Government of **Western Australia**
Department of **Health**

Contemporary Assisted Reproductive Technology and Surrogacy Legislation for Western Australia

Public discussion paper on behalf of the Ministerial Expert Panel

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Contents

1 Introduction

The *Human Reproductive Technology Act 1991* (HRT Act) became law 30 years ago. In the time since the Act was first implemented there has been an extraordinary increase in the use of assisted reproductive technology (ART) to help families have children, when before this may not have been possible. It has also helped some families to access genetic testing and in vitro fertilisation (IVF) to avoid serious inherited illnesses. The *Surrogacy Act 2008* (Surrogacy Act), now in its 14th year, has meant people have been able to seek the assistance of an altruistic surrogate if they were unable to give birth or carry a pregnancy.

Since the enactment of the HRT Act and the Surrogacy Act much has changed in the field of ART. Over this time, societal views regarding the ethical, social and legal issues considered in earlier legislation have also changed. The Western Australian Government plans to introduce new, contemporary legislation for ART and surrogacy in WA while continuing to focus on the objectives of the current legislation. The objectives of the new legislation include focusing on:

- the rights and welfare of any child born using ART
- social justice and equity
- safe, high quality and accessible health services which are patient-centred, based on evidence, and within a culture of continuous improvement.

In 1978 the world's first child was born as a result of an IVF pregnancy. Today, nearly 5 per cent of Australian children are born from ART. Knowledge and understanding of ART, including the health, psychological and social impact upon the individuals, donors and families has greatly increased.

In 2018, the WA Government initiated an *Independent Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008* by Associate Professor Sonia Allan. Associate Professor Allan consulted extensively during the Review and provided recommendations in the published report (the Allan Review). The Allan Review identified areas where WA's legislation should be updated. In August 2021, the Government provided a detailed response to the Allan Review. The response was tabled in Parliament, with the Government committed to introducing new legislation for ART and surrogacy in WA.

Contemporary legislation will expand access to ART and surrogacy for Western Australians while prioritising the safety and welfare of all participants, including any children born from ART procedures. Robust regulation will ensure the values of non-commercialisation and non-exploitation of participants will remain. A targeted consultation process following the Allan Review recommendations will allow stakeholders, including the public, to further inform the Government response prior to new legislation being drafted.

This discussion paper is intended to inform stakeholders and members of the public of the areas for further consideration in developing the new legislation and invite comment on these specific topics. Information on how to provide comment/s on the key issues outlined in this discussion paper is included in Section 5 at the end of the document.

Comment/s provided will also be used to inform the Ministerial Expert Panel (MEP) appointed by the Minister for Health, The Hon. Amber-Jade Sanderson MLA, in making recommendations to the Minister regarding the new legislation, for government consideration.

1.1 The Ministerial Expert Panel

The ART and Surrogacy MEP will provide advice to the Minister for Health following completion of a brief targeted consultation process. A role of the MEP is to provide the Minister with assurance that the recommendations made by Associate Professor Allan remain contemporary. The aim of the targeted consultation is to address recommendations that the Government did not fully support from Associate Professor Allan's Review or where it was identified that further consultation is needed.

A final report will be prepared by the MEP at the completion of this process. The MEP will draft its report by considering expert advice on specific elements of ART and surrogacy services, and the comment/s received from the targeted consultation on specific topics. The MEP report will guide drafting of the new legislation, which will be presented to the Parliament in the form of a bill for consideration.

It is anticipated that new legislation will reflect advances in scientific knowledge, changes in medical treatments and societal views, and will ensure safety, quality and health outcomes for ART participants. The legislation will promote equity of access; address ethical challenges in delivering care; and prioritise the health and welfare of children born from ART and surrogacy.

1.2 Consultation timeframe

The targeted consultation is anticipated to occur between July and October 2022. Policy will be developed to inform drafting of proposed legislation in the form of a bill to be introduced into Parliament in 2023.

While every effort will be made to achieve this timeframe, it is acknowledged there may be events which delay the MEP's work (including implications associated with COVID-19).

1.3 Terms of reference

The areas for further consideration were identified in the Government response to the Allan Review. Consultation around these key issues will be led by the MEP. Key areas include:

- protecting the best interests, health outcomes, rights and welfare of the child who may be born
- development of a new advisory and review body for ART
- donor conception information and access to information by people who are donor conceived
- embryo storage timeframes
- posthumous collection and use of gametes and embryos by a partner
- preimplantation genetic testing (PGT) of embryos to prevent serious disease
- access to ART and surrogacy
- the approval process for a surrogacy arrangement.

1.4 Guiding principles for new legislation

The framework for new legislation will provide overarching principles that emphasise:

- the health, safety, welfare and rights of any child to be born from ART including surrogacy
- the health, safety, welfare and rights of those accessing ART, including individual participants, donors and surrogate mothers
- principles of non-discrimination
- the values of non-commercialisation of human reproductive materials or capabilities
- ensuring non-exploitation of participants engaged in ART and surrogacy.

2 Assisted reproductive technology legislation

2.1 Background

The current HRT Act is over 30 years old and was passed at a time when much was unknown regarding the risks and benefits of ART. Legislation needs to reflect society's current views regarding family formation, as well as the technological advances in ART, enabling more Western Australians to start or expand their family.

This discussion paper sets out the Government's proposed responses to the Allan Review and where further consultation is being sought to ensure that the intended legislation is consistent with best practice and community expectations. Many recommendations in the Allan Review were accepted by government and will be incorporated into legislation.

2.2 Key issues

2.2.1 Regulation of clinics that provide ART

Summary of Allan Review recommendations 1 to 13 (Report: Part 1):

- Address the need for contemporary legislation. A co-regulatory form of legislation is proposed, which involves partnership between industry and regulators to focus on risk-based regulation and outcomes.

The current HRT Act establishes the law governing access to, and delivery of, safe ART practices by fertility clinics. These clinics are licenced to undertake ART procedures and store gametes and embryos. In addition to licensing the clinics, the Act also requires the maintenance of registers of ART procedures, permits investigation of complaints and outlines disciplinary action and appeals when the law is not followed. Some of these responsibilities are currently carried out by the Reproductive Technology Council (RTC) who are appointed by the Minister for Health, and the WA Health Reproductive Technology Unit (RTU) within the Department of Health. In WA, fertility providers are required to be separately licensed by the Department of Health's Licensing and Accreditation Regulatory Unit (LARU).

In addition to following the requirements of the HRT and Surrogacy Acts, WA fertility clinics must comply with industry codes of practice in order to be licensed. The key industry codes of practice are the National Health and Medical Research Council (NHMRC) *Ethical guidelines on*

the use of assisted reproductive technology in clinical practice and research 2017 (NHMRC Guidelines) and the Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC) *Code of Practice*. ART clinic laboratories are also required to comply with the National Association of Testing Authorities (NATA) Standards. This framework of regulation is intended to continue under new legislation.

The Allan Review recommended the adoption of a co-regulatory approach intended to reduce the burden for individuals and fertility providers, without compromising safe clinical practice. The requirement to adhere to the NHMRC Guidelines and the RTAC Code of Practice will remain in place. A proposed annual registration system like the model used by New South Wales (NSW), Victoria and South Australia may be adopted as assessment of this approach has been positive. The continuing regulation of ART in WA is recommended to protect the health, safety and welfare of those accessing ART, donors, surrogate mothers and any children born from ART procedures.

The Allan Review recommended a new ministerial ART advisory body be established to replace the current RTC. The advisory body will:

- provide the Minister for Health and the Department of Health Director General with information regarding any research that may inform regulation and governance of ART
- advise the Minister for Health and the Director General regarding:
  - medical, social, scientific, legal and ethical issues arising from ART
  - any necessary directives/conditions of registration needed to clarify acceptable practice in WA.

In Victoria, legislation mandates a Patient Review Panel, separate from an advisory body, which approves applications for some ART procedures such as surrogacy, posthumous use of gametes/embryos and genetic testing. This panel can also formally review cases where a fertility clinic has denied treatment due to:

- concerns that the child that may be born would be at risk of abuse or neglect
- an applicant not meeting the criteria for treatment.

A version of an ART review board will be considered for WA. An appeal process for dispute regarding decisions of this board will also be considered.

2.2.2 Access to ART

Summary of Allan Review recommendations 1 to 6 (Report: Part 2):

- Legislation that discriminates against persons on the basis of sex, relationship status, gender identity, intersex status, sexual orientation and/or inhibits access to IVF should be repealed.

The current HRT Act permits ART procedures to be carried out to the benefit of single women or opposite sex couples where they are unable to conceive or carry a pregnancy. This eligibility restricts access to ART for some people on the basis of sex, relationship status, gender identity, intersex status and sexual orientation.

It is proposed that access to ART is expanded to everyone (regardless of sex, relationship status, gender identity, intersex status or sexual orientation) who meet the below criteria:

a) the person or couple are unlikely to become pregnant other than by an ART procedure.
b) the person or couple are unlikely to be able to carry a pregnancy or give birth to a child without an ART procedure.
c) the person is at risk of transmitting a genetic abnormality or genetic disease to a child born as a result of a pregnancy conceived other than by an ART procedure, including a genetic abnormality or genetic disease for which the person's partner is the carrier.

This would expand ART access to females who face impending infertility, single men, same-sex couples, transgender people and intersex people. As surrogacy is a form of ART, this would also expand access for surrogacy, as detailed at Section 3.2.1 in this paper. These changes would ensure that WA aligns with the *Sex Discrimination Act 1984* (Cth) and the WA *Equal Opportunity Act 1984.*

It is proposed that contemporary legislation use gender-inclusive language, replacing woman/man with person, and he/him and she/her with they/them where this is possible. Anatomical terms will also be used where best suited and would better reflect modern ART practice. The focus on women in current legislation does not recognise the ART procedures that treat male infertility and is not inclusive to non-binary, intersex and transgendered people who are not women but can still access IVF and other uterine ART procedures. Such language can also help to reduce the stigma of infertility being seen as a women's issue.

2.2.3 Management of donor conception

Summary of Allan Review recommendations 21 to 38 (Report: Part 1):

- New legislation to provide for a central donor register, birth certificate addendums, options for voluntary registration on the central register, removal of donor anonymity, with the inclusion of contact vetoes for donors.

In the early days of ART, the anonymity of people who were accessing donor-conception services and donors was encouraged by medical providers and those receiving the donation due to a perceived perception of stigma about infertility. As a result, many people who were donor conceived were unaware that they were conceived using donor sperm (the main form of gamete donation in donor conception at the time). Some had not discovered they were donor conceived until adulthood and some may still be unaware. In recent decades, there has been a shift towards recognising the interests of donor-conceived people. This is evident through universal rights for access to donor-identifying information being granted in Switzerland in 2001, Victoria in 2017 and Germany in 2018. This means that access to the identifying information may be granted regardless of whether donor anonymity was required or guaranteed at the time of donation.

Currently, in WA a person conceived from gametes donated on or after 1 December 2004 has a right to access identifying information about their donor from age 16 years. For people born prior to this date the information is released only with the consent of the donor where the

information is available. However, in WA there was no central register of information about donors and recipients before the HRT Act was in place – from around 1993 – when a register of this information was established by the WA Department of Health. People who were donor conceived before the central register was developed cannot access their donor's identifying information from a central register. It may be possible if the fertility provider has a record of the donation procedure, and with consent of the donor, that people who are donor conceived can find out this information if they approach the fertility provider who provided the treatment. However, records of artificial insemination were not systematically kept, and many records may no longer be available as medical practices may have closed or changed hands.

A proposal being considered for new legislation is that donor-conceived people will be able to seek identifying information about their donor regardless of when they were born. This proposal would retrospectively remove a donor's anonymity where records are held about a donor-conception procedure and give people who are donor conceived the opportunity to learn identifying information about their donor. The potential to access information held by providers, including fertility clinics, may be limited by the records they hold.

Consideration will be given to the rights of people who are donor conceived and donors who do not wish to have contact with donor-conceived offspring. Contact preferences, including contact vetoes, could be implemented. In this case the donor would be able to request 'no contact' or specify the type and timing of any contact. Breaching the veto would carry a penalty. If a donor-conceived person and their donor agreed to contact, counselling will be facilitated.

This proposal recognises that it is important for donor-conceived people to access information about their donors. This can support people who are donor conceived with their sense of self-identity and alleviate concerns about forming a relationship with a sibling. This proposal will also promote openness, equity and will lessen discrimination; and would enable WA to align with other jurisdictions who have contemporary legislation.

Some donor-conceived people are now identifying their donors and/or their close blood relatives through genealogical and DNA websites. This means that a person who has donated may not be able to maintain their anonymity. The new legislation seeks to offer opportunities for making identifying information available and supporting positive contact between donor-conceived people and those who provided the donation. However, it is important to also consider the right to privacy for donors.

It is also proposed that an addendum be made on birth certificates notifying the donor-conceived person once they have reached age 16 that more information (indicating that they are donor conceived or that their birth was the result of a surrogacy arrangement) is held about them on the birth register. This approach is used in Victoria. A replacement birth certificate could be issued at the request of a donor-conceived person, people born via surrogacy, or their legal parent(s) if they are under 16, that contains factual-information about their genetic and birth heritage.

It may be an option for information about a donor conception or surrogacy arrangement to be recorded on the birth certificate in the future, if the information is collected on the birth registration papers. This would enable a notation to be made on the original birth certificate indicating that additional information about their genetic origins and birth is available from the

Registry of Births, Deaths and Marriages (BDM). Donors could be notified of the birth of a baby from their donation – with no identifying information provided.

Further consideration needs to be given to the implications of these proposals, including the logistics of collating and disclosing donor information where it is not available from currently held Department of Health Registers, as well as what support services should be offered to both people who donated gametes and embryos, and people who are donor conceived.

2.2.4 Storage of gametes and embryos

Summary of Allan Review recommendations 39 to 48 (Report: Part 1):

- Time limits for storage of gametes and embryos should suit the person's/couple's needs as set out in the NHMRC Guidelines.

Historically, embryos were accorded a special status when compared to other human biological materials because they can lead to a new human life. There are complex ethical issues associated with their storage and disposal when they are no longer required by the person/s for whom they had been created. To safeguard the viability of human embryos and the wellbeing of the child which may be born, the HRT Act limited storage of embryos to 10 years, with extensions possible via RTC approval.

Since the HRT Act came into force there have been significant improvements in cryo-storage, with studies finding no clear negative impacts on live birth outcomes or child development. Current concerns with storage limits are mostly focused on social, ethical and legal issues.

The NHMRC Guidelines permit a person/couple to decide upon the storage period based upon their circumstances. When consenting to storage, people must also decide what will happen to their gametes and/or embryos if either or both of them separate, die, become unable to vary or withdraw consent, or fail to give instructions about what is to happen when the storage period expires.

Currently, in WA once embryos are created their fate rests with the person or couple for whom they were created. However, a gamete donor cannot veto the use of the embryo/s created for another person or couple. The donor can withdraw consent for the continued use of their unused stored gametes. This is unlikely to change with new legislation.

The UK Government has completed a consultation on gametes and embryo storage limits and has indicated a policy change to include 10 year renewable storage periods up to a maximum of 55 years for gametes and embryos to be available to all – irrespective of medical need. It is recommended that for new WA legislation the 10-year limit for embryo storage is removed, with ART consumers deciding on storage limits as part of their contractual agreement with their fertility clinic.

2.2.5 Posthumous use of gametes

Summary of Allan Review recommendations 49 to 54 (Report: Part 1):

- The intersection with the *Human Tissue and Transplant Act 1982* be addressed and the posthumous use of gametes (collected prior to or after death) and embryos be governed by conditions which recognise the intent of the (now deceased) individual to consent to such use.

Currently, in WA a designated officer in a hospital can authorise the removal of gametes from a recently deceased person at the request of the person's spouse or de facto partner where there was consent (or no reason to believe that the person objected) to the gametes being removed for reproductive purposes with their surviving spouse or partner. It is unlikely to apply to eggs as the person's death would need to coincide with the cyclical release of a mature egg.

While removal of gametes from a recently deceased person may be possible in WA, current WA law does not permit the posthumous use of gametes in assisted reproduction. This includes where the deceased person had stored their gametes or embryos prior to death with the intention of reproduction with their spouse or partner, even if their written consent was given for use in this circumstance.

It is proposed that in new legislation the posthumous use of gametes or embryos collected before or after a person's death be permitted, with the below criteria being followed:

- the deceased person left clearly expressed oral or written directions consenting to such use following their death or there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner
- the deceased was an adult at the time of their death
- the request to do so has come from the surviving spouse or partner of the deceased person, and not from any other relative
- the gametes or embryos are intended for use by the surviving spouse or partner for the purposes of bearing a child(ren) who will be cared for by the spouse/partner
- sufficient time has passed so that grief and related emotions do not interfere with decision-making
- the surviving prospective parent (the spouse or partner) has undergone appropriate counselling
- the surviving prospective parent (the spouse or partner) has been provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications of the proposed activity for the person who may be born.

Allowing the posthumous use of gametes or embryos would align WA with most states and territories in Australia, as well as NHMRC Guidelines.

2.2.6 Genetic testing of embryos

Summary of Allan Review recommendations 55 to 56 (Report: Part 1):

- Repeal of requirement for Reproductive Technology Council (RTC) approval for genetic testing of embryos. Clinics to comply with the NHMRC Guidelines.

Under current WA legislation, pre-implantation genetic testing (PGT) is permitted to test early embryos to identify genetic diseases or disorders that will affect a child born. Research suggests this testing does not harm the embryo.

PGT may be used together with human leukocyte antigen (HLA) typing (a technology that enables tissue type matching) to create a child with a tissue type that matches an existing sibling or close family member with a particular disease or disorder that may respond to stem cell therapy. The child created with the matching tissue type is sometimes referred to as a 'saviour sibling'. This use of PGT may be considered when no suitable donor is available for a person requiring a stem cell transplant, when the requirement is non-urgent.

However, under the HRT Act unless the parents are eligible for IVF, PGT for the purpose of tissue matching is not permitted. It is proposed that PGT for the purpose of tissue typing be allowed in new legislation, following strict criteria. This would align WA with NHMRC Guidelines.

The Allan Review recommends that an independent body be created to review applications for PGT for tissue matching to ensure:

- there is sufficient evidence to indicate that the person to be born would be a welcomed and respected new member of the family unit
- its use will not significantly affect the welfare and interests of that person
- the medical condition of the intended parent, sibling or other relative to be treated is serious and stem cell treatment is the medically recommended management of the condition.

2.2.7 Research involving human embryos

Summary of Allan Review recommendations 59 to 60 (Report: Part 1):

- The report recommends that WA legislation be amended to ensure it is consistent with that of the Commonwealth regarding human embryo research.

Regulation of ART and research involving human embryos and cloning is closely aligned. This is because excess ART embryos can be made available for research under certain circumstances. While the focus of research is to improve ART and prevent disease, the use of excess embryos from ART or those created using cloning techniques (somatic cell nuclear transfer – SCNT) remains controversial.

Commonwealth legislation (the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*) permits research on excess ART embryos in Australia under strict criteria, including donor consent. Certain practices remain

prohibited at a national level, such as human cloning. All research on human embryos requires licensing via the NHMRC's Embryo Research Licensing Committee.

Inconsistencies between WA's current HRT Act and Commonwealth legislation has meant that research on excess ART embryos cannot currently be licenced in WA. It is proposed that WA introduce legislation to align with Commonwealth law, thereby permitting research on excess ART embryos in the state.

2.2.8 Add-on treatments, emerging technology and egg sharing

Summary of Allan Review recommendations 57 to 58, 61, 66, 67 (Report: Part 1):

- Address strength of evidence of the efficacy of treatments and 'add-on' treatments that are experimental or of unproven value and how this is presented to consumers who may be vulnerable.
- Engage in national consultations regarding emerging technologies such as mitochondrial donation, gene therapy and technology.
- Consult with the LGBTQI+ community and other stakeholders regarding egg sharing and/or embryo transfer for non-medical reasons.

2.2.8.1 Effectiveness of add-on treatments

There remain concerns that add-on fertility treatments may not be as effective as claimed. These treatments promote that they can improve the chances of increasing the number of embryos created, conceptions or number of pregnancies. The Allan Review recommended that information regarding scientific rigor and the effectiveness of fertility treatments should be addressed through collaboration and consultation with other regulatory agencies, the scientific community and with industry.

In the UK, the Human Fertilisation and Embryology Authority (HFEA) have a traffic light system for assessing the effectiveness of several IVF add-ons (external site), which can provide consumers with more information on potential treatments.

2.2.8.2 Emerging technology

The WA Government engages with national consultations on emerging health technology. A recent example involved the national consultation on mitochondrial donation. Mitochondrial disease causes long-term ill health with an average lifespan of 3 to 12 years in affected children, although it can affect people at any age. Mitochondrial donation aims to prevent women transmitting mitochondrial disease to their biological children. The technique is used in conjunction with IVF, resulting in the creation of an embryo that will include nuclear DNA from a man and woman (the mother) together with the mitochondria in an egg donated by another woman.

Both the NHMRC and the Commonwealth Department of Health undertook public consultation to identify community views on the potential introduction of mitochondrial donation into clinical practice in Australia. Following this, the *Mitochondrial Donation Law Reform Bill (Maeve's Law)* was passed in the Australian Parliament on 30 March 2022. Following an extended period of research and testing, it is expected the *Mitochondrial Donation Law Reform Bill* will amend the

Prohibition of Human Cloning for Reproduction Act 2002 and the *Research Involving Human Embryos Act 2002,* thereby allowing mitochondrial donation in Australia.

It will be important for any new WA legislation to be able to regulate new and emerging technologies and medical treatments. This will enable Western Australians to benefit without being excluded due to restrictive state law.

2.2.8.3 Reciprocal IVF

Reciprocal IVF (also called egg sharing) may be used by female same-sex couples. It involves implantation of an embryo formed with a partner's egg. This enables both members of a couple to contribute to a child's creation. This process is currently restricted in WA as IVF can only be accessed due to infertility or other medical reasons.

If access to IVF is made possible for a wider range of circumstances, such as the inability to become pregnant as a result of your relationship status, it remains unclear whether reciprocal IVF will be permitted. To enable reciprocal IVF, new legislation would need to expand eligibility so that IVF could be accessed for this purpose, when other less invasive technology such as artificial insemination could be used to conceive a child. The Allan Review recommended further consultation in this area.

3 Surrogacy legislation

3.1 Background

All Australian states and the Australian Capital Territory (ACT) currently allow altruistic surrogacy. Legislation has recently been passed in the Northern Territory (NT) to also permit altruistic surrogacy in the NT. Commercial surrogacy is prohibited throughout Australia. Due to a range of ethical issues it is unlikely that this will change in the foreseeable future.

Within Australia, regulatory requirements relating to altruistic surrogacy vary between states and can make it difficult for families to find and work with a suitable surrogate. This has contributed to Australians engaging in overseas surrogacy arrangements, the majority of which are commercial. This could mean exploitation of both surrogates and children.

The WA Government supports improved access to altruistic surrogacy through the drafting of new surrogacy legislation that would expand access to single men, men in same sex relationships, and may recognise same sex relationships for women seeking to use a surrogate if they are unable to conceive or carry a pregnancy.

Staff from the WA Department of Health have contributed to a national working group aimed to inform a consensus approach on a nationally consistent regulation of altruistic surrogacy. This work builds on the 2009 report of the Standing Committee on Attorneys General – *A Proposal for a National Model to Harmonise Regulation of Surrogacy* which included 15 draft surrogacy principles. The benefits of greater consistency in surrogacy legislation across jurisdictions include:

- ensure Australia is consistently addressing its international human rights obligations
- enable more Australians to be a party to a lawful domestic altruistic surrogacy arrangement

- enable interested parties to better identify potential surrogates and facilitate domestic altruistic surrogacy arrangements
- reduce the potential for parties to arrange surrogacy between jurisdictions, particularly overseas where commercial surrogacy is legal or unregulated
- provide a consistent approach, as some states have penalties for engaging in commercial overseas surrogacy, noting these are rarely enforced.

It is envisaged that new surrogacy legislation in WA will seek greater consistency with approaches in other jurisdictions. The overarching principles that will continue to be reflected in new surrogacy legislation are:

- the best interests of the child are paramount
- the surrogate mother's ability to make free and informed decisions is upheld
- the protection of the surrogate mother from exploitation
- legal clarity regarding the resulting parent-child relationships and parentage orders.

3.2 Key issues

3.2.1 Access to surrogacy

Summary of Allan Review recommendations 1 to 6 (Report: Part 2):

- Legislation that discriminates against persons on the basis of sex, relationship status, gender identity, intersex status, sexual orientation and/or inhibits access to IVF should be repealed.

The Government supports greater access to altruistic surrogacy in WA, subject to ensuring the psychological and sociological wellbeing of all parties involved, recognising that the best interests of the child are paramount.

It is proposed that new legislation will extend eligibility for altruistic surrogacy to:

- females with impending infertility to permit them to store eggs or embryos for the purposes of fertility preservation – this includes women facing premature loss of fertility and those requiring surgery, chemotherapy or radiotherapy for cancer treatment
- single men
- people in same-sex relationships
- transgender people
- intersex people.

This is required so that WA complies with the *Sex Discrimination Act 1984* (Cth). This Act was amended in 2013 to allow protection on the basis of sexual orientation, gender identity and intersex status.

3.2.2 Application process for surrogacy

Summary of Allan Review recommendations 7 to 20, 26 to 30 (Report: Part 2):

- People need clear information about the prerequisites of a surrogacy arrangement, including allowable reimbursements.
- The unenforceability of surrogacy arrangements should be maintained.

In addition to expanding eligibility for ART and surrogacy, it is proposed that the application process for surrogacy be simplified to reduce red-tape for assessment. The current process has been considered onerous by some applicants.

It is proposed that the current requirement for psychological assessment of all parties is reviewed. It is also proposed that the following prerequisites for surrogacy approval are kept or introduced:

- Participants will receive individual and joint implications counselling.
- Each party will receive legal advice provided by separate lawyers. The parties include intended parent/s, the surrogate and their partner, and any known donor/s and partners.
- The fertility clinic or a general practitioner (GP) will undertake a medical assessment of the intended parent/s, the surrogate, and any known donor/s with the intent of ensuring the parties are healthy and able to safely participate in the surrogacy arrangement.
- A fertility counsellor will undertake a patient history and psychosocial assessment with the intended parent/s and surrogate with a focus on the safety of a future child (as outlined below in Section 3.2.3.). While ensuring there is no unlawful discrimination, the ART provider will make every effort to address concerns that arise including interpersonal violence, substance misuse, issues related to mental health, disability, etc.
- Opportunities for individual and joint counselling sessions throughout the pregnancy and after the birth for participants are available to assist with adjustment and offer support to participants during this process.

Information about surrogacy arrangements and expected costs will be provided by clinics, while family lawyers would provide information about legal agreements.

Reimbursements for surrogate mothers needs to be clearly defined so that there is clear separation between altruistic and commercial surrogacy. Allowable reimbursements should be documented in the surrogacy arrangement. Reimbursements currently include:

- medical expenses associated with the pregnancy or birth (doctors' fees, medication, medical scans, etc.)
- costs of legal advice and counselling necessary to satisfy the requirements for approval by the RTC, or prior to obtaining a parentage order
- lost earnings for up to 2 months prior to the birth/expected birth or for other medical reasons arising during pregnancy
- health, disability or life insurance premiums occurring as a result of the pregnancy.

Other states also include national travel and accommodation costs where these are incurred as a result of the surrogacy arrangement and 'other reasonable costs'.

Surrogacy arrangements will remain unenforceable so that the final decision regarding parentage is based on the best interests of the child. While this results in a level of uncertainty for intended parents, pre-surrogacy and post-birth counselling is intended to ensure that all parties consider the full implications. There are 2 exceptions to this – firstly, reimbursement of expenses would be enforceable, and secondly the court may remove the requirement for the surrogate mother to consent to the parentage order under certain circumstances.

3.2.3 Welfare of the child

Summary of Allan Review recommendations 21 to 25 (Report: Part 2):

- A regulatory framework that provides a systematic approach to consideration of the welfare/best interests of the child principle.

A guiding principle of the surrogacy legislation is that the health and welfare of any child born as a result of surrogacy is of paramount importance. Current practice relies on treating clinicians using their professional judgement to assess whether there would be a potential risk to child welfare in providing treatment. There will be a greater recognition of the health and wellbeing of all participants in the new legislation.

The Allan Review found support for, and recommended, an 'objective assessment of child welfare' tool to be used by clinics. An option is to adapt the 'Welfare of the child: patient history' form (external site) developed by the UK's Human Fertilisation and Embryology Authority (HFEA) and used by clinics to assess the health and wellbeing of potential surrogates and intended parents. If a concern arises as a result of the response to questions, further investigations can be conducted, with most resolved by obtaining extra information from the patient or their GP. A few investigations may involve consulting with medical/mental health specialists, or in the case of drug or alcohol misuse with social workers who have had professional contact with the intended parent(s). Refusals to treat are rare and there are no typical cases. The UK system has been found to be relatively simple to use and easy to administer by all staff.

Other Australian states have not introduced such a welfare assessment. Suitability of potential parents is left as a clinical decision. Victoria introduced criminal screening and child protection checks in 2008 but repealed these in 2020 on the grounds they were a source of delay, distress, and cost, and a significant administrative burden with no benefit. It is argued that these checks put an additional burden on intended parents that is not required from other parents. A 2018 review of the NSW *Surrogacy Act 2010* did not recommend implementation of criminal record checks for intended parents stating that this would cause 'unwarranted inconvenience, expense and distress'.

It is suggested that a combination of medical assessment, counselling, and patient psychosocial history assessment by staff in the fertility clinic would be enough to identify concerns and ensure the wellbeing of the child born from any surrogacy arrangement. Following the birth of the child the Family Court of WA would consider these assessments prior to awarding a parentage order.

3.2.4 Advertising and brokers

Summary of Allan Review recommendations 31 to 36 (Report: Part 2):

- Clinics be allowed to advertise to recruit altruistic surrogates and information should be made available to raise awareness of surrogacy laws.

Access to surrogacy would be improved by allowing clinics to recruit altruistic surrogates. This measure would allow women who are willing to volunteer to be an altruistic surrogate to provide this information directly to a clinic. This could be considered less risky than advertising to the public in general, while reaching a targeted audience, potentially in a safer environment. However, it is intended that a person may continue to publicly declare that they are seeking an altruistic surrogate or wishing to act as an altruistic surrogate. Brokerage of any kind that involves payment or reward for surrogacy services would continue to be prohibited. This is consistent with the prohibition of commercial surrogacy.

3.2.5 International commercial surrogacy arrangements

Summary of Allan Review recommendations 42 to 49 (Report: Part 2):

- In line with all jurisdictions, and recent reviews of legislation at state and commonwealth levels, commercial surrogacy would remain prohibited. Matters that lead people to engage in overseas commercial surrogacy arrangements should be addressed.

Domestic altruistic surrogacy is regarded as the most acceptable form of surrogacy with legislation aiming to prevent:

- exploitation of women and children
- treatment of children as commodities
- financial coercion of the surrogate mother.

Legislation also ensures that information regarding the child's biological heritage is retained.

Commercial surrogacy remains prohibited on the basis of human rights, child welfare and ethical concerns. The risk of exploitation of both surrogates and children would remain significant, even in a regulated system.

Commonwealth legislation allows for parents engaging in commercial surrogacy overseas to apply for 'citizenship by descent' for the child if there is a genetic relationship with at least one of the parents. Where there is no genetic relationship, they must apply for a long-term visa. They are not eligible to apply for legal parentage in Australia but can apply for parenting orders which are orders determining parenting responsibilities, in the best interests of the child. While this process is not consistent with Australian public policy prohibiting commercial surrogacy, it is generally shown to be in the best interests of the child.

Improving access to altruistic surrogacy in WA may reduce the demand for international surrogacy. In other states there are extra-territorial provisions prohibiting Australians from engaging in international commercial surrogacy. This is in place in NSW, Queensland and the

ACT. Additional options that may be considered in new legislation for WA include enforcement of penalties for engaging in international commercial surrogacy and regulation to prevent third parties facilitating commercial surrogacy.

The main penalty for parents participating in overseas commercial surrogacy is potentially not being granted a parentage order. Further consequences tend not to be imposed on parents because of the likely negative impact on the child.

4. Conclusion

Associate Professor Allan's Review was extensive and involved substantial community and stakeholder consultation on matters related to ART, including surrogacy, in WA. A role of the MEP is to consider specific elements of recommendations made in the Allan Review where the Government requires further information or additional consideration. Comment/s provided on the key issues outlined in this paper will inform the MEP in making its recommendations to the Minister for Health for government consideration. The MEP will provide the Minister with assurance that the recommendations made by Associate Professor Allan remain contemporary, in light of medical, scientific or social changes in recent years.

5. How to provide comment/s:

If you wish to provide comment/s on *key issues* outlined in this paper, please do so via:

Email to: ART.Secretariat@health.wa.gov.au

Alternatively, please send comments to:

ART Secretariat
PO Box 8172
Perth Business Centre
PERTH WA 6849

Please provide your name and contact email address in your response.

Comments are requested by 5:00pm on Monday 5 September 2022.

All comments will be treated as public documents, unless a specific request for confidentiality is made. However, please note that comments provided may be subject to release under the *Freedom of Information Act 1992*. Comments provided may also be quoted from in the final MEP report to the Minister for Health.

The MEP reserves the right to remove any content that could be regarded as derogatory or defamatory to an individual or agency.

Thank you for your interest.

Further updates regarding the work of the MEP will be posted on the Department of Health website.

Glossary

Accreditation: The Reproductive Technology Accreditation Committee (RTAC) provides accreditation to a person or group of people to conduct assisted reproductive technology (ART). It is an offence in Australian Commonwealth law to create or use human embryos in any way without RTAC accreditation.

Allan Review: The review of the Western Australian *Human Reproductive Technology Act 1991* (HRT Act) and the *Surrogacy Act 2008* (Surrogacy Act) was undertaken by independent reviewer Associate Professor Sonia Allan and makes 122 recommendations. The 2-part report is the most comprehensive review of WA's surrogacy and HRT regulations since the original legislation was enacted. Part one of the review focuses on the HRT Act and Part 2 on the Surrogacy Act.

ART with donor: ART may involve the use of donated gametes, spermatozoa (sperm) and/or oocytes (eggs), or donated embryo(s). The use of 'donor' gametes or embryos may occur when there are difficulties conceiving due to medical reasons such as infertility, when a person carries a disease or genetic abnormality, or when single people or people in a same-sex couple access ART to have children.

Assisted Reproductive Technology (ART): Includes a range of methods used to circumvent human infertility, including in vitro fertilisation (IVF), embryo transfer (ET), gamete intra-fallopian transfer (GIFT), artificial insemination (AI), all manipulative procedures involving gametes and embryos (including storage and screening), and treatment to induce ovulation or spermatogenesis when used in conjunction with the above methods.

Australia and New Zealand Assisted Reproduction Database (ANZARD): Is a data collection used to monitor perinatal outcomes and assess the effectiveness of ART. The ANZARD collection began in 2004 as a collaborative venture between the National Perinatal Epidemiology and Statistics Unit (NPESU) at the University of New South Wales, the Fertility Society of Australia and New Zealand (FSANZ) and fertility clinics across Australia and New Zealand.

Chief Executive Officer (CEO) of Health: The HRT Act refers to the Chief Executive Officer (CEO) of Health. The CEO of Health is the Director General of the Western Australian Department of Health.

Commonwealth legislation: Legislation relating to human embryo research exists at the Federal (Commonwealth) level and includes the *Prohibition of Human Cloning Act 2002*, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* and the *Research Involving Human Embryos Regulations 2017*.

Conception: The process of becoming pregnant involving fertilisation or implantation or both.

Donor insemination: Treatment that involves inserting a donor's concentrated semen through the cervix (neck of the uterus) into the uterus (womb) close to the time of ovulation, with the intention of achieving a pregnancy.

Egg donor: A woman who donates eggs (oocytes) for assisted reproduction for use by another person or couple to conceive a child, with the intention that the other person or couple will be the legal parent(s) of any child(ren) born as a result of the use of such eggs. The egg donor will have no rights or responsibilities in relation to that child.

Embryo: Once the sperm has fertilised the egg it is called an embryo.

Fertility Society of Australia and New Zealand (FSANZ): The FSANZ is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand. It includes the Reproductive Technology Accreditation Committee (RTAC).

Gamete: A word that describes reproductive cells i.e. the spermatozoa (sperm) and oocytes (eggs).

Human Reproductive Technology Act 1991 (HRT Act): An Act to establish the Western Australian Reproductive Technology Council (RTC) to require the compilation of a Code relating to the practice of, the procedures used in, and the ethics governing, human reproductive technology; to make provision with respect to the use of that technology in relation to artificially assisted human conception and for the regulation of certain research; and for related purposes.

Human Reproductive Technology Act Directions 2021 (Directions): Given by the Director General of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the Western Australian Reproductive Technology Council.

Human Tissue and Transplant Act 1982: An Act to make provision for and in relation to the removal of human tissues for transplantation, for therapeutic purposes, or medical or scientific purposes, or for post-mortem examinations. This Act permits the posthumous retrieval of gametes under specified circumstances. This Act is currently being revised.

Identifying and non-identifying information: In relation to gamete and embryo donation, identifying information is data shared with eligible donor-conceived people which identifies their donors, such as donor name, date of birth, place of birth, occupation and post code. Non-identifying information can include health history, and other characteristics such as hair and eye colour.

Infertility: Is the inability to conceive a pregnancy after one year of unprotected intercourse, in women under 35 years of age or after 6 months in women over 35 years of age, or the inability to maintain the pregnancy until fetal viability. The causal factors resulting in the inability to conceive may be attributable to structural defects of the male or female reproductive tract which may be present at birth, or acquired as a result of infection, injury or surgery, hormonal factors and other health conditions.

Intra-uterine insemination (IUI): Treatment that involves inserting concentrated semen through the cervix (neck of the uterus) into the uterus close to the time of ovulation with the intention of causing fertilisation of the egg resulting in conception.

In Vitro Fertilisation (IVF): The medical procedure by which an egg (oocyte or ovum) is fertilised with sperm in a test tube or outside the body, or where a sperm is injected into an egg, in a specialised laboratory. The fertilised egg (embryo) is grown in a protected environment for some days before being placed back (transferred) into the uterus or frozen for future fertility treatment.

Licensing and Accreditation Regulatory Unit (LARU): Responsible for the licensing and monitoring of private hospitals in Western Australia. LARU is within the Patient Safety and Clinical Quality Directorate, Clinical Excellence Division, WA Department of Health.

National Health and Medical Research Council (NHMRC): An independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act). As the government's lead agency for funding health and medical research, the NHMRC invests in the creation of new knowledge about the origins, prevention and treatment of disease and the promotion of health and wellbeing. Through clinical, public health and environmental health guidelines and other pathways, the NHMRC supports the translation of research into health practice and policy.

By providing guidance on responsible research practices and ethical issues, the NHMRC fosters the highest standards of ethics and integrity in the conduct of research and the delivery of health care. The NHMRC publishes the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (ART Guidelines).

Oocyte: A mature egg usually produced from one ovary each month.

Practice licence: A licence granted by the Director General of the WA Department of Health to a person or group of persons to carry out any artificial fertilisation procedure, not being a storage procedure, and any approved project of research.

Pre-Implantation Genetic Testing (PGT): A procedure for testing embryos for a specific single genetic disorder or chromosome variation that will result in a baby born with an inherited condition that will cause a significant disability, disorder or disease. Includes testing for monogenic/single gene disorders (PGT-M) and testing for chromosome structural rearrangements (PGT-SR). The procedure involves removing a cell from an embryo that was fertilised in an IVF procedure and testing it for a genetic condition before transferring the embryo to the uterus.

Pre-Implantation Genetic Testing for Aneuploidy (PGT-A): A procedure for testing embryos fertilised by IVF where the gamete providers are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. The procedure is to find out if the embryos have normal chromosomes overall. The procedure involves screening embryos for aneuploidy (missing or additional numbers of chromosomes) or for unspecified and multiple genetic or chromosomal abnormalities. The procedure involves removing a cell from an embryo that was fertilised in an IVF procedure.

Reproductive Technology Accreditation Committee (RTAC): A professional group of the Board of the FSANZ. It is charged with the responsibility of setting standards for the performance of ART through an audited Code of Practice and the accreditation of ART providers within Australia.

Reproductive Technology Registers (RT Registers): Multiple registers kept by the WA Department of Health containing information specified in the HRT Directions and other legislation. In operation since 1993, these include information about licensed clinics and storage facilities, individual's treatment cycle data, identifying information about participants, partners and donors, non-identifying data about donors, and birth outcomes for treatments in other jurisdictions using donated material exported from WA. The purpose of keeping the RT Registers is to ensure the safety and quality of ART in WA by monitoring its outcomes and for maintaining information about donation, genetic parentage and donor conception. There are multiple other registers for other purposes.

Semen: The ejaculated fluid comprising sperm and other secretions of the sex glands.

Spermatozoa (sperm): The reproductive cell produced in the testes required for fertilisation of an egg.

Sperm donor: A donor who provides spermatozoa (sperm) for its use by another person or couple to conceive a child, with the intention that the other person or couple will be the legal parent(s) of any child(ren) born as a result of the use of such sperm and the sperm donor will have no rights or responsibilities in relation to that child.

Storage licence: A license granted by the Director General to a person or group of persons that authorises the licensee to carry out any procedure related to the storage of eggs to be used for IVF or embryos or eggs undergoing fertilisation and sperm, and any approved research related to such storage.

Surrogacy arrangement: a person (surrogate mother) agrees to carry a child on behalf of another person or couple, with the intention:

(a) that a child born as a result of the pregnancy has parenting responsibilities and legal parentage transferred to the intended parent(s) (whether by adoption, agreement or otherwise).

(b) of transferring custody or guardianship in a child born as a result of the pregnancy to the intended parent(s).

Surrogacy can be:

(a) traditional surrogacy – surrogate mother conceives with her own eggs, with sperm from an intended father or a donor.

(b) gestational surrogacy – surrogate mother becomes pregnant after transfer of an embryo resulting from fertilisation of an egg from the female intended parent or an egg donor with sperm from the male intended parent or a sperm donor.

Surrogacy Act 2008: An Act legislating arrangements for surrogate births and children born under those arrangements and for related purposes. These arrangements are required to interact with other legislation including:

- the *Births, Deaths and Marriages Registration Act 1998*
- the *Children and Community Services Act 2004*
- the *Family Court Act 1997*
- the *Guardianship and Administration Act 1990*
- the *Human Reproductive Technology Act 1991*
- the *Interpretation Act 1984*.

Uterus (womb): The reproductive organ that supports the developing fetus.

Other relevant legislation:

- *Artificial Conception Act 1985* (WA): sets out rules relating to maternity and paternity in relation to artificial fertilisation procedures.
- *Prohibition of Human Cloning for Reproduction Act 2002* (Cth): prohibits certain human reproductive cloning and other assisted reproductive technology activities.
- *Research Involving Human Embryos Act 2002* (Cth): permits certain human embryo research, under a licence issued by the Embryo Research Licensing Committee of the NHMRC.
- *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth): amends the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* consistent with the 2005 recommendations of the Legislation Review Committee (also known as the Lockhart Review).

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