasty, phalloplasty, gonadectomy, or hormone treatments that produce secondary sex characteristics that would be permanent even if the hormone treatment were to cease.

If something is a restricted medical treatment, it will need to be covered by a treatment plan that is approved by a new statutory body, the Restricted Medical Treatment Assessment Board, to be set up under the legislation. The process will be similar to how some mental health treatments are administered under current ACT law.

The Board will be made up of individuals with expertise or experience in five different categories: human rights; medicine; ethics; lived experience of variation in sex characteristics; and provision of psychosocial support. Each time a decision is required, an assessment committee will be created, made up of one member from each of the five categories of expertise from the Board’s membership. In the case of the medicine category, there will be additional guidance in the regulations to support recruitment of members with relevant medical specialities.

We know that timeliness can be important to care decisions, so we are suggesting the legislation will require that a committee must be convened within a reasonable timeframe, at most, 14 days after the application is received. In practice, if an applicant tells the Board that there is a reason they need faster consideration, we expect the Board to be responsive to that.

There will be two types of treatment plans: individual, and general.

An individual treatment plan will be a plan approved by a committee for a particular person. A proposed individual plan can be submitted by treating doctors or by parents or guardians, with the input of the person affected, if they are able to communicate their wishes. The proposed treatment plan will need to set out a range of information and evidence. Some of this will be specified in the legislation; some may be requested by the committee. If the individual treatment plan is approved, then treatment can occur consistent with the plan.

A general treatment plan will be a plan approved by a committee for medical treatments of a particular type or for all people with a particular variation in sex characteristics. General plans will not refer to a specific individual, although each individual will still need to be appropriately involved in decision making that occurs under a general plan. It is expected that these applications will usually occur for the more common variations in sex characteristics, and where there is a strong evidence base for treatment that should commence during childhood. Just to illustrate the kind of thing that could be in scope of a general plan, a hypothetical example could be the administration of growth hormone from a young age, with or without oxandrolone, for children with a Turner Syndrome-type diagnosis. It is expected that in most cases general treatment plan applications will come from groups of health professionals or specialist associations, or from an association of people with variations in sex characteristics.

Once a general treatment plan has been approved by a committee, it will be published, so that it is accessible for all health professionals and families. Health professionals can then undertake a medical treatment of the type covered by a general plan, without needing an application for an individual medical treatment plan. The consideration and approval of proposed general treatment plans will include a period of consultation, including with health professions and community organisations.

In considering either a general or individual treatment plan, the legislation will require committees to approve plans where all the necessary criteria are met. Their role is not to determine the best treatment for an individual, but to check that any proposed treatments will be consistent with the rights of people with variations in sex characteristics. In a moment, I will talk about what the decision criteria for the committees are, because they have changed since the previous draft bill.

Individual treatment plans are expected to be approved for a period of up to three years – it will be up to the committee, drawing on information provided in the application and all other information available to them, to determine what is the right time period for that individual's plan. General plans are expected to be approved for a fixed period of five years and can be reviewed and renewed after this time.

If an applicant for a treatment plan – whether individual or general – is not satisfied with the committee's decision, the bill contains two levels of review. In the first instance, the applicant can seek internal review. In this case, a fresh committee, of five different members of the Board, is convened to review the decision. If the applicant is still not satisfied, there will be an avenue of review to the ACT Civil & Administrative Tribunal, or ACAT. In both cases, the intention is to provide easily accessible pathways for decision review, that do not require going to court.

Something that both health professionals and community advocates have sought is better information and longitudinal data about treatments of variations in sex characteristics. The bill will require treating medical professionals to report to the Board de-identified data about treatments performed under a treatment

plan. We also anticipate that it will require reporting of treatments that are undertaken under the exemption for urgent medical treatment. I will elaborate on this further shortly when I discuss scope of the scheme.

There are several things that this legislation does *not* do:

- It does not regulate decisions where the person themselves is consenting to the treatment, including a legally consenting child. The capacity to consent is covered by existing common law, unchanged by this reform.
- It does not replace parental decision-making. Parents will be able to choose and consent to any treatment that the committees have agreed should be available. Parents will be able to be the applicants for treatments to be approved. Parents will remain the people who consent to a treatment, where a child is not providing that consent themselves.
- It does not displace the role of multi-disciplinary teams. The government supports referral to MDTs, and advice from MDTs would be among the information a committee would consider when making decisions.

Key changes since the draft legislation was released in May 2022

The government received many suggestions and comments on the draft bill, which has led to an extensive overhaul. Two of the main areas of feedback have been the scope of the bill; and the decision-making criteria to be applied by committees when assessing treatment plans.

Scope

As I mentioned earlier, variations in sex characteristics are congenital conditions that involve atypical sex characteristics. The published medical literature is consistent in indicating what doctors consider this field to include. There are very few areas in which health professionals debate what is covered or not covered by the term. There is a slightly broader range of understanding in the advocacy community, but there is a common core of shared understanding across everyone.

Despite this, throughout this project, there have been strong differences of opinion between stakeholders about what the scheme should cover. Some of this disagreement is based on misunderstandings of the reform's intent; some is based on different views about the benefits and risks of the reform. Extensive consultations, workshops and meetings have done little to change the level of disagreement.

Given this, we have focussed on several factors in determining the scope. These are:

- ensuring a clear definition, so that whatever the scope may be, everyone understands it.
- ensuring the scheme, one of the first of its kind in the world, is not only legislated but successfully implemented, with meaningful decision reviews, effective care provision by the new psychosocial care unit, with resources not been stretched too thinly.
- Putting in place mechanisms that will support review and adjustment to the scope of the scheme, given its innovative nature.

The main change from the draft bill is that the law will no longer rely on a list of variations to define what is in scope. Regardless of formal diagnosis or label, congenital conditions that involve atypical sex characteristics will be covered by the law. The type of list you saw in the draft bill is being retained as a non-exhaustive list of what is included, but is no longer the way in which variations are defined, as this is

covered by the broad definition outlined earlier. The regulations will also include a list of some variations that are going to be excluded from the approval process.

We recognise that there may need to be future adjustments to explicitly bring a variation in sex characteristics into scope of the authorisation process or, possibly, to move it outside that process. There are at least two avenues to do so:

- individual diagnoses will be able to be brought in or out of scope through the making of a regulation, following a consultation process. The legislation itself will not need to be amended to achieve this; and
- a review of the operation of the scheme will be written into the Bill, providing a formal public opportunity for consideration of the scope, which will be five years after commencement.

Our intention is that the legislated authorisation processes will apply to all variations in sex characteristics, except for a small number of items. These have been excluded either because they are not generally considered to be variations in sex characteristics, or because their inclusion could place undue pressure on the resources of both the Board and the psychosocial care unit, without necessarily delivering evidence-based benefits for people with variations. The exclusions in the regulation are proposed to be:

(a) bladder exstrophy;
(b) epispadias;
(c) hypospadias, other than proximal hypospadias with cryptorchidism;
(d) gender dysphoria;
(e) polycystic ovary syndrome;
(f) undescended testis.

If a person with one of the above also has another variation, then they will be covered by the bill for all their variations. A person will only be excluded if the condition on that list is their only variation.

The government recognises that most stakeholders either want other things taken out, or want one or more of these exclusions re-inserted.

To those who want more removed, particularly some common endocrine variations, the government's emphasis is on providing additional protections and services, not impeding care decisions. This is why, for example, general care plans will be able to be put in place before the scheme becomes fully operational. By including these people, and allowing general treatment plans to support evidence-based treatments, it ensures that the person with the variation and their family have access to new psychosocial care services, ensures referral to peer support services, and helps support a focus on evidence, and on adopting the most recent evidence in the field. It also reflects that, even for common variations, the evidence base is often weak and sometimes contested, including amongst medical specialist researchers. In this environment, having additional 'eyes on' will contribute to outcomes upholding human rights, including to the best possible care.

To those who want exclusions brought back in, we point out that these exclusions are in the regulations, and have been based on weighing up all the information available. However, the government recognises the argument that, without information about what procedures are being performed, how can we be sure that it is the right call to exclude particular variations? Accordingly, it is now proposed that the bill require reporting to the Board de-identified data on all permanent medical treatments on people with the

excluded variations, and the publishing of summary data about these treatments, alongside data about the authorised treatments, in the annual report of the Board. We also expect the exclusion of variations, in particular non-proximal hypospadias, to be closely scrutinised in the legislated review.

In short, these are the initial policy settings, and we will continue to monitor evidence about the appropriateness of the exclusions. Among these, it is anticipated that there will be ongoing debate about the exclusion of some hypospadias.

Decision-making criteria

In the revised bill, the operation of the new statutory authority has been refined by limiting its role to testing whether a restricted treatment raises particular concerns, based on criteria set out in the bill. The criteria will be designed to address areas of known risk based on multiple sources of analysis and advice. These are:

1. Whether a person, particularly a child, may have the legal capacity to make the decision themselves, but they are not being recognised as the decision-maker;
2. Whether a person has been provided with the opportunity and appropriate support to form a view in relation to a treatment being suggested for them, and then been listened to;
3. Whether adequate information has been provided to a person and/or their family/guardian, including information about treatment choices and options to defer treatment;
4. Whether the person's views have been given sufficient weight;
5. Whether medical treatments are able to be deferred until the person is likely to be able to make, or to be involved in making, decisions about them, without risking harm to that person's health; and
6. Whether treatments are proposed to address a perceived risk of discrimination or stigmatisation.

The committee's responsibility will be to apply criteria that ensure these things have been appropriately considered and addressed. It will not be making treatment decisions or determining a person's best interests: it will be ensuring that people are protected and supported in addressing known areas of risk. The decisions must be made consistent with principles of administrative law, which include requirements around procedural fairness, protections against bias of a decision-maker, consideration of only relevant matters, and no consideration of irrelevant matters.

Other changes to the Bill

There are several other areas in which we have made changes to the draft bill circulated in May 2022.

The bill increases the visible role of parents, including by allowing both health professionals and parents or guardians to apply for medical treatment plans and to ask for reviews of statutory authority decisions.

Regarding timing: The government is giving careful consideration to how to avoid disruption to care of existing patients as well as to ensure care decisions can be made for new patients, including babies born during this current period when the bill is being prepared for introduction. This requires training of the healthcare workforce ahead of the legislation taking effect. It also requires a system that will ensure treatment plans are ready to support care decisions when the bill's provisions become mandatory. This is

being achieved by staging commencement to allow a period – which we are suggesting be six months - from when the bill is passed to when the Restricted Medical Treatment Assessment Board is established, then a further period – which we are suggesting be 12 months - in which the Board can operate and consider applications for treatment plans, before the regulatory provisions requiring authorisation of restricted medical treatments take effect around December 2024.

In response to representations from medical professionals, there will be included in regulations a requirement that the Minister, when appointing the members of the 'medicine' category, must seek to appoint members from specific medical specialities. These will include neonatology, paediatric endocrinology, paediatric urology, paediatric/adolescent gynaecology, general paediatricians, adolescent physicians, and clinical geneticists.

The bill will include some maximum time frames for key steps in the oversight process, to ensure that applications are considered quickly. These include the suggested 14 day period to convene a committee, that I mentioned earlier.

We are proposing adjustment to one of the two offences in the bill. The draft bill contained an offence that was specifically about moving a person across the border out of the ACT to secure an unapproved medical treatment. The form of this offence is proposed to be changed, though the intention of the offence is unchanged. In the final bill, it would be an offence for someone to deliberately authorise or arrange for restricted medical treatment to be undertaken on a prescribed person, even though they knew that authorisation is required. Deliberately organising to take someone outside the ACT to avoid the scheme would be an example of this. This version of the offence also has a higher burden of proof than the one in the draft bill, to ensure that it does not capture people who were not aware that the treatments was restricted.

There have been some questions raised about why there are offences in the bill. There are several reasons. The first is that offence provisions are the normal mechanism for supporting compliance with a law. It would be less effective to have a law requiring certain conduct, yet with no consequences written in that law for not complying. Second, the adverse effects of restricted medical interventions, performed for inappropriate reasons or without adequate care, on people with variations in sex characteristics, can be extremely serious. Some of the outcomes that have been evidenced to us have included lifelong psychological or physical pain, and unnecessary and permanent loss of fertility. The community expects there be consequences for deliberate and reckless disregard for laws designed to protect vulnerable people. The offences and penalties have been drafted with careful reference to other offences across ACT and national laws, including other offences in laws governing health professionals.

This policy reform is leading nationally and internationally. It will require careful implementation and evaluation over time. There is now a requirement in the bill for a review of the operation of the legislation after five years.

Next steps

The next stage in the process is government approval of the final bill to be introduced into the Legislative Assembly. We anticipate that it could be introduced towards the end of the first quarter of 2023.

The intention is for most of the bill's provisions to take effect six months after commencement, which could be around December 2023 depending on when the bill is ultimately passed. At that point, it will be possible

for people to apply for individual or general treatment plans. A year after that it will become a requirement that restricted medical treatments only occur consistent with an approved treatment plan.

Alongside the bill, the other elements of the reform will take place. We expect the psychosocial care unit to be established within Canberra Health Services during 2023. The administrative support for the new Board will also be set up, and will begin preparing templates, advice and guidance for people with variations in sex characteristics, their families, and health professionals.

Community awareness-raising will begin following passage of the legislation and health professional training materials will be developed and delivered prior to the full commencement of the legislative scheme.

There will be a review of the legislation after five years.

If you have questions

We expect that stakeholders may have questions about the legislation, or other aspects of the reform, beyond what was addressed in this information session. We will release the final draft of the bill prior to its introduction into the Legislative Assembly. We will write to stakeholders when it is available.

We are preparing a frequently asked questions (FAQ) paper that we will publish on our webpage. We will look at the questions submitted during this session. You can also send us questions by email to intersex@act.gov.au and we will take these into account in preparing the FAQ. We will not answer every question in that document, but we will try to cover as many as possible.