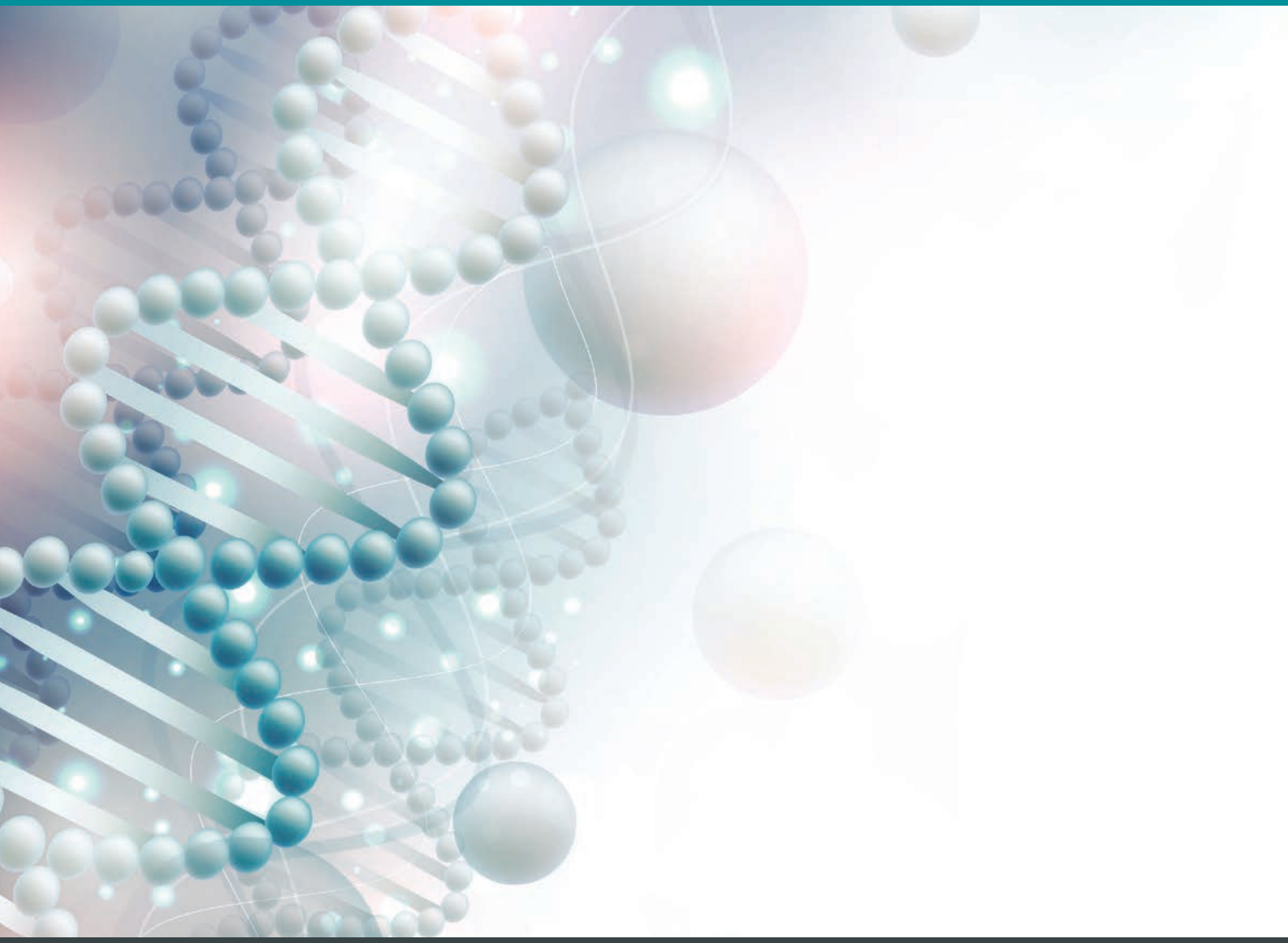
Independent Review



The Review of the Western Australian *Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008*

(Report: Part 1)

by Sonia Allan

The Review of the Western Australian *Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008* (Report: Part 1)

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January 2019

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The Review of the Western Australian *Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008*

Terms of Reference

The Review of the *Human Reproductive Technology Act 1991 (HRT Act)* is to consider such matters as appear to be relevant to the operation and effectiveness of this Act including:

- the effectiveness of the current licensing regimen, including fee structure, reporting requirements, powers of inspection and powers of obtaining information
- the effectiveness of the operation of the Council and committees of the Council
- the Chief Executive Officer's (CEO) power to issue directions, the power to make a Code of Practice, regulations and guidelines, and the scope and effect of the existing directions and regulations under the *HRT Act*
- the effectiveness of powers of enforcement and disciplinary provisions under the *HRT Act* and the adequacy of offences and penalties
- whether there should be a process of review or appeal of decisions made (by the Reproductive Technology Council (Council)) under the *HRT Act*
- the impact on the *HRT Act* of relevant Commonwealth and State legislation, and aspects of legislation of other jurisdictions which could be incorporated into the *HRT Act*.
- the need for the continuation of the functions conferred, on the Council and on the CEO respectively by the *HRT Act*
- management of information / the Reproductive Technology Registers, including:
    - confidentiality of information
    - use of data for research
    - use of data for purposes of national data collection and
    - access to information about donation, genetic parentage and donor conception
    - the Voluntary Register (donor-assisted conception)
- rights to storage of gametes and embryos including:
    - rights upon separation or divorce, or the death or the physical or mental incapacity of an individual, or one or both members of a couple
    - rights of third parties such as subsequent spouses, and the rights of other relatives
- the storage of gametes, eggs in the process of fertilisation and embryos (including the duration of storage and procedures for extension of storage periods)
- posthumous collection, storage and use of gametes and embryos, including the consent required, conditions for use, and any impact on other legislation such as the *Human Tissue and Transplant Act 1982, Artificial Conception Act 1985, Births Deaths and Marriages Registration Act 1998, Administration Act 1903 and Family Provision Act 1972*

- Genetic testing of embryos, saviour siblings, mitochondrial donation and gene editing technology
- research and experimentation on gametes, eggs in the process of fertilisation and embryos. In particular, consider the current disparity between the *HRT Act* and relevant Commonwealth legislation and the need to adopt nationally consistent legislation regarding excess assisted reproductive technology (ART) embryo research and prohibited practices.

The review of the *Surrogacy Act 2008* is to include the effectiveness and operation of the Act with particular reference to:

- interaction with the *HRT Act*
- the need for provision as to the administration of the *Surrogacy Act* and any functions to be conferred on the Minister, Council, CEO and assisting staff/persons, respectively by this Act
- the effectiveness of the current regime, reporting requirements, powers of inspection and investigation, powers of obtaining information
- the effectiveness of powers of enforcement and disciplinary provisions under the *Surrogacy Act*, the adequacy of offences, penalties and timeframe for bringing proceedings
- the impact on the *Surrogacy Act* of relevant Commonwealth and State legislation and aspects of legislation of other jurisdictions, which could be incorporated into the Act, including consideration of harmonisation of domestic surrogacy legislation
- the need for continued prohibition on commercial surrogacy
- international commercial surrogacy arrangements
- international trade in gametes and embryos
- the effectiveness of the operation of the Council and committees of the Council
- whether there should be a process of review or appeal of decisions made (by Council) under the *Surrogacy Act*.

Foreword

I am very pleased to present my report, in two parts, on the Review of the *Human Reproductive Technology Act 1991* (WA) and the *Surrogacy Act 2008* (WA), 2019. I wish to thank the Honourable Roger Cook for putting his faith in me to lead the review. It is an honour to have been appointed to undertake such a task. It was also a privilege to have consulted with people across Western Australia to inform this report. Their contributions have enabled me to better understand the key issues and complexities faced in Western Australia regarding assisted reproductive technology (ART) and surrogacy. Via written submissions, meetings, and follow-up discussions, I gained an understanding of how current regulation and practices are meeting expectations, and where they are not. The contributions of many were fundamental to developing recommendations regarding how to improve the regulation and practice of ART and surrogacy.

Many significant issues were raised as part of this Review. It is apparent that society has changed and developed since ART was first practised in Western Australia and the initial regulation was enacted. Science and technology have also progressed and continue to do so at a rapid rate. ART is now very much an accepted practice, albeit there remains debate over ethical, social and legal issues raised by new technologies and possibilities. Many complex interests exist, including those of people seeking treatment, those who have accessed treatment, donors of gametes or embryos, women who act as surrogate mothers, and their partners and families. Central to all considerations remains the child who will be born as a result, and its best interests and well-being. When considering the regulation of ART and surrogacy the challenge now is to determine not only *when* to regulate and *where* to draw the line concerning permissible and prohibited activities, but also *how* to regulate in areas that are ever-changing and rapidly advancing. I hope that my recommendations provide an appropriate balance and flexibility to serve into the future.

In relation to the conduct of the review and the writing of the report, I wish to acknowledge and thank Dr Maureen Harris, Manager of the Reproductive Technology Unit, and program manager for the review. I am very grateful for the support she showed me. I am also grateful to all those within the Department of Health who provided very open and honest insights regarding the operation, functions, and challenges faced regarding the regulation of ART. Throughout the review I observed a commitment to seeing positive change. The insights I gained enabled me to make recommendations relevant to improving and developing a better regulatory scheme. I also thank Ms Alyssa Hiscox who assisted me in the initial qualitative analysis of submissions.

Finally, but not least, I am grateful to all the Members of Parliament and staffers who attended the Parliamentary briefings and/or have followed the progress of the review on behalf of their constituents. As the report is passed to the Minister, and then to the Parliament, it is with hope that the contents herein will find your support, and lead to positive change.

Sonia Allan

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Executive Summary

Chapter 1

Chapter 1 introduces the review. It provides the background to the review, noting the development of assisted reproductive technology (ART) and early regulatory response in Western Australia. It then details the reasons for the current review, the scope of the review, the qualifications and experience I brought with me and the approach I took to conducting the review. Chapter 1 also sets out the principles upon which the review was predicated, including independence, objectivity, an inclusive and rigorous methodology, and openness and transparency. Details are also given regarding the process of consultation. Chapter 1 notes that the focus of this, Part 1, is upon matters relevant to the *Human Reproductive Technology Act 1991* (WA) and the regulation of ART in Western Australia. Part 2 of the report focuses upon both the *Human Reproductive Technology Act 1991* (WA) and *Surrogacy Act 2008*, with a focus upon surrogacy, and matters relevant to access to ART and surrogacy, and the best interests of children who are born as a result of ART and/or surrogacy. Chapter 1 concludes by recommending regular review of the regulation of ART every five years.

Chapter 2

Chapter 2 details the regulatory system in Western Australia. It includes discussion of the *Human Reproductive Technology Act 1991* (WA) (*HRT Act*) and associated regulations and directions. It also provides information about the Reproductive Technology Council (RTC), the Reproductive Technology Unit (RTU), and the Data and Information Unit, which all operate to support the regulatory system. Details of other relevant regulation are also provided including discussion of the Reproductive Technology Accreditation Committee (RTAC) accreditation scheme; NHMRC Ethical Guidelines relevant to clinical practice and research in assisted reproduction; and the regulation of health practitioners, businesses, therapeutic goods, and funding of medical services. Chapter 2 also outlines regulation of ART in the other states and territories of Australia.

Chapter 3

Chapter 3 moves to evaluate the Western Australian regulatory system considering the following Terms of Reference (TOR):

- The effectiveness of the current licensing regimen, including fee structure, reporting requirements, powers of inspection and powers of obtaining information.
- The effectiveness of the operation of the Council and committees of the Council.
- The Chief Executive Officer's (CEO now referred to as the Director General (DG) of the Department of Health (DoH)) power to issue directions, the power to make a Code of Practice, regulations and guidelines, and the scope and effect of the existing directions and regulations under the *HRT Act*.
- The effectiveness of powers of enforcement and disciplinary provisions under the *HRT Act* and the adequacy of offences and penalties.

- Whether there should be a process of review or appeal of decisions made (by the RTC) under the *HRT Act*.
- The need for the continuation of the functions conferred, on the RTC and DG respectively by the *HRT Act*.

The current and future operation and effectiveness of the regulatory system are also considered in light of other Commonwealth and state legislation and aspects that may be incorporated into the regulation of ART in Western Australia. Recommendations are made to improve the regulatory system by providing a more streamlined, cooperative and responsive regulatory system, and reducing unnecessary regulatory burden and duplication.

Chapter 4

Chapter 4 examines requirements under the current *HRT Act* and associated directions regarding record-keeping and reporting requirements. This includes an examination of data recording and reporting relevant to the monitoring and evaluation of ART treatment at state and national levels as well as data for research. It discusses significant issues faced by the Reproductive Technology (RT) Register maintained by the DoH that were reported to be caused by:

- outdated legislation and directions
- interpretations given to legislation which have restricted the ability to follow up on or link certain data
- constraints on practice
- lack of adequate resourcing
- at times, operational conflict between units within the DoH.

Discussion of how to resolve such issues ensues and recommendations are made regarding how to streamline data reporting and address data collection and reporting issues.

Chapters 5 and 6

Chapters 5 and 6 focus on the terms of reference regarding access to information about donation of sperm, eggs, and embryos, genetic parentage and donor conception and the Western Australian Voluntary Register (donor-assisted conception). Chapter 5 provides background to donor-conception practices with a specific focus on the issue of secrecy and anonymity, and the evolution in some jurisdictions of laws that require record keeping and release of information about donor conception. It details reasons that have been given for seeking identifying information about genetic heritage and/or relatives and examines requirements pursuant to the *HRT Act* regarding record keeping and access to information via the RT and Voluntary Registers. Issues with the current RT Register as outlined in Chapter 4 and specific to donor-conception records, are noted and further examined. The operation of the Voluntary Register is also discussed. Chapter 6 focuses upon how best to ensure the rights and interests of those born as a result of donor-conception in Western Australia. It also makes recommendations for the future operation of the Donor Conception Register.

Chapter 7

Chapter 7 discusses the special status of gametes and embryos when compared to other human biological materials due to the potential that their use will lead to the formation, or development, of a human life. It recognises that connected to such status are many complex ethical issues associated with their storage. In light of such recognition consideration of the rights to storage of gametes and embryos includes:

- the storage of gametes, eggs in the process of fertilisation and embryos (including the duration of storage and procedures for extension of storage periods)
- rights upon separation or divorce, or the death or the physical or mental incapacity of an individual, of one or both members of a couple
- rights of third parties such as subsequent spouses, and the rights of other relatives.

Recommendations are made to improve current laws and requirements regarding the storage of gametes and embryos to better reflect and take into account the personal circumstances of those storing them.

Chapter 8

Chapter 8 examines the issue of posthumous retrieval, storage, and/or use of gametes and embryos. It provides an overview of the law in Western Australia and in other jurisdictions of Australia. It is noted that while it is possible to retrieve gametes posthumously in Western Australia, current law prohibits use. Examination of recent judicial decisions when an issue has reached the Courts is then had. In giving consideration to such matters recommendations are then made concerning how Western Australian law may be improved regarding the posthumous use of gametes to better reflect the current state of law across the country.

Chapter 9

Chapter 9 addresses the Terms of Reference for the Western Australian Review of the *HRT Act* requiring examination of pre-implantation genetic diagnosis (PGD), pre-implantation genetic screening (PGS) and 'saviour siblings'. It discusses the acceptability of PGD screening dependent on the type of disease or illness, the reasoning behind such screening, and current requirements placed upon patients for approvals by the RTC prior to accessing such screening. Such requirements are found to be duplicative and redundant.

The chapter also examines PGD for sex-selection. When used to avoid sex-linked disease or disorder, this is accepted in Western Australia pursuant to meeting the access provisions of the *HRT Act*. PGD for sex selection when used for social reasons (for example, 'family balancing') is not possible in Western Australia. The chapter finds that such positions should be maintained.

Examination of PGD for tissue matching to assist an ill relative then ensues. It is found that it would be consistent with the practice of other states and territories to support the amendment of the *HRT Act.* This is in line with NHMRC Ethical Guidelines which set the parameters for the use of PGD for such tissue matching.

Chapter 9 also examines the need to ensure patients are not offered 'add-ons' to their in vitro fertilisation (IVF) procedures that do not have a sound evidence base but add significant cost onto their treatments.

Chapter 10

Chapter 10 examines research and experimentation on gametes, eggs in the process of fertilisation and embryos. It outlines the Australian Commonwealth legislation that was introduced in 2002 to govern research involving human embryos and cloning for human reproductive purposes. Current inconsistency in the Western Australian *HRT Act* with such laws is examined, noting the implications this has for research and practice in Western Australia. Discussion ensues concerning the need to adopt nationally consistent legislation regarding excess ART human embryo research and prohibited practices.

Chapter 11

Chapter 11 examines the emerging research concerning mitochondrial donation and gene editing. It reiterates the importance of Western Australia keeping its Council of Australian Governments (COAG) commitments regarding research involving human embryos and prohibited practices (discussed in Chapter 10) and continuing to engage with the national system of regulation. It also highlights the need to anticipate that there may be further amendments to that scheme and requirements for flexibility into the future as emerging technologies continue to present themselves. The chapter recognises that there is a need for wider consultation and scientific advice than was possible in the current review on such matters and that Western Australia should engage with national and international discourse on research regarding emerging technologies.

The chapter again highlights that the *HRT Act*, having been drafted in 1991 and last having seen amendments in 2004, is not operating in a manner that is responsive to rapidly changing technology. It is reiterated that it will be important to not only address the issues that have been raised in this review but to adopt a regulatory approach that remains flexible and responsive into the future.

Chapter 12

Chapter 12 discusses other matters concerning the *HRT Act* and the regulation of ART in Western Australia that people raised in their submissions but for which the Review did not receive sufficient submissions/input to be able to address the issue in depth. This includes the following:

- age limits regarding access to treatment
- the ability for clinics to refuse treatment in certain circumstances
- egg sharing by same-sex female couples
- the creation of embryos surplus to a patient's needs.

The issues raised and recommendations for further action are noted, including the opportunity for the recommended newly formulated advisory body to play a role in further considering such issues, educating clinics and the community, and/or in advising the Minister.

Findings

Introduction (Chapter 1)

1. That regular review of the *HRT Act* and associated regulations, directions, guidelines or other conditions of registration should be had.

The Western Australian Regulatory System (Chapters 2-3)

1. The 'command and control' regulatory system implemented in Western Australia in 1991, while having served a significant purpose in the early years of ART, is no longer effective or required. There is a need to adopt a regulatory structure that better responds to risk while removing duplication, redundancy, and unnecessary regulatory burden on those who comply.
2. A co-regulatory system that involves active participation in the regulatory system by both Government and clinics, cooperation and responsive regulation, would be more suitable to the governance of ART than the current 'command and control' system.
3. The Minister for Health/DG of the DoH should retain responsibility for the Government's role in the regulation of ART, with powers to issue conditions on the registration of clinics, regulations, directions, and guidelines when required.
4. Enforcement and disciplinary mechanisms should continue to be included in the legislation but should only be exercised when lower level compliance mechanisms have failed or where behaviour has been or is suspected to be particularly egregious. The power of enforcement/disciplinary measures should fall to the Minister/DG of the DoH.
5. The effectiveness of the Reproductive Technology Council (RTC) and its committees in relation to the early governance of ART should be recognised. However, the continuation of the functions conferred on the RTC as a regulator and enforcer are no longer suitable.
6. The RTC should be abolished and a new advisory body established. The committees of the RTC should also be abolished.
7. Provision should be made, and information clearly communicated regarding rights of review or appeal of decisions made by government departments regarding matters governed by the *HRT Act* and associated legislation.

Managing Information: Data Collection and Reporting (Chapter 4)

1. The RT Register faces significant issues of concern caused by:
   - outdated legislation and directions
   - interpretations given to legislation which have restricted the ability to follow up on or link certain data
   - constraints on practice
   - lack of adequate resourcing, and at times, operational conflict between units within the Department of Health.

   It is not currently in a state that the data within it can be relied on with confidence.

2. The issues faced by the RT Register again illustrate that the current regulatory system is not achieving its aims or objectives. This, in turn, has resulted in a lack of faith in the RT Register and data reporting requirements.
3. The Data and Information Unit has undertaken work to address issues with the RT Register, but, such work is in its early stages and much of what is proposed is aspirational. Significantly more work and financial commitment over time would be required to create a register that is fit for purpose. In the meantime, the current state of the RT Register raises significant issues of concern that require immediate action.
4. The recommended revision of the *HRT Act* and Directions, including repeal of provisions that are no longer relevant or effective, provides the opportunity to also address policy and processes that have proved not to be working in relation to data collection and reporting.
5. While there was an argued benefit in maintaining data specific to Western Australia at the DoH and being able to link that data to other Western Australian registries for the purposes of monitoring the outcomes of ART, reporting, public policy, and for research purposes, the current system is unique to Western Australia.
6. There was no robust argument put to the Review as to why the ART data collection could not, or should not, be aligned with the data reported to Australian & New Zealand Assisted Reproduction Database (ANZARD). ANZARD provides a uniform data reporting system for all clinics practising within Australia and New Zealand. It has a robust and operational data verification process that utilises modern online technologies. ANZARD confirmed that data points specific to Western Australia could be added to their database and thus could also be verified via that collection.
7. To protect privacy, it is possible for the data to be supplied to ANZARD in de-identified form (e.g. cycle code, recipient code, donor code, birth outcome code), and the final verified data could then be returned to the clinics and/or the DoH to be linked with the identifying information of recipients, gamete providers, and offspring as required.
8. Aligning the data collection and reporting process with ANZARD requirements would reduce the burden on those being regulated who currently are exposed to two separate reporting regimes, operating in different manners, with slightly different data points and with different reporting periods. On the latter point, it was not clear why a quarterly reporting period had been imposed in relation to the RT Register, nor why such a period needed to remain. Reporting via financial year was also not found to be suitable, as births are recorded by the calendar year.
9. There are significant and unnecessary cost and time burdens placed on clinics in relation to reporting. Freeing up the clinics from duplicative and burdensome processes and streamlining data collection and reporting with ANZARD requirements would enable professionals to focus on maintaining good clinical and laboratory practices and data management. Cost and time savings could then also be directed to supporting things (directly or indirectly) such as the recommended Donor Conception Register and provision of information to those seeking treatment, donating gametes or embryos, and people born as a result of ART and donor-conception.
10. There was no provided justification for adding further data points (Category D) to the RT Register. Such data points are not reported anywhere else in the country and would create an added reporting burden on WA clinics, as well as additional expense to clinics and the DoH.

Managing Information: Access to Information about Donation, Genetic Parentage, and Donor Conception (Chapter 5)

1. Donor-conceived people seek information about their donors and siblings for many varied reasons including, but not limited to, understanding their biological heritage, a sense of self and identity, to obtain or share medical information, fear and risks of forming consanguineous relationships, concern for each other's well-being, and a desire for openness, honesty and equality.
2. While there is legislative provision for access to information by donor-conceived people in Western Australia, this does not apply to all people. The *HRT Act* provides that donor-conceived people born after 2004 have a right to access identifying information about their donor at age 16.
3. Several jurisdictions around the world provide via legislation or the common law the right for donor-conceived people to access identifying information about their donor. Some such jurisdictions have moved to allow access to information by all donor-conceived people regardless of when the donation took place, and regardless of whether there was a promise of anonymity made to the donor.
4. At the time of writing, there was not a stand-alone donor-conception register held at the DoH. Rather data is held on the RT Register, which is a database that holds a variety of data collected from licensed clinics in Western Australia. The data custodians of the RT Register have reported that they are not confident, given the current state of data on the RT Register, that they could provide information to donor-conceived people without risk of error. The RT Register was reported to 'not be fit for purpose'.
5. A Voluntary Register was established in 2002 in Western Australia to enable donor-conceived people born prior to 2004 to access identifying information about their donor and siblings if the donor/siblings also place their name on the register. The register has no legislative framework and has developed over time based on a number of iterative and undocumented changes. Its current operation is based on 'policy' and processes that have been determined by RTU staff and the DoH. Processes, limitations, restrictions, and operational issues at times hinder access to information and have led to the distress of those seeking information.
6. Requirements for mandatory counselling imposed by the Voluntary Register are not meeting the needs of donor-conceived people. At present such counselling may only be provided by the RTC approved counsellors (which involves a limited list of fertility counsellors, two of whom sit on the RTC); people are required to pay for such counselling themselves, and release of matched information will not be provided until all parties have undertaken such counselling. This creates unnecessary barriers for donors and donor-conceived people to exchange information.

Managing Information: The Future Operation of the Donor Conception Register (Chapter 6)

1. One central donor-conception register should be established and maintained at the office of Births, Deaths, and Marriages (BDM), which is responsible already for the collection and management of data relevant to the birth of people in Western Australia.
2. To complement the information service that BDM provides, and to enable search and find functions and intermediary and support services, an independent agent with the necessary expertise, should be contracted to provide such services. The provider of such services should have 'trusted agency' status and be enabled to operate in an effective manner in terms of conducting search and find and family-linking services including but not limited to being able to access necessary records via BDM, the clinics, and otherwise as required. (Such services could also, in the interim, take over the Voluntary Register).
3. Intermediary services should be optional except in cases that involve the retrospective release of identifying information. In that case the intermediary service should be involved in initial contact with the donor to advise of an inquiry, explaining the contact veto system, and supporting any further requests to liaise between the parties.
4. Support services (such as counselling) for donor-conceived people, recipients, or donors, and their families, in relation to seeking information about genetic heritage and biological relations should be optional. All mandatory requirements for counselling should be repealed.
5. The option or requirement to engage with support or intermediary services should be free for donor-conceived people, recipients, donors, and their families. In practical terms, this means that such services will need to be subsidised by the Government and/or fees levied upon clinics as determined by the Government.
6. Access to identifying information about donors by donor-conceived people should be available regardless of when a donor-conceived person was born, subject to a contact veto system for those conceived with donated gametes or embryos prior to 2004.
7. Donors should be actively notified of all live births, sex of the child(ren) born, and the year of birth, in relation to their donation by clinics.
8. Donor-conceived people should be notified of any other donor-siblings, including the donor's own children, regarding the number of siblings, sex, and year of birth, upon request to the Donor Conception Register and/or a clinic.
9. Access to identifying information about donor-conceived people should only be available to donors and siblings of the donor-conceived person if the donor-conceived person (or recipient parents if the donor-conceived person is under 16) has registered their consent to the release of identifying information on the central register. However, outreach to donors and donor-conceived people by the intermediary and support services should be available in special circumstances for example, if there is a serious heritable illness or matter about which the donor/donor-conceived person should be notified.
10. Voluntary registration should be permitted on the central donor conception register to people for whom records may have been destroyed but are aware of their donor-code, and as a result of DNA testing identifying biological relatedness and subject to the testing being recognised as a legally valid test in establishing relatedness (e.g. from a National Australian Testing Authority (NATA) accredited facility) and any other requirements of BDM to ensure the integrity of the data held on the register.

11. An addendum to a donor-conceived person's birth-certificate should be placed on the register at BDM notifying the person that there is more information held about them on the register – being that they are donor-conceived. This addendum should be available to the donor-conceived person when they request their birth certificate after the age 16 or when they are of sufficient maturity, aligning with the legal age of access to information about donors in Western Australia and enabling them to decide if they wish to seek further information.
12. Recipient parents should be supported prior to receiving treatment, during pregnancy, and after the birth of a child(ren) with provision of information, education and clinics, and fertility counsellors about the importance of disclosure to children about their donor-conceived status, how to have discussions with children about such status, and the law providing the child with rights of access to information about their donor.
13. Donors should be provided information and counselled at the time of donation about the laws in Western Australia and disclosure to children about their donor-conceived status. They should also be informed of a child's right to access identifying information about their donor.

ART Issues: Storage of Gametes and Embryos (Chapter 7)

1. Current provisions regarding time limits for storage of embryos and gametes intended for personal use, and associated required periods of consent, in Western Australia are unsatisfactory and inconsistent with practices across Australia. Arbitrary time limits for storage imposed upon patients in relation to their gametes/embryos intended for their personal use are not evidence-based, and do not respect patient autonomy to consent to a period of storage that meets their personal needs and circumstances.
2. Time limits for storage of gametes or embryos for a person/couple's personal use would best be decided upon by that person/couple in consultation with their clinician, as per the requirements of the NHMRC Ethical Guidelines. They should not be stored after a person's death other than where there is evidence they have consented to the posthumous use of such gametes/embryos by their surviving spouse.
3. A distinction should be made for donated gametes/embryos, due to the implications for donor-conceived people. As such, and consistent with the states of New South Wales and South Australia, donated gametes/embryos should not be stored for more than 15 years after the date of donation, unless granted authority to extend that period by the Minister for Health. Preferably, a maximum cut-off-age should also be agreed upon (for example, a storage period that does not go beyond the donor's 50th birthday or a lesser time if stipulated by the donor), and not for a period beyond the donor's death.
4. Section 26(2) of the *HRT Act*, provides for the maintenance of storage where a couple for whom an egg in the process of fertilisation or an embryo disagree about its continued storage. Further clarification regarding this matter is needed. The *HRT Act* and HRT Directions should be consistent with the NHMRC Ethical Guidelines by drafting take place *at the time embryos are being stored* about the clinic's policy in relation to disputes, any pre-agreement by the parties, and discussion regarding what the law provides and requires.

5. The *HRT Act* should also be consistent with the NHMRC Ethical Guidelines that a decision to suspend the agreed time should be reviewed every five years, and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and the agreement made at the time of storage.
6. If a person is physically incapacitated, provided they still have the cognitive capacity, they will still be able to direct what happens to their stored gametes or embryos.
7. If a person suffers incapacity that results in lack of cognitive function or inability to make decisions or give consent, but such incapacity is impermanent (the person is expected to recover), then any storage limit should be suspended until the person recovers.
8. If the cognitive incapacity of a person that results in them losing decision-making capacity is assessed by a medical practitioner as permanent (such as they are in a persistent vegetative state from which they will not recover) or is due to brain death, then the person's wishes as expressed prior to this state should be taken into account in relation to the storage of their gametes or embryos. This should include consideration of if there was any explicit consent in writing as to what should happen to any gametes or embryos the person has stored for their personal use, which should have been discussed at the time of storage, or other evidence as to what the person would have wanted in relation to continued storage and the possibility of posthumous use by their surviving spouse.
9. Section 26(1)(b) provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman… in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death would then be directed by the law on the posthumous use of gametes/embryos.
10. Gametes or embryos stored for a person's personal use with their spouse should not be stored (or used) beyond a person's death if they have objected to such storage (or their use).
11. Subsequent spouses of the partner, or the relatives of a deceased person, should not have a 'right' conferred upon them to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1), and then will be subject to provisions relevant to the posthumous use of gametes/embryos.
12. If both members of a couple die (for example in a car accident), the clinic must allow any stored gametes/embryos to succumb, following approval by the Minister/DG of the DoH.

ART Issues: Posthumous Use of Gametes (Chapter 8)

1. The posthumous collection, storage and/or use of gametes and embryos collected either before or after a person's death is a sensitive and complex issue. Over many years laws and guidelines have been developed across Australia that permit such collection, storage and/or use subject to the deceased and the surviving spouse/partner having met certain requirements.
2. The current provisions in the *Human Tissue and Transplant Act 1982* (WA) permit the posthumous retrieval of gametes and have been held by the Court to provide valid criteria under which such retrieval may occur.

3. The posthumous retrieval of gametes should continue to be permitted in Western Australia pursuant to current provisions in the *Human Tissue and Transplant Act 1982* (WA) (*HTT Act*), and added provision being made in the *HRT Act*. However, as per the *HTT Act* the posthumous collection, storage and/or use of gametes should not occur when the deceased person, in their lifetime, objected to such collection, storage or use.
4. The current HRT Direction that effectively prohibits the posthumous use of gametes and embryos in Western Australia is inconsistent with:
    - the law that allows their collection
    - the recent Western Australian Supreme Court decision recognising the surviving spouse's/partner's right to possession of such gametes and right to direct the transfer of such gametes to a jurisdictions where they may be used
    - state and territory laws and guidelines across Australia.

    It also creates unnecessary distress and cost burdens on the surviving spouse (for example, via requiring court action) and does not ultimately prevent the posthumous use of gametes (or embryos).
5. Posthumous use of gametes and embryos collected before or after a person's death should be permitted subject to meeting requirements that:
    - 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 as a result.
6. Provision should be made in such circumstances for the deceased to be listed on the birth certificate as the parent of any child that is born as a result.

ART Issues: PGD, PGS, Saviour Siblings, and 'Add-on' Treatments (Chapter 9)

1. The acceptability of PGD screening may depend upon the type of disease or illness, and the reasoning behind such screening.
2. The *HRT Act* allows access to IVF, and use of PGD, when a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or a disease, and PGD is permitted, subject to RTC approval. A person or couple would not be able to access ART in circumstances in which they are in fact able to conceive a child but wish to access IVF to have a child whose tissue would match that of a parent, sibling or another relative.
3. The NHMRC Ethical Guidelines provide further guidance concerning when PGD would be acceptable, and what is required, including an express prohibition on the use of PGD for the prevention of conditions that are not 'seriously harmful' to the person to be born.
4. Examination of the past five year's Annual Reports of the RTC and consultation found that the RTC rarely, if ever, rejects such applications. The requirement for RTC approval and related processes were outdated, bureaucratic, and hindered patient ability to engage with techniques that could assist them in achieving the birth of a child, causing stress for people seeking treatment.
5. It is unsatisfactory to require RTC approval for PGD when the patients have already undertaken significant steps to determine its use, and the RTC approval process adds little if anything to the process. It is also unreasonable in the circumstances to limit patients to creating only three embryos without RTC approval. Such requirements should be repealed.
6. PGD for sex-selection to avoid sex-linked disease or disorder is accepted in Western Australia pursuant to the access provisions of the *HRT Act*. PGD for sex selection for social reasons (for example, 'family balancing') is not possible in Western Australia. The respective positions on PGD screening for sex-linked disease or disorder and PGD screening for social reasons should be maintained.
7. Regarding the use of PGD for the purpose of tissue matching, it would be consistent with the practice of other states and territories to support amendment of the *HRT Act* in line with the NHMRC Ethical Guidelines which set parameters for when the use of PGD for such tissue matching would be appropriate. Like other states, an independent ethics committee should be utilised and is best suited to make such assessments.
8. The use of PGS (PGT-A) has been questioned internationally with recent studies finding it does not result in any difference to live birth outcomes. It remains yet to be determined whether benefits in reduced miscarriage and/or embryo transfer outweigh the costs for the patient, higher workload for the IVF laboratory, and the potential effect on the children born.
9. The above raises a further issue regarding ensuring patients are not offered 'add-ons' to their ART procedures that do not have a sound evidence base but add significant cost onto their treatments. Clinics and health practitioners need to be aware of their obligations under Australian Consumer Law in relation to false and misleading conduct and advertising, as well as their obligations in relation to informed consent, including not providing unnecessary treatments to patients that have no therapeutic value.

ART Issues: Research Involving Human Embryos (Chapter 10)

1. The Commonwealth provides legislation and oversight of research involving human embryos and prohibited practices, including a national NHMRC licensing scheme.
2. New South Wales, Queensland, South Australia, Tasmania, Victoria and the Australian Capital Territory have enacted consistent legislation with the Commonwealth legislation and regulation governing research involving human embryos and prohibited practices.
3. Western Australia no longer has consistent legislation with that of the Commonwealth. As a result embryo research cannot be licensed in Western Australia. This includes research that was previously permitted. Consequently, research required to be licensed by the NHMRC Licensing Committee is not being undertaken in Western Australia.
4. It would be in keeping with Western Australia's COAG commitments to have uniform legislation in this area.

ART Issues: Emerging Technologies and Practices (Chapter 11)

1. Research involving human embryos that promises to cure diseases, or to assist women to bear children free of heritable disease continues to progress. While the *HRT Act* has not permitted such research in Western Australia, new applications and technologies continue to evolve in other jurisdictions. Most recently, this has included research involving mitochondrial donation, and research involving gene editing using CRISPR-Cas9.
2. The Commonwealth Senate Community Affairs References Committee has recommended that further public consultation and scientific advice is needed in relation to mitochondrial donation, at a national level, led by the NHMRC. Western Australia should engage with that process via COAG when it proceeds, as well as exploring its own stance on such issues further via the recommended advisory body.
3. Similarly, in relation to human genome editing, much wider consultation and scientific advice are needed than was possible in this Review. Western Australia should engage with wider national and international discourse on such research, as well as examining state-based understanding and attitudes further.
4. It is important to not only address the issues that have been raised in this review but to adopt a regulatory approach that remains flexible and responsive into the future.

ART Issues: Other Matters (Chapter 12)

1. There were a number of matters presented to the review that require further consideration, clarification, direction, and/or guidance from the Minister, DG, and/or the DoH regarding:
    - age limits regarding access to treatment
    - the ability for clinics to refuse treatment in certain circumstances
    - egg sharing by same-sex female couples
    - the creation of embryos surplus to a patient's needs.

Recommendations

Regular Review of legislation (Chapter 1)

1. Provision should be made in the *HRT Act* and *Surrogacy Act 2008* (WA) for review of their operation and effectiveness every five years after the date of the report from the last review being received by the Minister.

The Western Australian Regulatory System (Chapters 2-3)

2. The *HRT Act*, HRT Regulations, and HRT Directions be revised and/or repealed to create a co-regulatory system for the governance of ART including setting the parameters for ART practice in Western Australia, implementing principles of cooperation and responsive regulation in the carrying out of the Department of Health's regulatory functions, and attending to matters discussed in the review of the *HRT Act* and *Surrogacy Act 2008* (WA).
3. The framework legislation provides overarching principles that emphasise:
    - the paramountcy of the health and welfare of any child to be born as a result of ART
    - the health and safety of those accessing ART, donors and surrogate mothers
    - principles of non-discrimination
    - the values of non-commercialisation of human reproductive materials or capabilities.
4. The framework legislation provides that:
    - conditions of registration may be applied to all clinics/practitioners or be responsive to a clinic's practices if required (for example, if a clinic fails to meet RTAC standards, registration might be limited to six months instead of a year with requirements that the clinic address the issue)
    - directives may be issued by the Minister from time to time as the need arises, informed by advice received from the new body, research, or broader consultation to allow for responsive and flexible regulation.
5. The RTC be abolished and a new 'body' be established whose role is to:
    - provide the Minister/DG of the DoH with information regarding any research that may inform regulation and governance of ART
    - advise the Minister/DG of the DoH regarding medical, social, scientific, ethical, legal, and moral issues arising from ART and any necessary directives/conditions of registration needed to clarify acceptable practice in Western Australia.
6. The advisory body's membership include in addition to membership reflective of the current RTC at least a donor of gametes/embryos, a recipient of ART, a person born as a result of donor-conception, and that each membership role be represented by one person each.

7. The advisory body's membership should be rotated every three years to allow other members of the public and professions to participate and that reappointments should only occur if there is no other person who has expressed interest in being on the adivsory body.
8. The current committees of the RTC should be discharged and their functions repealed. This should occur alongside recommended changes to the *HRT Act* regarding licensing, storage periods, posthumous use of gametes, and PGD. (Functions of the scientific advisory committee will continue within the broader remit of the new advisory body functions).
9. Requirements for 'approved counsellor' status be repealed, and all references to 'approved counsellor' be amended to counsellor. That counsellors be appropriately qualified AHPRA registered mental health professionals (for example, a psychologist) or equivalent (for example, a suitably degree qualified social worker).
10. The Minister/DG/DoH should:
    a. provide information to the public and health professionals regarding what is permissible under the Act
    b. receive from clinics a copy of the RTAC audit and any recommendations for improvement, and any further reports necessary to inform the Minister/DG of action that has been taken in response
    c. impose any conditions of registration that may need to be applied
    d. consider the results of any inspection or audit undertaken by a suitably qualified person appointed by the Minister and any appropriate enforcement action to be taken by the Minister or the DG of the DoH on the Minister's behalf
    e. report annually (per calendar year) on the above, as well as on outcomes of ART in Western Australia, and any other matters decided by the Minister/DG of the DoH.
11. Powers of enforcement continue to be included in the Act and fall to the Minister for Health or DG of the DoH to be exercised only when lower-level compliance mechanisms have failed or where behaviour has been or is particularly egregious.
12. Right of review concerning Government decision making is set out in the legislation and/or relevant DoH communications and be clearly communicated to the public and clinics.
13. The Minister, DG of the DoH, and the advisory body be supported in their functions by DoH staff member(s), including functions relevant but not limited to the implementation of the Act and public education, and that such staff be the point of contact for people who wish to seek ethical or policy guidance or raise issues regarding the Act, which may then be referred to the advisory body or Minister for Health or DG of the DoH as required.

Managing Information: Data Collection and Reporting (Chapter 4)

14. Identified issues regarding the data collection held by the Data and Information Unit be addressed as a *matter of priority* (urgency) to ensure data held is accurate and reliable.
15. The recommended revision of the *HRT Act* and Directions include revision of provisions, policy and processes that have proved not to be working in relation to data collection and reporting regarding ART in Western Australia.
16. The DoH streamline its reproductive technology data collection and reporting to align with the yearly ANZARD reporting including updating the data dictionary to mirror ANZARD, adding to ANZARD the additional Category C data-points specific to Western Australia and moving the reporting requirements to be per the calendar year.
17. No 'Category D' data be added, and therefore ANZARD not be required to establish changes to its databases other than to accommodate additional Category C data-points (thus avoiding the Western Australian clinics and government incurring unnecessary costs).
18. The DoH's processes regarding data collection be revised so that once data is verified via the ANZARD process clinics then provide a copy of such verified data re-linked with identifiers to the DoH Data and Information Unit for the purposes of monitoring, quality control, public reporting, policy and research as required.
19. The Minister for Health and/or the DG decides who will generate the annual data report, with the options being either:
    - the Data and Information Unit work cooperatively with the DoH support staff to produce an annual report. (Noting this will require an additional staff member who has reproductive technology data expertise being situated in the Data and Information Unit)
    - the Government otherwise commission ANZARD to generate a specific report for Western Australia (like New Zealand) at an estimated cost of $20,000-$30,000 per annum.
20. The revised *HRT Act* includes provisions that would enable linkage between the RT Register and other Western Australian registers, including but not limited to the Midwives Notification System, and BDM registers (noting this is where it is recommended donor-conception registers will be held).

Managing Information: Access to Information and the future operation of the donor-conception register (Chapters 5-6)

21. An audit should be undertaken of the data held on the RT Register as a matter of priority to ensure that all data held in relation to donors, recipients, and donor-conceived people is accurate and reliable, and may be linked with confidence.
22. New legislative provisions be drafted that provide for a donor-conception register that operates in a manner that will best serve access to information by donor-conceived people, donors, and recipients.
23. Pursuant to section 45 of the *HRT Act*, the DG of the DoH should cause a donor-conception register to be kept at the office of BDM (in a manner approved by the Minister for Health, and in consultation with other relevant government departments as

required). Noting that any new Act in the future should maintain provision for the donor conception register and its operation.

24. The donor conception register should be supported by an independent agency that is contracted to provide intermediary and support services to those seeking information about genetic heritage and biological relations, those about whom information is sought, and their immediate families; and relevant search and find services.
25. Any necessary provision required to enable such an agency to operate in an effective manner (including but not limited to being able to access necessary records via BDM, co-operation by clinics, and otherwise as required) be made.
26. Provision should be made within the new HRT Directions that intermediary services be *optional* except in cases that involve the retrospective release of identifying information in which case the intermediary service should, after locating the donor, make the initial contact to advise of an inquiry, explain the contact veto option, and provide further support if requested.
27. Section 49(2a) and s 49(2d) of the *HRT Act* be amended to remove the requirement for 'approved counselling' prior to release of identifying information to a donor-conceived person about their donor; and in the interim, pursuant to ss 49(2f) the DG include in new Directions that 'approved counselling' means counselling a person chooses to engage in and may include a discussion with the intermediary and support service provider about the implications of access to information.
28. Provision be made for intermediary and support services to be provided free of charge to donor-conceived people, donors, recipients, and/or their families in relation to access to identifying information about genetic heritage and relations, via government subsidy to the providing agency and/or fees levied upon clinics or as otherwise determined by the Government.
29. Section 49(2e) of the *HRT Act* be amended to enable access to identifying information about donors by all donor-conceived people when they reach the age of 16 or sufficient maturity, regardless of when they were born, subject to a contact veto system for those conceived prior to 1 July 2004; and that in the interim the DG provide direction regarding section (2e)(b)(ii) which allows release provided there was adequate information provision before donation that future changes in legislation might enable information to be divulged or communicated without the donor's consent.
30. The DG make provision within the new HRT Directions that donors be actively notified by clinics of all live births, sex of the the child(ren), and year of birth, resulting from their donation(s).
31. The DG make provision within the new Directions that donor-conceived people, upon request to the Donor Conception Register and/or a clinic, be provided with non-identifying information regarding the number, sex and year of birth of any donor-siblings, including the donor's own children.
32. Provision should be made for voluntary registration of consent upon the register by a donor-conceived person (or their recipient parent if the person is under 16) to enable access to identifying information about that person by their siblings or donor.
33. The new Directions make provision for outreach to donors and donor-conceived people by the intermediary and support services in special circumstances. For example, if there

is a serious heritable illness or a matter about which the donor/donor-conceived person should be notified.

34. The new Directions make provision for voluntary registration on the central donor conception register by people for whom records may have been destroyed but are aware of their donor-code, and as a result of DNA testing identifying biological relatedness, subject to the testing being recognised as a legally valid test in establishing relatedness (e.g. from a NATA accredited facility) and any other requirements of BDM (or the relevant government authority) to ensure the integrity of the data held upon the register.
35. Legislative provision should be made to require an addendum to a donor-conceived person's birth-certificate notifying the person that there is more information held about them on the register. This addendum should be available to the donor-conceived person when they request their birth certificate after the age of of 16 or when they are of sufficient maturity to enable them to decide if they wish to seek further information.
36. The Directions provide that recipient parents must be supported prior to receiving treatment using donated gametes or embryos, during pregnancy, and after the birth of a child(ren) via provision of information, education and clinics, and fertility counsellors about the importance of disclosure to children about their donor-conceived status, how to have discussions with children about such status, and the law providing the child with rights of access to information about their donor.
37. The Directions require that donors must be provided information and counselled at the time of donation about the importance of disclosure to children about their donor-conceived status, and the law in Western Australia and that donation cannot be accepted without consent to a person born as a result of such a donation having access to identifying information.
38. Legislative provision be made to allow the issuance of a second birth certificate at the request of a donor-conceived person, or person born as a result of surrogacy, or their legal parent(s) (if the person is under the age of 16) that contains factual information about a person's genetic and birth heritage.

ART Issues: Storage of Gametes and Embryos (Chapter 7)

39. The Minister repeal s24 of the *HRT Act* and Direction 6.8 which stipulate time limits for storage of embryos and gametes respectively, and provide in the new *HRT Act*/Directions that a person or couple, for whom gametes or embryos will be stored for their personal use in assisted reproduction, and the clinic must discuss and agree upon in writing:
    a. the storage period for the person or couple's gametes/embryo(s) that suits their circumstances
    b. the conditions and period of time upon which the gametes/embryos will be stored and will cease to be stored
    c. the gametes/embryos not being stored beyond death or a person unless there is consent regarding the posthumous use of such gametes or embryos by the surviving spouse.

40. The Minister/DG provide in the (new) HRT Directions the conditions pursuant to which a clinic may lawfully remove the gametes or embryo(s) from storage and allow them to succumb. Such conditions should include the failure of a person or couple to pay the storage fees (if any) for a period of more than five years and/or the failure of a person or couple to consent to a further storage period after the previously agreed storage period has expired, and there has been an inability to contact or trace the person or couple after reasonable attempts to do so have been made in relation to non-payment of storage fees or during the three months preceding the end of the storage period.
41. The new HRT Directions detail what constitutes a 'reasonable attempt' in relation to seeking contact with a person or couple who have stored gametes/embryos where storage fees have not been paid for a period of five years, or the expiry date of agreed storage is about to be/has been reached.
42. A section be drafted for inclusion in the (new) *HRT Act*/Directions that *donated* gametes/embryos should not be stored for a period of more than 15 years from the date of donation, and not after a) the gamete donor (donor of ova or sperm) has reached the age of 50 or is deceased; or b) in relation to a donated embryo, the donor(s) (or any gamete provider where the embryo has been created using both donated eggs and sperm) has reached the age of 50 or is deceased; unless authorisation has been granted by the Minister/DG. Such authorisation must not be given unless the Minister/DG is satisfied that there are reasonable grounds for extending the storage period having regard to any relevant guidelines issued by the Minister/DG.
43. Section 26(2) of the *HRT Act* be maintained (in the current or any new legislation) in that it provides for the maintenance of storage where a couple for whom an egg in the process of fertilisation or an embryo disagree about its continued storage. Further clarification should be provided in the HRT Directions – consistent with the NHMRC Ethical Guidelines – by requiring discussion to take place (at the time embryos are being stored) about the clinic's policy in relation to disputes, any pre-agreement by the parties and discussion regarding what the law provides. The HRT Directions should also specify that a decision to suspend the agreed time period should be reviewed every five years and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and agreement made at the time of storage.
44. The HRT Directions provide that persons who are physically incapacitated maintain the right to direct what happens to their stored gametes or embryos.
45. The HRT Directions provide that if a person suffers incapacity that results in lack of cognitive function or decision making capacity, but such incapacity is not expected to be permanent (i.e. the person is expected to recover), then any storage limit be suspended until the person recovers. If it is decided by a medical professional that they will not recover, at which point their prior wishes, and any agreement regarding storage should be taken into account, as well as any legislative provisions or directions relating to the vesting of rights in any spouse/survivor, to determine if or when such gametes/embryos may be permitted to succumb.
46. Section 26(1)(b) of the *HRT Act* be maintained (in the present Act and any new legislation) in that it provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death should be determined by the law on the posthumous use of gametes and embryos.

47. The HRT Directions provide that if both members of a couple die (for example in an accident), the clinic must allow any stored gametes/embryos to succumb, following approval by the Minister/DG of the DoH.

48. The HRT Directions provide that subsequent spouses of the surviving partner, or the relatives, of a deceased person, do not have the 'right' to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1), which is subject to provisions relevant to the posthumous use of gametes/embryos.

ART Issues: Posthumous Use of Gametes (Chapter 8)

49. In redrafting the *HRT Act* and repealing any current Directions, that provision be made that 'retrieval of gametes from a person who is unconscious and near death, or after their death may occur only when the requirements of s 22 of the *Human Tissue and Transplant Act* (WA) have been met, and only for the purpose of use by the surviving spouse or partner of the person, or a surrogate mother, for the purposes of bearing a child(ren) who will be cared for by the surviving spouse or partner.'

50. In redrafting the *HRT Act* (and repealing any current Directions) that provision be made that: 'The posthumous use of gametes or embryos collected before or after a person's death may only occur when:

    - 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.'

51. In redrafting the *HRT Act* (and repealing any current Directions) that provision be made that 'court approval is not required where the above conditions have been met.'

52. In redrafting the *HRT Act* and repealing any current Directions that provision be made that 'where there is evidence that a person has expressly objected to the posthumous use of their stored gametes or embryos, or the posthumous collection and/or use of gametes, the posthumous collection/use of the stored gametes or embryos to achieve pregnancy is prohibited'.

53. In cases in which a child(ren) have been born as the result of posthumous use of a deceased partner's gametes or an embryo made with such gametes, that provision in the *Births, Deaths and Marriages Registration Act 1998* be made to enable the deceased to be listed on the child(ren)'s birth certificate as a parent of that child.

54. Further research, consideration, and targeted consultation be undertaken in relation to any other necessary consequential amendments to the Western Australian *Administration Act 1903* and *Family Provision Act 1972*.

ART Issues: PGD, PGS, Saviour Siblings, and 'Add-On' Treatments (Chapter 9)

55. Provisions in the *HRT Act* and HRT Directions requiring RTC approval for PGD and related matters be repealed, subject to a condition of registration that clinics adhere to the NHMRC Ethical Guidelines regarding the use of PGD, including the restriction that PGD be used only to screen embryos for conditions that will be seriously harmful to a child born with such a condition.

56. Provision should be made either via the *HRT Act* or HRT Directions (as required) that PGD for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or other relative is acceptable subject to meeting the requirements of the NHMRC Ethical Guidelines.

57. It be a condition of registration that clinics do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or that are not supported by research to improve birth outcome.

58. It be a condition of registration that clinics obtain informed consent from patients in relation to all ART treatments, including but not limited to any 'add-on' treatments offered to the patient undergoing ART or to the gametes/embryos that will be used in the patient's treatment, and that clinics do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.

ART Issues: Research Involving Human Embryos (Chapter 10)

59. Western Australia should enact uniform legislation to the *Commonwealth Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition on Cloning for Human Reproduction Act 2002* (Cth), in keeping with its COAG commitments regarding research involving human embryos and prohibited practices.

60. Western Australia should consider how best to incorporate changes to Commonwealth legislation regarding human embryo research and related matters into its own law (for example via legislation, regulations, and/or directions) to allow for future flexibility, responsiveness, and regular review in anticipation of further advances in science and emerging technologies.

ART Issues: Emerging Technologies and Practices (Chapter 11)

61. Western Australia should engage with any national/COAG led public consultations and seeking of scientific advice regarding mitochondrial donation, gene technology, or other relevant emerging technologies, as well as exploring its own stance on such issues further via the recommended advisory body.

ART Issues: Other Matters (Chapter 12)

62. The Minister/DG provide clear and consistent guidance regarding how section 23(1)(d) of the *HRT Act* stipulating the reason for infertility must not be age, should be interpreted and applied.
63. Further research and consultation be conducted regarding the current section 23(1)(d) requirements having been interpreted as post 'average age of menopause' and whether a cut-off age or stage of life such a 'post-menopause' or otherwise continues to be appropriate.
64. Further consideration should be given to whether such limitations should only apply to women (as it appears is current practice), whether age limitations should also be applied to men, or whether a combined age cut off would be justified.
65. Provision should be made in the Western Australian legislation and/or directions that there be no obligation upon health practitioners or ART clinics to provide ART treatment.
66. Further consultation be had with members of the LGBTQI community, ART clinicians, counsellors, people born as a result of ART, legal and ethics experts and other interested parties, on issues related to egg sharing or use of an embryo formed with one partner's ova by the other female partner in a same-sex relationship.
67. The DoH provide education and information to clinics and consumers regarding the acceptable provision of treatment, treatment options, patient consent, and patient autonomy to decide the nature of treatment undertaken; as well options regarding what to do with excess embryos, and the provision of support in decision making in this regard (e.g. counselling).

Glossary

Artificial Fertilisation Procedure: Any artificial insemination procedure or in vitro fertilisation (IVF) procedure. (*HRT Act 1991*)

Artificial Insemination Procedure: A procedure where human sperm are introduced, by a non-coital method, into the reproductive system of a woman but which is not, and is not an integral part of, an in-vitro fertilisation procedure. (*HRT Act 1991*)

Assisted Hatching: A procedure in which the outer layer of the *embryo* [called the zona] is thinned by a laser to help the embryo implant more easily.

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 and treatment to induce ovulation or spermatogenesis when used in conjunction with the above methods.

ART with donor: ART may involve the use of 'donor' spermatozoa (sperm) and/or oocytes (eggs) gametes or 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.

Blastocyst: The term for an *embryo* five days after fertilisation which has now developed a distinctive shape with different parts clearly identifiable within its fluid-filled cavity.

Cervix: The neck of the womb. The *embryo transfer* normally involves passing a small soft catheter through this.

Donor insemination: The use of sperm from a male donor in order to achieve a pregnancy.

Egg collection: The stage of an IVF treatment cycle where the woman's eggs are collected under vaginal ultrasound.

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 and the egg donor will have no rights or responsibilities in relation to that child.

Embryo: Once the egg has joined with the sperm it is called an *embryo*.

Embryo Transfer: The stage of an IVF treatment cycle where the *embryo* is transferred back to the woman's uterus via a fine catheter.

Follicle: The sac of fluid that surrounds the egg and which can usually be seen on the ultrasound scan.

Follicle Stimulating Hormone (FSH): A hormone produced and released from the *pituitary gland*, to stimulate the *follicle* (and thus the egg) to grow.

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

hCG: The hormone that is produced by the *embryo* and is measured in a pregnancy test. Injections of *hCG* can be used to trigger maturation of the egg which is then followed by *ovulation*. Injections of hCG may also be used to maintain hormone levels in the second half (*luteal phase*) of the cycle.

ICSI (Intracytoplasmic Sperm Injection): The fertility technique where a single sperm is selected and directly injected into an egg. High magnification ICSI uses extremely high magnification to help sperm selection for specific patients.

Implantation: The embedding of the *embryo* in the lining of the uterus six to seven days after fertilisation.

Infertility: Is the inability to conceive after a year of unprotected intercourse in women under 35 or after six months in women over 35, or the inability to carry a pregnancy to term. Also included are diagnosed problems such as anovulation, tubal blockage, and low sperm count. The 'causes' of infertility may relate to ovulation, tubal or uterine factors, the male-factor, sperm mucous interaction, endometriosis, sexual dysfunction, or be simply unexplainable.

Intra-uterine Insemination (IUI): Treatment that involves inserting the partner's concentrated *semen* through the neck of the womb into the uterus itself close to the time of *ovulation*.

IVF (In Vitro Fertilisation): The procedure, by which an egg and sperm are joined together outside the body, in a specialised laboratory. The fertilised egg (*embryo*) is allowed to grow in a protected environment for some days before being placed back (transferred) into the uterus.

Oocyte: The fully mature egg produced from the ovary each month.

Ovarian Hyperstimulation Syndrome (OHSS): A condition where women over-respond to fertility drugs and can develop severe fluid retention and abdominal swelling.

Ovaries: The female sex glands which produce eggs.

Ovulation: The time the egg is released.

Ovulation Induction: Medication used to stimulate growth and release of the eggs. This may be used in combination with Intra-Uterine Insemination.

Pre-implantation genetic diagnosis (PGD): A procedure for testing early embryos to find out if a genetic disorder affects them. It involves removing a cell from an IVF embryo to test it for a specific genetic condition before transferring the embryo to the uterus.

Pre-implantation genetic screening (PGS): The term used to refer to screening embryos for overall chromosomal normalcy. It involves screening embryos for aneuploidy (missing or additional numbers of chromosomes) or for unspecified and multiple genetic or chromosomal abnormalities where the gamete providers are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. It has thus, more recently, been referred to as PGT-A – pre-implantation genetic testing for chromosomal abnormality.

Pre-implantation Genetic Testing (PGT): Testing the genetic makeup of the *embryo* before it is transferred back into the woman. Sometimes the use of the term PGT encompasses both PGD and PGS (above).

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

Spermatozoa (sperm): The male reproductive cells (gametes).

Sperm Donor: A male 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.

Surrogacy: Surrogacy is a practice whereby a woman agrees to become pregnant and bear a child for another person or persons, to whom she intends to transfer the child's care at, or shortly after, birth.

Ultrasound (scan): A modified form of radar used to see the follicles in the ovary and pregnancy in the uterus. This may be done either through the abdomen or (more usual in IVF) through the vagina.

Uterus (womb): The female reproductive organ that supports the developing foetus. It is the source of a woman's menstruation.

Chapter 1

Introduction to the Review

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Introduction to the Review

1.1 Background: Assisted reproductive technology

ART using artificial insemination, in vitro fertilisation, and several other techniques have presented new avenues for people suffering from infertility and/or childlessness to build a family. For some, this has meant using ART to create biologically related offspring using their own sperm and eggs. Other people have turned to donor conception – which involves the use of donated sperm, eggs or embryos – and/or surrogacy. The techniques used have evolved over time, as have debates and views regarding the ethical, social, and legal issues raised and what is considered acceptable.

A brief examination of the development of ART shows that human artificial insemination of a wife with her husband's sperm was reported to have occurred at least by the late eighteenth century.[1] The use of 'donor' sperm to achieve pregnancy, in response to male infertility, increased significantly following the discovery of techniques that allowed for the freezing of human sperm[2] and the addition of antibiotics to the sperm solution to prevent contamination.[3] Research followed that led to the creation of an embryo outside of a woman's body via in vitro fertilisation (IVF). The first human pregnancy resulting from IVF occurred in Victoria in 1973, and the first child was born as a result of full-term IVF pregnancy in 1978, in the United Kingdom.[4] The first child born as a result of IVF use in Australia was in 1981.[5]

As such advances in technology occurred many government inquiries across Australia were undertaken to examine the ethical, social and legal issues raised. There was a particular focus on issues such as legal parentage of the child born, children that were born as a result of the donation of gametes, and whether regulatory oversight of ART practices was necessary.[6]

1 F.N.L. Poynter, 'Hunter, Spallanzani, and the History of Artificial Insemination' in Lloyd G. Stevenson & Robert P. Multhauf (Eds) *Medicine, Science and Culture: Historical Essays in Honor of Owsei Temkin* (1968) pp 97, 99–100.

2 Polge, C. Smith, A.U. & Parkes, A.S. 'Revival of Spermatozoa after Vitrification and Dehydration at Low Temperatures' (1949) 164(4172) *Nature* 666.

3 Bratton, R.H. & R.W. 'The fertility of bovine semen in extenders containing sulfanilamide, penicillin, streptomycin, and polymyxin (1950) 33 J *Dairy Sci* 544-7.

4 P C Steptoe and RG Edwards, 'Birth After Re-implantation of Human Embryo', 2 *Lancet* 366 1978.

5 For an early history of IVF in Australia see J Leeton, 'The Early History of IVF in Australia and its Contribution to the World (1970–1990)' (2004) 44(6) *Aust NS J OBstet Gynaecol* 495 at 501.

6 See, for example, D Chalmers, *Final Report: Committee to Investigate Artificial Conception and Related Matters* (Hobart, June, 1985); Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation (Waller Committee) *Report on Donor Gametes in IVF* (advance copy, Victoria, August 1983); Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation (Waller Committee) *Report on the Disposition of Embryos Produced by In Vitro Fertilisation* (Vic Government Printer, August 1984); A F Connor and P Kelly, *Report of the Working Party on In Vitro Fertilisation and Artificial Insemination by Donor* (South Australia, January 1984); J Demack, *Report of the Special Committee Appointed by the Queensland Government to Enquire into the Laws Relating to Artificial Insemination, In Vitro Fertilisation and Other Related Matters* (Queensland, March 1984); Medical Research Ethics Committee, *Embryo Donation by Uterine Flushing. Interim report on Ethical Considerations* (Canberra, ACT, NHMRC, 1985); New

As a result, legislation was introduced in each of the states and territories that established the legal parents of a child born as a result of ART to be the woman who gave birth to the child and, if she was married or in a de facto relationship, her husband/partner provided he consented to the procedure.[7]

In addition, three states – Victoria, South Australia, and Western Australia – introduced regulatory systems to oversee clinical practice and provide for certain requirements that must be met prior to a woman (and her partner if any) being able to access ART. In Victoria, legislation was enacted in 1984, three years after the first IVF birth in Australia.[8] South Australia followed, introducing legislation in 1988;[9] and Western Australia passed legislation in 1991. New South Wales introduced legislation in 2010 to prevent the commercialisation of human reproduction and to protect the interests of people born as a result of ART treatment, providing gamete(s) for use in ART treatment or for research, and women undergoing ART treatment.[10]

The Australian Capital Territory, Northern Territory, Queensland, and Tasmania remain without a specific statutory regime governing clinical practice related to assisted reproduction.[11] However, there are National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*,[12] which clinicians in all states and territories are required to adhere to.

All states and territories, except the Northern Territory, have also introduced legislation relevant to surrogacy arrangements. Such legislation is discussed further in Part 2 of this report.[13]

South Wales Advisory Committee on Human Artificial Insemination, *Australian Attitudes to Human Artificial Insemination*, prepared by G Rawson (NSW Government Printer, 1984); New South Wales Law Reform Commission, *Human Artificial Insemination* (Discussion Paper 11, NSW Government Printer, 1984); In Vitro Fertilisation Ethics Committee of Western Australia., Michael, C. A., Meadows, R. J. *Report of the committee appointed by the Western Australian Government to enquire into the social, legal and ethical issues relating to in vitro fertilisation and its supervision*. (1986). Subiaco, W.A: University of Western Australia, Dept. of Obstetrics and Gynaecology.

7 See for exact provisions: *Status of Children Act 1996* (NSW) s 14; *Status of Children Act 1974* (Vic) ss 10C–10F; *Family Relationship Act 1975* (SA) s 10C; *Artificial Conception Act 1985* (WA) ss 5–7; *Parentage Act 2004* (ACT) s11; *Status of Children Act 1978* (Qld) ss 15–17; *Status of Children Act 1974* (Tas) s 10C. This would later be expanded to recognise the same sex partner of a woman who underwent a fertilisation procedure as a legal parent.

8 In 1984, following the Waller Committee inquiry into IVF the Victorian Government passed the Infertility (Medical Procedures) Act 1984 (Vic). The Infertility (Medical Procedures) Act was later repealed by the *Infertility Treatment Act 1995* (Vic). In the early 21st century, the legislation was again reviewed. *The Assisted Reproductive Treatment Act 2008* (Vic) came into operation on 1 January 2010.

9 The South Australian legislation was reviewed in 2010 with the original legislation being repealed and replaced with the *Assisted Reproductive Treatment Act 2010* (SA).

10 *Assisted Reproductive Technology Act 2007 (NSW)* s 3.

11 Note all states and territories except for the Northern Territory have legislation governing surrogacy. This will be discussed further below.

12 National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* 2017. Hereafter, 'NHMRC Ethical Guidelines'

13 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Report: Part 2),* 2019.

1.2 Background: The *Human Reproductive Technology Act 1991* (WA) and associated instruments

In Western Australia, the *Artificial Conception Act 1985* (WA) established legal parentage of people born as a result of ART. Then, in response to the considerable community disquiet in the 1980s about the ethical implications of ART[14] the Government established the 'In Vitro Fertilisation Ethics Committee of Western Australia'[15] to inquire into the social, legal, and ethical issues relating to in vitro fertilisation and its supervision. A 'Reproductive Technology Working Party' was tasked with making specific legislative recommendations based on the reports of the In Vitro Fertilisation Ethics Committee, an independent evaluation of IVF, and consideration of the newly enacted *Reproductive Technology Act 1988* (SA) in South Australia.

In 1988, the Reproductive Technology Working Party recommended that two separate Acts of Parliament should be established to govern reproductive technology and surrogacy respectively. A Select Committee then considered the recommendations[16] following which the *Human Reproductive Technology Act 1991* (*HRT Act*) was enacted, receiving Royal Assent on 8 October 1991 and coming into full operation on 8 April 1993. Note, surrogacy legislation did not follow until 2008. The regulation of surrogacy is discussed further in Part 2 of this report.[17] The *HRT Act* long title was and remains:

> *An Act to establish the Western Australian Reproductive Technology Council; 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.*

It provides for the Reproductive Technology Council to compile a 'Code of Practice', as well as for Regulations, which shall have effect notwithstanding any inconsistency with the Code of Practice; and, Directions given by the DG, which shall have effect except for any inconsistency with the Code or regulations.[18] A Code of Practice has never been compiled. The following Regulations, Directions, and Guidelines, were issued over time:

- The Human Reproductive Technology (Licenses and Registers) Regulations 1993 (the HRT Regulations);
- Draft Guidelines to assist in compliance with Directions issued by the Commissioner of Health (as the position was then referred to) under the *HRT Act 1991* on the advice of the WA Reproductive Technology Council (NB. These applied to the 1993 Directions below);[19]

14 Select Committee on the *HRT Act 1991* Report (1999), p 1.

15 See further In Vitro Fertilisation Ethics Committee of Western Australia, *Interim report of the In Vitro Fertilisation Ethics Committee of Western Australia* (1984; Michael, C. A., Meadows, R. J., In Vitro Fertilisation Ethics Committee of Western Australia., *Report of the committee appointed by the Western Australian Government to enquire into the social, legal and ethical issues relating to in vitro fertilisation and its supervision.* (1986). Subiaco, W.A: University of Western Australia, Dept. of Obstetrics and Gynaecology.

16 Western Australia Legislative Assembly, *Report of the Select Committee Appointed to inquire into the Reproductive Technology Working Party's Report*, 15 December 1988.

17 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Report: Part 2),* 2019.

18 *HRT Act* (WA) ss 5(2)(a), 5(4), 5(5) and 31.

19 *Western Australia Government Gazette* # 47 (Special). 22 March 1993.

- Directions are given by the Commissioner of Health (as the position was then referred to) to set the standards of practice under the *HRT Act 1991* on the advice of the WA Reproductive Technology Council (the HRT Directions) in 1993.[20] The Directions were revised in 1997[21] and revised and replaced in 2004.[22]

1.3 Background: *HRT Act* amendments and review

The *HRT Act* has seen relatively little revision since its enactment when compared to those other states that enacted legislation at the same time. Victoria reviewed, repealed, and replaced its legislation in 1995 and again in 2008, with that legislation currently again under review. South Australia reviewed, repealed and replaced its original legislation in 2010, with the further review being undertaken of its operation and effectiveness from 2015-2017.[23] (See further Chapter 2).

In Western Australia, minor amendments were made to the *HRT Act* in 1996[24] to provide for the extension of the storage period for embryos and eggs in the process of fertilisation, and for other purposes.[25] Following this, a Select Committee was appointed in May 1997 to review the operation and effectiveness of the *HRT Act* and the regulatory regime as well as surrogacy. That Select Committee reported in 1999.[26] Immediate action on its recommendations did not follow, but subsequent amendments pursuant to the *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* (WA) and national laws on research involving human embryos and prohibitions on human reproductive cloning did lead to some of the recommendations being reflected in later amended legislation. Particularly, in 2004 amendments were enacted:

- to make provision for women to access IVF procedures who for medical reasons cannot conceive or whose child is likely to be affected by a genetic abnormality or disease, without restriction on whether the woman is married, single or in a de facto relationship with a person of the same or opposite sex; and
- to remove the requirement that a heterosexual de facto couple wishing to access in vitro fertilisation procedures must have been in a relationship for five out of the last six years (although the stability of the relationship remained a relevant consideration in section 23(e) which required that IVF cannot be provided without consideration of the welfare and interests of any child who may be born as a result of the procedure).[27]

In addition, further amendments to the Act came into operation on 1 December 2004, which primarily implemented the COAG agreement of 2001 to bring a consistent national approach to research involving human embryos and human reproductive cloning.[28] This also included

20 *Western Australia Government Gazette* # 48. 22 March 1993.

21 *Western Australia Government Gazette* # 171. 3 October 1997.

22 *Western Australia Government Gazette* # 201. 30 November 2004. Previous directions were revoked.

23 Sonia Allan, *Report on the Review of the Assisted Reproductive Treatment Act 1988* (SA) (2017).

24 See further Chapter 2 for discussion of regulatory systems and review.

25 *Human Reproductive Technology Amendment Act 1996*. (Which amended the *Human Reproductive Technology Act 1991* (WA) ss 8 and 24 to extend the storage period for embryos and eggs, and to give discretion to approve longer storage periods to the Reproductive Technology Council).

26 Select Committee on the *HRT Act 1991* Report (1999).

27 *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* (WA). See also Clause notes for Acts Amendment (Lesbian and Gay Law Reform) Bill 2001.

28 Human Reproductive Technology Amendment Bill 2003 Explanatory Memorandum Legislative Council;

replacement of terminology used in the *HRT Act* to reflect 'current scientific knowledge' and amendment of prohibitions to ensure 'consistency with the way the offences are described in the national scheme (i.e. in relation to research involving human embryos and cloning)'[29] following Commonwealth enactment of the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition on Human Cloning for Reproduction Act 2002* (Cth). The *HRT Act* was also amended to provide people conceived using donated human reproductive material born after 2004 the right to access identifying information about their donor when they reach the age of 16.[30] Minor consequential amendments resulting from other legislation have been inserted into the *HRT Act* over time.

Amendments to the HRT Regulations have occurred in 1995 to allow for the keeping of a register containing information regarding the export of eggs, sperm or embryos from Western Australia and their subsequent use, dealing or disposal in:[31]

- 2004 to include reference to the State Administrative Tribunal[32]
- 2006 to change references to the 'Health Department of Western Australia' to 'Department' and to the 'Commissioner' to 'DG'[33]
- 2014 to increase fees related to an application for a storage licence[34]
- 2017 and 2018 to increase fees consequential to amendment of Health Regulations (Fees and Charges) Regulations.[35]

The HRT Directions were last reviewed and replaced in 2004 to reflect the legislative amendments arising from the *Acts Amendment (Lesbian and Gay Law Reform) Act 2002* (WA), the *Human Reproductive Technology Amendment Act 2004* (WA), and the *Acts Amendment (Prohibition of Human Cloning and other Practices Act 2004* (WA).

1.4 *Surrogacy Act 2008* and associated instruments

The above mentioned Select Committee report, published in 1999, supported the development of surrogacy legislation in Western Australia. However, surrogacy legislation was not enacted for almost a decade after that report. The *Surrogacy Act 2008* received Royal Assent on 9 December 2008. Surrogacy regulations and surrogacy directions were declared in the Government Gazette

Human Reproductive Technology Amendment Act 2004 (WA); Human Reproductive Technology Amendment (Prohibition of Human Cloning) Bill 2003.

29 Human Reproductive Technology Amendment Bill 2003 Explanatory Memorandum Legislative Council; *Human Reproductive Technology Amendment Act 2004* (WA); Human Reproductive Technology Amendment (Prohibition of Human Cloning) Bill 2003.

30 *HRT Act 1991* (WA), s 49.

31 Human Reproductive Technology (Licences and Registers) Amendment Regulations 1995 (amending Regulation 4(4) of the HRT Regulations 1993).

32 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2004 (amending Regulation 4(3) of the HRT Regulations 1993).

33 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2006 (inserting regulation 1A and amending Regulations 2-5 and the Schedule of the HRT Regulations 1993).

34 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2014 (amending Regulations 3(3) of the HRT Regulations 1993).

35 Health Regulations Amendment (Fees and Charges) Regulations 2017 Pt. 8; Health Regulations Amendment (Fees and Charges) Regulations 2018 Pt. 8.

in early 2009.[36] The *Surrogacy Act 2008*, Surrogacy Regulations 2009 and Surrogacy Directions 2009 set the current standards for use of an artificial fertilisation procedure in connection with a surrogacy arrangement. There also exists Family Court (Surrogacy) Rules 2009 which set out the form and process necessary for an application for legal parentage.[37]

A legislated review of the operation and effectiveness of the *Surrogacy Act 2008* (WA) was undertaken in accordance with section 45 of the Act in 2014. However, it was recognised that a limitation of that review was the small number of submissions received (17) and that there were no submissions from past or present surrogacy applicants in Western Australia.

Two specific recommendations were made to develop information resources and clear pathways to provide a better understanding of surrogacy legislation and policy for consumers in Western Australia; and regarding access to artificial fertilisation procedures before approval of a surrogacy arrangement, in circumstances where there is a medical need to do so. These recommendations have not to date been effectively implemented (as discussed in Part 2 of this report).[38] Five more general recommendations were made to support further Commonwealth and state government inquiries and research into domestic and international surrogacy, and to conduct a further review within five years.[39]

1.5 The current review

The operation and effectiveness of the *HRT Act* and the regulatory regime it established have not been comprehensively reviewed since the Select Committee reported in 1999, almost 20 years ago.[40] Since the tabling of the Select Committee's Report the *HRT Act* has seen some amendments, with the most substantial amendments being those made in 2004 – 14 years ago – following Commonwealth enactment of legislation relevant to research involving human embryos and cloning. The *Surrogacy Act* was introduced in 2008, and although a minor legislated review of the *Surrogacy Act 2008* (WA) occurred in 2014, the Act is now a decade old.

On 13 January 2018, the McGowan Government announced an independent review of the *HRT Act 1991* (HRT) and the *Surrogacy Act 2008* (WA). It was acknowledged that there exists considerable public interest in ART and surrogacy as about one in six couples have difficulty in conceiving a baby. About four per cent of births in Australia occur through ART. Further, the Government noted that there had been significant developments in technology and changes in community attitudes to ART and surrogacy and that the relevant Western Australian laws were 'outdated in parts and are arguably not meeting current needs and developments in practice occurring in other Australian states and territories.'[41] It was intended the review would provide

36 Surrogacy Regulations 2009, Western Australian Government Gazette on 25 Feb 2009 p. 501-8; Surrogacy Directions 2009, Western Australian Government Gazette 27 February 2009 p 512.

37 Western Australian Government Gazette 25 February 2009 p 491-499.

38 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Report: Part 2),* 2019.

39 Government of Western Australia, *Review of the Surrogacy Act 2008 Report to the Western Australian Parliament,* November 2014. Recommendations 3-7.

40 Select Committee on the *HRT Act 1991* Report (1999).

41 Government of Western Australia, Media Statement: Independent Review of Assisted Reproductive Technology and Surrogacy Legislation, 13 January 2018, The Hon Roger Cook, available at https://www.mediastatements.wa.gov.au/Pages/McGowan/2018/01/Independent-review-of-assisted-reproductive-technology-and-surrogacy-legislation.aspx accessed 12 July 2018.

a strong foundation for updating the regulation of ART and surrogacy. As such the terms of reference were drafted to provide an opportunity for a wide range of complex scientific, ethical and legal issued to be considered in today's society. The Government emphasised that the review should be consultative in seeking the public's views about the two acts and independent of government departments or agents.

1.6 Reviewer background

As the independent reviewer appointed by the Minister for Health to conduct the review of the *HRT Act* and *Surrogacy Act 2008* (WA), my qualifications, experience, and conduct of the review are noted below, to ensure openness and transparency to the public.

I hold a Bachelor of Law (Hons), Bachelor of Arts (Psychology) (Honours), Master of Public Health (Merit), Master of Laws (Global Health Law) (Distinction) and a PhD in law in which I examined the regulation of ART, stem cell research, human embryo research and cloning. I am trained in qualitative and quantitative research and analysis and am experienced in socio-legal research, public consultation, law reform, and report writing. I have been examining ethical, legal and social issues pertaining to assisted reproduction and surrogacy for 15 years. From 2003-2005 I worked for the Victorian Law Reform Commission on their reference on access to ART, surrogacy, legal parentage and adoption, conducting extensive consultation, research, analysis, and writing. As a legal academic and consultant, I have also built expertise in health law, including that I have closely examined and written on laws and practices relevant to health, ART, surrogacy, posthumous use of gametes, pre-implantation genetic diagnosis, and other ethical, legal, and social issues raised by existing or emerging technologies. I have examined models of regulation that are suitable and responsive to fields in which rapid changes in technology and practice may occur. I have also worked extensively on issues related to donor conception.

In 2011 I was awarded a Churchill Fellowship to conduct research in all countries that release information to donor-conceived people, and to bring the results of such research back to Australia. I was also a Global Health Law Fellow at Georgetown University in Washington D.C. from 2011-2012 where I furthered my understanding of global health law issues and regulation and presented research on ART, donor conception, and surrogacy. I have contributed to all government inquiries at state and federal level in Australia on ART and surrogacy that have been conducted over the past 15 years. I have also contributed to expert forums on cross-border ART and surrogacy in Australia, The Hague, and for the United Nations Population Fund, World Health Organization and Office of the High Commissioner on Human Rights at UNFPA's Asia and Pacific Regional Office in Bangkok. In 2014 I was appointed to the International Federation of Fertility Societies (IFFS) Surveillance Committee, which surveys laws, policies and practices around the world on ART and Surrogacy tri-annually. From 2015-2017 I led the review of the *South Australian Assisted Reproductive Treatment Act 2010*, having been directly appointed by its then Minister for Health in that state, the Hon. Jack Snelling.

1.7 Conduct of the Review

In having been appointed by the Western Australian Minister for Health, the Hon. Roger Cook, to lead this review, I brought with me the understanding that such reviews must be conducted based on principles of independence, objectivity, an inclusive and rigorous methodology, and openness and transparency.

To ensure independence, I was appointed as an external consultant to the Minister for Health independent of Government and its staff. The review had a Program Manager at the DoH, Dr Maureen Harris, who managed the practical interface between me, the DoH, and the public (e.g. scheduling appointments, room bookings, etc); ensured timelines for the review were met; and facilitated my access to information about policy and practice in Western Australia. All research, acceptance of written submissions, conduct of face-to-face consultations and meetings, analysis of submissions, and the writing of the report, including the development of recommendations, was undertaken independently of the DoH and its staff. Department staff were not present during my meetings with members of the public to ensure full and frank discussion could be had.

While I have drawn upon my own training and experience to conduct the review I have done so mindful of the need to remain objective, and to make recommendations premised upon a sound evidence base and information gathered during the review. This included consulting extensively with people who are impacted by laws and practices in Western Australia and hearing from those who have used (or have attempted to use) ART and/or surrogacy, donors of gametes, and those born as a result of the use of ART and donor conception. It also included being informed by those who work in the field of ART who were able to reflect upon their experience and views of the operation and effectiveness of the *HRT Act* and *Surrogacy Act 2008* (WA). In addition, I spoke to those who have regulatory or other associated roles both in Western Australia and in other jurisdictions. When meeting with people from within the DoH, both within and beyond the Reproductive Technology Unit, they were also able to speak to me without other members of the RTU or the Reproductive Technology Council being present so that I could gain a full and frank understanding of work and issues regarding ART and/or surrogacy. The consultation process gave me the opportunity to better understand the key issues, the complexities directly affecting consumers and the industry, and how current practices do or do not meet community expectations.

An inclusive and rigorous methodology was adopted in the conduct of the review. This included thorough information gathering, extensive public consultation, and ensuring all views and submissions were analysed and considered in reaching the final recommendations. Extensive research was conducted to understand current attitudes, experiences, and practices related to ART and surrogacy. Research was also conducted to inform recommendations to ensure their practicality and ability to be implemented. See further Section 1.9 below regarding qualitative analysis of written submissions.

Openness and transparency include my acknowledging my own background (detailed above) and making clear how my experience and training has, and has not, been used to formulate the recommendations made in this report. This report further details all manners in which information was gained, and how the review, analysis of data, and reporting has been conducted. In addition, it must be acknowledged that people working within the Department of Health gave me access to people and information in a very open manner. This included allowing me to be able to see their operations, interactions, and implementation of the *HRT Act*, *Surrogacy Act*, and associated matters, and to speak with staff individually who had been given the freedom to talk to me openly and frankly. Areas of difficulty were not hidden and were openly presented to me by several staff. Likewise, people who are the subject of the legislation participated in the review in an open and transparent manner. Such openness and transparency, was integral to me having the knowledge needed to make the findings and recommendations presented in this report.

I also considered principles for Better Regulation and the Regulatory Impact Assessment Guidelines for Western Australia[42] when examining the current law and regulation of ART and surrogacy, and in making recommendations regarding future regulation and practice, including the regulatory impact on business, consumers and those born as a result of ART and donor-conception throughout. In addition, I have taken a comparative approach throughout, in which I have reflected upon regulation and governance, as well as practice and developments in other jurisdictions to inform matters relevant to the review. Discussion of other jurisdictions and their approach to particular issues is provided in relevant chapters of the report.

1.8 The scope of the Review

The Terms of Reference were extensive and covered a wide variety of issues related to regulation, governance and practices associated with ART, surrogacy and donor conception. The review did not go beyond the scope of the Terms of Reference. Other legislation relevant to ART, surrogacy and associated considerations in Western Australia includes (but is not limited to) the *Artificial Conception Act 1985* (WA), *Births Deaths and Marriages Registration Act 1998* (WA), *Administration Act 1903* (WA) and *Family Provisions Act 1972* (WA). These Acts were not the subject of this review. However, incidental research, discussion and recommendations that may impact some such legislation occurs as a result of considerations under the HRT and Surrogacy Acts. In addition, discussion of other relevant legislation and common law decisions concerning, for example, the regulation of all health practitioners, sex discrimination, access to Medicare and/or private insurance, and/or family law matters, takes place when considering the operation and effectiveness of the HRT and surrogacy legislation and related matters.

1.9 Public consultation

The public consultation was advertised, and submissions invited and received in several ways.

1.9.1 Initial announcement and media

The Government of Western Australia announced the Review on the 13 January 2018 via a number of media statements and interviews.[43]

Information about the Review and public consultation was published on the Government of Western Australian Department of Health website.[44]

Advertisements were placed in close to 50 Western Australian newspapers and publications, announcing the Review, inviting public submissions and notifying the community of the public consultation forums (see Appendix 1).

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42 Western Australian Government, Regulatory Impact Assessment Support, https://www.treasury.wa.gov.au/Economic-Policy/RIA-Program/RIA-support/ accessed October 2018.

43 See for example, Government of Western Australia, Media Statement: Independent Review of Assisted Reproductive Technology and Surrogacy Legislation, 13 January 2018, available at https://www.mediastatements.wa.gov.au/Pages/McGowan/2018/01/Independent-review-of-assisted-reproductive-technology-and-surrogacy-legislation.aspx accessed October 2018.

44 See Government of Western Australia, Department of Health. *Review of the HRT Act 1991* and *Surrogacy Act 2008* available at https://ww2.health.wa.gov.au/review accessed October 2018.

The DoH Review Project Manager and Manager of the Reproductive Technology Unit, Dr Maureen Harris, also engaged in interviews with the media about the Review.

1.9.2 Written submissions

A call for written submissions to the Review was made on 13 January 2018, with a closing date of 16 March 2018 (although written submissions continued to be made and applications for extensions were accepted up until July 2018). The call was made via the Review webpage;[45] regular postings on social media such as Facebook and Twitter to alert the public to the Review were made by the DoH's communications team; the reviewer using social media to regularly 'tweet' and post to Facebook via my personal accounts, to raise awareness and to encourage participation in the review; 141 personal letters of invitation to make written submission to the review were also sent in the first month of the consultation period (See Appendix 2); further reminder letters sent on the 7 February 2018 to clinics (Concept Fertility Centre, PIVET, Fertility Great Southern, Fertility North, Fertility Specialists South, Fertility Specialists WA, Keogh Research Institute, and Hollywood Fertility Centre) to notify them of upcoming face-to-face consultations, ask them to encourage participation by consumers and to remind them of the written submission period. (See Appendix 3).

A flyer was also developed to invite people to make submissions to the Review which was included in social media posts and reminder letters to the clinics. (See Appendix 4).

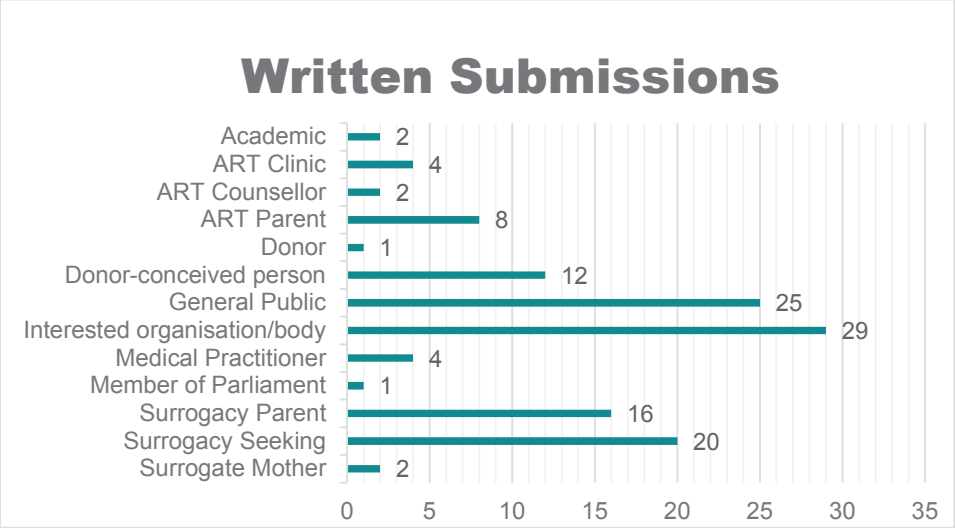
Written submissions to the Review were received via a designated email address for the Review and via the post. In total, the Review received 138 written submissions. There were 126 written submissions accepted on the basis that the submitter was an identifiable person or organisation. When a submission was made in which a submitter could not be identified as a real person or organisation, an email was sent to ask them to provide further details in all but one case in which no contact email or address was provided. It was explained that the submission could be confidential but that it could not be completely anonymous. In many cases the submitter replied immediately with information that could be confirmed and the submission was accepted. However, 12 written submissions could not be accepted, as the identity of the submitter could not be confirmed. For example, if an email address of 'jane.doe@hotmail.com' was supplied the submission could not be included to ensure the integrity of the Review. These submissions were read, and any issues raised that had not been raised elsewhere were followed up via research to ensure relevant issues were not missed.

Written submissions were numbered from one to 126 in the order of receipt, with the 12 excluded submissions not being included in the numbering. Twenty submissions requested confidentiality as to their identity.

45 Ibid.

Figure 1.1 below shows the types of organisations and persons who lodged written submissions to the review. All written submissions are listed in Appendix 5.

Figure 1.1: Written Submissions to the Review, by submitter category



* Figure above displays the total accepted submissions by submitter category n = 126
** Submissions that could not be accepted and are not included in the above table: n = 12

The qualitative analysis of written submissions adopted a thematic analysis approach. Familiarisation with and organisation of the data enabled a broad understanding of the data prior to the generation of themes (assisted reproduction, donor conception, record keeping and data collection and use, regulation, research and experimentation, and surrogacy) and categories within them. The list of themes and categories that were drawn from the written submissions may be found in Appendix 6. An independent research assistant was used to do an initial coding of the data in which she was required to extract data from each submission and place it into the respective categories. Independent coding was also conducted by me which enabled emergent understanding of the data. The analysis of submissions, research, and data was then used to formulate this report and recommendations to the Government.

1.9.3 Public consultation forums

Table 1.1: Face-to-face public consultation forums conducted from 9-20 April 2018

Date	Time	Venue
Friday 13 April 2018	2 pm to 4 pm	Health Consumers' Council, Perth
Saturday 14 April 2018	1 pm to 3 pm	Joondalup Library, Joondalup
Monday 16 April 2018	10 am to 12 pm	Bunbury Library, Bunbury
Friday 20 April 2018 (LGBTQI)	2 pm to 4 pm	Health Consumers' Council, Perth

Approximately 60 people attended the public consultation forums. This included people who were donor-conceived, donors, people seeking assisted reproduction and/or surrogacy, parents of children born as a result of ART/donor conception/surrogacy in Western Australia, other states of Australia and abroad, people who had engaged in ART or surrogacy but remained childless, surrogate mothers, members of the Christian church, a lawyer representing people who had engaged in cross-border surrogacy, parents of people who had faced infertility or sought ART or surrogacy, and other members of the public. Attendees represented people from across Western Australia, with some attendees travelling from rural areas to contribute.

1.9.4 Individual meetings

Individual meetings were held in February 2018, during the face-to-face consultation period from 9-20 April 2018, through to August, in person, via Skype or via telephone with:

- Members of the public:
  - a donor-conceived person who was born and resides in Perth, who had found a sibling via the WA Voluntary Register, and her donor via direct-to-consumer DNA testing and ancestry tracing
  - a donor-conceived person who was born and resides in Perth, who had found her donor via direct-to-consumer DNA testing and ancestry tracing
  - a donor-conceived person who resides in the Northern Territory for whom sperm sourced from Perth had been used in her conception in the Northern Territory
  - a donor-conceived person who was born and resides in Perth, who had found her donor via direct to consumer DNA testing and ancestry tracing
  - an egg donor and her donor-conceived daughter, who was not seeking information about her donor
  - a couple who had accessed commercial surrogacy in India (and had a daughter as a result)
  - an egg donor who had assisted two different women to have children
  - a recipient of egg donation, who had children as a result
  - a woman who had engaged in IVF overseas and in Australia and was calling for more information regarding clinic success rates
  - a Rabbi
  - a woman who had engaged in commercial surrogacy in the United States, following cancer and loss of her fertility
  - a woman who had engaged in commercial surrogacy in the United States, who had suffered previous IVF failure and miscarriage
  - a sperm donor who has been contacted by his donor-conceived daughter, subsequent to direct-to-consumer DNA testing and ancestry tracing
  - the above sperm donor's wife.

- Professionals:
  - a lawyer who has represented parties to surrogacy agreements
  - a counsellor from Jigsaw adoption and donor-conception support services
  - a United States-based psychologist associated with a clinic that requires open-identity donations
  - the Chair of the Australian and New Zealand Infertility Counsellors' Association.
- Office Holders and Government Employees – Western Australian Government:
  - the Chair of the RTC
  - Executive Director/Policy Officer of the RTC/RTU
  - policy officer supporting the RTC. RTI and voluntary register
  - policy officer supporting the RTU, RTC
  - employees working in the WA Department of Health Data and Information Unit including the Director of the data unit, Manager of the Maternal and Child Health Unit; and a consultant researcher regarding data collection and reporting (two meetings)
  - senior solicitor, Legal and Legislative Services, at the WA DoH
  - The Registrar of the WA Registry of BDM.
- Officials and representatives from other jurisdictions – National and State matters relevant to the review:
  - the Chief Justice of the Federal Circuit Court, Justice Pascoe (dealing with family law matters relevant to ART and surrogacy, and the Australian representative to The Hague expert committee on cross-border surrogacy)
  - Professor Constantine Michael AO (former Chair of the National Embryo Research Licensing Committee, also former Chair of the RTC)
  - Minister for Health and Well-Being in South Australia, the Hon. Stephen Wade
  - NSW Ministry of Health Donor Register Officer
  - CEO Victorian Assisted Reproductive Authority, Victoria
  - Director of the National Epidemiology and Statistics Unit.
- Other Law Reform Reviewers:
  - South Australian Law Reform Institute in relation to its review of surrogacy laws and practices in South Australia
  - Michael Gorton AO who is leading the current review of the Victorian *Assisted Reproductive Treatment Act 2008* (Vic) and Victorian Department of Health policy officers
  - United Kingdom Law Reform Commission in relation to its current review of surrogacy laws and practices in the United Kingdom.

1.9.5 Meetings with clinics and associated employees:

Visits were undertaken with Concept Fertility Centre, PIVET, Fertility North, Keogh Research Institute and Hollywood Fertility Centre. I spent from two hours up to six hours at the respective sites, with visits at most clinics being on average four to five hours. I spoke with 31 people working at the five licensed sites I visited, including key personnel such as the:

- Medical Director
- Scientific Director
- Nurse Manager
- Senior Counsellor
- Head of Donor Program
- Person/people responsible for records management
- Managing Director/CEO/authorised officers.

Each person I spoke to spent between 30 minutes to 1.5 hours talking to me. If personnel could not attend (and in the case of one meeting when I had to leave after four hours) to attend my next meeting, I arranged a time to speak to them separately.

1.9.6 Parliamentary briefings

I engaged in seven parliamentary briefing sessions with members of the Greens, Labor Party, Liberal Party, National Party, Shooters Fishers and Farmers Party, and their staffers, to discuss the Terms of Reference, brief the members about the review, hear from them concerning any issues they wished to raise or have me examine, and ask them to communicate with their constituents about the Review. I invited all Members of Parliament to contact me throughout the Review if they would like to have further input.

I also kept the Hon. Roger Cook and the DoH informed of any pertinent issues to ensure timely responses if required.

1.10 Advice to participants

All people who participated in the review, either by making written submissions, engaging in meetings or forums, or speaking via telephone or Skype with me, were informed that once the Review was completed a report would be produced. They were told that the report would include recommendations regarding the regulation of ART and surrogacy in Western Australia and that their input could help shape the recommendations in the report. They were further informed that the report would be tabled in Parliament and be made publicly available and that the Government would consider the recommendations. It was communicated that if the Government decided to proceed with any recommendations that required legislative change, then a Bill would be drafted and would be debated in Parliament and that such debate would determine whether and how such change was implemented into law.

To encourage full and frank disclosure of matters pertinent to the Review, people were told that confidential submissions would be accepted, and that in this event the material in the submission would be used to inform the review, but the submitter would not be referred to by name or

otherwise identified to the best of the reviewer's ability. In addition, some people chose to speak to me in 'complete confidence' with the guarantee that I would not identify them in the report or otherwise. This was particularly important to enable full and frank disclosure of matters relevant to the review.

People were informed that if they did not mark a written submission as 'Confidential' that it may be published on the DoH's website after the review had been concluded.

1.11 Conclusion

It being almost 20 years since the last comprehensive review of the *HRT Act 1991* (WA) and 10 years since the enactment of the *Surrogacy Act 2008* (WA), it was clear that the issues raised during the review reflected that community attitudes toward ART and surrogacy had changed significantly since the first passing of such Acts. For example, Australia has seen much greater acceptance of ART and surrogacy as a means by which families may be formed, significant advances in the recognition of the rights of donor-conceived people to access information about their genetic and birth heritage, and significant changes in community attitudes, acceptance, and calls for non-discrimination in relation to marital status, sexual orientation, and gender identity. Same-sex marriage has also been overwhelmingly supported across Australia. In Western Australia, out of 801,575 votes returned in the State, 63.7 per cent of registered voters indicated Yes in support, with 36.3 per cent voting No. There has also been the introduction of other regulatory systems, including a national scheme to provide for health practitioner registration and accreditation for 15 health professions that did not exist when the *HRT Act* and *Surrogacy Act 2008* (WA) were passed. Technology is also rapidly advancing.

In light of such things, as well as the passage of time since the original legislation was enacted, there was much to say about how best to refine the regulatory system that has been adopted; and how to implement or change provisions in the respective Acts and associated instruments to better serve those born as a result of ART, recipients of treatment (and their partners if any), intended parents, surrogate mothers, donors of gametes and/or embryos, and the people who work to support and help people to create families and ensure their health and well-being.

In addressing the Terms of Reference for the Review I considered the current legislation in Western Australia and in other jurisdictions, the oral and written submissions made to me as the independent reviewer, relevant research on ART and associated matters, and other information gathered at meetings conducted throughout the course of the review. These form the basis of the discussion and recommendations that follow in this report. Many of the issues raised during the Review required a significant amount of in-depth analysis and discussion in order to reach a conclusion about what recommendation(s) should be made. The discussion in the following pages reflects this, with a more expansive discussion of some areas that presented challenges or required detailed analysis of not only the steps that should be taken but the operational considerations to be had. I have included background, comparisons, research and discussion of the results of the consultation, as a means of making clear how such recommendations have been reached.

In the following chapters, I provide an overview of the regulatory environment, information about its operation and effectiveness and discussion of issues raised. Where relevant I have stated what I have found in relation to the Terms of Reference and issues raised (headed 'Findings'), as well as recommendations regarding what action needs to be taken (headed 'Recommendations') to ensure the effective operation of the legislation that regulates human reproductive technology,

surrogacy and related matters in Western Australia. Recognising that legislative change takes time (due to the need for drafting, Parliamentary debate, and enactment), and that some issues need to be addressed immediately, and at the request of the DoH, I also include a table in each of the chapters that include 'Findings' and 'Recommendations' that includes more detail regarding:

- recommended legislative changes needed (if any)
- recommended changes that may be made to the Directions that may serve to address issues immediately, and/or in the interim
- recommended operational changes.

No doubt attitudes, knowledge, understanding, and practices will continue to evolve and change over time. It is also important, therefore, to be mindful that whatever the results of this Review, further continuous review in the future will be needed. The first recommendation of this report is, therefore, to make provision in the *HRT Act* for regular review. (A similar recommendation is made in Part 2 of this report in relation to the *Surrogacy Act 2008*).

Recommendation

Recommendation 1

That provision should be made in the *HRT Act* and *Surrogacy Act 2008* for review of its operation and effectiveness every five years after the date of the report from the last review being received by the Minister.

Chapter 2

The Regulatory System

Chapter 2:
The Regulatory System

2.1 Introduction

This chapter details the current Western Australian regulatory system, outlines other laws and regulation relevant to clinical and associated practice of ART and provides a brief overview of how other jurisdictions govern ART. The chapter is relevant to the Review in relation to the *HRT Act 1991* and associated regulations and directions. It provides the background to the discussion in the chapters that follow regarding the specific terms of reference, the findings and recommendations of the Review.

2.2 Regulation specific to ART in Western Australia

As noted in Chapter 1, the enactment of the *HRT Act 1991* (WA) (the *HRT Act*) and the establishment of the Western Australian RTC followed committee reviews during the 1980s concerning the ethical implications of human reproductive technology advances.[46] The approach adopted is known as 'direct'[47] or 'command and control' (CCR) regulation.[48] CCR uses the force of the law to prohibit certain activities, to demand some sort of positive action, and/or to prescribe conditions for entry into a certain sector.[49] Rules are contained in primary or secondary legislation which is then enforced by regulatory bureaucracies.[50] The regulatory agency may also be granted some rule or decision-making power. Command and control approaches also often involve some sort of licensing process to screen entry into a certain activity and may also set out such things as expected standards, the manner of conducting the activity, the allocation of resources, or any other thing deemed necessary to control the actions and/or functions of those being regulated.[51]

46 See further In Vitro Fertilisation Ethics Committee of Western Australia, *Interim report of the In Vitro Fertilisation Ethics Committee of Western Australia* (1984; Michael, C. A., Meadows, R. J., In Vitro Fertilisation Ethics Committee of Western Australia., *Report of the committee appointed by the Western Australian Government to enquire into the social, legal and ethical issues relating to in vitro fertilisation and its supervision.* (1986). Subiaco, W.A: University of Western Australia, Dept. of Obstetrics and Gynaecology; and Western Australia Legislative Assembly, Report of the Select Committee Appointed to inquire into the Reproductive Technology Working Party's Report, 15 December 1988.

47 Neil Gunningham, Peter Grabosky and Darren Sinclair, *Smart Regulation: Designing Environmental Policy* (1998), 39.

48 Robert Baldwin and Martin Cave, *Understanding Regulation: Theory, Strategy and Practice* (1999), 9.

49 Baldwin and Cave, above n 48, p 35.

50 Baldwin and Cave, above n 48.

51 Baldwin and Cave, above n 48.

2.2.1 The *HRT Act*

In Western Australia, rules are contained in the *HRT Act* 1991 as well as Regulations and Directions. The *HRT Act* preamble states it is:

> *An Act to establish the Western Australian Reproductive Technology Council; 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.*

The *HRT Act* establishes a system of licensing for persons or organisations that either carry out ART procedures or maintain storage facilities for human sperm, eggs or embryos. No artificial fertilisation procedure[52] may be carried out except pursuant to a licence or an exemption.[53] Practice or storage facilities must renew their licence every three years.

Administration of the Act is vested in the DG of the DoH, subject to the Minister for Health. The DG is responsible for the licensing of reproductive technology practices, for issuing of Directions to licensees, for maintaining registers of reproductive technology procedures, for issuing complaints about any offences under the Act and is involved with disciplinary action and appeals. In practice, much of the work in relation to such things is undertaken by the RTC and the RTU subject to the DG's approval.

The *HRT Act* is separated into six Parts, as follows:

Part 1 of the *HRT Act* contains preliminary provisions introducing the Act and its objects, which are specifically stated to be:

a. to regulate, and to provide guidance in, the use of reproductive technology by:
    i. the establishment of the Council, with the functions referred to in section 14;
    ii. the compilation and implementation of a Code of Practice;
    iii. the imposition of licensing requirements; and
    iv. the enforcement of (the) Act; ...
b. to ensure adherence to standards in the practice of reproductive technology that are proper and suitable; ...
c. to allow beneficial developments in reproductive technology, but to discourage, and if required to prohibit, developments or procedures that are not both proper and suitable;

52 Artificial fertilisation procedure is defined by the Act as 'any artificial insemination procedure, or in-vitro fertilisation procedure': *HRT Act* 1991 (WA) s 3.

53 *HRT Act* 1991 (WA) s 6(1)(c); an exemption from the licence requirement may be granted in respect of artificial insemination: s 28. See also Human Reproductive Technology (Licences and Registers) Regulations 1993.

d. to ensure:

   i. that artificial fertilisation procedures may only be carried out for the benefit of persons who, in accordance with this Act, are eligible to be so treated; and

   ii. that the participants are adequately assessed medically as to the need for any procedure, and counselled and informed as to its implications; and

   iii. that the welfare of participants is properly promoted; and

   iv. that the prospective welfare of any child to be born consequent upon a procedure to which this Act relates is properly taken into consideration; ...

e. to require that equity, welfare and general standards prevailing in the community are taken into account in the practice of reproductive technology; ...

f. to provide a forum whereby:

   i. debate by the community on reproductive technology issues may be conducted; and

   ii. proper standards to evaluate and monitor reproductive technology can be determined, established and maintained; and

   iii. policy decisions may be made about reproductive technology, on an informed basis.

Specific offences are contained in Part 1 of the *HRT Act* prohibiting unlicensed practices[54] and regarding undertaking research or certain diagnostic procedures without relevant approval.[55] Penalties range from one year (for summary conviction) to five years imprisonment.

Part 2 of the Act establishes the RTC. (See further below at paragraph 2.2.2).

Part 3 sets out the concept of the Code of Practice, as well as containing provisions regarding consents,[56] when procedures may be carried out,[57] storage,[58] and rights in relation to gametes and embryos.[59]

Part 4 covers a wide variety of matters within its Divisions:

Part 4, Division 1 provides for Licensing, including that the DG having regard to RTC advice may grant storage and/or practice licences.[60] An exemption from licensing is conferred under the Act in relation to artificial insemination procedures by medical practitioners, subject to notification and approval by the DG, and an undertaking to observe and comply with the Code of Practice and any directions or conditions placed upon them.[61]

54 *HRT Act 1991* (WA), s 6.

55 *HRT Act 1991* (WA), s 7.

56 *HRT Act 1991* (WA), s 22.

57 *HRT Act 1991* (WA), s 23.

58 *HRT Act 1991* (WA), s 24.

59 *HRT Act 1991* (WA), ss 25-26.

60 *HRT Act 1991* (WA), s 27.

61 *HRT Act 1991* (WA), s 28.

Part 4, Division 2 provides for the making of directions and conditions that may be given to a person who is a licensee or exempt practitioner;[62] and Part 4, Division 3 includes sections relevant to contravention of conditions or directions; suspension or cancellation of a licence, and disciplinary action, including penalties.[63]

Part 4, Division 4 enables review by the State Administrative Tribunal regarding licence applications; as well as confers power on the State Administrative Tribunal to restrain activities, suspend or cancel a licence or revoke an exemption, if on application made by the DG that a licensee is committing or permitting the commission of a contravention of any term, condition, or direction applicable to a licence or exemption.

Part 4, Division 5, contains provisions relevant to records of procedures,[64] registers of identity,[65] access to information,[66] annual returns,[67] exchange of information,[68] confidentiality,[69] and false or misleading statements and records.[70]

Part 4 Division 6 sets out requirements of the 'licence supervisor', provides for liability of the licensee for actions of employees or agents, and liability in relation to offences by bodies corporate and partnerships.

Parts 4A and 4B of the Act,[71] which were inserted into the Act in 2004,[72] mirror relevant provisions of the *Prohibition on Human Cloning for Reproduction Act 2002* (Cth); and the *Research Involving Human Embryos Act 2002* (Cth) as they were originally enacted. (Note, further changes to the Commonwealth legislation have not been enacted in the WA legislation. See further Chapter 10.)

Part 5 of the *HRT Act* provides for enforcement of the Act. Part 5, Division 1, relating to powers of authorised officers to enter, inspect any equipment, examine any records, search, take possession of or an account of any human gametes, egg undergoing fertilisation, or human embryo, and/or require any licensee to provide any record or other information, amongst other things, if relevant to the grant, variation and/or suspension of a licence or for being used as evidence in any disciplinary or offence proceedings under the Act; and entry search and seizure by warrant. Part 5, Division 2, provides for Proceedings regarding offences under the Act.

Part 6 of the *HRT Act* includes provisions regarding administration in relation to staff, facilities of departments, agencies; subsidiary legislation; and the original 1991 requirement for review of the Act five years after its commencement.

62 *HRT Act 1991* (WA), Part 4, Div 2.

63 *HRT Act 1991* (WA), Part 4, Div 3.

64 *HRT Act 1991* (WA), s 44.

65 *HRT Act 1991* (WA), s 45.

66 *HRT Act 1991* (WA), s 46.

67 *HRT Act 1991* (WA), s 47.

68 *HRT Act 1991* (WA), s 48.

69 *HRT Act 1991* (WA), s 49.

70 *HRT Act 1991* (WA), s 50.

71 *HRT Act 1991* (WA), ss 53A and 53S.

72 Human Reproductive Technology Amendment Bill 2003 Explanatory Memorandum Legislative Council; *Human Reproductive Technology Amendment Act 2004* (WA); Human Reproductive Technology Amendment (Prohibition of Human Cloning) Bill 2003.

2.2.2 The Reproductive Technology Council (RTC)

The inaugural meeting of the RTC was convened by the then Minister for Health on 28 April 1992. The RTC functions are prescribed in the *HRT Act*.[73]

Pursuant to the *HRT Act* licences are granted by the DG having regard to any advice received from the RTC,[74] which in practice means that before a practice licence (or exemption) is granted, the application is referred to the RTC.[75] The *HRT Act* also creates a number of offences which may arise when a person carries out certain activities without a licence [76] or conducts research or diagnostic activities not approved by the RTC or pursuant to a licence.[77] In addition, the RTC:

- provides advice to the Minister for Health on issues relating to ART and the administration and enforcement of the *HRT Act*
- provides advice to the DG of DoH on matters relating to licensing, administration and enforcement of the *HRT Act*
- reviews any directions and guidelines and thereby regulates the proper conduct of ART
- promotes research into the causes and prevention of all types of human infertility and the social and public health implications of ART
- promotes informed public debate on issues arising from ART and communicates and collaborates with similar bodies in Australia and overseas.[78]

The Minister for Health determines RTC membership and is required to ensure that Council comprises individuals with special knowledge, skills and experience in ART, members who are consumer representatives and members with expertise in public health, ethics and law.

Committees of the RTC

The RTC has established five committees which have operated since its inception. They are the Counselling Committee, Embryo Storage Committee, Licensing and Administration Advisory Committee, Pre-Implantation Genetic Diagnosis (PGD) Committee, and Scientific Advisory Committee. The Committees generally have four members plus the executive officer and deputy executive officer from the DoH.[79] (Note, the Executive Officer of the RTC is the Manager of the RTU while the two Deputy Executive Officers are Senior Policy Officers within that Unit. See further below for an explanation of the RTU). The current Terms of Reference for the RTC Committees are as follows.

73 *HRT Act 1991* (WA), s 14.

74 *HRT Act 1991* (WA) s 27(1).

75 *HRT Act 1991* (WA) s 27(1).

76 *HRT Act 1991* (WA) s 6.

77 *HRT Act 1991* (WA) s 7.

78 *HRT Act 1991* (WA), s 14.

79 See Western Australian Reproductive Technology Council. (2017). *Western Australian Reproductive Technology Council Annual Report 2016–2017.* Western Australian Reproductive Technology Council, Perth, Western Australia, pp 6-8.

Counselling Committee: Terms of Reference

- Establishing standards for approval of counsellors as approved counsellors as required by the Code of Practice or Directions of the *HRT Act* for counselling within licensed clinics, and for counselling services available in the community.
- Recommending to the RTC those counsellors deemed suitable for RTC approval or interim approval and reconsidering those referred to the Committee by the RTC for further information.
- Monitoring and reviewing the work of any approved counsellor.
- Convening training programs for counsellors if required.
- Establishing a process whereby counsellors may have approval withdrawn or may appeal a RTC decision.
- Reporting annually as required by the RTC for its annual report to the DG of DoH, including information on its own activities and information reported to it by approved counsellors.
- Advising and assisting the RTC on matters relating to consultation with relevant bodies in the community and the promotion of informed public debate in the community on issues relating to reproductive technology.
- Advising the RTC on matters relating to access to information held on the IVF and Donor Registers.
- Advising the RTC on psychosocial matters relating to reproductive technology as the RTC may request.

Embryo Storage Committee: Terms of Reference

- Make decisions on applications for extension of the periods of storage of embryos on a case by case basis, based on the criteria agreed by RTC, and to provide to the next meeting of RTC details of all decisions made since the previous meeting.
- Provide other advice or carry out other functions relating to the storage of embryos, as instructed by the RTC.

Licensing and Administration Advisory Committee: Terms of Reference

- Advise the RTCl on matters relating to licensing under the *HRT Act*, including the suitability of applicants and conditions that should be imposed on any licence.
- Advise the RTC generally as to the administration and enforcement of the *HRT Act*, particularly disciplinary matters.
- Advise the RTC as to suitable standards to be set under the *HRT Act*, including clinical standards.
- Advise the RTC on any other matters relating to licensing, administration and enforcement of the *HRT Act*.

PGD Committee: Terms of Reference

- To advise the RTC on a suitable framework for the approval of PGD under the *HRT Act* both generally and for specific cases.
- To advise the RTC on factors that it should consider when deciding whether to approve PGD.
- To advise RTC on standards for facilities, staffing and technical procedures.
- To approve PGD applications for translocations, cystic fibrosis and Huntington's disease.
- To advise as to how the ongoing process of approval of PGD should be managed effectively by the RTC.
- To advise the RTC on other relevant matters as requested by the Council.
- The Committee may consult with relevant experts in the preparation of this advice for the RTC including, counselling in relation to PGD with the Counselling Committee.

Scientific Advisory Committee: Terms of Reference

This Committee may provide the RTC with scientific advice in relation to:

- Any project of research, embryo diagnostic procedure or innovative practice for which the specific approval of the RTC is or may be sought.
- Review of the *HRT Act*, which is to be carried out as soon as practicable after the expiry of five years from its commencement and any other matter as instructed by the RTC.

2.2.3 The Reproductive Technology Unit (RTU)

In addition to the RTC there exists a Reproductive Technology Unit (RTU) that operates within the Western Australian DoH. The RTU has three full-time staff, comprising a Manager and two Senior Policy Officers, who work on ART matters, and provide support to the RTC (as above-mentioned, the Manager of the RTU serves as the Executive Officer to the RTC. The two policy officers of the RTU are listed as Deputy Executive Officers to the RTC). Such staff are also responsible for the operation of a 'voluntary donor register' which does not fall within the current legislative framework. (See further Chapter 5 Section 5.6.2).

It was apparent throughout the Review that many clinic staff, consumers of ART, donors, donor-conceived people and their families, did not differentiate between the RTC and the RTU. This was unsurprising as most often they were dealing directly with people who held dual roles including the Manager of the RTU/Executive Officer of the RTC or the Policy Officers/Deputy Executive Officers. Below, when comments are made regarding the RTC, they are equally interpreted as applying to the RTU, unless a specific distinction was made.

2.2.4 Data and Information Unit

There also exists a 'Data and Information Unit' within the DoH, which is responsible for the collection of data for the 'Reproductive Technology Registers'. (See further Chapters 4 and 5).

2.2.5 Subordinate legislation and regulatory rules

As noted in Chapter 1, despite the *HRT Act* providing for a Code of Practice to be promulgated by the RTC, one does not exist and never has. Current subordinate legislation and directions include: The Human Reproductive Technology (Licences and Registers) Regulations 1993 (HRT Regulations); and Directions given by the DG to set the standards of practice under the *HRT Act* 1991 on the advice of the WA RTC (HRT Directions), implemented in 1994, revised in 1997, and last revised in 2004.[80]

The HRT Regulations

The HRT Regulations 1 and 1A provide for the name of the regulation and the interpretation section respectively.

Regulations 2 and 3 set out the procedure and requirements for applying for an exemption relating to artificial insemination and associated fees; and procedures regarding application or renewal of a licence, including the fee for practice and storage licenses.

Regulation 4 sets out the prescribed information required to be kept on a register of identity in respect of a licence,[81] exemption,[82] disciplinary proceedings,[83] and registers containing information relating to the export from Western Australia of gametes, eggs in the process of fertilisation or embryos, and their subsequent use, other dealing or disposal.

Regulation 5 pertains to the details that must be included on a certificate of identity to be issued to an authorised officer.

Minor amendments to the HRT Regulations have occurred as follows:

- 1995 to allow for the keeping of a register containing information regarding the export of eggs, sperm or embryos from Western Australia and their subsequent use, dealing or disposal[84]
- 2004 to include reference to the State Administrative Tribunal[85]
- 2006 to change references to the 'Health Department of Western Australia' to 'Department' and to the 'Commissioner' to 'DG'[86]
- 2014 to increase fees related to an application for a storage licence[87]

80 Western Australia Government Gazette # 201. 30 November 2004. Previous directions were revoked.

81 Pursuant to ss 45(1)(b)(i) of the HRT Act.

82 Pursuant to ss 45(1)(b)(ii) of the HRT Act.

83 Pursuant to ss 45(1)(d) of the HRT Act.

84 Human Reproductive Technology (Licences and Registers) Amendment Regulations 1995 (amending Regulation 4(4) of the HRT Regulations 1993).

85 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2004 (amending Regulation 4(3) of the HRT Regulations 1993).

86 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2006 (inserting regulation 1A and amending Regulations 2-5 and the Schedule of the HRT Regulations 1993).

87 Human Reproductive Technology (Licences and Registers) Amendment Regulations 2014 (amending Regulations 3(3) of the HRT Regulations 1993).

- 2017 and 2018 to increase fees consequential to the amendment of Health Regulations (Fees and Charges) Regulations.[88]

The HRT Directions

The HRT Directions are 60 pages long. They contain the following Parts and Schedules:

Part 1 Personnel, premises and minimum standards of practice which provides directions regarding personnel, premises and minimum standards of practice related to IVF; Artificial insemination (AI); collection and storage; storage; exemptions; renewal of a licence or an exemption; and notifications.

Part 2 Records and reporting which provides directions regarding what records must be kept and for how long; communication of information; reporting; transfer of information; restrictions regarding provision of donated semen to medical practitioners, and reproductive material to practice licensees, storage licensees or exempt practitioners; reporting to the DG; reporting donor identity and exceptions; reporting on excess ART embryos donated for research; providing copies of reports to NHMRC Licensing Committee to the RTC; timing of transfer of information to the Register; annual reporting; notification of change in circumstances or details of licensee; required notification of changes to patient information and consent forms; method of required notification; and further particulars.

Part 3 Consent which provides directions regarding consent for keeping any gametes being required to be renewed every five years; consent in relation to artificial fertilisation procedure, use of donated gametes, use of embryo or egg undergoing fertilisation, to allow an embryo to succumb, regarding innovative procedures, research or diagnostic testing, and for the use of excess ART embryos; requirements for donors and recipients of gametes, embryos and eggs undergoing fertilisation to be aware of *Artificial Conception Act 1985* (which pertains to legal parentage); donors of excess ART embryos for research to be informed that further, specific consent may be required; donors of excess ART embryos for research to be informed of eligibility to apply for an extension of storage period.

Part 4 Information which relates to information to be provided prior to consent; additional information to be given in relation to the use of donated reproductive material; and information to be given in relation to the use of donated embryos for a use requiring an NHMRC licence.

Part 5 Assistance with decision making and counselling which provides directions that persons undergoing an IVF procedure must have access to an approved counsellor; that an approved counsellor is not to be a staff member directly involved with the ART procedures; cost of treatment is to include time with approved counsellor; cost of counselling to be transportable; IVF participants must be provided with information as to counselling entitlements; information about counselling is to be provided to donors of semen where recipient is unknown to the donor; information about counselling is to be provided to donors of eggs, embryos or eggs undergoing fertilisation where recipient is unknown to the donor; psycho-social preparation required where recipient is known to the donor; and counselling prior to provision of information about the identity of a donor, participants or child born as a result of any artificial fertilisation procedure.

88 Health Regulations Amendment (Fees and Charges) Regulations 2017 Pt. 8; Health Regulations Amendment (Fees and Charges) Regulations 2018 Pt. 8.

Part 6 Use and storage of gametes and embryos which provides directions regarding the import and export of donated reproductive material; the RTC being able to approve import or export of donated gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure; the export of embryos for prohibited uses; the transfer of excess ART embryos; the maximum period of storage of gametes; the RTC being able to approve extension of storage period for gametes; records of period of storage of embryos and eggs undergoing fertilisation; when an embryo or egg undergoing fertilisation must be allowed to succumb; extension of storage period for embryos and eggs undergoing fertilisation for use in an artificial fertilisation procedure; extension of storage period for excess ART embryos donated for research; and time for applications for approval to extend storage period of excess ART embryo.

Part 7 Eligibility and assessment which provides directions setting a minimum age for donation; requiring that a donor is not to have been coerced; that sperm from a woman's male relative is not to be used in artificial fertilisation of the woman's ova; that ova from a man's female relative is not to be fertilised with the man's sperm; that practitioners are to maintain a record of reasons for decision relating to eligibility for ART; that counsellor roles are to be separate from any assessment process, and regarding IVF treatment to avoid likely transmission of an infectious disease.

Part 8 Specific clinical practice issues which provides directions regarding limits to the number of recipient families using gametes of a donor being five, unless the RTC approves a use that may result in more than five recipient families in exceptional circumstances; restriction on use of donated reproductive material, of fresh donated eggs, and on the use of reproductive material donated prior to 1 December 2004; prohibiting deliberate confusion of biological parentage; restrictions on collection of eggs; that the RTC may approve collection of eggs despite Direction 8.7 in exceptional circumstances; and that prohibit posthumous use of gametes.

Part 9 Approval of laboratory and clinical procedures which requires clinics to maintain a protocol manual and contains directions regarding approval of routine laboratory and clinical procedures; changes to approved routines or procedures; approval for innovative procedures; applications for approval for innovative procedure; approval for research; applications for approval for research; application for embryo research to include evidence of matters referred to in section 14(2a) of the Act; approval of diagnostic procedures involving embryos; applications for approval of diagnostic procedures involving embryos; application for approval of diagnostic procedures involving embryos to include evidence of matters referred to in section 14(2b) of the Act.

Part 10 Revocation of Directions, which revokes the previous directions published in 1997.

The Schedules contain the following: Schedule 1 Forms; Schedule 2 Data Structure for Reporting; Schedule 3 Annual Reporting; Schedule 4 Counselling; and Schedule 5 Protocol Manuals. The Schedules make up the bulk of the pages in the Directions. (See further Chapter 3, section 3.5).

2.3 Current licences and exempt practitioners in WA

There are currently eight licensed clinics operating in Western Australia.[89] Up until July 2018, there was also one exempt practitioner who held a storage and treatment licence, but that practitioner relinquished their licence from that date due to regulatory burden (See further section 3.4.4). Licences are issued for each ART site. Practice or storage facilities must renew their licence every three years. The RTC provides advice to the DG regarding the licensing of fertility clinics. In addition, facilities are required to demonstrate compliance with provisions under the *HRT Act*, and the current version of the Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice and Certification Scheme, which also requires adherence to the NHMRC Ethical Guidelines. Laboratories must comply with relevant National Association of Testing (NATA) standards.

2.4 The RTAC accreditation scheme

RTAC is a self-regulatory body established by the Fertility Society of Australia (FSA), which is the professional body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand. RTAC is charged with the responsibility of setting standards for the performance of ART through an audited Code of Practice and the granting of licences to practise ART within Australia – known as 'the RTAC Accreditation Scheme'. It reports to the FSA and local state authorities where required. The RTAC code was revised in 1992, 1997, 2001, and 2005. It was rewritten in 2008, with revisions in 2010, 2014 and October 2017.[90] The international version of the Code was released in 2015.

Accreditation of ART treatment centres by RTAC requires compliance with the RTAC Code of Practice. Accreditation review is conducted as an audit by an independent Certification Body that is approved by the Joint Accreditation System of Australia and New Zealand. Following the granting of a primary licence, surveillance auditing takes place on an annual basis.

89 Reproductive Technology Council, Consumer Information, http://www.rtc.org.au/consumer/index.html accessed 8 January 2017.

90 Fertility Society of Australia, Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (Revised 2017).

Each audit includes all of the 'Critical Criteria' contained in the RTAC Code, and one-third of the 'Good Practice Criteria' set out in the Code, with all areas of the 'Good Practice Criteria' being examined over a three-year period. 'Critical Criteria' include:

- compliance with statutory and regulatory requirements, including compliance with the law, policy, the RTAC Code and NHRMC Ethical Guidelines
- access to competent staff (medical, scientific, nursing, and counselling)
- acknowledging and investigating complaints
- acknowledging and investigating adverse events
- ensuring gametes, embryos and patients are correctly identified and matched at all times;
- medication management (safe drug storage, supply and administration)
- minimising the incidence of multiple pregnancies
- minimising the incidence of Ovarian Hyper-Stimulation Syndrome; ensuring access to emergency care; data monitoring (including undertaking reviews of treatment outcomes);
- data reporting to the Australia and New Zealand Assisted Reproduction Database (ANZARD)[91]
- ensuring gametes, embryos and tissues are safe for donation and use in surrogacy arrangements and ensuring appropriate counselling has been provided (which includes compliance with NHMRC Ethical Guidelines and any applicable state or territory legislation)
- management of risk of infection transmission
- ensuring treatment occurs with fully informed consent
- ensuring that doctors providing medical management and care of infertile patients comply with qualifications and training, continuing medical education, and appropriate supervision.

'Good Practice Criteria' include that the organisation must:

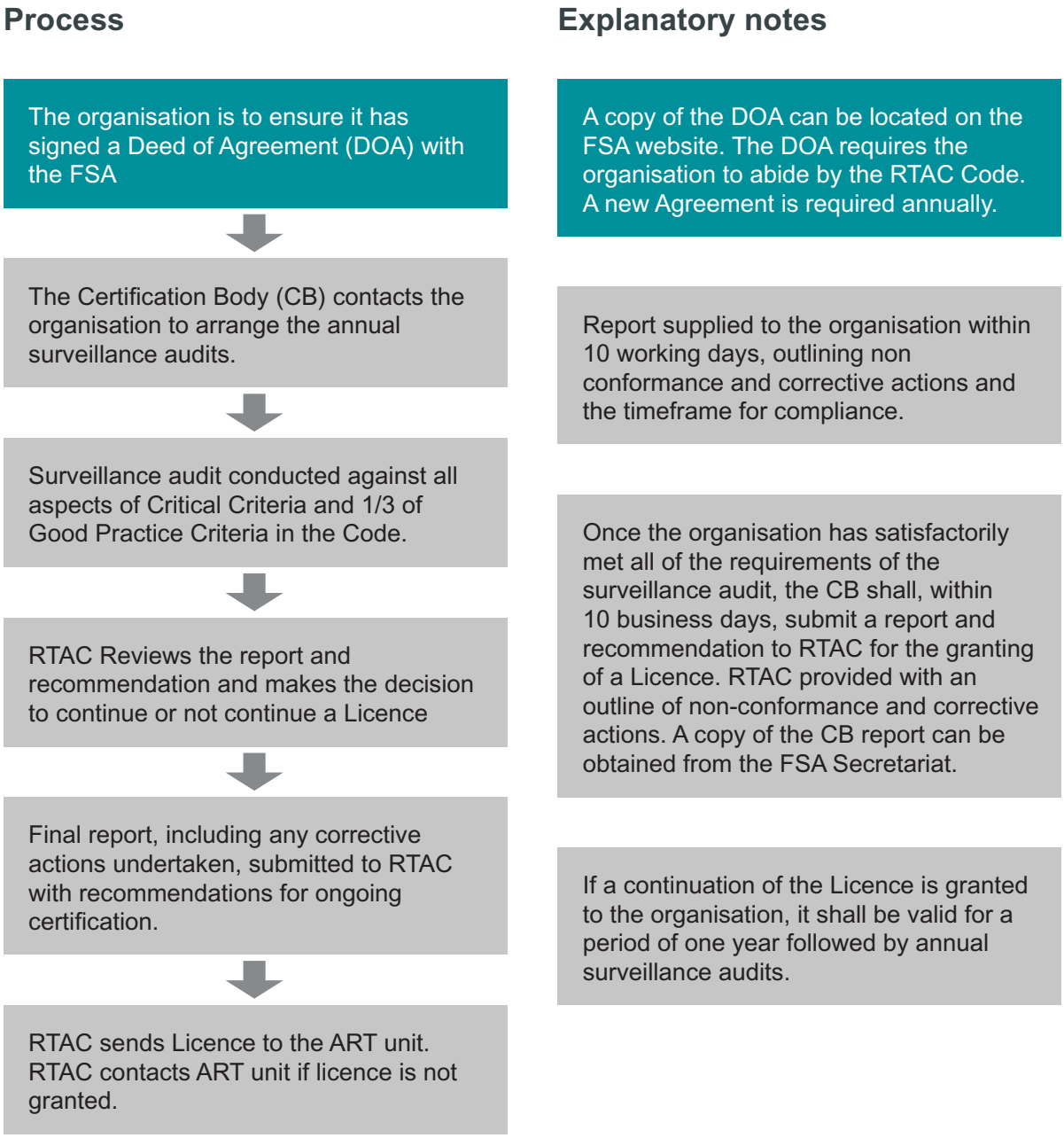
- have a quality management system
- provide patients with information that is accurate, timely and in formats appropriate to the patient
- ensure it meets the reproductive health needs of the men and women under its care
- ensure safe management of cryopreserved gametes, embryos and tissues
- undertake regular stakeholder feedback.

When a clinic first applies for accreditation all of the above are established; then yearly surveillance proceeds. The flow chart on the following page depicts the yearly surveillance auditing process.[92]

91 ANZARD was created in 2004. It is an initiative of the Fertility Society of Australia (FSA) to provide a joint data collection for both the National Perinatal Epidemiology and Statistics Unit (NPESU) and the Reproductive Technology Accreditation Committee (RTAC) of the FSA. The purpose of the ANZARD collection is to monitor the perinatal outcomes of assisted reproduction and to assess the effectiveness of ART treatments. (See further Chapters 4 and 5 regarding data collection).

92 Content reproduced from www.fertilitysociety.com.au/wp-content/uploads/201011201-final-rtac-scheme.pdf accessed October 2018.

Flowchart: RTAC Yearly Surveillance Auditing Process



When a clinic gains accreditation it is issued with an RTAC accreditation number which is relevant, for example, to patients being able to access IVF medicines via the Pharmaceutical Benefits Scheme. Thus, all clinics across Australia are incentivised to have RTAC accreditation. (See further section 2.7.5).

2.5 The NHMRC Ethical Guidelines on ART

The National Health and Medical Research Council (NHMRC) is an independent statutory agency established by the *National Health and Medical Research Council Act 1992* (Cth) (NHMRC Act).[93] The *NHMRC Act* provides for the NHMRC to pursue activities designed to raise the standard of individual and public health throughout Australia; foster the development of consistent health standards between the various states and territories; foster medical research and training and public health research and training throughout Australia; and foster consideration of ethical issues relating to health.

In 2004, the NHMRC published the NHMRC Ethical Guidelines to provide guidance on the use of ART in clinical practice and research within Australia.[94] The NHMRC Ethical Guidelines were revised in 2007, and again in 2017. Review of the Guidelines is undertaken via the appointment of a Committee, public consultation, circulation of proposed draft revisions, and further review/ approval by the Australian Health Ethics Committee.

The NHMRC Ethical Guidelines are approximately 140 pages long and address wide-ranging aspects of ART including providing guiding principles for the clinical practice of ART;[95] information, counselling and consent;[96] use of donated gametes and embryos in ART procedures;[97] storage of gametes and embryos;[98] data collection and reporting;[99] and the ethical practice of research involving human embryos and gametes.[100] Particular ethical issues are also noted, including fertility preservation,[101] surrogacy,[102] sex-selection,[103] pre-implantation genetic diagnosis,[104] and the collection and use of gametes posthumously.[105]

As aforementioned, RTAC requires compliance with the NHMRC Ethical Guidelines for ART treatment centres to gain accreditation for clinical practice within the RTAC self-regulatory system.

93 Section 5B.

94 National Health and Medical Research Council, *Ethical guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2017). Hereafter, 'NHMRC Ethical Guidelines'.

95 *NHMRC Ethical Guidelines*, pp 19–29.

96 *NHMRC Ethical Guidelines*, pp 29–41.

97 *NHMRC Ethical Guidelines*, pp 41–55.

98 *NHMRC Ethical Guidelines*, pp 55–59.

99 *NHMRC Ethical Guidelines*, pp 83–87.

100 *NHMRC Ethical Guidelines*, pp 93–113.

101 *NHMRC Ethical Guidelines*, p 61.

102 *NHMRC Ethical Guidelines*, p 65.

103 *NHMRC Ethical Guidelines*, p 69.

104 *NHMRC Ethical Guidelines*, p 73.

105 *NHMRC Ethical Guidelines*, p 75.

2.6 National Association of Testing (NATA) standards

ART clinic laboratories must comply with the relevant National Association Testing Authorities, Australia (NATA) standards. NATA was established in 1947 and is responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of reference materials and proficiency testing schemes across Australia. It is also Australia's compliance monitoring authority for the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice (GLP). It has a Memorandum of Understanding with the Australian Government and agreements with various state and territory governments and government departments to be the Government's partner for accreditation and related services. Specifically, NATA provides independent assurance of technical competence through a process of accreditation, which formally recognises that NATA-accredited facilities produce reliable technical results. NATA's work is targeted at mitigating risk.

2.7 Other relevant laws and regulation

There also exists other regulatory oversight of health practitioners and businesses in Western Australia relevant to ART services, and products and medicines used. These include (but are not limited to) those discussed in the following paragraphs.

2.7.1 National health practitioner registration and accreditation

In 2010 Australia introduced a nationally consistent scheme for registration and accreditation of health practitioners (and students undertaking programs of study leading to the registration as a health practitioner).[106] This was achieved via the introduction of the *Health Practitioner Regulation National Law Act 2009* (Qld) (the 'National Law') following which other states and territories entered the scheme as participating jurisdictions. Western Australia enacted its *Health Practitioner Regulation National Law Act 2010*, on the 18 October 2010. The National Law currently applies to 15 professions[107] including but not limited to medical practitioners, nurses, and psychologists who work in ART clinics and other related practices (for example, cancer specialists).

The registration and accreditation scheme was established in 2010 to 'provide stronger safeguards for the public, facilitate health practitioners moving around the country more easily, reduce red tape and promote a more flexible, responsive, safe and sustainable workforce'.[108] Registered practitioners are overseen by the Australian Health Practitioner Regulation Agency (AHPRA).[109]

106 Consumer Health Forum of Australia, *Australian Health Practitioner Regulation Agency Consumer Information Paper* (September 2012) at three.

107 Aboriginal and Torres Strait Islander health practitioners; Chinese medicine practitioners; Chiropractors; Dental practitioners; Medical practitioners; Medical radiation practitioners; Nurses and midwives; Occupational therapists; Optometrists; Osteopaths; Paramedics; Pharmacists; Physiotherapists; Podiatrists; and Psychologists.

108 Australian Health Practitioner Regulation Agency, Annual Report 2010–2011 at 7.

109 *Health Practitioner Regulation National Law Act 2009*. (National Law).

The Australian Health Practitioner Regulation Agency (AHPRA)

AHPRA is the organisation responsible for the implementation of the National Registration and Accreditation Scheme across Australia. It is the secretariat for professional boards and publishes national registers of practitioners to ensure information about the registration of individual health practitioners is available to the public. It manages the registration and renewal processes for health practitioners and students across Australia and has offices in each state and territory where the public can make a complaint about a registered health practitioner or student.

AHPRA is also tasked with managing investigations into the professional conduct, performance or health of registered health practitioners, on behalf of the professional boards.[110] In addition, it works with the Health Complaints Commissions in each state and territory to make sure the appropriate organisation deals with community concerns about registered health practitioners.

National and State boards

Each health profession that is part of the National Registration and Accreditation Scheme is represented by a national board, established pursuant to the National Law,[111] for example, doctors by the Medical Board of Australia;[112] psychologists by the Psychology Board of Australia. The Ministerial Council determines the membership, size and composition of each national board.[113] Membership must consist of at least half but not more than two-thirds of persons who are practitioner members.[114] two members must be appointed as community members.

There are six registration types under the National Law: general,[115] specialist,[116] provisional,[117] limited,[118] non-practising,[119] and student[120] registrations. All types of registration are required to be renewed after a period of 12 months.[121] Pursuant to the National Law, each national board is required to, in conjunction with APHRA, 'keep the public national register … that is to include the names of all health practitioners, other than specialist health practitioners, currently registered by the Board'.[122] The register must also include details of any reprimand the practitioner has received, conditions imposed or undertaking entered into, details regarding any applicable suspension or endorsement of registration, and other languages fluently spoken by the

110 This is so in Western Australia and in other states and territories of Australia except in NSW where this is undertaken by the Health Professional Councils Authority and the Health Care Complaints Commission, and Queensland where this may be undertaken by the Queensland Health Ombudsman.

111 *National Law* s 31.

112 *National Law* s 32 Table 1.

113 *National Law* s 33(3).

114 *National Law* s 33(4).

115 *National Law* Pt 7, Div 1.

116 *National Law* Pt 7, Div 2.

117 *National Law* Pt 7, Div 3.

118 *National Law* Pt 7, Div 4,

119 *National Law* Pt 7, Div 5.

120 *National Law* Pt 7, Div 7.

121 *National Law* s 56(1): general registration; s 61(1): specialist registration; s 64(1): provisional registration; s 72(1): limited registration; s 76(1): non-practising registration.

122 *National Law* s 222(1)(a). Registration of a health practitioner can be checked on the AHPRA website at http://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx, accessed October 2018.

practitioner.[123] The national boards must also maintain a public register of all health practitioners whose registration has been cancelled.[124]

One of the dominant functions of the national boards is to develop and recommend to the Ministerial Council registration standards for health practitioners. These standards include the requirement of professional indemnity insurance, matters regarding criminal history of applicants, requirements as to continuing professional development, requirements about English language skills and requirements in relation to the nature, extent, period and recency of practice. In developing guidelines, standards and codes, the national board must ensure there is 'wide-ranging consultation about its content'.[125]

State or territory boards may also be established to enable the national board to 'exercise its functions in the jurisdiction in a way that provides an effective and timely local response to health practitioners and other persons in the jurisdiction'.[126] For example, the Medical Board of Australia has retained local boards in each state and territory 'to manage the large volume of registration and notification matters in medicine, to be responsive and timely in making decisions about individual practitioners and to ensure the profession and the community get the benefit of local knowledge in decision-making.'[127]

All medical doctors, nurses, and psychologists (as well as other health professions) practising in the area of ART need to maintain AHPRA accreditation.

2.7.2 Regulation of businesses (The Australian Consumer Law)

Assisted reproductive technology clinics and associated businesses are subject to regulation as businesses, commercial providers of services, and advertisers in Australia. Relevant also, therefore, is the national statutory framework to ensure that trading is fair for businesses and consumers. The framework is administered and enforced by the Australian Competition and Consumer Commission (ACCC). The Australian Consumer Law (ACL) provides regulations on unfair contract terms, consumer rights guarantees, product safety laws, unsolicited consumer agreements, lay-by agreements and penalties, and other areas.

In addition to Australian Government legislation, state and territory laws also provide consumer protection. A fair-trading office in each state or territory provides advice on business rights and obligations.

123 *National Law* s 225(a)–(p).

124 *National Law* s 222(2).

125 *National Law* s 40(1).

126 *National Law* s 36(1).

127 Medical Board of Australia, Submission to the Victorian Legal and Social Issues Legislation Committee, 28 February 2013, at two.

2.7.3 Regulation of false, misleading or deceptive advertising

The above-mentioned Health Practitioner Regulation National Law prohibits a person from:

- advertising a regulated health service, or a business that provides a regulated health service in a way that is false, misleading or deceptive or is likely to be misleading or deceptive
- offering a gift, discount or another inducement to attract a person to use the service or the business unless the advertising also states the terms and conditions of the offer
- using testimonials or purported testimonials about the service or business
- creating an unreasonable expectation of beneficial treatment
- directly or indirectly encouraging the indiscriminate or unnecessary use of regulated health services.[128]

Breach of the National Law may result in a $5,000 penalty per offence (for an individual) or a $10,000 penalty per offence (for a body corporate). Note, guidelines for advertising regulated health services have been developed jointly by the national boards.[129] The guidelines apply to registered practitioners, employers of those practitioners and others who provide services through the agency of a registered practitioner. In addition, conduct in relation to advertising is regulated by Commonwealth and state legislation including the *Competition and Consumer Act 2010* (Cth), the *Therapeutic Goods Act 1989* (Cth), the *Therapeutic Goods Regulations 1990* (Cth) and relevant state and territory Fair Trading or consumer protection legislation.[130]

This is relevant to ART clinics. For example, if the way ART clinics conduct business or advertise falls short of the national statutory framework, their behaviour may be referred to the Australian Competition and Consumer Commission (ACCC) which has the power to require businesses to address such behaviour.[131] This was illustrated in November 2016 when the ACCC required some of Australia's major IVF clinics to change the way they advertise 'success rates' following an investigation in which the ACCC found a number had made claims regarding success that focused upon pregnancy rather than birth rates, which could mislead consumers.

2.7.4 Medicare, Pharmaceutical Benefits Scheme

National law and policy regarding Medicare, the Pharmaceutical Benefits Scheme (PBS), and private health insurance rebates also play a role in relation to access and funding of ART services. Subject to an ART clinic holding RTAC accreditation, Medicare provides access to rebates for many different fertility treatments. The Medicare Safety Net can also provide additional rebates for patients who have reached a certain threshold. The Medicare Safety Net threshold for 2018 is $2,093.30. In order to receive Medicare rebates on IVF cost, consumers need to have a valid referral letter from their GP or specialist gynaecologist/obstetrician.

128 *National Law* s 133.

129 AHPRA, Guidelines for Advertising Regulated Health Services, http://www.ahpra.gov.au/Publications/Advertising-resources/Legislation-guidelines/Advertising-guidelines.aspx accessed 21 July 2018.

130 In Western Australia, the Fair Trading Act 2010 (WA).

131 See ACCC Media Release 'IVF 'success rates' under the microscope', MR212/16, 16 November 2016.

In addition, patients undergoing IVF are prescribed a variety of medicines, which include PBS-subsidised medicines on the highly specialised drugs list.[132] From 1 July 2015, the way PBS-subsidised IVF medicines are prescribed, dispensed and accessed has been aligned with other medicines on the highly specialised drugs list. Access to IVF medicines may occur via a community pharmacy, private or public hospital pharmacy or an approved medical practitioner ('dispensing doctor'). Like other PBS-subsidised medicines, patients contribute a PBS patient co-payment. The PBS patient co-payment will count towards a family's PBS Safety Net. There are prescribed patient and prescriber eligibility criteria. Since 1 July 2016, it has been mandatory to include the Reproductive Technology Accreditation Committee (RTAC) accreditation number within the PBS online claim for IVF medicines.

2.7.5 Regulation of therapeutic goods

The Commonwealth Therapeutic Goods Authority is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. This includes the regulation of drugs, poisons and other therapeutic goods under the *Therapeutic Goods Act 1989* (Cth) for example, regarding ART culture medium and medicines used in ART.

Note, reproductive tissue for use in assisted reproductive therapy is not regulated by the TGA. For example, products that are excluded goods include sperm, eggs, and embryos for in vitro fertilisation and other ARTs. This exclusion reflects the decision of the Australian Health Ministers' Conference in July 2008 that reproductive tissues should not be regulated by the TGA because 'use of these tissues was already coherently and consistently managed.'[133]

2.7.6 Regulation of patient-practitioner relationships

Laws relevant to consent

The requirement for consent in relation to health care treatment protects the right of patients and clients to choose what is done to their bodies. The general rule regarding health care treatment, therefore, is that consent needs to be present for the treatment to be lawful. The requirement for consent before touching (or restraining) others (which includes doing such things in relation to the provision of health care treatment) is found in legislation and the common law, and is protected via actions such as criminal assault, trespass to the person – which includes assault, battery, and false imprisonment – and negligence. A breach of criminal laws can result in penalties such as imprisonment and/or fines. A breach of civil law trespass or negligence can lead to an order to compensate the person whose rights have been infringed.

132 See *National Health Act 1953* (Cth), s 100 and National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010 (PB 116 of 2010) (Cth).

133 Australian Government Department of Health, 'What is regulated as a biological Australian Regulatory Guidelines for Biologicals (ARGB)' Version 1.0, July 2018.

The law of negligence

The law of negligence is governed by both statute[134] and common law. It is relevant to diagnosis, treatment and the provision of information and/or advice in the context of healthcare practitioner and patient relationships. Specifically, it applies in instances where the expected diagnosis, treatment or information provided falls short of what a reasonable person would expect and consequentially some damage is suffered by the patient or possibly others. In such instances, a person may make a civil law claim against the practitioner and/or their employer.

Laws relevant to health care information

During diagnosing, treating and advising patients, healthcare practitioners (and the businesses they work within or for) receive, collect and store information about those persons. They may also, during consultations, receive information about a patient's relatives or sexual partners. Additionally, healthcare information is collected by agencies such as health insurance companies and by government departments in the form of databanks.[135]

While most Australian states and territories also have individual privacy laws that may apply, it is noted that Western Australia does not have privacy legislation or specific legislation dealing with health information. Protection of health information occurs via the common law as well as at a national level by which Australia has national privacy legislation, overseen by the Office of the Australian Information Commissioner (OAIC), that regulates how businesses can collect, access, and store personal information and communication. There are specific requirements on the management of sensitive information, such as medical records. Access to information is provided for via such statutory regulation.

Criminal law

If a healthcare practitioner's behaviour was particularly egregious, they may also fall subject to the criminal law and relevant penalties, which include imprisonment and/or fines.

Western Australian Health and Disability Service Complaints Office

In addition to, or as an alternative to, seeking common law redress, a person who has received a service or their representative, or a provider, may make a complaint about a health care provider or health or disability service to the Health and Disability Services Complaints Office (HaDSCO). HaDSCO is an independent State Government agency providing an impartial resolution service for complaints. The HaDSCO service is free and available to all users and providers of health or disability services. Acting impartially and in confidence, HaDSCO reviews and reports on the causes of complaints; undertakes investigations; suggests service improvements; and advises service providers about effectively resolving complaints.

Complaints can be made against any individual or organisation that provides, or claims to provide, a health service. These may include (but are not limited to) medical practitioners; nurses and midwives; pharmacists; psychologists; and social workers in a health setting.

134 In Western Australia being the *Civil Liability Act 2002* (WA).

135 Databanks can collect information such as that derived from interviews, and from an analysis of human tissue: see the National Statement on Ethical Conduct in Human Research, Ch 3.2 (2007 (updated 2015), Australian National Health and Medical Research Council).

Complaints may include allegations that a service provider has acted unreasonably by:

- refusing to provide a service
- the manner a service was provided
- providing a service
- denying or restricting the user's access to records
- breaching confidentiality
- charging an excessive fee
- not effectively dealing with a complaint.

(Note, complaints can also be made about health practitioners to AHPRA – see above at 2.7.1).

2.7.7 Other

There are also rules and standards of accreditation for private hospital facilities or day procedure centres. Licensing of private hospitals, day hospitals, nursing posts, nursing homes and psychiatric hostels is regulated by the *Private Hospitals and Health Services Act 1927* (WA).[136] The Department of Health Licensing and Accreditation Regulatory Unit (LARU) is responsible for the licensing and monitoring of such hospitals, posts, and homes in Western Australia.

2.8 Regulation of ART in other states and territories

All of the various laws and regulatory schemes described in the section above are relevant to each jurisdiction within Australia, noting the specifics of state/territory law differ across the country, while Commonwealth laws apply equally in all jurisdictions.

The Commonwealth does not have the constitutional power to legislate over ART. Its regulation, therefore, falls to the respective states and territories and varies across the country. However, the Commonwealth has used its corporations and external affairs powers to enact national legislation regarding research involving human embryos and prohibitions on reproductive cloning, which was initially mirrored in state-based legislation across the country. Western Australia, however, did not adopt changes that were made in 2007, and as a result, is seen to fall outside of this scheme. See further Chapter 10.

In addition to Western Australia, three states have legislation governing aspects of ART – New South Wales, South Australia, and Victoria. However, of these states, Victoria stands alone in having a designated regulatory authority. New South Wales and South Australia have light touch legislative systems without a designated regulatory body or authority. The Australian Capital Territory, the Northern Territory, Tasmania, and Queensland do not have legislated regulatory schemes or requirements for licensing or registration.

136 See also the provisions of the Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987 and the Hospitals (Licensing and Conduct of Private Psychiatric Hostels) Regulations 1997.

2.8.1 Legislative regimes requiring registration

New South Wales, South Australia and Victoria, currently have systems that require 'registration' of clinics. Victoria and South Australia once had licensing schemes but in moving to 'lighter touch' regulation, moved to systems of 'registration'. The systems then vary in terms of the extent to which oversight of clinics occurs.

New South Wales

The *Assisted Reproductive Technology Act 2007* (NSW) commenced in 2010 and is an Act for 'the regulation of assisted reproductive technology services, the registration of assisted reproductive technology service providers and the prohibition of commercial surrogacy, and for other purposes'.[137] The objects of the Act are:

- to prevent the commercialisation of human reproduction
- to protect the interests of a person born as a result of ART treatment, a person providing a gamete for use in ART treatment or for research in connection with ART treatment, and a woman undergoing ART treatment.[138]

One of the primary focuses of the New South Wales legislation is on matters related to the recording and release of information on the donor register[139] or by ART providers.[140]

The New South Wales Act also requires registration of persons who provide ART services.[141] Clinics may subject themselves to the RTAC accreditation scheme and adhere to NHMRC Ethical Guidelines, although there is no legislative requirement to do so. Registration is straightforward and will be granted after paper application to the Director General providing the following information:

- the name of the ART provider
- the address of each premise at which the ART provider provides ART services
- the name of each registered medical practitioner who undertakes or supervises ART services provided by the ART provider
- the name of each person who provides counselling services in relation to ART services provided by the ART provider.[142]

In addition, a registration application requires a statement as to whether the applicant has been convicted of contravening any ART legislation, or RTAC accreditation has been refused, suspended, cancelled or revoked; and that registered clinics must adhere to certain infection standards if they do not have RTAC accreditation.[143] Registration occurs via a form being sent to

137 *Assisted Reproductive Technology Act 2007* (NSW), Long title.

138 *Assisted Reproductive Technology Act 2007 (NSW)* s 3.

139 *Assisted Reproductive Technology Act 2010* (NSW), Part 3.

140 *Assisted Reproductive Technology Act 2010* (NSW), Part 3A.

141 *Assisted Reproductive Technology Act 2007 (NSW)* s 6. There is a maximum penalty of 1000 penalty units in the case of a corporation or 400 penalty units or imprisonment for two years, or both, in any other case for advertising or providing ART services when not registered.

142 *Assisted Reproductive Technology Act 2007 (NSW)* s 7.

143 *Assisted Reproductive Technology Regulations 2014* (NSW), reg 8.

the regulation and compliance unit at the Ministry of Health detailing the names and addresses relevant to those providing ART services. Such information is then held on the 'register'.[144]

Enforcement provisions are contained in Pt 6 of the Act, and provide that a person may be prohibited from carrying on a business that provides ART services if they are found to have contravened the Act, legislation governing research involving human embryos and cloning,[145] or relevant surrogacy legislation;[146] or have been refused accreditation by RTAC.[147] A further oversight mechanism is available in that the Secretary may appoint any member of the staff of the Department or any person who is suitably qualified for the purpose to be an inspector for the purposes of the *Assisted Reproductive Technology Act 2010* (NSW).[148]

New South Wales does not have a specific regulatory authority that oversees matters pertaining to ART. There is no reproductive technology unit within its health department. Registration forms are sent to the Director of the Regulation and Compliance Unit. A policy officer oversees the central and voluntary donor-conception register.

As at July 2018, there were 15 registered ART service providers registered in New South Wales, and 27 RTAC-accredited clinical sites.

South Australia

Following significant amendments to the legislation governing assisted reproduction in South Australia being enacted in 2010, regulation of ART in South Australia occurs via a 'co-regulatory' approach. This approach combines framework legislation, which stipulates registration conditions for ART providers, with self-regulation pursuant to the RTAC accreditation scheme and adherence to NHMRC Guidelines. The overarching principle of the legislation is that 'the welfare of any child to be born as a consequence of the provision of assisted reproductive treatment …must be treated as being of paramount importance, and accepted as a fundamental principle, in respect of the operation of this Act'.[149]

A person must not provide assisted reproductive treatment in South Australia unless the person is authorised to do so in accordance with the regulations published under the Act and registered with the Minister for Health and Ageing.[150] To be registered, the applicant must establish that he or she is a fit and proper person to be registered; and holds any licence, accreditation or other qualification required by the regulations for the purposes of registration; and satisfies any other requirements prescribed by the regulations.[151] The regulations provide that 'a current RTAC licence is required for the purposes of registration'.[152] The Minister may impose conditions

144 *Assisted Reproductive Technology Act 2007 (NSW)* s 8.

145 Including the *Human Cloning for Reproduction and Other Prohibited Practices Act 2003* (NSW); the *Research Involving Human Embryos (New South Wales) Act 2003* (NSW); the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth); the *Research Involving Human Embryos Act 2002* (Cth).

146 *Surrogacy Act 2010* (NSW).

147 *Assisted Reproductive Technology Act 2007 (NSW)* s 56.

148 *Assisted Reproductive Technology Act 2010* (NSW), Part 5.

149 *Assisted Reproductive Treatment Act 1988* (SA) s 4A.

150 *Assisted Reproductive Treatment Act 1988* (SA) s 5. The section provides for penalties of up to $120,000.

151 *Assisted Reproductive Treatment Act 1988* (SA) s 6.

152 Assisted Reproductive Treatment Regulations 2010 (SA) cl 6.

on registration[153] and may suspend or cancel such registration in certain circumstances.[154] The legislation requires adherence to the NHMRC Guidelines be a condition imposed on all registrations.

Changes to the South Australian legislation in 2010 included repeal of provisions that established the South Australian Council on Reproductive Technology (SACRT) and a Code of Ethical Practice promulgated by SACRT which carried detailed requirements regarding the practice of ART. (The function of SACRT and the Code was much like that which exists in Western Australia currently). While the discussion in Hansard regarding the changes to the Act in 2010 indicates that a specialist Ethics Health Advisory Sub-Committee was expected to advise the Minister when needed, this has not occurred, and there is now primary reliance upon the RTAC accreditation scheme and NHMRC Ethical Guidelines in that state.

In the Report of the Review of the *Assisted Reproductive Treatment Act 1988* (SA) (2017)[155] it was found that the dissolution of SACRT, without providing for a point of guidance for clinics and active participation in the co-regulatory scheme by Government, was seen by consumers, clinics, and those born because of the use of ART, to have left a regulatory gap. It was recommended that some sort of ethics body should be established in its place – as originally intended by Government – while ensuring not to create or reinstate unnecessary regulatory burden or functions. This was agreed to in principle in November 2017 by the previous Labor government. Following a change of government in early 2018, the Executive Director of the Health Department informed me that they are still committed to implementing the recommendations from the Review.

There is currently a designated Senior Policy Officer in the Department for Health and Ageing who works on matters relevant to assisted reproduction, as well as other policy and legal officers as required.

There were five registered clinics in South Australia as of July 2018.

Victoria

In Victoria, following the Waller Committee inquiry into IVF which was established in 1982, the Victorian Government passed the *Infertility (Medical Procedures) Act 1984* (Vic). The Infertility (Medical Procedures) Act was later repealed by the *Infertility Treatment Act 1995* (Vic), which established the Infertility Treatment Authority (the ITA) and a system which again, was much like that which currently exists in Western Australia.

In the early 21st century, the legislation was again reviewed. The *Assisted Reproductive Treatment Act 2008* (Vic) came into operation on 1 January 2010 (the Victorian Act). The new legislation established the Victorian Assisted Reproductive Authority (VARTA), which is funded by the Victorian Department of Health and Human Services.

The 2010 revisions to the Victorian Act were intended to create a 'lighter touch' regulatory system, but, the legislation remains far more prescriptive than that in New South Wales or South Australia. Nevertheless, VARTA's regulatory functions were greatly reduced from its predecessor, the Infertility Treatment Authority (ITA), and there is less regulatory burden than in the prior regime

153 *Assisted Reproductive Treatment Act 1988* (SA) s 9.

154 *Assisted Reproductive Treatment Act 1988* (SA) s 10.

155 Sonia Allan, *Report of the Review of the Assisted Reproductive Treatment Act 1988* (SA) (2017).

under which the ITA operated. The Victorian Act, like New South Wales and South Australia, now also requires 'registration' of ART clinics as opposed to the previous licensing system. The Victorian Act contains several guiding principles as follows:

a. the welfare and interests of persons born or to be born as a result of treatment procedures are paramount
b. at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise:
    i. the reproductive capabilities of men and women
    ii. children born as a result of treatment procedures.
c. children born as a result of the use of donated gametes have a right to information about their genetic parents
d. the health and well-being of persons undergoing treatment procedures must be protected at all times
e. persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.[156]

The above enshrines in law minimal ethical standards considered necessary for the practice of ART.

VARTA's functions in relation to regulatory compliance are to:

- register ART providers, including the imposition of Conditions for Registration
- monitor programs and activities carried out under the *ART Act*
- report actual or potential breaches of the *ART Act*
- breaches of the Conditions for Registration, and significant developments in research or treatment of infertility to the Minister
- approve applications for the import or export of donor gametes and embryos formed from donor gametes.

In addition, VARTA:

- has responsibility for managing the central and voluntary donor-conception registers
- providing counselling and support services for people born as a result of donor treatment procedures, their parents and donors, including as part of the management of the donor-conception registers
- public education in relation to treatment procedures and the best interests of children born as a result of treatment procedures
- community consultation about matters related to the *ART Act*
- monitoring programs and activities carried out in relation to the causes and prevention of infertility and programs and procedures used outside of Victoria in the practice of ART
- promoting research into the causes and prevention of infertility.

156 *Assisted Reproductive Treatment Act 2008* (Vic) s 5.

VARTA has a Board consisting of seven members, a DG, and at June 2018 employed the equivalent of 9.5 full time staff (an increase from previous years) – which include information management (2.4), finance, HR, and compliance and regulation (2.0 FTE), communications, public health and health promotion (2.2), donor register services management and counselling (2.5), and research and scientific writing (0.3). They also have a voluntary advisory panel from whom they may seek advice.

Currently, to register as an ART provider in Victoria a person must hold RTAC accreditation.[157] VARTA may impose conditions on registration[158] and may suspend a registration if a contravention of the requirements for RTAC accreditation occurs.[159] The legislation, like South Australia's, therefore also allows for more responsive regulation, via being able to place conditions an individual clinic's registration. The CEO of VARTA, Louise Johnson, informed me they have imposed conditions which provide for further auditing and inspections of clinics at the clinic's own expense, if VARTA perceives a particular issue, as VARTA has felt that reliance upon RTAC accreditation alone was not acceptable.

In Victoria, the regulatory system also establishes a 'Patient Review Panel'[160] whose function is to consider applications from patients regarding surrogacy arrangements,[161] posthumous use of gametes[162] and failure to meet the eligibility criteria set out in the Act.[163] Applications to the Patient Review Panel are considered by a full Division of the panel consisting of the Chairperson, a Deputy Chairperson and three other members, at least one of whom has expertise in child protection. The Patient Review Panel currently consists of 17 members including the Chairperson, and three Deputy Chairpersons. The Department of Health and Human Services employs an Assisted Reproductive Treatment Policy Manager, an Associate (legal officer) and a Project Officer who support the Patient Review Panel. The Patient Review Panel appears to operate quite separately from VARTA.[164]

In 2017-2018 VARTA received $2,035,265 funding, up from $1,758,401 the previous year. Costs and funding of the Patient Review Panel members and the officers within the Department of Health and Human Services are unknown.

There were six registered clinics across 17 treatment sites in Victoria as at July 2018.

157 *Assisted Reproductive Treatment Act 2008* (Vic), s 74.

158 *Assisted Reproductive Treatment Act 2008* (Vic), s 75.

159 *Assisted Reproductive Treatment Act 2008* (Vic), ss 76-77.

160 *Assisted Reproductive Treatment Act 2008* (Vic), Pt 9, ss 82-98.

161 *Assisted Reproductive Treatment Act 2008* (Vic) s 85(a).

162 *Assisted Reproductive Treatment Act 2008* (Vic) s 85(c).

163 *Assisted Reproductive Treatment Act 2008* (Vic) s 85(e).

164 It is noted that the imposition of criminal record and child protection checks on all ART applicants and panel review regarding who may or may not access ART has been criticised by patients and clinicians as burdensome, expensive, and discriminatory. Christopher Scanlon, 'Police Checks on IVF Patients add to the Pain', Sydney Morning Herald, 27 September 2013, http://www.smh.com.au/comment/police-checks-on-ivf-patients-add-to-the-pain-20130926-2ugs6.html accessed 21 July 2018. Emily Bourke, 'IVF Patients Enraged over Police Checks' PM ABC 3 September 2009, http://www.abc.net.au/pm/content/2009/s2675919.htm accessed 21 July 2018.

2.8.2 Self-regulatory regimes

The Australian Capital Territory, Tasmania, and Queensland

Queensland, the Australian Capital Territory and Tasmania[165] do not have legislation governing ART. Instead, health professionals, clinics, and those generally practising in the area of ART follow the NHMRC Ethical Guidelines and the RTAC Code of Practice.[166] There were three RTAC-accredited clinics in the Australian Capital Territory, three RTAC-accredited clinics in Tasmania, and 26 RTAC-accredited clinics in Queensland as at July 2018. 32 clinics in total.

The Northern Territory

While there is no specific legislation governing reproductive technology in the Northern Territory, reproductive medicine services in the territory are provided by South Australian clinicians operating under guidelines consistent with the South Australian legislation. There was one RTAC-accredited clinic in the Northern Territory as of July 2018.

2.9 Discussion and summary

The question of whether, and to what extent, the law should govern the use of ART is one that has long been debated. Some argue that ART is simply a medical procedure which should not be regulated differently from any other treatment, emphasising that principles of individual autonomy and reproductive freedom should prevail. Pursuant to this view, decisions should be made by the treating doctor and the patient, subject to meeting legal standards of care and consent. Others argue that ART is different from other forms of medical treatment because it specifically aims to create children, may pose risks to those undergoing treatment, and raises complex ethical, legal, and social questions. On this basis, one may argue that the state should regulate ART.

When regulation has been implemented, it has varied regarding whether it involves legislation, guidelines, or prescribed or voluntary codes of practice, and what it addresses. For example, some states (Victoria, South Australia, and Western Australia) have included eligibility provisions concerning the types of people who may access treatment and the circumstances in which treatment may be provided. In contrast, New South Wales firmly took the position that it is not the role of the state to determine who may become a parent. Regulation across the country has also demonstrated objectives that have related to some or all of the following:

- protecting patients and children to be born, against the risk of harm by requiring safeguards and ensuring the quality of services
- establishing procedures to support patients through the process and ensure they are able to make informed decisions about treatment options
- prohibiting particularly harmful or unacceptable activities such as the implantation of multiple embryos, human reproductive cloning, or inheritable germline modification

165 Note in Tasmania in December 2017 the House of Assembly Standing Committee on Community Development, *Inquiry into Donor Conception Practices in Tasmania Final Report* (2017) recommended some regulation and legislation be introduced in relation to donor conception records. At the time of writing no proposed legislation had been drafted or introduced into parliament.

166 Reproductive Technology Accreditation Committee, *Code of Practice for Centres Using Assisted Reproductive Technology*, (revised, 2014).

- requiring decision-making processes to be fair and transparent and for the people responsible for those decisions to be accountable
- clarifying the status of children and parents where donated gametes have been used to conceive a child
- providing access to information about biological heritage and relations for donor-conceived people, their siblings, and donors
- controlling the expenditure of public funds
- instilling public trust and confidence in the delivery of services using emerging technologies
- providing processes for consultation and review about future changes to legislation and/or guidelines in response to rapidly changing technology.

Table 2.1 summarises the regulation of ART across Australia.

Table 2.1: Regulation of ART across Australia

Jurisdiction	Specific ART Legislation	Regulatory Authority	NHMRC Guidelines and RTAC	Other laws and regulation*
Australian Capital Territory	✗	✗	✔	✔
New South Wales	✔	✗	✔	✔
Northern Territory	✗	✗	✔	✔
Queensland	✗	✗	✔	✔
South Australia	✔	✗	✔	✔
Tasmania	✗	✗	✔	✔
Victoria	✔	✔	✔	✔
Western Australia	✔	✔	✔	✔

* Other laws and regulation include (but are not limited to) the National Health Practitioner Registration and Accreditation Scheme; Australian consumer protection laws; Regulation of Therapeutic Goods; Medicare and PBS; laws pertaining to consent, negligence, health information; laws governing research involving human embryos and cloning; and other rules and standards relevant to labs, day procedure units, etc.

Chapter 3

Evaluation of the WA Regulatory System

Chapter 3:
Evaluation of the WA Regulatory System

3.1 Introduction

The regulatory approach adopted in Western Australia in the early 1990s in relation to assisted reproductive medicine was closely aligned with the mode of regulation that was implemented by Victoria and South Australia in the mid- to late-1980s when IVF technology was in its infancy. It was robust and responded to technology and practices that were new, unknown, and feared. However, ART is no longer considered novel. With approximately one in six Australians facing issues relevant to fertility, Medicare funding for a number of procedures, significant increases in understanding and shifts in social attitudes, it is now an accepted means of family formation. This chapter, therefore, examines a number of issues in light of the requirement for the Review to engage with the following terms of reference:

- the effectiveness of the current licensing regimen, including fee structure, reporting requirements, powers of inspection and powers of obtaining information
- the effectiveness of the operation of the Council and committees of the Council
- the Chief Executive Officer's (CEO now referred to as the Director General (DG) of the Department) power to issue directions, the power to make a Code of Practice, regulations and guidelines, and the scope and effect of the existing directions and regulations under the *HRT Act*
- the effectiveness of powers of enforcement and disciplinary provisions under the *HRT Act* and the adequacy of offences and penalties
- whether there should be a process of review or appeal of decisions made (by the Reproductive Technology Council (Council)) under the *HRT Act*
- the need for the continuation of the functions conferred, on the Council and on the DG respectively, by the *HRT Act*.

All such terms of reference relate to the regulatory system adopted, its operation and effectiveness. In addition, the review required consideration of the impact on the *HRT Act* of relevant Commonwealth and State legislation and aspects of legislation of other jurisdictions which could be incorporated into the *HRT Act* which was taken into consideration for each issue raised.

Note that due to the nature of some of the information that was provided to me regarding views and/or experiences with the RTC/RTU much of the discussion in this chapter does not identify specific people. Many, although mentioning some things in written submissions if they had made one, spoke comprehensively in face-to-face meetings to convey their experiences and/or concerns. I was asked to commit to complete confidentiality and to undertake that I would speak more generally in my report about the issues raised, without identifying specific people or cases unless permission to do so was granted. This was seen as particularly important as people otherwise feared that speaking frankly and with full disclosure to me may impact their future practice, employment, access to ART, and/or support. In the interests of being able to gather information relevant to the review, I gave my commitment to provide full confidentiality.

3.2 Overall operation of the current regime

From a regulatory perspective it has long been recognised that in areas of rapidly changing technology and an environment in which social attitudes have significantly changed, legislation can quickly become redundant, unworkable or obstructive. These problems generally arise when legislation or subordinate rules are too prescriptive. While legislative restrictions may have been intentional at the time of enactment based on a decision about where the boundaries should lie in respect of scientific advances, a lack of flexibility can have a range of undesirable effects. For example, it may result in legal challenges to the validity of the legislation, such as has occurred in other states regarding discrimination based on marital status;[167] or, when there is no prospect of being treated in Western Australia, people may travel to jurisdictions with less restrictive laws.

The current review revealed that such concerns are being borne out in Western Australia. For example, during face-to-face consultations one nurse described the regulation as follows:

> *Having some regulation can be a good thing in having a structure and guidelines to work within. But it is very difficult when you look at how different it is in other states. It feels like we are just years behind here. It's like going back in time for people who come to live in Western Australia and end up needing assisted reproduction.*

It was also apparent that the legislation and regulatory environment had become outdated in relation to discrimination against people based on their relationship status, sexual orientation or gender identity (see further discussion in Part 2 of this report)[168] and by preventing access to a variety of treatments. There was extensive community concern over such things conveyed during the review.

Research and improved clinical techniques were also seen to be hindered by laws, regulations, directions, and procedural requirements that had become outdated. One practitioner noted during a face-to-face meeting:

> *Technology that we are using today, didn't exist five years ago, let alone thirty years ago when they made the Act. And who knows what will exist in five years' time. We need regulation that is flexible. Responsive. Enables us to use new technology that is better for everyone. Imagine having a better way to treat people and not being able to use it because of some archaic law or council.*

A scientific director also said,

> *Once again, the technology is moving so fast. For some things, I think we are nowhere near it being used in human embryos … but in 20 or 30 years' time where we have the potential to use this technology to eradicate these diseases, I don't want the situation to happen again where they legislated back in 1991 about PGS and we are stuck with this legislation where everyone else in Australia and the world are using this technology and we are not.*

167 See *Pearce v South Australian Health Commission* (1996) 66 SASR 486; *McBain v State of Victoria* (2000) EOC 93-102; [2000] FCA 1009.

168 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Report: Part 2),* 2019.

A simple example of how directions, forms and requirements had become outdated and/or problematic was highlighted by reference to the HRT Directions Schedule 2, Part 2(6), which provides that treatment cycle data *can be sent on a CD or Floppy Disk with IBM format* (note – people do not actually submit via CD or Floppy Disk). However, much more substantive issues were also found to exist. In relation to data collection, this was drawn to the attention of the review by the Director of the DoH Data and Information Unit who said:

> *The current Directions are very technical in nature, albeit somewhat antiquated and reflecting the language and prevailing data collection processes of the time they were drafted…There are outdated, unclear and ambiguous requirements in existence in the Directions that are not conducive to good data provision from clinics.*

Other matters are discussed throughout the report.

All such things indicated that the existing regulation was failing to achieve its objective, creating unintended consequences, and that there were social goals and equity issues that needed to be addressed. This was found largely to be due to the regulatory system being outdated. Further examination of issues within the terms of reference confirmed this, alongside other concerns. It is noted here that the Regulatory Impact Assessment Guidelines state that in such circumstances it is necessary to consider whether an alternative regulatory instrument or policy or deregulation may be more effective in addressing the issue and attaining the Government's objectives.[169] This is also further explored below.

3.3 The effectiveness of the current licensing regimen

The Terms of Reference required examination of the effectiveness of the current licensing regimen, including fee structure, reporting requirements, powers of inspection and powers of obtaining information. As noted above, the current Western Australian licensing scheme is an example a 'top-down' regulatory oversight system, in which licences are granted by the DG,[170] subject to applications first having been referred to and approved by the RTC.[171] Pursuant to the legislation licences should be granted if they comply with a 'Code of Practice' which is to be published by the RTC and is intended to set out guidelines and establish ethical standards required of licensees.[172] No such code has been drafted. Instead, guidelines are contained in Directions formulated by the Commissioner.[173] The use of Directions is not in itself disadvantageous, as this may allow for greater flexibility if regularly revised. However, *regular revision of the legislation or directions has not occurred* with the last significant changes having occurred 14 years ago.

The Review received three written submissions that commented directly in relation to the licensing scheme. There was also extensive discussion within the face-to-face consultations regarding the operation and effectiveness, and the practical implementation, of the scheme.

169 Department of Treasury and Finance, Regulatory Impact Assessment Guidelines for Western Australia, 2010, p4.

170 *HRT Act 1991* (WA), s 27(3).

171 *HRT Act 1991* (WA), s 27(1).

172 *HRT Act 1991* (WA), s 14.

173 Western Australian, Human Reproductive Technology Directions, 30 November 2004, Published by authority of John A Strijk, Government Printer, State of Western Australia.

In the written submissions, the Australian Medical Association (AMA) acknowledged that the current licensing scheme is unique to Western Australia and expressed their support 'given the complex and specialised area of medicine'.[174]

In contrast, Dr Melanie Walls, the Scientific Director at one of the clinics in Western Australia, was concerned that the regulatory system 'creates needless red tape within the industry, the disparity in practices between states and contains discriminatory elements for some patients' and suggested removing the *HRT Act* altogether. She preferred a requirement to adhere to NHMRC and RTAC guidelines as per Tasmania, Queensland and the Australian Capital Territory. However, Dr Walls also urged that at a minimum, the licensing scheme should be *brought into line with other state's requirements*.[175]

Dr Vincent Chapple noted:

> *ART units currently require annual RTAC and NATA accreditation, and an annual and ever-increasing ANZARD data submission. Any further impost on clinics would appear hard to justify and place unfair burden on the clinics. It is difficult to see why the clinics are charged any licence fee at all. What do we get for the fee paid? It seems very little at all, while cost of data collection and submission alone adds a hidden further licensing fee for data we do not even retain the right of access to. It seems a very lopsided arrangement…That said I believe in giving the RTC the right to inspect clinics if a matter covered under the Act has been reported to them. They should be entitled to patient-specific data without breaching patient confidentiality...*[176]

In the face-to-face consultations, numerous issues with the current regime were raised. This included the view that the system had led to the unnecessary development of complex and inflexible rules both within the legislation but also imposed by the RTC; and that the whole system was premised on *'over-regulation, legalism, delay, intrusion and the strangling of competition and enterprise'*.[177] Issues regarding the conduct of officials were also raised, with the approach to enforcement giving rise to contention, and making people feel very uncertain or individually targeted and/or threatened. Examples of how this has borne out in practice in Western Australia when regulating licence holders were clearly described and/or demonstrated during the review. One clinician gave an example as follows:

> *We get in trouble for really trivial things. So, for example, we had a link to the donor conception support group on one of our forms. They rang us up and told us we have to change that because it was wrong. But, the real issue is how they did it. Ironically, we had got the link off their website. Why do they feel it necessary to speak to us as they do?*

A manager noted his dismay:

> *We need the RTC to be our partner, not our policeman. We aren't bad people, let alone criminals, and we shouldn't be treated as such. It's awful. It impacts us as professionals, it impacts us as people. It also impacts our patients.*

174 Australian Medical Association, Submission 96.

175 Dr Melanie Walls, Submission 26.

176 Dr Vincent Chapple (Fertility North), Submission 28.

177 This was a view reiterated by both consumers and clinicians and was expressed by many during the face-to-face consultations.

A nurse practitioner said:

> *We have to do applications for a lot of things. That can be cumbersome, and I personally don't think it is strictly necessary. They could trust the clinics to use their own judgement a little better. Or more importantly, they could trust patients to make their own choices. For example, we don't want to be left with an abundance of embryos. People don't want to create unlimited numbers of embryos either. Instead, we have to wait for an RTC meeting, postpone cycles. The impact on patients is really negative. It would be nice to be trusted.*

While expressions of regulatory toughness, often fundamental to the 'command and control' approach, might be good in 'dealing with the few bad apples, they may be self-defeating in dealing with the majority of good apples'.[178] Such approaches may result in resentment and resistance, a system in which information sharing is undermined, and one that diverts the energies of both sides into 'pointless legal routines and conflicts'.[179] Regulatory experts Baldwin and Cave state that in such situations 'rules …may, accordingly, fail to cover conduct that should be controlled or else may constrain activity that should be unrestricted.'[180] The approach may also lead to difficulties in compliance or unnecessarily prevent activities that should be permissible.[181] Further, problems of 'creative compliance' in order to 'avoid the intention of the law without breaking the terms of the law' may ensue.[182] Such consequences of the current Western Australian human reproductive technology regulatory system were evident throughout the Review.

3.4 The effectiveness of the operation of the RTC and its committees

3.4.1 Function, membership and roles of the RTC/RTU

There was confusion among consumers regarding the function, membership and roles of the RTC/RTU. Many were not sure or did not understand what the RTC did, its membership, and/or how membership was decided. There was also clear consumer confusion about the distinction between the RTC and the RTU, with most people not being aware that there was a distinction. This had a negative impact on consumers. For example, donor-conceived people were confused when asking for assistance from the RTC in relation to the voluntary register only to be informed that the register does not fall under the RTC's remit (it is managed by the RTU). They found further difficulties when dealing with the RTU. Requirements were imposed upon them that are not contained in any legislation, directions, or written policy documents, but appear to have been decided on internally within the RTU/DoH over time.

178 Eugene Bardach and Robert A. Kagan, *Going by the Book: The Problem of Regulatory Unreasonableness* (2002), 94-120, p119.

179 Ibid.

180 Robert Baldwin and Martin Cave, *Understanding Regulation: Theory, Strategy and Practice* (1999), 38.

181 Bardach and Kagan, above n 178.

182 Ibid.

In addition, the membership, functions and transparency of the RTC were raised as an issue, with many people stating the RTC needed to have a more representative mix of people. For example, the Western Australian RTC Approved Australian New Zealand Infertility Counsellors (ANZICA) said:

> *The function, membership and roles of the RTC and its committees, including the Counselling Committee, are not clear. It is not clear how committee members are selected and remunerated, and what their responsibilities are, both in relation to the RTC and approved counsellors. We support greater transparency regarding membership, function and role of the RTC and RTC committees and improved communication between these bodies and others in the sector.*[183]

Dr Melanie Walls expressed concern that there was no embryologist on the Council's main committee stating:

> *There should ALWAYS be a [RTC] member elected from practising scientists in WA clinics, on the main [RTC] and all relevant subcommittees. This could involve the current representative being elevated to the main RTC or a nomination through the Scientists in Reproductive Technology (SIRT) WA membership.*[184]

The Womens and Newborn Health Services called for the RTC to include at least two licensees or experts in reproductive technology *'to ensure more consultative, relevant, and expert-led decision making'*.[185]

Mr Damian Adams, a research scientist and donor-conceived person stated that RTC membership must be altered to 'include the triad of donor-conceived person, recipient parent/ infertile person and donor of reproductive material'.[186] Similarly, a recipient parent stated *'To be truly effective and balanced, the [RTC] must have laypersons sitting on the RTC that have personally dealt first hand with fertility problems and donated material scenarios*.[187] At the time of review the RTC did not have a donor-conceived person or a donor, there was a member who had experienced IVF, who held a dual role.

In relation to the RTC Committees the ARMS submission noted:

> *The Council's capacity to delegate its responsibilities to committees raises a number of concerns. What might be the makeup of the 'Committee'? Will its membership have a vested interest in a particular outcome? How does the Council ensure that both the spirit and the letter of the Act is reflected in any decisions made by the Committee? It is critically important that the makeup of the committee reflects a true balance of the competing interests in this Act and is not dominated by the medical, legal and the surrogacy industries.*[188]

183 ANZICA Fertility Counsellors (WA) Joint Submission 61; Hollywood Fertility, Submission 75.

184 Dr Melanie Walls, Submission 26.

185 Women and Newborn Health Services (Jenny O'Callaghan), Submission 121.

186 Damian Adams, Submission 40.

187 Confidential, Submission 84.

188 ARMS, Submission 33.

In the face-to-face consultations, some people called for a rotation of membership to ensure individual agendas *'could not be pushed'* through the Council. There were also calls for better representation of people working in the field of ART, consumers, donors, and donor-conceived people. Some members were perceived as having conflicts of interests, for example in which RTC requirements directed consumers to them, which in turn meant they would benefit financially. One person described this as *'nothing short of corrupt'*. One donor-conceived person conveyed that she had asked to be a member of the RTC but had been told that all positions were filled. She said that she had experienced great difficulty with how she had been treated by the RTU and said, *'they would never let me on the Council'*.

While it must be recognised that the many people who have been involved over time with the RTC/RTU have given significant time and energy and made their best efforts to implement the regulatory system, it was apparent that the current operations, functioning and membership were not seen by those being regulated and/or those that the system is intended to serve and support, as adequate.

3.4.2 Workload of the RTC/RTU

The RTC met on 11 occasions during the 2016-2017 year. The Counselling Committee met four times. The PGD Committee met twice, with most applications for PGD considered out of session. The Embryo Storage Committee met twice with most applications for extension of storage considered out of session. The Scientific Advisory Committee met once, with additional business conducted out of session. The Licensing and Administration Advisory Committee met once, with additional business conducted out of session. This totals 21 meetings plus out-of-session work.

Some committee members and support staff of the RTC were concerned that the workload of the RTC had become unwieldy and that they were loaded down with unnecessary forms, applications, and bureaucratic processes. Some committee members also said they felt they were being given work that the RTU could not complete due to a lack of resources. Members, clinics, and consumers alike expressed concern about unnecessary approvals having to be given by the RTC, the paperwork that ensued, and the delays this caused in terms of treatment or decision making. For example, in relation to PGD/PGS, extensions regarding embryo storage and consent.

Internal interviews with DoH staff revealed that preparing for the meetings, minutes, and associated paperwork of the RTC current functions takes up a significant amount of the respective Executive Officer's (i.e. policy officer's) time in the RTU.

3.4.3 Advice and interpretation of the *HRT Act* and Directions

There appeared to be fear concerning legal risk regarding the *HRT Act* and those functions of the RTU that were not governed by legislation (e.g. the voluntary donor register). Views were expressed internally about *'not wanting to be sued'* and/or *'not wanting to be blamed when things go wrong'*. This appeared to lead to more restrictive interpretation and practice. It also contributed to costly and time-consuming processes, which did not appear to serve consumers or those born as a result of ART. Clinicians and consumers reported finding themselves unable to proceed due to the regulatory bureaucracy's interpretation or application of the regulatory rules, or alternatively because of the RTC/RTU's inertia.

The RTC was also observed to be challenged in resolving matters of interpretation of the legislation and/or directions. Internally, there were examples of the RTC/RTU/legal officers having to seek legal advice about the *HRT Act* and HRT Directions through the State Solicitor's Office to assist with how the legislation and/or directions should be interpreted. This might have led to changes in how the *HRT Act* was enforced but did not necessarily lead to clear guidance being provided to clinics or the public. A variety of staff at all clinics in Western Australia also complained of the RTC's lack of willingness to provide advice in relation to the legislation. For example, one clinician stated:

> *If we write to them and want answers on how something needs to be interpreted, I want them to give me guidance, I don't want them to tell me to go and see a lawyer. It also has to be consistent, it has to be across the board, they can't be playing favourites, they can't say one thing one week and another thing another week. There has to be consistent application. We want to be acting in the patient's interest. We want to minimise problems …which they are not doing. They are working in their own ivory tower telling people how it should be, and that is not right.*

At another clinic a practitioner said:

> *I don't understand what they do other than say no, the computer says no, and that is about as good as it gets.*

A nurse at a third clinic reported:

> *We contacted the RTC for help…But, most of the time when we contact the RTC we get the standard answer, seek independent legal advice. This is costly and a lot of paperwork to go through, and then you still don't know if the RTC will come after you and tell you 'you are in breach of the Act'. It would be helpful if when you make an enquiry you get an answer. They are the ones that know the rules and regulations and make sure we follow them, so they should be able to give us an answer. Most of the time we have to find it ourselves.*

At a fourth clinic a health practitioner said of her experience:

> *Everything is so protracted. It's like a bureaucracy gone mad, you have to make applications for everything, wait for RTC meetings and approvals, and are subject to their interpretation. But then when you need help, there is no help. We are told to get our own legal advice on everything. Why are they even there?*

At the fifth clinic another practitioner said:

> *I also find that when I ask the RTC for advice, they are very non-committal. It is very frustrating. Very frustrating. The only thing I can say is that they are consistent in their non-commitment. There is a lack of willingness to give anyone a clear answer or they just quote the legislation back to you. But if we are asking for them to explain we don't need them to do that. They don't qualify anything, it is a blank "seek your own advice".*

Another person at that clinic said:

> *What the RTC currently does appears like bureaucracy sometimes, rather than being supportive, and giving people advice and information. Although on the other hand, sometimes there can be positive outcomes too. For example, where people have to improve their practices and improve their protocols. When that has happened that has been good. But, yes, it would be so much better if the RTC was an advisory council which not only offered advice to the Minister but was able to give advice to clinics on the sticky ethical issues. That would be so much better.*

Some consumers and donor-conceived people reported having felt the same.[189] Several of them were very upset and distressed by the interactions they had experienced with members of the RTC and/or the RTU in their Executive and/or policy roles. Many agreed that they thought it is (or should be) the role of the RTC to provide advice on matters relevant to ART, but then observed that the RTC was not willing to do so. The inability to gain assistance had led some people to 'give up' on seeking the RTC/RTU's advice or assistance, while others described having gone interstate or overseas for treatment where they described feeling 'more supported'.

3.4.4 The RTC/RTU's operation and effectiveness

Favourable comments to the review about the current functioning of the RTC were made by a number of people who hold a seat on the Council or are/were associated with the RTC in some way. Other members of the RTC expressed concern that the work of the RTC had become unwieldy. Some RTC Members said they thought the RTC's role would be *'much better if it focused on giving information, education, and advice, rather than being all about processing applications and approvals.'* This illustrated the good intentions of a number of RTC members, and their desire to improve functions to move away from unnecessary or outdated processes and requirements. Some expressed feeling very constrained by the current laws and interpretations and expressed their hope that the review would lead to positive change.

The AMA (WA) submission stated:

> *The AMA (WA) is not aware of any issues with the effectiveness of the Reproductive Technology Council (RTC). The Council should maintain its balance of members, including those from industry, academia, medical professionals, legal representatives, and ethicists to offer balanced views, reflective of societal values.*[190]

The RTC/RTU was described by numerous consumers and practitioners in terms of being 'obstructive', 'unhelpful', 'punitive', 'bureaucratic' and/or 'outdated'. Some called for its removal altogether, for example, stating:

189 Face-to-face forums, April 2018 and personal communications during the review.

190 AMA (WA), Submission 96.

> *The RTC should not involve itself in defining or overseeing clinical practices. We have not been impressed with the RTC's licensing processes and such should be entirely scrapped. Furthermore, the annual RTC report is a low-quality document which does not reflect the extensive advanced processes, procedures and research being undertaken in the state of Western Australia. The bureaucracy developed in WA is a completely unfriendly hindrance to normal clinical practices which already function at the highest level achievable on any international scale. Any State desire to evaluate the outcomes of IVF or Surrogacy should be obtained from the national ANZARD database which is a highly respected source. The annual ANZARD report supersedes the annual RTC report.*[191]

Many clinicians and consumers said they would like to see the functions of the RTC change to be one of education and the provision of information and support to the public.[192] This accorded with the above-mentioned views of some of the RTC members.

In relation to overseeing clinics several people called for a more responsive regulatory system.[193] Others added that the RTC could play an important role if its functions and membership were revised. For example, the Women and Newborn Health Service submitted:

> *The RTC is effective in managing legislative differences and/or lacunae in NHMRC Guidelines, provides expert guidance on ethical considerations of ART and individual cases, and is a mechanism for regulation of clinics. However, the RTC could be more inclusive of fertility clinic and researcher views…. [We recommend] …updating the legislation to reflect more modern research and ethical requirements, and expanding the membership of the Council to include clinic and industry perspectives…*[194]

As noted above, submissions called for membership to also include a donor-conceived person, recipient parent(s), and donor on the Council.[195]

Several complaints were made to me during the review about interactions between some clinics, consumers, and donor-conceived people had experienced with the RTC/RTU. For example, a donor-conceived person, Beth, described a situation she found particularly distressing in relation to interactions with DoH staff managing the voluntary register. She reported having found the people she had dealt with to be *'rude'* and *'obstructive'*, as well as feeling her issues were dealt with *'insensitively'* and *'without tact'*. Beth's experience is further explored at 5.5.2 when discussing the recording and release of information essential to donor-conceived people. Others, including clinics and consumers, described years of frustration regarding dealing with the RTC/RTU. Some consumers said they *'just didn't know what the RTC does'*. It was reiterated numerous times to the review that some people found the RTC processes to be *'outdated'*, *'time consuming'* and/or *'bureaucratic'*.[196]

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191 PIVET Medical Centre, Submission 114. See also Stephen Page, Submission 65.

192 ANZICA Fertility Counsellors (WA) Joint Submission 61; Hollywood Fertility, Submission 75. Also stressed by several people during face-to-face meetings.

193 AMA (WA), Submission 96. Also stressed by several people during face-to-face meetings.

194 Womens and Newborn Health Service, Submission 121.

195 Damian Adams, submission 40; Confidential, Submission 84; supported in face-to-face forums.

196 Communicated to the reviewer during face-to-face consultations and meetings with clinics and consumers subject to the regulation or requirements placed on them by the RTC/RTU.

Specific issues were also raised during the review concerning the way in which licensees experienced interactions with the RTC/RTU. This included, but was not limited to, an 'exempt practitioner' who ran a not-for-profit clinical treatment and research institute dedicated to endocrine (hormonal) disorders who reported the regulatory burden and costs were too great to bear. This practitioner subsequently withdrew from providing any services that fell under the auspices of the *HRT Act* and HRT Directions (as well as RTAC). This decision was influenced by matters regarding difficulties experienced in meeting the requirements of the HRT Directions (discussed further in Chapter 7). In response to the issues, the licensee met with the DG of the DoH, a DoH lawyer and RTU manager; was inspected by the RTU policy officers; and was offered what the DoH perceived as 'practical suggestions on improvements and good laboratory practice through site visits, email, and telephone support' over a period of 12-18 months.[197] In contrast, interactions with the RTC/RTU were perceived by the exempt practitioner as 'adversarial', 'suspicious', often negative and very stressful (sometimes dependent on who it was they were dealing with). This highlighted that the experience of those being regulated did not reflect the stated intentions of the regulator.

The exempt practitioner also highlighted a level of bureaucracy that resulted in frustration and confusion. For example, when relinquishing their licence, they were 'given time…to seek [their] own independent legal advice' concerning what they should do regarding stored gametes they held, but, when they did seek such advice and communicated the steps they would take were 'strongly advised' not to do so until the DG of the Department sought [legal] advice, considered the matter, and formally responded, as 'to do so otherwise may be in breach of the *HRT Act*…'. The DoH subsequently confirmed that the action proposed was acceptable. Staff at the institute reported feeling dismayed over what had occurred, albeit 'a sense of great relief' in deciding to focus on providing the research and treatment services that did not fall under the auspices of the *HRT Act* or HRT Directions and thus RTC/RTU licensing.

In discussing the RTC/RTU functions and the complaints received with the people tasked with implementing the regulatory system, some staff conveyed feeling very constrained by the *HRT Act* and HRT Directions, internal 'policy' decisions, and/or their work environments. Such people expressed that they felt they 'had no choice' or had 'no control' and were limited by legal interpretations or instructions that determined what they could or could not do and how they did it. Sometimes although asking for change, they had not been able to achieve it. There was also difficulty for those who interfaced with the public in not having the training or expertise to deal with some of the issues they were presented with. For example, the Manager and policy officers in the RTU have backgrounds in midwifery and/or laboratory science but are not trained to give legal advice or as psychologists or counsellors. Sometimes the staff themselves reported feeling distressed by some interactions with clinicians and/or the public. They sometimes received very aggressive or abusive phone calls and were not trained or equipped to handle them. In all such instances, they also expressed hope that the review would lead to change. Some emphasised that *'there are good stories too, but we don't hear about those.'*

In a few conversations, others strongly defended the RTC noting that they were 'the regulator' and stated they were 'there to enforce the Act'. In some instances, there was demonstrated suspicion of, and distrust toward ART practitioners, repetition of individual incidents that had occurred decades ago (which had been addressed at the time), a focus on 'what ifs', judgement about particular consumers or people, and/or an 'us' and 'them' attitude conveyed. This was despite there having in fact only been five instances of conduct that have led to disciplinary action,

197 Letter from DoH to Licence Holder dated 23 March 2018.

four of which resulted in 'reprimands' in the 25-year operation of the RTC (see further below at 3.6.2).

There was some fear expressed by people in the DoH who had worked hard for many years concerning change. For example, one person conveyed concern that changing things would devalue the work that person had undertaken over a long period of time. There were also some apparent tensions within and across some of the DoH units meant to support the functioning of the RTC and the *HRT Act*. Human resourcing and the lack of use of modern technology also appeared to be an issue. It appears that the constraints within which people had been working for long periods of time, were also impacting the operation and effectiveness of the regulation of human reproductive technology in Western Australia. These issues, therefore, also need to be addressed, recognising the value of the work that people have done while supporting them to move toward better regulatory practices within a modern regulatory system. This includes a need to support the RTC/RTU with appropriate resourcing, training, and technology.

3.4.5 Committees of the Council

Specific issues concerning the committees of the RTC were also raised with me by those subject to the regulation (consumers, practitioners, and people born as a result of ART), as well as some departmental/RTC/RTU personnel.

The Counselling Committee

The RTC has established criteria that they require for the 'recognition of suitably trained and qualified counsellors as 'Approved Counsellors''.[198] 'RTC Approved Counsellors are required to apply to the RTC to become an 'Approved Counsellor' and for renewal of their approved status every three years. An applicant must be able to demonstrate appropriate university-recognised training and qualifications in counselling theory and technique, involving counselling as an integral and recognisable part of that training; substantial and satisfactory supervised, post-training counselling experience in an applied setting utilising therapeutic skills; and reasonable knowledge of lifespan issues associated with infertility and psychosocial issues in infertility treatment. In addition, applicants must be eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) and the Directions state 'it is desirable that she/he has broad clinical experience that includes assessment and diagnostic skills.'

In practice it was reported that meeting the RTC requirements involved a significant amount of work that was duplicative and/or sometimes far exceeded what was required for professional registration. It also exceeds that which is expected of counsellors in all other states of Australia. For example, one psychologist said that 'to get the status of an *'Approved Counsellor' it took jumping through more hoops than it took to get my Clinical Psychologist specialist accreditation'* within the AHPRA National Health Registration and Accreditation Scheme.

Terms such as 'substantial' and 'satisfactory' used in the HRT Directions were seen to introduce a subjective element into the process that is applied differently. Some counsellors complained that they had been audited or exposed to what they perceived as arbitrary questioning by the RTC in relation to the renewal process without transparent cause. Some said they perceived requirements were applied inconsistently to different counsellors associated with different clinics.

198 HRT Directions Schedule 4.

Part of the approval and re-approval process includes that counsellors must demonstrate engagement in ongoing professional development. As part of this 'Approved Counsellors' are required to attend the RTC public events or they would not get their three-yearly approval. Some found this useful and said it kept them connected to other people in the field and helped expose them to broader issues; however, some felt the events were not relevant to them, and/or said that the speakers sometimes didn't show up. Several counsellors questioned the requirement to prove professional development to the RTC given that they also had to prove professional development yearly for AHPRA registration. It was suggested that keeping a professional development log, which could be audited, would be preferable to being scrutinised by the RTC/Counselling sub-committee where competing interests may exist (actual or perceived) due to the members also being contracted to other clinics or running their own practices.

Several Approved Counsellors saw it as 'unfair' to have 'additional', 'duplicative', and 'unnecessary' regulatory burden placed upon them given their professional qualifications and ANZICA membership. They noted the additional State-based approval criteria placed upon Western Australian counsellors was not required anywhere else in Australia.

ANZICA membership requires all counsellors to have a mental health background and to register via a two-stage process. This includes that the counsellor must demonstrate that they:

- have at least a four year tertiary academic qualification from a recognised institution and registration to practice as a psychologist in Australia or New Zealand; or membership of, or eligibility for, membership of the Australian Association of Social Workers or the New Zealand Association of Social Workers; or registration to practise as a psychiatrist in a State of Australia or New Zealand; or other equivalent professional and academic qualifications from Australia, New Zealand or from other countries
- are counselling clients who are concerned about issues related to infertility
- have at least two years full-time or equivalent supervised postgraduate counselling experience
- have demonstrated current knowledge of infertility and infertility treatments.

In exceptional circumstances, ANZICA may admit to full membership a person who is able to demonstrate an equivalent qualification has been obtained. Once ANZICA membership is approved the counsellor must also become a member of the FSA. There was support from the WA counsellors of membership and participation with ANZICA.

Consumers, as well as some of the counsellors/psychologists, also expressed concern about the very limited number of people who have been given RTC 'Approved Counsellor' status. They said this limited the ability of consumers to choose an experienced counsellor that they wished to work with. There was also perception, by some, that the 'closed shop' may boost the financial interests of only a select few and that this was not appropriate. A clinical psychologist stated:

> *My view is that we need to grow the industry. There are more people coming to get ART treatment, how can we be so closed?*

Others said that it appeared that other professions that may bring a wider perspective to ART in supporting patients or people born as a result of ART were 'shut out'.

Some donor-conceived people were distressed by the RTU mandating they had to see an 'RTC Approved Counsellor' when this included only people associated with infertility treatment. They

said such counselling should be their choice, and if they did need support they would prefer to see someone experienced in working with people seeking biological heritage and family information. (These issues are further examined in Chapter 5 and 6). Some donor-conceived people perceived a conflict of interest given the list of 'Approved Counsellors' they were supplied included two RTC Counselling Committee members and only counsellors associated with commercial infertility clinics.

Several of the 'Approved Counsellors' questioned why there was a counselling sub-committee on the RTC at all and said that they did not think that it should exist. One counsellor said she had 'never been advised who is on the committee, how they were appointed, whether that needs to be changed, whether there should be a rotation on the committee, or anything else'. Several counsellors perceived a lack of transparency about all RTC processes.

Embryo Storage Committee

Section 24 of the *HRT Act* specifies that embryos must not be stored for a period exceeding 10 years except with the approval of the RTC and if there are special reasons for doing so. Applications are considered on a case-by-case basis by the Embryo Storage sub-committee which consists of four RTC members and the Executive and Deputy Officers. The issues relevant to the storage of gametes and embryos are further discussed in Chapter 7.

It is here noted that the findings in Chapter 7 support changes to the way in which storage periods are decided, and by whom. In particular, and consistent with the NHMRC Ethical Guidelines, it is recommended that storage of gametes and embryos for personal use by an individual or couple should be decided by them and their clinicians in light of their personal circumstances. For example, a young cancer patient may store for a significantly longer period of time than a couple being treated in their late 30s. In addition, restrictions on the number of embryos that may be stored are also recommended to be repealed.[199] As a result it is recommended that the embryo storage sub-committee should be disbanded.

Licensing and Administration Advisory Committee

The review did not receive any specific comments regarding the Licensing Committee. However, comments in relation to the general regulatory regime and requirements for licensing at section 3.3 above in this report are noted.

Pre-implantation Genetic Diagnosis Committee

Pre-implantation Genetic Diagnosis (PGD) involves the testing of one or more cells from an embryo for the presence of a gene or genes that may harm the embryo and developing child, and/or looking at chromosomes that may be of the correct number, but where a piece (or more) of the chromosome is translocated onto another chromosome. In Western Australia, approval from the RTC is required before a fertility clinic can create embryos for PGD.[200] However, as discussed in detail in Chapter 9, the steps involved before an application for such approval are extensive. It is thus found in that chapter that the application to the RTC delays patient treatment, and is unnecessary given the process that patients had to go through and added stress and burden. No other jurisdiction in Australia requires special approval when PGD is used to screen

199 HRT Directions 8.7.

200 HRT Directions 9.9 and 9.10.

for a genetically linked disease or disorder. Victoria requires an application to be made to its Patient Review Panel for PGD if it is to be used for sex selection, but not related to screening for disease.[201] Table 3.1 illustrates the approach taken in other jurisdictions across Australia.

Table 3.1 PGD Approval Requirements

Jurisdiction	The requirement for PGD Approval by a Regulator or Government Panel
Australian Capital Territory	✗
New South Wales	✗
Northern Territory	✗
Queensland	✗
South Australia*	✗
Tasmania	✗
Victoria	✗ ✔ PGD for sex selection (Patient Review Panel)
Western Australia	✔ RTC

✗ = no legislated requirement for approval by a regulator or Government panel

Scientific Advisory Committee

The review did not receive any written submissions regarding the scientific advisory committee. During face-to-face consultations, people did submit that it was important that the RTC keep up to date with scientific advances and provide a forum for discussion, education, and advice regarding any ethical, social and legal issues raised.

3.5 Code of Practice, directions and regulations

The terms of reference require consideration of the DG's power to issue directions, the power to make a Code of Practice, regulations and guidelines, and the scope and effect of the existing Directions and Regulations under the *HRT Act*. As detailed in Chapter 2, although the *HRT Act* conferred power on the RTC to make a Code of Practice, this has never been acted upon – there is no Code of Practice in Western Australia. Rather, the DG's power to issue regulation and guidelines has been exercised, and there are Regulations and Directions that supplement the requirements in the *HRT Act*. These currently include: The Human Reproductive Technology (Licenses and Registers) Regulations 1993 (HRT Regulations); and Directions given by the DG to set the standards of practice under the *HRT Act* 1991 on the advice of the WA Reproductive Technology Council (HRT Directions), implemented in 1994, revised in 1997, and last revised in 2004.[202]

201 *Assisted Reproductive Treatment Act 2008* (Vic), ss 31-34A.

202 Western Australia Government Gazette # 201. 30 November 2004. Previous directions were revoked.

A detailed description of the subordinate legislation and regulatory rules may be found above in Chapter 2 at section 2.2.5. In short, the HRT Regulations set out the procedure and requirements for applying for a licence or exemption under the *HRT Act*; requirements for information that must be kept on a register in respect of a licence,[203] exemption,[204] and any disciplinary proceedings;[205] and requirements regarding registers containing information relating to the export from Western Australia of gametes, eggs in the process of fertilisation or embryos, and their subsequent use, other dealing or disposal. They also provide the details that must be included on a certificate of identity to be issued to an authorised officer.

The HRT Directions include directions regarding: personnel, premises and minimum standards of practice; records and reporting; consent; information; assistance with decision making and counselling; use and storage of gametes and embryos; eligibility and assessment in relation to donors; specific clinical practice issues relevant to gamete donation; and that prohibit posthumous use of gametes; approval of laboratory and clinical procedures; and that revoke the previous directions published in 1997. The HRT Directions also include Schedules which contain:

- nine forms to be used when making applications to the committees, and in relation to the collection of information about donors;
- directions regarding data structure for reporting to the health department regarding identifying information and treatment cycles;
- directions regarding annual reporting by storage licensees about donated semen, embryos, and counselling (including a counselling reporting form);
- directions regarding approved counsellors and psychosocial preparation for participants prior to known donation; and
- requirements for protocol manuals.

The Schedules make up the bulk of the Directions.

3.5.1 Powers to issue Code of Practice, regulations and directions

The review received several submissions that demonstrated divergent views regarding the powers to issue, the utility of, and/or the need for a Code of Practice, regulations and directions. (Some referred to all collectively; others appeared to refer to the HRT and HRT Directions as the 'Code').

Iolanda Rodino and Antonio Clissa, who are 'Approved Counsellors' and members of the RTC stated: *'We support …the power to make a Code of Practice, regulations and guidelines and the scope and effect of the existing directions and regulations under the HRT Act.'* [206]

203 Pursuant to ss 45(1)(b)(i) of the HRT Act.

204 Pursuant to ss 45(1)(b)(ii) of the HRT Act.

205 Pursuant to ss 45(1)(d) of the HRT Act.

206 Rodino and Clissa, Submission 4.

In contrast, Dr Vincent Chapple, an ART clinician, submitted:

> *The 1991 Act established [the ability to enact] a Code of Practice at a time when one did not previously exist and helped establish a framework of understanding for both patients seeking treatment and doctors working in the field. In that current ART clinic accreditation is based on adherence to national RTAC and NH&MRC standards, which are independently verified, the whole rationale for a State-based Code of Practice has largely been lost and challenges the need for a distinct state-based Code of Practice.*[207]

Mr Damian Adams, a research scientist and donor-conceived person from South Australia, a jurisdiction in which the former Code of Practice was repealed in favour of reliance upon the NHMRC Guidelines submitted:

> *A Code of Practice must be implemented as the NHMRC Guidelines are a blunt instrument that has no force of law whereas a "Code of Practice" can. The Code can also be used to identify areas of legislation and/or guidelines that lack clarity and provide the direction required. The Code of Practice must first and foremost follow the principle of looking after the welfare of the most vulnerable as the primary consideration, and in which the most vulnerable is always clearly the person created through these technologies.*[208]

However, note, the review of the South Australian Assisted *Reproductive Treatment Act 1988* conducted from 2015-2017 did not recommend reinstatement of the Code of Practice.[209]

The Women and Newborn Health Services submitted that:

> *The current parameters of the CEO's role to issue directions and write a Code of Practice and make regulations are significantly hindered by deficiencies in the existing Act which will be rectified by updating the legislation as part of this review. It is envisaged that the role of the CEO to interpret and administer the Act will be enhanced by more modern and streamlined legislation.*[210]

The Womens and Newborn Health Service also recommended changes to nomenclature and function of roles (for example that the definition and role of the DG needs to be clarified in light of the *Health Services Act 2016*; and that the definition of the Chair of Council and their relationship with the Minister and the DG be clearly outlined within the legislation).[211]

3.6 Powers of enforcement and disciplinary provisions

The Terms of Reference require examination of the effectiveness of powers of enforcement and disciplinary provisions under the *HRT Act* and the adequacy of offences and penalties.

207 Dr Vincent Chapple (Fertility North), Submission 28.

208 Damian Adams, Submission 40.

209 Sonia Allan, Report on the Review of the *Assisted Reproductive Treatment Act 1988* (SA).

210 Womens and Newborn Health Service, Submission 121.

211 Womens and Newborn Health Service, Submission 121.

3.6.1 Regulatory provisions

There are extensive enforcement and disciplinary provisions found in Parts 4, 4A, 4B, and 5 of the *HRT Act*. Parts 4 and 5 focus upon the actions of licensed or exempt ART practitioners relevant to clinical practice; while Parts 4A and 4B provide for separate offences, oversight and enforcement provisions relevant to monitoring and inspection by the National Embryo Licensing Committee of the NHMRC in relation to human embryo research.[212] As there is no such licensed research taking place in Western Australia, Parts 4A and 4B are not discussed further in this section. Discussion regarding these provisions occurs in Chapter 10.

Part 4, Division 3 specifically addresses the suspension or cancellation of licence or exemption and disciplinary action as follows:

Section 36 provides the DG powers to suspend or cancel a licence or exemption, other than on disciplinary grounds by providing three months' notice if in the opinion of the DG the licensee has failed to carry on a reproductive technology practice or procedures authorised by the licence or exemption, in the manner required by the public interest; and to suspend the operation of any licence or exemption with immediate effect, by reason of any requirement of public health, where in the opinion of the DG imminent risk of serious harm to a person may occur.

Section 37 provides for summary determinations by the DG after seeking advice from the RTC and subject to warning the person/licensee to whom such penalty determination will be liable in person or via publication in the Gazette setting out short particulars of the reason and giving that person a reasonable opportunity, within a period specified in that notice, to show cause to the DG why effect should not be given to that determination. If the person then consents and does not appeal the summary determination, a warning or penalty as the DG may think appropriate may be imposed. This may include, pursuant to section 40(1)(a)-(f):

- a reprimand
- the imposition of a condition to which a licence or exemption is to be subject, limiting the authority conferred by the licence or exemption
- the variation or cancellation of a term or condition to which a licence or exemption is subject
- a requirement that a person to whom the licence applies or who is interested in the licence or exemption enter into a written undertaking or a bond, or give a prescribed security, for future conduct
- a requirement as to the conduct of the reproductive technology practice under the licence or exemption, contravention of which may result in its mandatory suspension
- a requirement that specified action be taken by the licence supervisor within a specified period, contravention of which may result in mandatory suspension of the licence or exemption.

and any such other ancillary order, including an order for the payment of costs not exceeding the prescribed amount, as the DG thinks fit.

212 *HRT Act* Parts 4A and 4B.

Section 38 provides for disciplinary action where the licensee or another person liable to a warning or penalty does not consent to a summary determination or submit to the discretion of the DG under section 37; or it appears to the DG that a penalty provided by section 40(1)(a) to (f) may not be appropriate the DG may make an allegation to the State Administrative Tribunal (SAT) in respect of the matter. In such circumstances, the DG shall consult the RTC and subsequently advise the RTC that the allegation has been made. Section 39 provides that it may be a cause for disciplinary action if:

- any reproductive technology practice, or any procedure authorised under a licence or exemption, is not properly conducted or carried out in accordance with the licence or that exemption
- a person to whom the licence applies has contravened a requirement of the *HRT Act*, a term or condition of that licence or any direction
- a licensee has contravened a term or condition applicable to an exemption
- a person to whom the licence applies has been convicted of:
  - an offence under the *HRT Act*
  - an offence under the *Health (Miscellaneous Provisions) Act 1911* or the *Public Health Act 2016* in relation to the conduct of the reproductive technology practice or premises to which the licence or exemption relates
  - an offence in the State or elsewhere that implies that the person is unfit to be a licensee.
- a licensee at a material time employed or engaged, in relation to the practice carried on under the licence or exemption, a person who in the course of that practice committed any offence of a kind to which paragraph (d) refers and of which that person was convicted
- the person to whom the licence applies, or any person holding a position of authority in a body that holds a licence or who has a material interest in a reproductive technology practice, is or becomes not a fit and proper person to hold that position or to be so interested
- activities conducted under the licence or on the premises to which this licence relates are jeopardising public health, and the continuation of the licence or exemption would not be in the public interest
- the premises to which the licence relates, or other circumstances material to the conduct of the practice authorised, are no longer suitable for the research or procedures authorised under the licence or exemption
- information given for the purposes of this Act by or on behalf of the licensee was in any material respect false or misleading
- information which this Act requires to be kept confidential is not so kept
- the safety, health or welfare of persons who resort to a reproductive technology practice as participants or prospective participants is endangered by an act or neglect of the licensee
- an order made under section 40 in respect of a determination previously made under section 37 or by the State Administrative Tribunal in proceedings commenced under section 38 has been contravened.

In relation to section 38 issues or a section 36 matter referred to the SAT, section 40 provides that if the SAT is of the opinion that cause exists for disciplinary action, the Tribunal may impose any one or more of the following penalties:

- a reprimand
- the imposition of a condition to which a licence or exemption is to be subject, limiting the authority conferred by the licence or exemption
- the variation or cancellation of a term or condition to which a licence or exemption is subject
- a requirement that a person to whom the licence applies or who is interested in the licence or exemption enter into a written undertaking or a bond, or give a prescribed security, for future conduct
- a requirement as to the conduct of the reproductive technology practice under the licence or exemption, contravention of which may result in its mandatory suspension
- a requirement that specified action be taken by the person responsible within a specified period, contravention of which may result in mandatory suspension of the licence or exemption
- the suspension of the operation of a licence or exemption:
  - until further order
  - for a specified period.
- the suspension of the operation of the licence or exemption for so long as a person is:
  - the holder of a position of authority in a body that holds a licence
  - directly or indirectly materially interested in a reproductive technology practice carried on under a licence or exemption.
- the cancellation of a licence, or the revocation of an exemption
- the disqualification, for such period as the Tribunal thinks fit, of a licensee from holding a licence or exemption
- an order that the person to whom the licence applies pay to the Crown a monetary penalty not exceeding the prescribed amount.

Where the DG or SAT finds that a proper cause for disciplinary action exists in relation to a licence or an exemption held by a proprietary company, relevant penalties may be imposed on or in relation to any person who occupies a position of authority in that company or any related body corporate. Part 4, Division 3 penalties are not to be imposed if it is proved that the person concerned did not know of or could not reasonably have been aware of or have prevented, the matter upon which the ground of complaint was made out; or had taken reasonable steps to prevent the occurrence of the matter about which the complaint related.

Further enforcement provisions are also found in the *HRT Act* Part 5 which focus on powers of authorised officers to enter and inspect premises,[213] including powers to require licensees or any person in the position to do so to produce records;[214] provisions that any questions put to a person by an authorised officer must be answered;[215] power to examine records, copy, take extracts, or take possession of records;[216] powers to take possession of anything which an officer has reasonable grounds to believe may be required i) for the purpose of the functions of the DG relating to the grant, variation and suspension of licences; or ii) for the purpose of being used in evidence in any disciplinary proceedings or proceedings for an offence under this Act, and retain it for so long as it may be required for that purpose;[217] powers regarding entry, search and seizure under warrant.[218] The *HRT Act* provides that such powers:

> *Shall only be exercised at reasonable times and at reasonable intervals unless the authorised officer has good grounds or a reasonable belief for doing otherwise and has prior to exercising the powers other than at reasonable times and intervals recorded his grounds or beliefs in writing and signed that record and had his signature witnessed in writing, noting the date and time of signature. The authorised officer shall place his record of grounds upon a register kept by the CEO for that purpose as soon as practicable.*[219]

In addition to the above powers, it was noted that recent proposed amendments to the *HRT Act* were to include further investigatory powers for licensees or providers of ART in relation to surrogacy services if an offence is or is likely to be committed by a licensee or provider.

Part 5, Division 2 provides for matters related to proceedings regarding offences under the Act.

3.6.2 Regulatory approach

All the above represent strict disciplinary and enforcement mechanisms which may be suitable in cases of actual or suspected egregious conduct. However, when considering the enforcement and disciplinary measures contained in the Act it is necessary to also consider the context of the operation and effectiveness of the regulatory system in its entirety. To this end, the review was consistently presented with views from Western Australian people, be they donor-conceived, donors, recipient parents, or those seeking ART or surrogacy, as well as from those practising or working in areas associated with ART and/or surrogacy, that the regulatory structure created unnecessary burden and red-tape, and that the current approach was one in which 'enforcement' outweighed the interests of participants. The comments of Dr Vincent Chapple provide a succinct example of such a view:

> *The current RTC seems to have forgotten the promotion of the welfare of participants in favour of the strict enforcement of the Act.*[220]

213 *HRT Act* s 54(1)(a).

214 *HRT Act* s 54(1)(b)(i).

215 *HRT Act* s 54(1)(b)(ii).

216 *HRT Act* s 54(2).

217 *HRT Act* s 54(3).

218 *HRT Act* s 55.

219 *HRT Act* s 55.

220 Dr Vincent Chapple (Fertility North), Submission 28.

What appeared to many who participated in the Review to be significantly absent from the regulatory approach adopted was a level of cooperation, mutual respect, and oversight which is responsive and flexible. They called for the use of regulatory and compliance mechanisms such as education, information dissemination, good communication, an openness to feedback from those being regulated (including addressing consumer and clinic complaints), support and flexibility, which was seen as significantly lacking. (See also above discussion at 3.4.4). It is certain that such approaches are far more suitable to regulating those who are doing the right thing, while the most stringent enforcement mechanisms should be saved only for instances in which there is significant or repetitive wrongdoing. This seemed most appropriate given there have been only five instances of conduct that have resulted in disciplinary action over 25 years since the RTC has been operating. These included:

1. 1994: a clinic carried out activities that required the approval of the RTC without such approval, namely the administration of growth hormone on three occasions and the use of SUZI[221] on another, resulting in a 'reprimand'
2. 1993/1994: a clinic supplied donor semen on several occasions to two medical practitioners who were not 'exempt practitioners' from the requirement to be licensed as set out in HRT Direction 2.21, resulting in a 'reprimand'
3. 2001: a clinic contravened the requirements of section 24(1)(b) of the *HRT Act* in storing embryos in excess of the permitted storage period, resulting in a written warning
4. 2012: a clinic's serious failure to comply with requirements in relation to the provision of proper information to a participant, obtaining effective consent or use an embryo without effective consent, securing proper arrangements for the safekeeping and disposal of human embryos, supervision and training of staff. This resulted in a reprimand and requirement as to conduct and ancillary orders that the licensed supervisor provide a full written account of the measures and controls that had been put into place to prevent a recurrence of the incident and its consequences, and thereafter complied with the said measures and controls approved by the Council and the *HRT Act* (or otherwise face mandatory suspension)
5. 2017: gametes were stored without the effective consent of the gamete providers and beyond the 15-year storage period without RTC approval, resulting in a reprimand.

221 SUZI – Sub-zonal insemination is a type of in vitro fertilisation that involves carefully selecting sperm and injecting them underneath the outer layer of the egg. This type of assisted conception helps men who have low sperm counts to conceive a baby.

3.7 Whether there should be a process for review or appeal of decisions made under the *HRT Act*

3.7.1 Review in relation to disciplinary and licensing matters

The *HRT Act* makes provision for review via the State Administrative Tribunal (SAT), which was established in Western Australia in 2004, in relation to disciplinary and licensing matters as follows:

- when the DG refers a matter to the tribunal[222]
- when the licensee or other person liable to a warning or penalty does not consent to a summary determination or submit to the discretion of the DG under s 37[223]
- when it appears to the DG that a penalty provided by ss 40(1)(a) to (f) may not be appropriate or that effect has not been given to the summary penalty imposed, the DG may make an allegation to SAT in respect of the matter[224]
- when the DG refuses an application for the grant, variation or renewal of a licence; an exemption or an authorisation; decides to impose or vary any condition in respect of a licence or exemption; or suspends the operation of a licence or exemption, cancels a licence or revokes an exemption; or as a consequence of a contravention an applicant for licence or licensee may apply to the SAT for review[225]
- Any person liable to a penalty under the *HRT Act* or to be adversely affected thereby may apply to SAT for review of any decision made by the DG by way of a summary determination in respect of a disciplinary matter.[226]

In an application by the DG of the DoH, where the SAT is satisfied that a licensee is by any act committing, or permitting the commission of, a continuing contravention of any term, condition or direction applicable to a licence or exemption the SAT may (a) by Order restrain the continuance of that act; and (b) make a further Order that – (i) the operation of the licence or exemption may be suspended for a specified period; or (ii) the licence may be cancelled or the exemption revoked with immediate effect, by the DG if the DG is satisfied that the restraint Order has been contravened.[227] It may otherwise determine that disciplinary measures or penalties are not to be applied.

To have matters heard by the SAT there is an application fee of $500.00 and a $500.00 hearing fee for each day or part thereof allocated, other than a first.

222 *HRT Act* s 36A.

223 *HRT Act* s 38(1)(a).

224 *HRT Act* s 38(1)(b).

225 *HRT Act* s 42(2).

226 *HRT Act* s 42(3).

227 *HRT Act* s 43(1).

3.7.2 Review in relation to other RTC decisions

The *HRT Act* does not explicitly provide for a right of appeal in relation to decisions made by the RTC concerning required approvals under the *HRT Act* or Directions – for example, in relation to import/export of gametes/embryos; posthumous use of gametes; surrogacy agreements; or decisions made by the various committees of the RTC. There is also an absence of any information provided by the RTC/RTU about how to ask for a review or what types of review people may engage with and when. Nevertheless, rights of review regarding individual decisions or actions by government departments or public officials are often possible pursuant to the body of law known as 'administrative law'. This allows for review by reconsideration, merits review, judicial review, or complaint to a body, such as an Ombudsman or other complaints body. These are considered in turn in relation to the *HRT Act*.

Reconsideration

Pursuant to administrative law, provided the original decision-maker has not exhausted their power, they may be able to reconsider their decision. The decision-maker may thus be asked whether they are prepared to reconsider the matter and the decision they have made. Despite this being an apparent (albeit not publicised) option in Western Australia the view conveyed during face-to-face consultation was that the RTC/RTU was not open to reconsidering its decisions.

Review on the merits

A review on the merits generally means that a higher official, a Minister, a specialist tribunal (within or outside the departmental framework), or an independent general tribunal (such as the SAT) is given the power to look again at a decision that has been made and make what they think is the correct and preferable decision instead. The person conducting the review will usually be able to consider any additional material provided to them and come to their own decision about the facts of the case. They will then be able to substitute their decision for the decision originally made. Note, this would only apply if the *HRT Act* or HRT Regulations gave people such a right of review.

Judicial review

Judicial review is review by a court, which determines whether the decision complained about is unlawful and of no effect. It involves the person about whom the decision has been made or relates applying to a court. The court may then exercise its discretion regarding whether to grant relief. Note, the court only has the power to review the decision in relation to whether the decision-maker *made the decision lawfully*. It usually does not have the power to review the decision on its merits, however some grounds of review do require the court to consider such things as whether the decision-maker took into account an irrelevant consideration, or if the decision is manifestly unreasonable. Recourse to judicial review has been had in Western Australia in relation to decisions made by the RTC, most recently in relation to the posthumous use of gametes.[228] However, such recourse can be expensive, and a number of people who participated in the review expressed that they could not afford to apply for judicial review.

228 See for example, *GLS v Russell-Weisz* [2018] WASC 79. (Re posthumous use of sperm – see further Chapter 8).

Making a Complaint

People can also complain about the RTC and the DoH to the Ombudsman in Western Australia. The Ombudsman has the power to investigate complaints about decisions of Government officers and agencies, as well as systemic issues, and can decide whether any complaint should be investigated. After the investigation, an Ombudsman will make a report but cannot directly overturn the original decision or substitute their decision for that under review.

3.7.3 Submissions that called for a right to review

Several submissions supported that there should be a process of review or appeal of decisions made by the RTC. [229]Some referred to the SAT.[230] One submission said that the RTC should be able to make decisions related to certain matters only if it was more representative and included a donor-conceived person, recipient, and donor.[231] That submission, however, argued that issues related to enforcement or interpretation of the Act should be able to be appealed to a higher authority.[232] In some such submissions there was not an awareness that such rights to review may in some cases already exist. This was perhaps illustrative of the lack of information provided to consumers and those being regulated about their rights to review. Other submissions called for ongoing parliamentary scrutiny and revision of the Act as an important form of review. They said:

> *Given the critical importance of the issues involved and the protections needed, it is essential that the operation of both Acts and the operational bodies (such as the Council) are open to proper, periodic parliamentary scrutiny by both Houses of the Western Australian Parliament and their committees.*[233]

3.7.4 Consumers who approached the RTC/RTU for review

Some people who attended the face-to-face forums or approached me in confidence displayed significant upset and distress concerning how their requests for review and/or clarification of decisions had been handled by the RTC/RTU. A number complained about the manner in which they were communicated with, which they reported as being 'rude', 'obstructive', 'unhelpful' and 'lacking understanding'. None were provided with further information about what to do if they did not agree with a decision made by the RTC/RTU or the people they were communicating with. Some pursued their own research and inquiries and reported having approached the Health Consumer Council and/or the Ombudsman to complain about the RTC/RTU handling of their matters or being in the process of doing so. There were also examples of people who had taken their complaints to Court.[234] Others gave up as described below.

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229 For example, see Rodino & Clissa (Counsellors), Submission 8; Dr Vincent Chapple (Fertility North), Submission 28; Trevor Harvey, Submission 47, Brenda Harvey, Submission 51, and Julie Waddel, Submission 64 (these submissions were made separately but mirrored each other); ANZICA WA Fertility Counsellors (Joint submission), Submission 61; Hollywood Fertility, Submission 75; Confidential, Submission 84.

230 Rodino & Clissa (Counsellors), Submission 8; ANZICA WA Fertility Counsellors (Joint submission), Submission 61; Hollywood Fertility, Submission 75.

231 Damian Adams, Submission 40.

232 Damian Adams, Submission 40.

233 Trevor Harvey, Submission 47, Brenda Harvey, Submission 51, and Julie Waddel, Submission 64 (these submissions were made separately but mirrored each other).

234 *GLS v Russell-Weisz* [2018] WASC 79.

3.7.5 Consumers who did not exercise their rights to review

Several consumers who participated in the Review said that they had chosen not to exercise their rights to review or had given up after having approached the RTC/RTU. Such people emphasised a variety of reasons for this including that:

- time and costs were of the essence
- they felt that engaging in any type of fight with the RTC/RTU would take too long
- it would be too cost prohibitive and was 'exhausting'
- they feared fighting the RTC/RTU would be fruitless or damaging to them.

Such reasons were particularly relevant to patients who were also facing significant costs in relation to their treatment. Some such people reported they would prefer to engage in treatment in other states or territories of Australia or overseas or had already done so. Others were left without being able to resolve their issues and absent of treatment, access to information, and/or an inability to proceed. They expressed significant distress and frustration with the system and felt they had nowhere to turn.

3.8 Commonwealth and State/Territory legislation

The Terms of Reference required consideration of the impact on the *HRT Act* of relevant Commonwealth and State legislation and aspects of legislation of other jurisdictions which could be incorporated into the *HRT Act*. This section discusses such laws in relation to the regulatory system with reference to other regimes that have been implemented since the inception of the *HRT Act* that now serves to regulate practice; and better regulation principles.

3.8.1 Commonwealth and State laws

In Chapter 2, at paragraph 2.7, other relevant laws and regulation were detailed that govern:

- the registration and accreditation requirements for health practitioners
- businesses
- false, misleading and deceptive conduct (including for example, advertising)
- the provision of Medicare and PBS funded services
- the regulation of therapeutic goods
- the regulation of patient-practitioner relationships (for example, via laws on consent, negligence, criminal behaviour)
- the state-based health and disability services complaints system
- the regulation of laboratory and other services and practices relevant to ART.

Many such systems have developed and/or significantly evolved since the time that the *HRT Act* and HRT Directions were implemented in the early 1990s (and last revised in 2004). For example, the National Health Practitioner Registration and Accreditation scheme was introduced in 2010; the Australian Consumer Law was introduced in 2011, and Medicare and PBS funding related to ART services have evolved as technology has advanced. Access to Medicare and PBS funding requires proof of RTAC Accreditation, which in turn requires adherence to the RTAC Code of

Practice (which was revised in 1992, 1997, 2001, and 2005, and rewritten in 2008, with revisions in 2010, 2014 and 2017) and NHMRC Ethical Guidelines (which were introduced in 2004, and revised in 2007 and 2017).

It was found that with the instigation of such systems and/or their ongoing revision, many functions carried out by the RTC are duplicative or redundant. Some requirements under the *HRT Act*, associated regulations and directions, and/or requirements of the RTC, therefore created additional regulatory burden and costs (both financial and time-related) that in light of other Commonwealth and state law was unnecessary. This not only impacted those offering ART services in Western Australia but also often directly or indirectly impacted consumers. This is not to say that legislation or regulation is not required (this is further discussed below), but rather recognises that developments since the early implementation of the *HRT Act* and associated instruments implicate redefinition of what is necessary for the present day.

Better regulation

Over the past decade Australian jurisdictions have implemented a variety of requirements on regulatory agencies with the intention of reducing the regulatory burden on businesses and individuals. These approaches can generally be divided between inward-directed governance requirements about operational practices to be undertaken by regulatory agencies, affecting how regulations are implemented; and outward-directed requirements, affecting how regulations are designed. In relation to how regulations are designed it is now widely accepted that outcomes-based and risk-based regulation is more efficient and effective than 'command and control' systems for both regulators and regulated entities.[235]

Following a 2014 Productivity Commission Report,[236] the Commonwealth Government mandated 'better regulation' and introduced the Regulator Performance Framework in 2015. The framework requires regulatory agencies to report against key performance indicators of good regulatory practice, covering reducing regulatory burden, communications, risk-based approaches, efficient and coordinated monitoring, transparency and continuous improvement. The aim is to eliminate inefficient or unnecessary regulation that imposes unwarranted burdens on business, individuals and the community. There exists the Office of Best Practice Regulation and a deregulation unit in each portfolio to assist this.

At a state level, both New South Wales and Victoria have also imposed mandatory requirements on how regulators are to undertake their functions. New South Wales has a Better Regulation Division within its Department of Finance Quality; Victoria has within its Department of Treasury and Finance a better regulation unit with requirements on regulators found in their Statement of Expectations Framework.[237]

235 Productivity Commission. Digital Disruption: *What do governments need to do?* (2016) Australian Government. Canberra, Australia. p123.

236 Productivity Commission. 2014. *Regulator Audit Framework*. Australian Government. Canberra, Australia.

237 Department of Treasury and Finance, *Statement of Expectations Framework for Regulators* (2017). Victorian Government. Melbourne, Australia.

Other jurisdictions, including Western Australia, do not impose whole-of-government requirements on regulators as to their operational or policy practices, although many individual regulatory agencies manage their business along best-practice and risk-based principles, adopting 'better regulation' and reduction of red-tape initiatives. For example, in Queensland there is the Office of Best Practice Regulation within the Queensland Productivity Commission and a Queensland Government Guide to Better Regulation.[238] In South Australia the Department of Treasury and Finance suggests five-yearly reviews of regulation and there is a Better Regulation Handbook.[239] In Western Australia there is the Better Regulation Unit and Red Tape Reduction Unit within Department of Treasury and Regulatory Impact Assessment Guidelines.[240]

In relation to ART current regulatory approaches in other states and territories as set out in Chapter 2, section 2.8 include that New South Wales, Victoria, and South Australia have legislative schemes which maintain systems of 'registration' and variations of lighter touch regulatory oversight than that of Western Australia; while the Australian Capital Territory, Tasmania, the Northern Territory, and Queensland do not have legislative schemes at all. Those jurisdictions instead rely solely on other laws that govern health practitioners and health services, the RTAC Accreditation Scheme and the NHMRC Ethical Guidelines.

Further noted is that South Australian laws, upon which the Western Australian *HRT Act* was modelled, were changed in 2010 to move from a licensing scheme to one of registration, to change prior regulatory oversight and advice mechanisms that existed via the South Australian Council on Reproductive Technology (SACRT) by removing that Council, and repealed the Code of Ethical Clinical Practice that contained detailed provisions governing ART. The changes introduced in 2010 saw South Australia move to a 'co-regulatory' system implementing framework legislation, which stipulates registration conditions for ART providers and requires adherence to NHMRC Ethical Guidelines combined with the self-regulatory Reproductive Technology Accreditation Committee (RTAC) accreditation process. Examination of the intentions of Parliament reveals that the changes were intended to reduce duplication in terms of regulatory oversight and ethical guidance, regulatory costs and burden, and to improve the regulation of ART practices in that state.

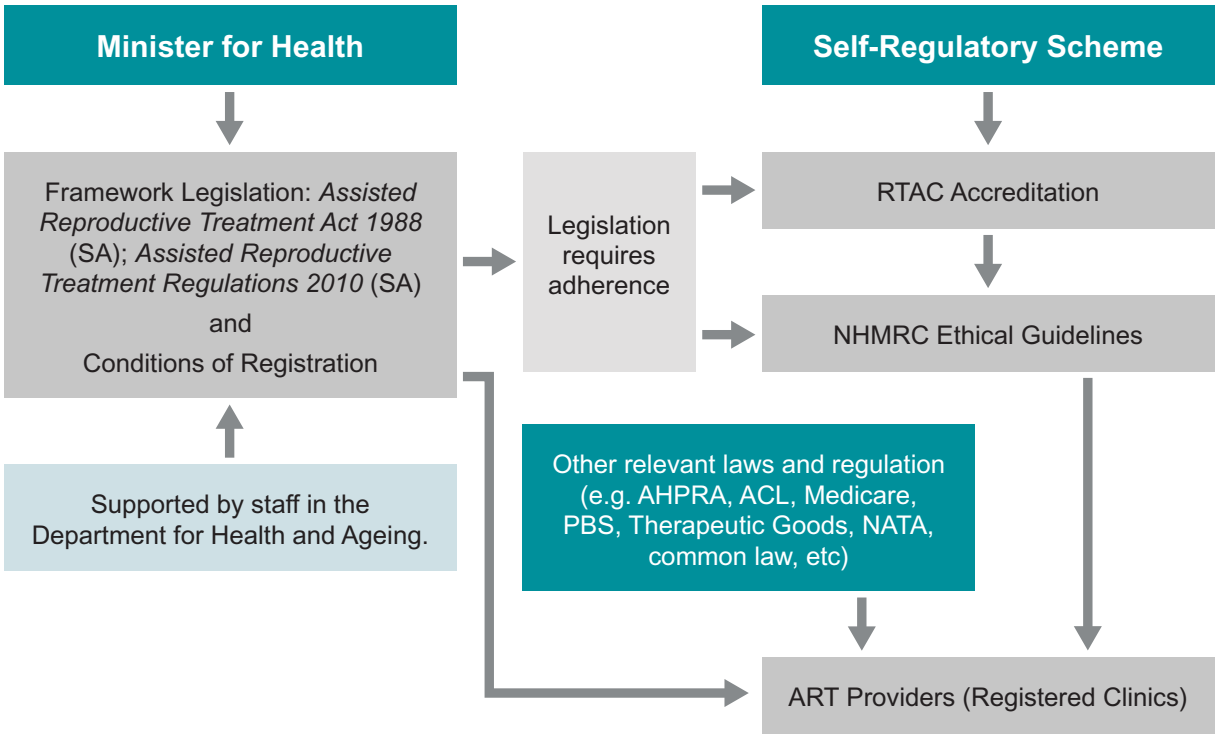
238 Queensland Treasury. *The Queensland Government Guide to Better Regulation*. Queensland Government. (2016) Brisbane, Australia.

239 South Australian Government. *Better Regulation Handbook*. (2011) Adelaide, Australia.

240 Department of Treasury and Finance. *Regulatory Impact Assessment Guidelines for Western Australia*. (2010) Government of Western Australia. Perth, Australia.

South Australia's current system is depicted in Figure 3.1 below.

Figure 3.1: South Australia Current ART Regulatory System



3.9 Is there a need for the continuation of the functions conferred on the RTC and the DG?

3.9.1 Should specific regulation of ART in Western Australia continue?

Western Australia introduced a command and control licensing and oversight regulatory scheme in the 1990s to protect emerging innovative enterprises in ART before national regulatory and oversight mechanisms were developed. Since then ART has become mainstream. Australia has been found to have a good record for safe, high-quality ART services and is at the forefront of emerging technologies and quality standards frameworks via the RTAC Accreditation Scheme and NHMRC Ethical Guidelines.[241] A number of other oversight systems that set standards for health practitioners and business have also been put into place and have developed to create a system of significant broader regulation relevant to the delivery of ART services and patient-practitioner interactions. The Commonwealth Government has publicly funded ART services under the Medicare Benefits Scheme and Pharmaceutical Benefits Scheme for many years; both require adherence to the RTAC Accreditation Scheme.

241 Assisted Reproductive Technologies Review Committee, *'Report of the Independent Review of Assisted Reproductive Technologies'* (2006) Commonwealth, Australia.

The Western Australian RTC was, in 1991, given the task, under the newly established *HRT Act* to develop a Code of Ethical Clinical Practice. Such a Code has never been developed; regulations and directions do exist. The RTC was also given other statutory functions under the Act. It is apparent that it fulfilled a much-needed role at the time of the *HRT Act*'s enactment and over the following early years of ART. This includes that it has played an important role in administering the Act, advising various Ministers of Health on issues that relate to ART as they arise, issuing licences and exemptions to ART providers in Western Australia, and enforcing the *HRT Act*. It is evident that it has been served by members who have offered their time, dedication and hard work and who have assisted in laying the foundations for the ART sector in Western Australia. However, in 2018 the *HRT Act* and the role of the RTC as it was first instigated and has continued are no longer suitable. The *HRT Act* and associated Directions are outdated, several requirements established by the regulatory scheme are redundant or duplicative of new schemes that have since been implemented and there is significant 'red-tape' for ART providers and consumers alike.

Identifying the costs

The costs of the current scheme are significant:

1. There are costs to the taxpayer that are administrative in nature, such as the cost of providing the licensing system, and of monitoring it. While there are application fees for the grant or renewal of a licence, such fees are small and do not operate on a cost-recovery basis.
2. There are significant costs to consumers. That is, while services are offered to public and private patients by the clinics, much of the treatment (hormone treatment, medical tests) is conducted out of hospital thereby incurring medical costs rather than hospital costs. The PBS and MBS gap costs of this treatment can be significant. Discriminatory restrictions within the legislation and delaying or restricting access to services which are accepted in other jurisdictions of Australia add additional costs to the citizens of Western Australia who seek access to ART. Some will bear the burden of those costs and proceed with treatment. Others may seek treatment in other states of Australia or abroad. Some may be unable to have treatment due to this being cost-prohibitive. The costs, however, are not just financial, they also raise issues of social justice and equity, which impact people negatively.
3. People who seek access to information (e.g. donor-conceived people, recipient parents, or donors) also bear the costs of either not being able to access such information or paying fees as a result of mandated counselling which they report creates barriers and that they have not found to be beneficial (see further discussion in Chapters 5 and 6).
4. There are costs to service providers in meeting duplicative or redundant requirements (for example, see further Chapter 4 regarding data reporting).
5. There are costs to the State in answering legal proceedings taken against the RTC be that in the SAT or Courts; and/or in the DoH seeking legal advice to interpret an outdated Act.
6. There are also costs to the State by impeding acceptable practice, research, and procedure potential in the field of reproductive technology, which constitutes a further loss of economic potential.

Identifying the benefits

The benefits of having a (well designed) regulatory scheme that is specifically designed for ART are, *prima facie*, that it may serve the best interest of the public and those born as a result of such treatment. That is, although ART is now commonplace, there remain ethical issues, risks, and community concerns which may justify some regulation. This includes for example, that there may be short- and long-term risks to the health and well-being of children born as a result of ART and donor conception, to those people undergoing treatment, and to donors of gametes and/or embryos. There may also be other risks related to inter-generational outcomes of ART, a lack of quality research and evidence regarding certain practices and outcomes, and risks associated with the ethical, legal and social issues raised by ART. The increased commercial nature of ART may also pose risks to consumers.[242]

While some people submitted they would like to see the *HRT Act* repealed and the RTC dissolved, most people who participated in the Review wanted a framework to work within which sets reasonable boundaries and regulation that is responsive, supportive, and flexible in an environment of rapid change. Thus, the question became one of what form of regulation was most suitable.

3.9.2 What regulatory approach should be taken?

As noted above it has been recognised that while expressions of regulatory toughness, often fundamental to the 'command and control' approach, might be good in 'dealing with the few bad apples, they may be self-defeating in dealing with the majority of good apples'.[243] Such approaches may result in resentment and resistance, a system in which information sharing is undermined, and one that diverts the energies of both sides into 'pointless legal routines and conflicts'.[244] This was clearly the position that now existed in Western Australia. Further, while modern regulatory theory recognises that 'command and control' design may be usefully maintained to address breaches of legislation by non-licence holders and serious breaches by licence holders, greater use of other forms of regulation of those who are acting in a professional manner is preferred. When considering what regulatory approach should be taken, alternatives to the current scheme that were considered include self-regulation, enforced self-regulation, and co-regulation.

Self-regulation

Self-regulation in its most basic form involves an organisation or association developing a system of rules that it monitors and enforces against its members.[245] In this sense the rules are self-made and self-administered without government oversight.[246] An example of this would be if the ART industry adhered to the Fertility Society of Australia's RTAC Code of Practice and Accreditation Scheme – without any legislative requirement to do so. This closely mirrors the approach taken in the Australian Capital Territory, Tasmania, and Queensland, although one should note that the lack of specific ART legislation does not mean that there is no government oversight of the industry in other ways. (See discussion at 2.7 'Other relevant laws and regulation').

242 See ACCC Media Release, above n 131.

243 Bardach and Kagan, above n 178, p 119.

244 Ibid.

245 Ibid.

246 Ibid.

Enforced self-regulation

When it is subject to some sort of government oversight or structuring, self-regulation can be classified as 'enforced'. Thus 'enforced' self-regulation may be a regime that is mandated by government but implemented by the organisation or association itself, or legislation might subject self-regulation to scrutiny and approval by a government department.[247] The strengths of enforced self-regulation regimes are said to include the high level of commitment of associations to 'their own' rules; well informed rule-making; low costs to governments; a close fit between rules and standards that the association accepts as realistically attainable; greater detection of violations and in securing convictions where prosecutions are necessary; greater comprehensiveness of rules; the ability of self-regulatory rules for rapid adjustment to circumstances; and more effective complaints procedures.[248] This type of regulation, however, has also been criticised on a number of bases, including that:

- there is a danger that rules will often prove to be self-serving
- the potential that rule setting procedures might lack openness, transparency, accountability and acceptance by the public and consumers
- the difficulty associated with some compliance units within associations always retaining their independence
- lack of trust from the public regarding internal compliance units in being able to apply rules in the public or consumer interest
- the fact that the public may demand that the government take responsibility for a sector or community rather than relying on self-regulation.[249]

In addition, self-regulation or enforced self-regulation may prove inadequate when the consequences of non-compliance are severe and stronger mechanisms for dealing with non-compliance, such as legislated penalty provisions, are required.

Co-regulation

Co-regulation is an approach in which various methods of regulation are brought to bear on a specific problem. It may be seen as the middle ground between traditional statutory regulation and private self-regulation.[250] Typically co-regulation involves both primary legislation and self-regulation or, if not self-regulation, at least some form of direct participation of bodies that represent stakeholders in the regulatory decision-making process.[251] This reflects a regulatory design strategy which combines the elements of legislation – especially in its predictable and binding nature – with the more flexible regime of self-regulation. It thus involves self-regulation and legislative action working together in a manner that mutually reinforces one another.[252] The legislature therefore first sets the essential legal framework, the stakeholders or parties

247 Ibid.

248 Ibid, 40.

249 Ibid, 40-41.

250 Kelley Lee and Jeff Collin, *Global Change and Health* (2005), 192.

251 P. Eijlander, 'Possibilities and Constraints in the use of Self-Regulation and Co-Regulation in Legislative Policy: Experience in the Netherlands – Lessons to be Learned for the EU?' (2005) 9(1) *Electronic Journal of Comparative Law*.

252 Ibid.

concerned then participate in the details, and the public authorities can monitor the outcome.[253] Co-regulation thus implies taking self-regulation one step further in a cooperative approach to governance. Rather than the mere co-existence of self-regulation and regulation, it involves the sharing of responsibilities between public and private partners.[254] Most importantly, it remains possible for the Government to intervene when specific rules are needed or with higher level enforcement mechanisms if there is non-compliance or particularly egregious behaviour.[255]

Co-regulation is, therefore, most appropriate where there is a good reason to have government involvement and formal laws contained within legislation, for example providing a framework for action, and in instances where self-regulation would not be satisfactory alone. The result is wider ownership of the policies in question by involving those most affected by the rules in their preparation and enforcement, but an ability to respond to egregious behaviour or heightened risk when required. In this regard, co-regulation also addresses the shortfalls of both command and control and self-regulation and achieves better compliance.[256] There may be a cooperative, co-regulatory design as the main 'on-the-ground' strategy, but the potential for greater command and control where that fails – which amounts to responsive regulation. (Note, that even at the level of non-compliance a cooperative and supportive approach may be taken in the first instance to help people achieve compliance). This design may thus work well in governing an area that raises moral and ethical concerns and/or issues of risk, such as ART, while also being a good option for reducing regulatory burden and costs of over-regulation or elaborate stand-alone statutory systems. It recognises that the expertise of those being regulated can inform the regulatory process and that risk dictates that government oversight is also necessary.[257]

When considering the other jurisdictions in Australia that have adopted legislation, New South Wales and South Australian regimes are illustrative of co-regulation, although in a different form. New South Wales is the lightest touch.

The New South Wales legislation aims to achieve its objectives to prevent the commercialisation of human reproduction, and to protect the interests of people born as a result of ART treatment; people providing gamete(s) for use in ART treatment or for research in connection with ART treatment; and women undergoing ART treatment, by requiring ART providers to be registered with the NSW Ministry of Health and by setting core standards for the provision of ART treatment. New South Wales also maintains broad powers of enforcement, including the ability to appoint inspectors if required in relation to ART or surrogacy. The Act is administered by the Ministry of Health; there is no separate statutory authority. The Act does not require RTAC Accreditation nor adherence to the NHMRC Ethical Guidelines (although as noted above, nationally this is required for Medicare and PBS funding).

South Australia also requires registration. It has framework legislation that enforces self-regulation and provides for the South Australian Minister for Health to set the parameters for practice and respond to changing technology or individual clinical practice by being able to place 'conditions

253 Linda Senden, 'Soft Law, Self-Regulation and Co-Regulation in European Law: Where do they Meet?' (2005) 9(1) *Electronic Journal of Comparative Law.*

254 Opinion of the European Economic and Social Committee on Simplification, *Official Journal of the European Communities*, (2002) c48/28, http://eur-lex.europa.eu/LexUriServ/site/en/oj/2002/c_048/c_04820020221en01300141.pdf.

255 Ibid.

256 Ibid.

257 Ibid.

on registration'. Its system was designed to reduce regulatory burden and duplication while being able to respond to risk.

A review conducted from 2015-2017 found that South Australia had been successful in reducing regulatory burden and duplication, but, in relation to responding to risk and operationalising the co-regulatory regime, could be improved. Clinics and consumers lamented the complete removal of the previous council SACRT stating it had left a gap particularly as NHMRC Ethical Guidelines were difficult at times to interpret. This had led to different interpretations of the NHMRC Ethical Guidelines by clinics (and their legal advisers) and resulted in inconsistencies in practice. They called for an advisory body that could give guidance and support public education on such matters. There was also the view that slight improvement could be made regarding oversight/ enforcement. The review of the South Australian legislation thus recommended that to improve the operation and effectiveness of their current co-regulatory regime they should:

- include an ethics advisory body to provide education and advice to clinicians and consumers[258]
- keep some decision-making capacity about what was ethically acceptable within the state rather than complete deference to the NHMRC Ethical Guidelines
- include the ability to appoint an independent person to conduct audits/inspections regarding compliance with the regime from time-to-time (like New South Wales) for when there was a concern about a clinic for example, due to RTAC Accreditation issues, or other issues drawn to the Minister's attention.

The recommendations of the South Australian review were intended to avoid over-reliance on self-regulatory accreditation schemes and enable the government to be an active participant in co-regulation.[259]

When put to participants in the Western Australian Review, many responded that they would like to see a similar model to that recommended for South Australia adopted, stating it would be *'a vast improvement on what we have now'*.

3.10 Discussion

Western Australia needs significant changes to its current regulatory system for ART. Current regulatory provisions, as well as the operation and approach taken by the regulators, are causing unnecessary regulatory burden, give rise to inequities, and at times, lead to distress by those subject to the regulatory system. There is a need for immediate change, and as such, I have taken a two-pronged approach to make recommendations, recognising that changes to the legislated regime may be slower to occur than via the more flexible HRT Directions.

258 Sonia Allan, Report on the Review of the *Assisted Reproductive Treatment Act 1988* (SA) (2017

259 Ibid. An analogy was drawn with findings of the Duckett review of Victorian hospital safety and quality oversight, which found the Victorian Department of Health had over-relied on accreditation processes for hospitals and did not have all the information it needed to ensure services were providing consistently safe and quality care. See Stephen Duckett (Chair), Targeting zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care. Report of the Review of Hospital Safety and Quality Assurance in Victoria. (October 2016).

It is recommended that, like the other states that introduced early legislation, the original Western Australian legislation (being the *HRT Act* 1991) be repealed and replaced with a modern piece of legislation that incorporates principles of better regulation. A co-regulatory regime is recommended, with a regulatory design that enables flexibility and responsiveness. This should address that there are provisions within the current legislation that are significantly outdated, that impede acceptable practice, and do not support people who need ART in Western Australia to build their families within acceptable parameters, nor the people born as a result of the use of ART. Western Australian scientists and researchers are also impacted by provisions within the *HRT Act*. Some such issues may only be addressed via changes to the legislative provisions in the *HRT Act*. They should be addressed *as a matter of priority*.

In addition, acknowledging that legislative change may take some time, it is also recommended that immediate action should also be taken via repealing and replacing the HRT Directions and addressing the operational issues raised in this report. In this regard, Western Australia can operationalise the flexibility and responsiveness that is made possible by having Directions, noting that such Directions can, and should be, revised on a regular basis. It is unfortunate that this has not occurred for 14 years.

Findings

1. The 'command and control' regulatory system implemented in Western Australia in 1991, while having served a significant purpose in the early years of ART, is no longer effective or required. There is a need to adopt a regulatory structure that better responds to risk while removing duplication, redundancy, and unnecessary regulatory burden on those who comply.
2. A co-regulatory system that involves active participation in the regulatory system by both government and clinics, cooperation and responsive regulation, would be more suitable to the governance of ART than the prior 'command and control' system.
3. The Minister for Health/DG of the DoH should retain responsibility for the Government's role in the regulation of ART, with powers to issue conditions on the registration of clinics, regulations, directions, and guidelines when required.
4. Enforcement and disciplinary mechanisms should continue to be included in the legislation but should only be exercised when lower-level compliance mechanisms have failed or where behaviour has been or is suspected to be particularly egregious. The power of enforcement/disciplinary measures should fall to the Minister/DG of the DoH.
5. The effectiveness of the RTC and its committees in relation to the early governance of ART should be recognised. However, the continuation of the functions conferred on the RTC as a regulator and enforcer are no longer suitable.
6. The RTC should be abolished and a new advisory body established. The Committees of the RTC should be abolished.
7. Provision should be made, and information clearly communicated, regarding rights of review or appeal of decisions regarding matters governed by the *HRT Act* and associated legislation.

Recommendations

Recommendation 2

The *HRT Act*, HRT Regulations, and HRT Directions be repealed or revised to create a co-regulatory system for the governance of ART including setting the parameters for ART practice in Western Australia, implementing principles of cooperation and responsive regulation in the carrying out of the Department of Health's regulatory functions, and attending to matters discussed in the review of the *HRT Act* and Surrogacy Act.

Recommendation 3

That the framework legislation provides overarching principles that emphasise:

- the paramountcy of the health and welfare of any child to be born as a result of ART
- the health and safety of those accessing ART, donors and surrogate mothers
- principles of non-discrimination
- the values of non-commercialisation of human reproductive materials or capabilities.

Recommendation 4

That the framework legislation provides that:

- conditions of registration may be applied to all clinics/practitioners or be responsive to a particular clinic's practices if required (for example, if a clinic fails to meet RTAC standards, registration might be limited to six months instead of a year with requirements that the clinic address the issue)
- directives may be issued by the Minister from time to time as the need arises, informed by advice received from the new advisory body, research, or broader consultation to allow for responsive and flexible regulation.

Recommendation 5

That the RTC should be abolished and a new advisory body established whose role is to:

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

Recommendation 6

That the new advisory body's membership include in addition to membership reflective of the current RTC at least a donor of gametes/embryos; a recipient of ART; and a person born as a result of donor-conception and that all membership roles are represented by one person each.

Recommendation 7

That the new advisory body's membership should be rotated every three years to allow other members of the public and professions to participate and that reappointments only occur if there is no other person who has expressed interest in being on the advisory body.

Recommendation 8

That the current committees of the RTC should be discharged and their functions repealed. This should occur alongside necessary changes to the *HRT Act* regarding licensing, storage periods, posthumous use of gametes, and PGD. (Functions of the scientific advisory committee will continue within the broader remit of the new advisory body functions).

Recommendation 9

That requirements for 'Approved Counsellor' status be repealed, and all references to 'Approved Counsellor' be amended to counsellor. That counsellors be appropriately qualified AHPRA registered mental health professionals (for example, a psychologist) or equivalent (for example, a suitably degree qualified social worker).

Recommendation 10

That the Minister/DG/Department should:

a. provide information to the public and health professionals regarding what is permissible under the Act

b. receive from clinics a copy of the RTAC audit and any recommendations for improvement, and any further reports necessary to inform the Minister/DG of action that has been taken in response

c. impose any conditions of registration that may needed to be applied

d. consider the results of any inspection or audit undertaken by a suitably qualified person appointed by the Minister and any appropriate enforcement action to be taken by the Minister or the DG of the Department on the Minister's behalf

e. report annually (per calendar year) on the above, as well as upon outcomes of ART in Western Australia, and any other matters decided by the Minister/DG of the Department.

Recommendation 11

Powers of enforcement continue to be included in the Act and fall to the Minister/DG of the Department and/or their appointed representative to be exercised only when lower-level compliance mechanisms have failed or where behaviour has been or is particularly egregious.

Recommendation 12

Rights of review concerning government decision making should be set out in the legislation and/or relevant DoH communications and be clearly communicated to the public and clinics.

Recommendation 13

The Minister, DG of the Department, and the new advisory body be supported in their functions by DoH staff member(s), including functions relevant, but not limited to the implementation of the Act and public education; and that such staff be the point of contact for people who wish to seek ethical or policy guidance or raise issues regarding the Act, which may then be referred to the advisory body or Minister or DG of the Department as required.

Figure 3.2: Recommended ART Regulatory System

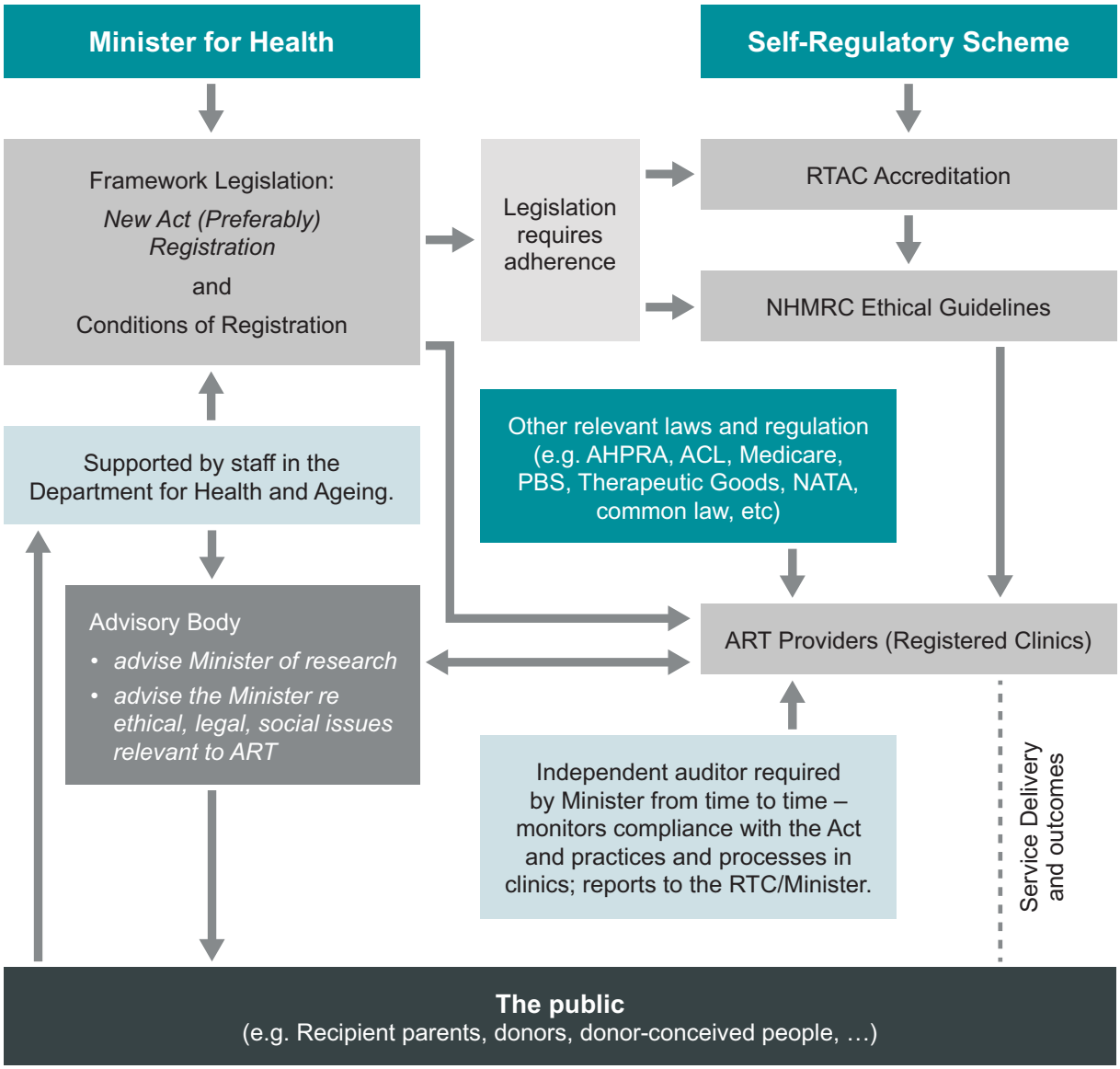
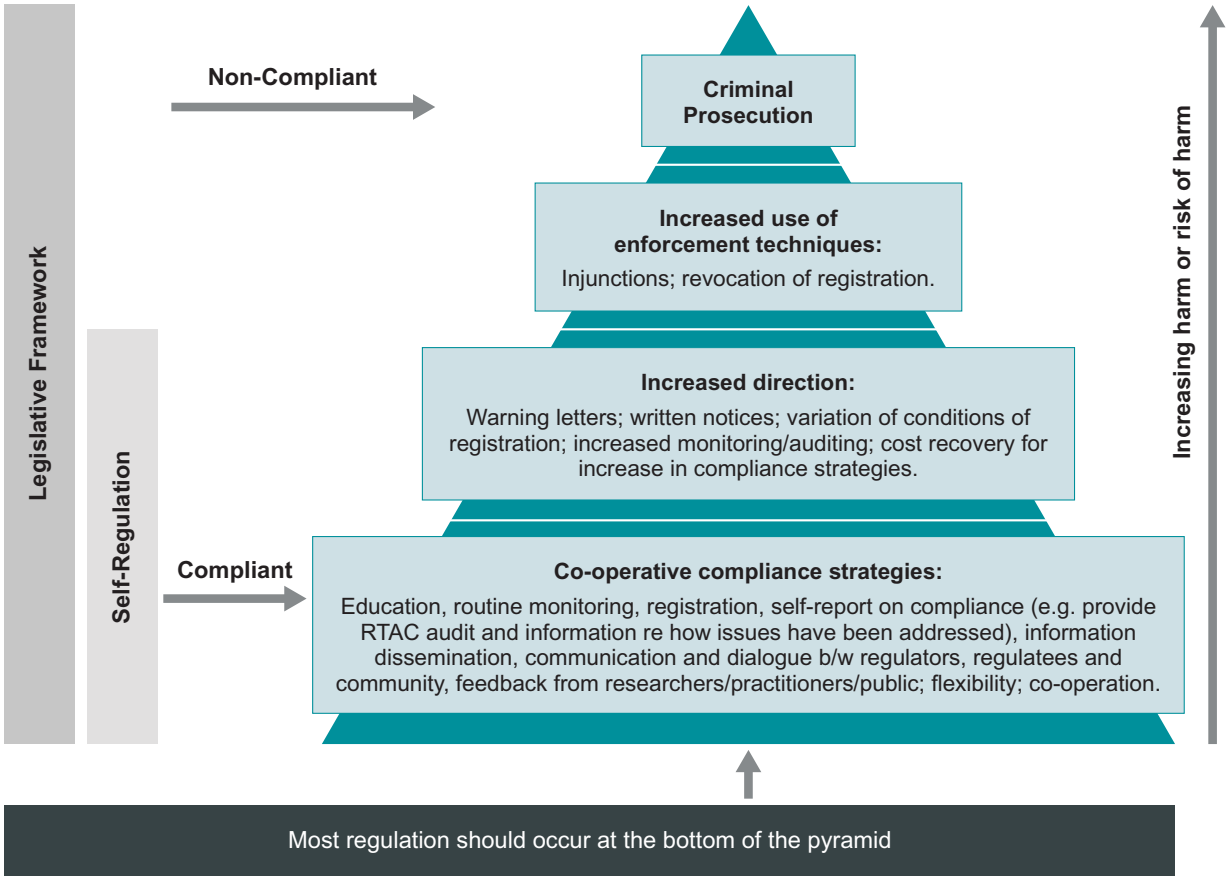


Figure 3.3 depicts the recommended responsive regulatory framework.

Figure 3.3: Responsive Regulatory Approach



Responsive regulation emphasises discretion about which enforcement strategy to use. In relation to compliant activity undertaken by clinics, regulation occurs at the bottom of the pyramid where the co-regulatory system is operationalised – *this should be where most regulation occurs*. Increased enforcement strategies are used only when necessary, determined by the frequency and severity of non-compliance and/or whether lower-level compliance strategies are being ignored. This takes into account that such non-compliance may lead to increasing harm or risk of harm. Compliance at any stage would lead to a return to the bottom of the pyramid. In instances where people who are unregistered commit an offence, or where there is severe non-compliance by a registered clinic/practitioner, immediate use of higher level sanctions would be warranted.

* Note all other self-regulatory mechanisms and laws still operate
(e.g. regulation of health practitioners, ACL, common law, Medicare, PBS, etc.).

Table: Required change and action

Table 3.2 details the changes required relevant to the discussion above of the current regulatory regime and associated matters, considering that:

* Legislative change may take time due to drafting, approval, and parliamentary processes, but, is nevertheless recommended as a *matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 3.2: Recommended Changes to Legislation, Directions and Operations Regarding Regulatory Regime

Required Change	Legislation*	Directions**	Operation**
Modern regulatory approach: co-regulation; responsive; flexible; reduce regulatory burden and red-tape	Repeal and replace current *HRT Act* 1991 (and subordinate legislation)	Repeal and replace current HRT Directions (last revised in 2004)	Attend to operational issues and functioning of RTC/RTU and associated interactions with the public, licensees, exempt practitioners, and other departments
Licensing requirements (*HRT Act*, Part 4; HRT Directions, Part 1) Licensing; Personnel, Premises, and Minimum Standards of Practice	*HRT Act* to move to provisions that require a system of registration (consistent with New South Wales, South Australia, [and Victoria – in modified form] requirements)	Maintain Part 1 of the HRT Directions regarding personnel, premises, and minimum standards of practice. (Ensure consistency and alignment with the intentions of the recommendations made in this report and suggested changes).	Attend to process and requirements immediately – reduce regulatory burden and requirements imposed by RTC/RTU in regard to licensing to align with current practice in New South Wales and South Australia as discussed at 2.8.1 of this report. For example, paper form application/registration; copy of RTAC licence and any other accreditations supplied; (if applicable, reporting of any incidents/required improvements and how they have been addressed.) Remove any duplication imposed on licensees taking into consideration their other regulatory obligations (RTAC, NATA, AHPRA, ANZARD, LARU).

Required Change	Legislation*	Directions**	Operation**
Licensing requirements (*HRT Act*, Part 4; HRT Directions, Part 2.19-2.22) Notifications to be made		Revise HRT Directions 2.19-2.22 to include modern requirements for notification to the *DG of the DoH* (for example, reporting of insolvency, change in constitution/management/ personnel; adverse incidents; disciplinary proceedings by AHPRA; investigation by the ACCC; legal proceedings; issues raised by RTAC re-accreditation, etc).	Respond in a co-operative and responsive manner. Act only as necessary and do so in the spirit of supporting practice improvement, achieving positive outcomes, using least restrictive measures, avoiding punitive measures except in circumstances that cannot be addressed via co-operation, education, and support.
RTC/RTU: Membership and Transparency	Amend legislation to emphasise the need for appropriate consumer representation; Require that membership on the RTC should be rotated every three years and that no member will be renewed if there is a suitable alternative candidate.	To operationalise current Section 2(a) of the *HRT Act*, require appropriate consumer representation on the RTC, which at a minimum should include: 1. A person who is donor-conceived 2. A recipient parent 3. A donor of gametes/embryos Require that membership on the RTC should be rotated every three years and that no member is renewed if there is a suitable alternative candidate.	Operationalise Section 2(a) of the *HRT Act* to include in the RTC membership 'adequate representation of the interests of women, parents, children born as a result of ART, and participants in ART. (I.e. consumer representation). Ensure members of RTC declare conflicts of interest, and that a plan be put into place to manage such conflicts. Facilitate information to the public, clinics and other interested parties about RTC membership; make a wide call for membership to provide the best opportunity for rotation of membership every three years.

Required Change	Legislation*	Directions**	Operation**
RTC/RTU: Function	Repeal and replace current *HRT Act* Part 2, Section 14 to make clear the functions of the RTC and to emphasise its role as an *education and advisory body* and in encouraging and facilitating research. Remove reference to Code of Practice (see further below). Make provision for information provision to public.	Provide any necessary directions that will focus the RTC and supporting officers' role on advising the Minister/ DG of the DoH, consulting with the public, publishing guidelines/educational materials relevant to ART, and supporting people born as a result of, or seeking ART and/or surrogacy in Western Australia. (See further below and discussion throughout the report).	Focus the functions and role of RTC on: 1. *advising* the Minister/ DG of the DoH on ART and incidental matters (and generally as to the enforcement and administration of the Act) (ss14(1)(a) and 14(1)(b)) 2. *consulting* with relevant bodies and the public, and *publishing guidelines and/ or educational materials* about ethical standards relevant to ART and/ or matters instructed by the Minister/DG of DoH relevant to the practice of ART and surrogacy in WA (e.g. what is legally permissible, responses to clinic and public questions regarding the law; support documentation). Change the internal culture of RTC/RTU as viewing its functions primarily as the 'regulator and enforcer' to one of an 'advisory body' that is the 'facilitator and supporter' of people seeking to build their families within acceptable parameters and children born as a result. Engage with people, and the practitioners involved, in a co-operative, responsive, and supportive manner. Address operational issues and behaviours that were reported as being adversarial, bureaucratic, obstructive, and unnecessarily punitive.
HRT Act – Provision for Code of Practice Part 3, Division 1	Repeal Part 3, Division 1 (noting there has never been such a Code, and no such Code is required) Make/maintain a clear provision for the DG of the DoH to be able to make Directions and/or to place conditions of registration on practitioners and/or clinics. Require that Directions be revised every three years and that the Act should be revised every five years.		Maintain a website with plain English, clear, searchable, and easy to find information that informs the public about ART and surrogacy in Western Australia. (Suggest that the website be DoH-based and not RTC). Include links to relevant regulation and information as required. Educate the public about where current rules, regulations, and directions may be found.

Required Change	Legislation*	Directions**	Operation**
RTC Committees *HRT Act*, s 10	Maintain the option for the RTC to appoint a committee from time to time (s10) Provide that such a committee should only be appointed on an ad hoc basis to undertake a certain project and that its work should not replace the role or functions of the RTC as the recommended 'education and advisory body' nor that of the supporting DoH staff.	Amend/draft directions to remove requirements that currently lead to duplicative processes, and unnecessary approvals or processes (often currently dealt with or decided upon by the current RTC Committees). (as further set out below)	In light of recommendations regarding the removal of current duplicative processes and revised requirements for licensing and approvals disband the current RTC Committees.
RTC Approvals – 'Approved Counsellors' Requirements to be considered an 'Approved Counsellor'	(NB. These recommendations do not affect *HRT Act* provisions at s22(7) – that before a licensee gives effect to a consent for the purpose of the Act that each participant must have been given the opportunity to receive proper counselling about the implications of the proposed procedure.)	Repeal Schedule 4 Part 1 – 'Approved Counsellors' to remove additional and duplicative requirements to gain approval status via RTC approval. Provide new Directions that counsellors be appropriately qualified AHPRA registered mental health professionals (for example, a psychologist) or equivalent (for example, a suitably degree qualified social worker). Retain Part 5 of the Directions (albeit revise to ensure they meet contemporary expectations and practices and are consistent with other recommendations in this report – e.g. see recommendations in relation to access to information by donor-conceived people).	Discharge the RTC Counselling Committee. Refer any residual functions to main RTC where representation, including community representation, exists. Remove redundant processes and bureaucratic requirements that have served to limit entry into the profession. Support a process that is inclusive of counsellors who are suitably qualified mental health professionals. Establish an accessible and functioning system of registration in which people who meet the criteria may provide their name, practice address, and qualifications (in brief) to the DoH, for inclusion on a publicly available list (e.g. on the website, in print form available at all clinics, etc).
RTC Committees – Embryo Storage Committee	See Chapter 7 discussion and recommendations.	See Chapter 7 discussion and recommendations.	Discharge (remove) Embryo Storage Committee as it is no longer necessary pursuant to recommendations in Chapter 7.
RTC Committees – PGD Committee	See Chapter 9 discussion and recommendations.	See Chapter 9 discussion and recommendations.	Discharge (remove) PGD Committee as it is no longer necessary pursuant to recommendations in Chapter 9.
RTC Committees – Licensing Committee	As per discussion and recommendations in this chapter.	As per discussion and recommendations in this chapter.	Discharge (remove) Licensing Committee as it is no longer necessary pursuant to the recommendations above.
RTC Committees – Scientific Advisory Committee	As per discussion and recommendations in this chapter.	As per discussion and recommendations in this chapter.	Discharge (remove) Scientific Advisory Committee pursuant to its functions being continued within the RTC.

Required Change	Legislation*	Directions**	Operation**
RTC Approvals – Post-humous use of gametes	See Chapter 8 discussion and recommendations.	See Chapter 8 discussion and recommendations.	See Chapter 8 discussion and recommendations.
RTC Approvals – Projects of Research (*HRT Act*, s 20); Approvals of laboratory and clinical procedures (HRT Directions, Part 9)	Repeal and revise section 20 (Redundant approval requirement which is unnecessary if the independent Human Research Ethics Committee (HREC) or Institutional Ethics Committee (IEC); approval has been obtained).	Repeal Part 9 of the Directions. To address current provisions, insert Direction: That any research experiment, or practice considered to be experimental or innovative, must not be conducted without approval from an independent HREC or IEC; and that such HREC or IEC approval will be considered to satisfy 'general approval' relevant to the research project by the RTC pursuant to section 20(2) of the Act.	Reduce the regulatory burden. Remove duplicative requirements for approvals. Consider whether there should be notification of study project name/innovative technique and HREC/Institutional Ethics Committee approval number and date to the DoH for record keeping purposes (see further Chapter 4).

Chapter 4

Managing Information – Data Collection

Chapter 4:
Managing Information – Data Collection

4.1 Introduction

This and the following Chapters 5 and 6 examine the management of information, including but not limited to record keeping, reporting, and access to data. As required by the terms of reference this includes examination of confidentiality of information, use of data for research, use of data for purposes of national data collection, access to information about donation, genetic parentage and donor conception, including data collected for the Reproductive Technology Register, and the Voluntary Register (donor-assisted conception).

This chapter examines requirements under the current *HRT Act* and associated directions regarding record-keeping and reporting requirements. This includes an examination of data recording and reporting relevant to the monitoring and evaluation of ART treatment (at State and national levels) as well as data for research. Chapters 5 and 6 then address the issues of recording of, and access to, information about donation, genetic parentage and donor conception.

4.2 Background

4.2.1 Record-keeping and reporting requirements under the *HRT Act*

Record keeping

Section 44 of the *HRT Act* requires record keeping by licensees and exempt practitioners regarding:

- human gametes:
  - the identity and consent of the donor from whom they were received
  - the date they were collected
  - the place, period, and method of collection and keeping
  - the identity of the person(s) to whom the human gametes were supplied and used.
- human eggs undergoing fertilisation or human embryos:
  - their biological parentage and the date that fertilisation commenced
  - the place, period, and method of collection and keeping
  - the identity of the person(s) to whom the human gametes were supplied and used.
- all artificial fertilisation procedures carried out by or on behalf of the licensee:
  - the identity of, and full particulars as to the consent given by, each participant
  - the reasons why each participant was assessed as being an eligible person in respect of that procedure
  - the nature of the procedure
  - the identity of the individual who carried out that procedure

- where known the outcome of the procedure; whether any children were born that appear to the licence supervisor to have been born as a result of the procedure; and sufficient particulars to identify each such child
- all research relating to reproductive technology conducted, authorised or facilitated by or on behalf of that licensee
- any other information, procedure or matter of which a record is required under this Act or any other written law.

The *HRT Act* provides that such records are to be kept in such a manner as to comply with the terms of, and any condition imposed on, the licence or any approval or direction relating to that licence and any requirement under the Act, unless the DG, in writing, otherwise directs.

Section 44 of the Act further provides that records are to be kept and retained in such a manner as to keep secure the confidential nature of the information contained therein, in a place in the State approved by the DG, for the prescribed number of years, and be made available for inspection by an authorised officer when required. In addition, a licensee shall, if so required by the DG, furnish in a form acceptable to the DG any record and reports containing such further or other information as the DG may reasonably require in respect of any research; or concerning any artificial fertilisation procedure using any human gametes, a human egg undergoing fertilisation or a human embryo, or the keeping thereof; or relating to any other matter, specified by the DG as being relevant to the administration of the *HRT Act*, whether in relation to a licence or exemption or otherwise.

It is an offence not to comply with the section 44 HRT record-keeping and production requirements, carrying a penalty of $5,000.

The 'Reproductive Technology Registers' (the RT Registers)

Section 45 provides that the DG shall cause to be kept, in a place and manner approved by the Minister, registers that contain current information supplied by, or otherwise obtained from, licensees in respect of:

- the identity of participants
- the outcome of procedures, showing the genetic origin of the human gametes, human egg undergoing fertilisation or human embryo used
- the identity of children born as a result of an artificial fertilisation procedure, including the identity of each biological parent
- such relevant demographic and clinical information, as may have been required to be supplied under the Act regarding the licence, licensee, or exempt person, including any disciplinary proceedings, information in relation to any NHMRC licences held or applied for in this State; and/or
- any other matters as may be prescribed.

The register is required to be compiled in a manner that enables such information to be made readily available in a manner permitted under the Act but keeps secure the confidential nature of the register.

Section 46 then provides for access to information. First, the *HRT Act* provides that it does not prevent a person who is or was a participant in a procedure from accessing information

about themselves and that procedure from the licensee who must facilitate any such access requested.[260] The *HRT Act* otherwise provides that a person may access information on the register (after payment of a prescribed fee) if:

- the information supplied related to that person in their capacity as a participant in an artificial fertilisation procedure
- the information provided does not identify, but relates to a biological parent of that person; or a child of whom that person is a biological parent
- it is sought by a person so authorised by the DG
- it discloses only the social or public health connotations of reproductive technology
- a written law so provides.

Information may also be given to an authorised officer under the Act or to the licensee who supplied the information (or a person authorised by that licensee) in order to carry out an artificial fertilisation procedure or to conduct research.

The Western Australian statutory Reproductive Technology Register (RT Register) was established in 1993/94. Database 1 was an MS Access database where DoH staff added data from paper forms submitted by licensed clinics and exempted practitioners. Forms were first included in the HRT Directions 1997. The DoH subsequently moved to Database 2 which is an access database where DoH staff either upload data from data files or add data from paper forms submitted by licensed clinics and exempted practitioners. Data and Forms are regulated in the HRT Directions 2004. Data from the access database is extracted to SAS data files and can be provided to data recipients as MS Excel files, MS Access database or another file type enabled by SAS.

The Assistant Director General – Clinical Excellence (ADG-CE) is the Data Steward for the RT Registers. The RT Register currently sits within the Purchasing and System Performance Division in the Data and Information Unit.

Data Stewards have the delegated responsibility for the overall strategic direction of the data collections. There are two joint data custodians, being the Manager of the Maternal and Child Health Unit, within the Data and Information Unit, and the Manager of the RTU. Data custodians have the delegated responsibility for the ongoing development, data collection, maintenance, and review of the collection. They are responsible for the quality of the data, its security, timeliness and adherence to standards. All licensed ART units and exempt practitioners are required to report to the RT Register submitting the following data: individual treatment cycle data quarterly and aggregated treatment cycle data for the recent financial year for inclusion in the RTC annual report (see further below at 4.3.1).

Due to significant problems with the current registers and reporting requirements there has been discussion of 1) moving to a third iteration of the database (Database 3), which would involve a new data management system, interface, data submission portal processes, and security; or 2) using the Australia and New Zealand Assisted Reproduction Database (ANZARD) reported data. The issues with the registers and options are discussed further below, following elaboration of what current ANZARD reporting entails.

260 *HRT Act* 1991, s 46(1).

4.2.2 External reporting to ANZARD

In 1979 the Assisted Conception Data Collection (ACDC) was established to record information on the outcomes of clinical pregnancies that resulted from assisted conception in Australia and New Zealand. At the time Australia had neither formal reporting guidelines for ART clinics nor nationally agreed guidelines for follow-up and notification of birth defects generally. ART clinics were requested as part of the ACDC to report as much detail as was known about the outcomes of ART including births and birth defects, with such information being drawn from birth registration forms, autopsy reports and doctors' letters. (Note, this did not include long-term follow-up and the scope of the ACDC was limited to information on cycles that resulted in a clinical pregnancy).

The ANZARD superseded the ACDC in 2004. An initiative of the Fertility Society of Australia (FSA), ANZARD provides a joint data collection for both the National Perinatal Epidemiology and Statistics Unit (NPESU) housed at the University of New South Wales, and the Reproductive Technology Accreditation Committee (RTAC) of the FSA. It requires a collaborative effort between the NPESU, the FSA, and the fertility centres in Australia and New Zealand – the last of which provide data to ANZARD on an annual basis. The NPESU is the ANZARD data custodian for all fertility centres in Australia and New Zealand who provide data to the NPESU.

The purpose of the ANZARD collection is to monitor the perinatal outcomes of assisted reproduction and to assess the effectiveness of ART treatments. ANZARD thus includes information about:

- the ART treatment procedures of in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), gamete intrafallopian transfer (GIFT) and intrauterine insemination (IUI) using donated sperm (IUI-donor) (but not if the woman's partner's sperm was used)
- ART treatment using thawed embryos; treatment involving donated gametes or embryos; the use of techniques such as assisted hatching, preimplantation genetic diagnosis and blastocyst culture
- pregnancy and birth outcomes, including the method of birth, birth status, birthweight, gestational age, plurality, perinatal mortality and selected information on maternal morbidity.

Fertility clinics are required to submit individual treatment cycle data to the National Perinatal Epidemiology and Statistics Unit to be entered into the ANZARD to maintain RTAC accreditation. Clinics submit their calendar year data to ANZARD after the birth outcomes of treatment are known. ANZARD does not collect identifying information about recipients, donors, or children born as a result of ART or donor-conception.

4.3 Operation and effectiveness of the Reproductive Technology Registers

4.3.1 Current operation

Data currently required to be submitted to Database 2 is specified in the HRT Directions 2004 forms and specifications as follows:

- donor non-identifying data Form 4, Schedule 1
- identifying data submission by clinics Part 1, Schedule 2
- treatment data submission by clinics Part 2, Schedule 2
- donor-insemination data submission by exempt practitioners Form 5, Schedule 1
- donor-identifying data submission for donor-insemination by exempt practitioners Form 6, Schedule 1
- participant-identifying data submission for donor-insemination by exempt practitioners Form 7, Schedule 1
- annual report data submission by clinics and exempt practitioners Schedule 3.

All clinics and exempt practitioners are asked to submit data using secure file transfer provided by DoH (MyFT) but, some do not appear to use this system and submit data files attached to emails.

Clinics submit treatment data quarterly regarding cycle dates between:

- January and March submitted by 30 June
- April and June submitted by 30 September
- July and September submitted by 31 December
- November and December submitted by 31 March.

Treatment data includes Participant ID, Partner ID (if applicable), Donor ID (if applicable) and procedure type. Between 31 March and 30 April, all Participant, Partner and Donor IDs submitted in treatment data are compared with identifying data previously provided by that clinic. If no identifying data is found for an entry the clinic is requested to provide identifying data by 30 April.

The Data and Information Unit provided the review with the following information contained in Box 4.1 and Box 4.2 regarding upload of data and validation.

Box 4.1: Upload of data to D2 RT Registers

1. **Treatment data is received in an MS Excel file format from each clinic.** The files must be reconfigured to conform to expected formatting i.e. Columns re-ordered; Column headings corrected; Date, numeric and text fields formatted as expected; Data received as a paper form is entered into MS Access database (Form 4) or into a MS Excel file (Forms 5, 6, 7) for upload.
2. **Identifying data is received in an MS Excel file format from each clinic.** The file is configured to conform to expected formatting i.e. Columns re-ordered; Column headings corrected; Date, numeric and text fields formatted as expected;
3. **Upload of data files is managed using SAS code to append data files to appropriate SAS data tables:** Treatment data table (Participant ID, Partner ID and Donor ID link to other records and tables, Fertilisation Code links to other records using embryos); Identifying data table; Form 4 data table.
4. **SAS data tables are replicated in MS Excel and MS Access formats to enable team members not using SAS to have access.**

Box 4.2: Validation of data in D2 RT Registers

Validation of treatment and identifying and non-identifying donor data is based on the following levels of validation:

Data file: Data file is named as expected; Data file is type and format as expected; Data file contains data items as expected. This process is performed upon receipt of the file by DoH.

- **Level 1 – Data item is not missing and is in the correct format for the specified data item** i.e. date is in DD/MM/YYYY format. This validation is performed on a limited number of key data items in each D2 treatment and identifying record i.e. procedure type, cycle ID, Unit ID, cycle ID, participant ID.
- **Level 2 – Data is within the expected range for specified data item** i.e. a cycle date is within 12 months of current date or is within the date range reported by the data file or is not a future date.
- **Level 3 – Data is consistent with data in other data items in record** i.e. a tallying of the number of oocytes picked up and their dispersal would raise a validation error if they do not add up as expected.
- **Level 4 – Data is consistent with data in other records** i.e. a fertility code reported for an embryo in an embryo transfer cycle should be consistent with the fertility code from an IVF cycle and unless donor material used in some instances should have a consistent Participant ID. This involves also seeking data records that are missing from the RT Registers in relation to all Participant IDs, Partner IDs, Donor IDs to ensure all treatment records have a corresponding record in Identifying data – this matching is done annually, and clinics are required to provide identifying data as required.

4.3.2 Identified strengths of RT registers

That legislation exists to support the purpose and process of data reporting and collection has enabled data collection about ART in Western Australia since 1993 is commendable. There is significant interest in data held in the RT Registers both for research purposes and monitoring of the outcomes of ART. It was evident that there has been significant investment in time and passion in creating and managing the RT Registers, and that this continues at Director and Executive Director levels. This was clearly demonstrated via a willingness to invest effort and resources into resolving data management problems that plague the RT Registers (see below).

The importance of the early RT Register was emphasised by the Telethon Kids Institute, who submitted:

> *In its early days, the WA RT Register was the envy of researchers and health professionals in the ART field internationally – a statutory collection sitting in the midst of a whole network of other population-based health registers which could be linked together with the assistance of a dedicated data linkage branch. The first research study to use linked data from the RT Register examined birth defect prevalence following IVF conception. The findings showed that births conceived using ART in WA from 1993-1997 had a two-fold increased risk of major birth defects compared with naturally conceived births, and the paper was published in the New England Journal of Medicine (2002). The study raised awareness of the importance of long-term follow-up of ART children, stimulated many other research groups to assess the prevalence of birth defects in ART cohorts, and led to changes in the information provided to patients at pre-treatment counselling; it has since been cited over 1000 times. 15 years later, WA remains the only state in Australia where such research can be undertaken...*[261]

4.3.3 Identified issues of concern

However, despite the goodwill and the intention of maintaining the RT Register, the review found that there were numerous issues of concern about the current RT Register. This too was noted in the Telethon Kids Institute submission:

> *…but the RTR has languished and the current poor data quality means that we are unable to adequately address the many unanswered questions in this field that an up-to-date register would allow us to address.*[262]

Many other issues were identified via further investigation during the review and are noted in this section.

261 Telethon Kids Institute, Submission 34.

262 Telethon Kids Institute, Submission 34.

Issues regarding data specifications and forms

I met and corresponded with the Director of the Data and Information Unit and his team during the review. The Director was clear that data specifications contained in the HRT Directions 2004 are *'outdated, unclear and ambiguous'* and that they *'are not conducive to good data provision from clinics'*. He said:

> *The current Directions are very technical in nature, …antiquated and reflect… the language and prevailing data collection processes of the time they were drafted. The detail should be reduced, and the specification redrafted and tested for clarity with the Clinics.*

It was submitted that an updated Data Dictionary with high-quality metadata is required.

It was also noted by the Data and Information Unit that some forms that are specified in the Directions are not used. For example,

- clinics are requested to provide a Form 4 for Donor IDs, but the Data and Information Unit report they have never had a Form 4 submitted;
- some forms are used incorrectly. For example, requests for provision of Form 5 data ceased in 2004 and hence Form 6 and 7 data is required for these cycles. This appears to have been an error.
- requests to exempt practitioners and sperm storage units to provide Form 5, 6 and 7 data were not happening but should have, and thus was re-initiated in 2016 for cases that occurred since 2003.

The Data and Information Unit submitted that:

> *The Directions are very convoluted and complex. This has resulted in difficulties in administration, conformance, review and amendment. A failure to amend the Directions has resulted in the data provided to the RT registers becoming redundant and out of date. The requirements to use each of multiple forms and/or data files and when these should be used or reported have confused those trying to conform with the legislation.*[263]

Issues regarding the RT registers and the reliability of data

Reviews conducted internally within the DoH of historical documents (minutes, annual reports, and briefing notes) were reported to me to have shown there were difficulties in implementing the RT registers. This has included database development problems, data items being embargoed as not useable for research purposes, incomplete and/or inaccurate submissions, errors in patients' names, errors in reporting the number of eggs, embryos and egg and sperm donation. Such issues have led to the view that the RT registers *'are not fit for purpose'* due to a lack of ability to monitor or report upon activities of fertility clinics, and lack of confidence in being able to match records (e.g. between donor and recipient).

In addition, it was noted that since before 2012, the RT registers have been used to determine donors, donor offspring and genetic siblings to respond to applications to the Voluntary Registers, which were said to have been found to be *'incomplete and unreliable'*. I was informed that confirmation of data is currently being sought from RT clinics.

263 Confidential, Submission 111.

A review of certain data from the RT register, again conducted internally within the DoH, found:

- results concerning the number of single embryo transfers recorded on the RT Register in 2014 and 2015 did not align with ANZARD data from the same year
- examination of women's ages recorded on the RT Register in relation to treatment cycles identified outliers (aged 56, 58, 59, 65, 69, 105). Issues related to such outliers included such things as a partner's birthdate being appended to the woman's date of birth (x2); three cases were not treatment cycles but rather related to the movement of embryos; an error regarding entry into the register of the year 00, which was thus calculated as 1900
- DoH RT register data versus annual data for the year 2012-2013 were not consistent
- some blank fields are not explained, and it is, therefore, difficult to determine whether it indicates a null value or unreported data
- some variables were only recorded for some clinics instead of all clinics
- some variable data was missing or incomplete (e.g. no birth date recorded; procedure type)
- birth outcome data are missing from a high proportion of RT register records for the years 2010-2014.

The above issues are of significant concern. In relation to data relating to donor-conceived people, the law provides for the release of information to those who reach the age of 16 from 2020. However, confidence in being able to provide accurate data cannot be had. This leads to a high-risk situation that must be addressed. (See further Chapters 5 and 6 regarding donor-conception and recommendations regarding the Donor Conception Register). In addition, the data, being considered 'not fit for purpose', cannot reliably be supplied or used for research or monitoring of ART practice and outcomes – contrary to the intention of the establishment of a data collection system.

Issues regarding data validation

There were also issues reported concerning data validation. An internal report on the RT register found failings in checking data for internal consistency and non-standard entries, as well as missing items, compromised error identification and reporting, and difficulties with follow-up of birth outcome data. The Data and Information Unit confirmed that documentation on RT Registers, metadata, validation rules, validation processes, data submission specifications, report specifications are *'insufficient or non-existent for D1 and D2'*. They further noted the following issues regarding data validation:

- **Level 1:** Many data items specified for reporting can be null or not applicable in many records.
- **Level 2:** This validation is performed on a limited number of key data items in each D2 treatment and identifying the record. More should be done; however, specifications and metadata are required to be finalised so that a validation manual can be finalised that includes actions to be taken when a record fails the validation rule.
- **Level 3:** In 2011, a significant amount of work on validation rules was undertaken; however, it required additional data items to be reported by clinics which were not included in specifications for data provision and thus was inconsistently reported.

The work also incorporated data editing with no metadata on when, why or what was changed in data records. Some editing occurred without correlation with clinic records or approval by clinics. To ensure D2 data was consistent with data held by clinics, a large amount of this work was undone in 2013. It was also found that some of the algorithms determined for validation rules were incorrect.

- **Level 4:** Validation and editing at this level have not been performed in recent years and needs to be incorporated in future validation processes.

The Data and Information Unit said that RT clinics have *'a lack of faith in the validation process and thus some do not respond to requests to validate data'*. This has *'prevented improvement in their treatment data.'*

Issues regarding birth outcomes data

There were also issues regarding the process and timing of data provision to RT Registers, in particular relating to the requirement that data be reported *before birth outcomes are known*. The Director of the Data and Information Unit was of the view that the requirement for quarterly data collection needs to include the provision of 'refreshed' data for previous three quarters in order to improve the quality and completeness of data and specifically to optimise the collection of RT treatment outcomes. Others thought that it would be preferable to report on an annual basis, with data being reported late in the year about the preceding year as is done in relation to the ANZARD collection (see below at 4.4.2).

Beyond this, where and how data about birth outcomes is obtained was identified to be of issue. That is, the Data and Information Unit reported that the RT registers contain birth outcomes data that have originated from a wide range of sources and processes. Clinics have retrieved birth outcomes data from birth and death notices in the paper, letters from obstetricians, summaries from maternity hospitals, other sources, and have provided these data to the RT registers for appending to the treatment record previously provided.

The RT Directions 2004 also specify that identifying data is collected annually for RT treatment data to enable linking to the Midwives Notification System (MNS) data. RT register staff have retrieved birth outcomes data from the MNS either via manual matching of identifying data from RT registers with identifying data in MNS or using computer program matching processes between an extract file from RT identifying data Register and an MNS data extract. However, the Data and Information Unit noted that:

> *Incorrect matching can have occurred. Birth data may have been appended to the wrong treatment record.*

The Data and Information Unit further noted that:

- RT clinics do not provide pregnancy and birth care and pregnant women are referred to maternity care providers early in pregnancy
- there is no legislated requirement on maternity care providers to provide outcome summaries on pregnancies to RT clinics
- it is rare for a discharge summary to be provided to RT clinics
- there is a legislated requirement on midwives to report *'fertility treatment = Yes'* to the MNS. A midwife including this data item in the notification requires that the participant includes this information in her pregnancy care record available to the midwife but *there is under-reporting of this data*
- some RT clinics foster a relationship with maternity services to request outcome data on participants they know intended to give birth at that maternity service. Approvals and processes to provide such information is randomly applied and is not supported by legislation or policy
- there is no legislation to support the release of identified MNS data from the DoH to RT clinics. Unfortunately, the DoH adopted a policy concerning this issue that determined that providing MNS data to RT clinics for them to confirm that outcome data is consistent with their own records, is a breach of the *HRT Act*. The Review was informed that the staff managing the RT registers have therefore not requested birth outcome data from clinics since before 2011.

A data workshop between Maternal and Child Health Unit (MCHU), RTU and RT clinic staff in 2012 indicated that implementing a process to allow maternity services to request outcome data on participants ((e) above) would be the most useful to RT clinics. However, such a process was not implemented due to the lack of legislative support to release identified MNS data to the RT clinics ((f) above). Again, it was found that the DoH's position on this matter had prevented the linkage of MNS data to the RT Register.

Due to concern about the records at the DoH, it became evident that clinics are being asked to resubmit data. At one clinic I was informed that they had been asked to resubmit data from 2003 to 2017. It was noted by the clinic that even without having to do this, in order to do their reporting on birth outcomes they had to contact approximately 300 women a year. The burden of doing this was significant. To then be asked to resubmit such a large amount of data was of great concern.

The Director of the Data and Information Unit said:

> *A fundamental data element in the Data Collection is the treatment outcome, and in particular, whether the treatment results in a pregnancy and birth. At present there is no consistent mechanism to obtain this information on a case-by-case basis as the quarterly data submission does not include the refreshing of the specific data elements for data reported in previous submissions, and the creation of linkage keys for RT data that would enable linkage to Midwives data for specific projects is not routinely occurring (last linked for 2016 treatment data). Ideally if [these things] were occurring, the treatment outcomes could be returned to the clinics as part of a data validation process if legislation (Health Act and HRT Act) supported that.*

Issues regarding the provision of data from RT registers for reporting

There also appeared to be issues regarding the provision of data from the RT Registers for reporting, as well as difficulties related to RTU requests for data and what is or can be, provided by the Data and Information Unit. For example, it was reported to the Review that:

- In 2013 the RTU asked that the RT Registers be used to recreate summarised data provided by RT clinics for the annual report (Schedule 3 of the HRT Directions 2004). However, the Data and Information Unit reported that as Schedule 3 reporting contains no specifications for how counts are determined and appear to use data not available in the RT Registers, such reporting was not able to be completed. It noted such summarised data is provided by RT clinics and exempt practitioners to the RTU within one month of the end of the financial year. The Data and Information Unit further noted that the data is unable to be verified with data held in the RT Registers both because the Registers do not contain all the data reported at that time and data summarised in the annual report is not included in the registers. There is no later validation process to determine if data reported for the annual report by the RT clinics is supported in their data reported to the RT Registers. As such, while the RTU Manager has asked the MCHU Manager to endorse that the annual report data is accurate the MCHU Manager said it is not possible for such a guarantee to be provided.
- In 2015, the RTU Manager requested summary data from the RT registers. These reports were drafted from draft specifications agreed with RTU. The initial drafts of the reports were determined not to be useful or accurate by RTU and further work was not progressed. These reports were also provided to RT Clinics for comment. No comment was received.
- In 2017, the RTU Manager requested that reports be drafted from the RT registers based on reports published by the United Kingdom. Specifications for these reports were not documented and the first draft of such reports was determined not to be useful or accurate by RTU. Further work was not progressed.

Issues regarding communication with data providers

The Data and Information Unit also submitted to the Review that there had been significant issues regarding communication with data providers.

Prior to 2016, clinics were phoned or emailed requesting data provision or validation of data received. However, the Data and Information Unit reported that ad hoc provision of data occurred. In 2016, therefore, the Maternal and Child Health Unit, Information and System Performance Directorate (MCHU) staff working on RT registers formalised fortnightly meetings to discuss RT registers, determine work required and what needed to be communicated to clinics. From that time, the Data and Information Unit said that every fortnight an email was sent to each clinic with an updated list of data provision or validation awaited and one month before quarterly treatment data provision is due, the email includes a reminder to provide data by due date. It was reported to the Review that some clinics responded well to this communication strategy while others did not change strategies to provide data or validate data previously sent. (Note, others did not require improvement to meet their data provision deadlines.)

Failure to collect data from exempt practitioners

Data reporting by exempt practitioners about donor insemination has not been required for RT registers since 2003. This was an oversight picked up by the MCHU and reported to the RTU staff in 2016. Some efforts have been made to rectify this omission, but many exempt practitioners are no longer practising. One has indicated they lost their records in a fire and cannot report them to RT registers.

This again is of great concern for those conceived as a result of donor-insemination.

Experiences of clinics required to report the data

Clinics also identified that there were many issues in relation to the data reporting requirements during the Review. Illustrative of the issues spoken about was the following explanation by a person responsible for reporting:

> *There are significant issues under the current legislation concerning data reporting. There is a lot of replication. We need to submit data to ANZARD database and to the RTC. But really ANZARD is perceived as the main database that we deal with. The RTC require us to submit data every three months, but this data is never complete. If you have snapshots of three monthly data sets you never have pregnancy outcome data. ANZARD allows all births to take place; live birth is much better to measure. Meanwhile, the RTC require clinical pregnancy data. This can be used to pick up outcomes of processes, but you need live birth data. So ANZARD collects that annually and reports for the January to December period with a two-year lag – which makes sense because then you can be sure of the outcomes. Personally, I haven't seen any good coming from submitting data to the RTC. It doesn't make any sense, its actions seem at best spasmodic, and it is really not clear what they are doing. In addition, the legislation requires that you submit hard copy from previous by financial year – silly to have this type of data on a financial year; very much outdated summary report of what we do. It's been a nightmare. They say they want to fix it going forward, but they also require re-reporting going backwards so that they have a full data set.*

Another laboratory director reported:

> *I've been in this role for 10 years now. Reporting is a nightmare. We have an annual report to the RTC and then we are required to submit quarterly data to the Health Department under the legislation. Most of the information we report to ANZARD but in a slightly different way. Then we report drug data that we don't report to ANZARD. There is a problem with the Health Department data in that we don't know the [birth] outcome when we report. Hence why ANZARD is two years behind. So, the RTC has never asked us for outcome data until this year and now they have asked us for 10 years of data. I don't know what they want it for. It seems they are collecting data for the sake of collecting data. Up until last year, it seemed like there was no validation process. You should compare this to the reporting of day surgery data – it goes to a different place where they vigorously check this.*

Another clinic said:

> *If we are collecting data and submitting data, then we should have a report on that data… The Annual Report is not very useful. It is really important to know what the outcomes for children are. Where are the reports? It seems to have fallen dead because of the lack of linkage. When that all stopped, it's been so difficult for clinics to take on that burden independently, and then we are trying to chase data based on self-report. Some of it is really hard. We ring people and they've had a really bad outcome, a death, or a stillbirth. It's really difficult. Although, some patients do like it when we ring them up, and it can be good to talk to them, but it's time-consuming. I call 300 women a year and have to report on them at intervals, so at a minimum, I need to call each woman three times a year, which is 900 calls. I guess if we had feedback from a linked database it would be more reliable. We really need to be reporting the same data we report to ANZARD, it is unclear why we are reporting to the Department of Health if they are not doing anything with that data and not reporting it back.*

Operational issues between internal Department of Health units and data custodians

The Review found there to be disagreement internally regarding where the RT registers should be situated, data collection processes and who should manage the data. Communication between staff and/or Units were reported as being adversarial at times.

In addition, management of the databases was found to have been compromised by changes over time. That is, it was reported to the Review that database development of the original database (Database 1) was conducted by an external contractor for the RTU; then individual staff sitting in various locations within the Department have had responsibility for the database over time.

It was further reported that documentation for Database 1 and use of the database is entirely different from that expected for managing the second iteration of the database (Database 2).

Database 2 was developed prior to the HRT Directions 2004 being drafted and appears to be where numerous problems were introduced. Processes for uploading of data files to the database instead of direct data entry were not well developed or understood. Development work was conducted on Database 2 between 2004 and 2007 to enable better data file upload and meant that validation processes were not re-applied.

Management of the RT registers moved to the Data and Information Unit in 2008 or 2009 and since that time management of the Registers has not been able to resolve many of the issues. The Data and Information Unit reported that expertise regarding the reproductive technology clinical environment and subject matter is not sufficient in the MCHU staff managing the RT registers. There were also issues regarding the level of resourcing in terms of staffing available. While it was noted that *'there are more staff managing the RT Registers currently than ever before'* (as a result of a single HSU4 staff member that came with the Register being expanded to part of a HSU10 manager role, part of a PSA6 data analyst role, part of a PSA4 collections officer and one to two days a week from an agency supplied technical administrator), the RT registers were still lacking the resources necessary to address past issues and establish robust recording and reporting operations. The Director of the Data and Information Unit said:

Additional dedicated resources are needed to support the RT Data Collection. The current resourcing involves the equivalent of one full-time position. This FTE was 'sourced' originally from an existing low level 'data' position approximately eight years ago. The RT role was partly incorporated into a junior analyst position created at the time, but which has other Data Collection responsibilities. This position, together with the Manager and two other positions in the Maternal and Child Health Unit contribute on a 'part-time' basis to the one FTE of resourcing allocated to the RT Collection. All positions have responsibilities for two other Data Collections. A transfer of an FTE from the RTU is one possible means of shoring up the resourcing.

In the meantime, the RT Register appears to have been languishing for years. There are numerous areas of concern, most concerning of which is that the data currently held on the RT Register *cannot be confidently relied upon*.

4.4 Addressing the issues regarding the RT registers

The issues above were found to have been recognised by the Department of Health and it has been exploring various options to address the issues regarding the RT Registers. The following discussion examines the 'RT Register Project' and use of the ANZARD collection (Note – issues and recommendations concerning data recording and access to information about donor-conception are addressed in Chapters 5 and 6.)

4.4.1 The RT register project

To improve the content and validity of the RT Registers the Director and Executive Director of the Data and Information Unit have supported an 'RT Register Project'. The Director of the Unit said:

The RT Registers should be rehabilitated to become a robust, reliable, contemporary and sustainable data collection. The RT Register Project should be continued to the optimal outcomes of a rejuvenated and contemporary IT database to support data collection and provision, monitoring and evaluation, research, public policy, and public interest.

The RT Register Project has thus had as its aim to implement a third iteration of the data management system – Database 3 – where Department of Health staff either upload data from data files or add data from paper forms submitted by licensed clinics and exempt practitioners. It was reported to the review that the technology proposed is an SQL database, with the user interface yet to be determined. Data submission portal processes and security are yet to be determined. Data and Forms to be specified by an instruction process are also yet to be agreed.

The Data and Information Unit proposed that Database 3 will incorporate data from D1 and D2 and will be supported by high standard metadata and transparent documented validation processes. The reported aim was that Database 3 will have standard and ad-hoc reporting capability and will involve the use of a robust software platform to be formally managed in the Department of Health infrastructure. The proposal was that a data portal for file submission and validation will also be developed, *'perhaps in the near future but not in Phase 1 of the project'*. The Data and Information Unit expected that the requirement to report will be regulated in the new version of *HRT Act* and/or new Directions. Further to this, they noted that direct engagement between the Department of Health and clinics is needed to resolve data collection and data quality issues. The Director of the Data and Information Unit said they were:

> *In the throes of establishing a Data Collection Steering Group to facilitate enhanced communication … At meetings of this group, issues affecting the provision of good quality, complete data could be addressed, and issues resolved in a collaborative manner in which all clinics and the Department in its role of Data Collection Manager could benefit.*

It appeared that despite their best efforts, there was significant work to be done regarding all aspects of the RT Register, as well as to resolve internal operational and communication issues.

4.4.2 Utilisation of the ANZARD collection processes

Also being explored by the RTU was the utilisation of the ANZARD collection processes as an alternative means of managing data collection and reporting for Western Australia. I, therefore, undertook further investigation of the ANZARD collection process to inform the Review. The following information reflects what was found.

The ANZARD calls for an annual submission of data by the calendar year. Clinics upload the data through an automated web-based data portal as a batch file (like Excel file). There is real-time validation, which means that any errors are immediately reported to the clinic and they must correct them before being able to finalise the submission. Some data can be overridden if there is a special case that explains the 'error', some data cannot be overridden (for example, if something is not possible). ANZARD also does a range of other checks, back and forth to the clinics, regarding pregnancy and birth outcomes (for example, whether a child lived or died within 28 days, birth weight, birth defects). Once the data submission period is closed off, ANZARD produces an annual report which is timed to be released with the annual Fertility Society of Australia meeting (Sept/Oct). There is an ANZARD review committee that looks at the report. The report reflects data collected from across Australia.

Such data collection and public reporting have no doubt made a significant contribution to ART practice in Australia and New Zealand. It was put to the Review by the current data custodian for ANZARD that it has, for example, contributed to Australia having the lowest multiple birth rate in the world by making the results of ART visible, championing a low multiple birth rate based on evidence of better outcomes for patients and children, and being able to contribute to evidence-based policy and practice.

ANZARD also undertakes individual 'benchmarking' for clinics which indicates their performance and provides feedback to them. Such benchmarking is risk-adjusted for performance measures as it is noted that the 94 clinics in Australia may differ regarding who they treat (e.g. by age, parity) and size of clinic, and as such a crude rating would not show the full picture. ANZARD then also work with RTAC to notify them of underperforming clinics (this is confidential between ANZARD, RTAC and the clinics). The idea is that RTAC may, as a result, work with the clinics to assist them to improve. For example, if frozen embryo transfers are good but the clinic is not good with fresh cycles they may be directed to examine their data and practices to find out what is happening. Note, the review did find that the confidentiality of the results of such benchmarking has been criticised by some who have argued that clinic performance significantly impacts out-of-pocket costs for patients and Medicare funding where, for example, the range of performance in terms of live birth rates/cycle has been as wide as 4% from the lowest performing clinic to 30.9% from the highest performing clinic (based on the crude rating, not risk-adjusted rating).[264]

264 Norman Swan, 'Millions wasted by low performing IVF clinics, says leading fertility expert' ABC AM,

More recently, ANZARD has conducted research on cumulative live birth rates via tracking women through the database which, rather than giving a simple number of live birth/cycle figure, can look at cycle specific live birth rates (i.e. chance in the first cycle, second, third…) and then the cumulative birth rate. Such findings were published in the Medical Journal of Australia last year.[265] The data provides a fuller picture of estimated outcomes for ART, which can, in turn, be used when counselling women about their likelihood of having a baby using ART treatment, and to inform public policy. They are currently also doing research funded through the NHMRC on being able to track perinatal outcomes for babies via linking to several other databases using the Australian Capital Territory and New South Wales as their pilot.

Western Australian data

In early 2018, ANZARD was asked to do a review of the WA data dictionary and to do a quotation and proposal for looking after the data. WA gave a specification of need and ANZARD put together a quotation in March 2018. ANZARD suggested that to try to streamline the process, so that it could work to make data reporting less burdensome for the clinics, they would send in their one submission to ANZARD (as already required), but it would now include additional data items specific to Western Australia. Then ANZARD would validate the data and send it back to the clinic. The clinic would have the data and they could then forward to the WA Department of Health – validated and consistent with ANZARD data reporting.

I spoke with the ANZARD data custodian and she confirmed that ANZARD could produce a customised report for Western Australia if that was what was needed – noting they already do this for New Zealand. ANZARD said that if there was concern about sending full names of people and addresses to them that they did not require this. The Clinic could use the Clinic ID and cycle ID (i.e. deidentified) and then once data was validated ANZARD could send the validated data back to the clinic which could re-link it with names and addresses of people and supply to Western Australia Health. Alternatively ANZARD could send data to the Western Australian DoH and it could do the re-linking. (Although for data integrity purposes it was preferable that the clinics did this).

ANZARD identified four different categories of data related to Western Australia which would need to be managed, including:

Category A – data that is in full concordance with ANZARD and WA being 65 variables;

Category B – five categories that needed a small amount of data development due to slightly different permissible values, but this could be easily addressed;

Category C – which included 21 categories that Western Australia currently collects that ANZARD was not currently collecting; for example, Western Australia collects more information on PGD/PGS, the reason for treatment, gravidity and parity; and on donor and embryo disposal cycles;

interview with Professor Richard Henshaw 11 May 2015, available at http://www.abc.net.au/am/content/2015/s4233161.htm. (Referring to data from 2012).

265 Georgina M Chambers, Repon C Paul, Katie Harris, Oisin Fitzgerald, Clare V Boothroyd, Luk Rombauts, Michael G Chapman and Louisa Jorm, 'Assisted reproductive technology in Australia and New Zealand: cumulative live birth rates as measures of success' *Med J Aust* 2017; 207 (3): 114-118.

Category D – which were 19 new categories that the Department of Health RTU was proposing that would be new to both ANZARD and Western Australia. For example, tracking every single embryo and oocyte. These included items that ANZARD said did not seem necessary and/or recommended further consultation with clinics. They also noted that they would need to redesign their database for the new Category D items. For example, at present their spreadsheet is based on a cycle – such as four oocytes, three embryos, one transferred. The WA suggestion would require a new line for each oocyte, each embryo and then what happened to that. ANZARD was concerned about what this would mean for reporting. There was a question of determining what value collecting certain data would have. It also noted that RTAC do audit data in terms of tracking what has happened to reproductive materials. The view was that there is a need to determine what the register is for, and why such data is needed – noting the registries are for quality control, public reporting, policy and research, and adding unnecessary items in should be avoided.

Overall it was estimated that setting up the ANZARD to suit Western Australian requirements would cost $200,000 over two years, and then $30,000 per year for state-specific reporting. This was said to be at cost price and costs were saved due to the ANZARD structure already being there. It is significantly less expensive than setting up a new registry. Note the set-up costs in relation to utilising ANZARD were a result of Western Australia suggesting new 'Category D' items (above) which would require ANZARD to reconfigure their database. It was not clear why the additional data points had been suggested and to what use the additional data would be put other than to meet the needs of one research institute. I found this is not adequate justification for the burden and expense such collection would impose. In addition, such additional data points are not reported anywhere else in the country.

Other states and territories (and New Zealand)

New Zealand utilises ANZARD to supply them with a customised report each year, at a cost of around $20,000 per year, depending on what they want the report to focus on.

In Victoria, VARTA sends the ANZARD data to a team based at UTS who produce a state-specific report. The process of using a separate team at UTS is because the director of the UTS team used to look after ANZARD but moved to UTS in 2014.

South Australia does not currently report on state-based data, although it did prior to its 2010 legislative amendments. The 2010 amendments made provision for reporting in the new legislation, but reporting has not yet been put in place. Researchers in South Australia lamented the loss of state-specific reporting. The South Australian Department for Health has made enquiries with ANZARD to have a state-specific annual report produced for them but had not decided yet on what data or reporting they would require and are currently considering these matters.

The other states do not maintain separate registries, do not publish state-based reports, and do not ask for individualised reports from ANZARD. Across Australia and New Zealand (and beyond), if researchers need data, they can apply to ANZARD and go through a process of approval. Clinics are also able to have their data back. ANZARD reported that sometimes an individual clinic will ask them to do a simple analysis for them, which they do.

4.5 Discussion

The maintaining and utilisation of registry data is a specialised field. ART data is complex having layers to it that other datasets often do not contain. Australia has superior ART registry arrangements when compared to those around the world via ANZARD. Because it is linked to RTAC accreditation, ANZARD achieves a 100% reporting rate. In comparison, the current WA ART Registers have been deemed as *'not fit for purpose'*, and require significant work, upgraded technology and more resourcing.

While recognising that ANZARD began as an industry-funded database there are benefits in having a central place for reporting Australian and New Zealand ART data when compared to data being collected in a fragmented and splintered way. ANZARD also attracts significant government funding for research into ART and as such is not solely beholden to the industry. It provides independent state or country-specific reports to governments (such as New Zealand) at their request for a fee. ANZARD is situated in a clinical school in the Centre for Science and Data, populated with people who have significant expertise. It also practises good governance (for example, always running code twice to ensure all work is checked). Of benefit is that it situates people who work on the ANZARD within a centre with other people, ensuring that a person's working life is not limited to collecting and validating data but also providing an opportunity for them to be involved in setting up research, conferences, and working with students.

However, there is also value in having state-specific data, and the desire to link ART data with other state-based registries is important. ANZARD is piloting this with the Australian Capital Territory and New South Wales. It may be that Western Australia wishes to ensure that that is done internally at the DoH, and as such there were arguments to continue to have ART data also reported to it. Nevertheless, it would be beneficial for the DoH to work with ANZARD and the clinics to streamline data collection and reporting – including timing being moved to coincide with the calendar year instead of a financial year.

Arguments that further support utilising and/or streamlining processes to align with the ANZARD also include that it will reduce burden and duplication for clinics, which currently must submit data in slightly different forms to both the Department of Health and ANZARD across different timelines; provide the Department of Health with complete data that has already been error checked and validated by the ANZARD process; resolve maintenance and system development pressures; enhance confidence in the quality of the reproductive technology register data; enable compliance with data-reporting requirements of the *HRT Act*. This was supported by clinics in face-to-face meetings who all called for streamlining the data collection and reporting system with ANZARD. One laboratory director said:

> *It would be great if we could submit the ANZARD data, and then the additional things WA wants such as identifying information and drugs. I mean now some of our reporting is the same, but the fields are named differently. We have to do a whole separate extraction for the Department of Health data. ANZARD has a fantastic system. We enter our data online, and it automatically comes back with a report. If there are errors, we can immediately go back and check it. As we do this we then fix our own data, and we know that it is reliable. That's a big thing that can't be ignored. We really would like to see the data collection and reporting processes fixed.*

A scientific director said:

> *Mainly the biggest issues I have had with the RTC come down to data monitoring, research practices and novel techniques…I don't think that the data monitoring is necessary on a state level… it is very comprehensive on a national level, they put out reports in a very timely fashion, the reports are extensive and accurate. Recent developments in WA have shown that data monitoring has not been optimal…I guess the mismanagement of the data has been a big thing for me, especially coming new into this role. I suppose the most frustrating thing is that we have already submitted this data to ANZARD…but due to the RTC requirements there are two completely separate reports that we have to generate … it seems to be systemic to the RTC, there is over reporting, over submission of documents that are unnecessary a lot of the time.*

Findings

1. The RT Register faces significant issues of concern caused by:
   - outdated legislation and directions
   - interpretations given to legislation which have restricted the ability to follow up on or link certain data
   - constraints on practice
   - lack of adequate resourcing, and at times operational conflict between units within the DoH.

   It is not currently in a state that the data within it can be relied on with confidence.
2. The issues faced by the RT Register again illustrate that the current regulatory system is not achieving its aims or objectives. This in turn has resulted in a lack of faith in the RT Register and data-reporting requirements.
3. The Data and Information Unit has undertaken work to address issues with the RT Register, but such work is in its early stages and much of what is proposed is aspirational. Significantly more work and financial commitment over time would be required to create a register that is fit for purpose. In the meantime, the current state of the RT Register raises significant issues of concern that require immediate action.
4. The recommended revision of the *HRT Act* and Directions, including repeal of provisions that are no longer relevant or effective, provides the opportunity to also address policy and processes that have proved not to be working in relation to data collection and reporting.
5. While there was an argued benefit in maintaining data specific to Western Australia at the DoH and being able to link that data to other Western Australian registries for the purposes of monitoring the outcomes of ART, reporting, public policy, and for research purposes, the current system is unique to Western Australia.
6. There was no robust argument put to the Review as to why the ART data collection could not, or should not, be aligned with the data reported to ANZARD. ANZARD provides a uniform data reporting system for all clinics practising within Australia and New Zealand. It has a robust and operational data verification process that utilises modern online technologies. ANZARD confirmed that data points specific to Western Australia could be added to their database and thus could also be verified via that collection.

7. To protect privacy, it is possible for the data to be supplied to ANZARD in de-identified form (e.g. cycle code, recipient code, donor code, birth outcome code), and the final verified data to be returned to the clinics and/or the DoH to be linked with the identifying information of recipients, gamete providers, and offspring as required.
8. Aligning the data collection and reporting process with ANZARD requirements would reduce the burden on those being regulated who currently are exposed to two separate reporting regimes, operating in different manners, with slightly different data points and with different reporting periods. On the latter point, it was not clear why a quarterly reporting period had been imposed in relation to the RT Register, nor why such a period needed to remain. Reporting via financial year was also not found to be suitable, as births are recorded by the calendar year.
9. There are significant and unnecessary cost and time burdens placed on clinics in relation to reporting. Freeing up the clinics from duplicative and burdensome processes and streamlining data collection and reporting with ANZARD requirements would enable professionals to focus on maintaining good clinical and laboratory practices and data management. Cost and time savings could then also be directed to supporting things (directly or indirectly) such as the recommended Donor Conception Register and provision of information to those seeking treatment, donating gametes or embryos, and people born as a result of ART and donor-conception.
10. There was no provided justification for adding further data points (Category D) to the RT Register. Such data points are not reported anywhere else in the country and would create an added reporting burden on WA clinics, as well as additional expense to clinics and the DoH.

Recommendations

Recommendation 14

Identified issues regarding the data collection held by the Data and Information Unit be addressed *as a matter of priority* (urgency) to ensure data held is accurate and reliable.

Recommendation 15

The recommended revision of the *HRT Act* and Directions include revision of provisions, policy and processes that have proved not to be working in relation to data collection and reporting regarding ART in Western Australia.

Recommendation 16

The DoH streamline their reproductive technology data collection and reporting to align with the yearly ANZARD reporting including updating data dictionary to mirror ANZARD; adding to ANZARD the additional Category C data-points specific to Western Australia and moving the reporting requirements to be per the calendar year.

Recommendation 17

No 'Category D' data be added, and therefore ANZARD not be required to establish changes to its databases other than to accommodate additional Category C data-points (thus avoiding the Western Australian clinics and Government incurring unnecessary costs).

Recommendation 18

The DoH's processes regarding data collection be revised so that once data is verified via the ANZARD process, clinics then provide a copy of such verified data re-linked with identifiers to the DoH Data and Information Unit for the purposes of monitoring, quality control, public reporting, policy and research as required.

Recommendation 19

The Minister for Health and/or DG of the Department decide who will generate the annual data report, with the options being either:

- that the Data and Information Unit work cooperatively with the DoH support staff to produce an annual report. (Note, this will require an additional staff member who has reproductive technology data expertise being situated in the Data and Information Unit)
- the Government otherwise commission ANZARD to generate a specific report for Western Australia (like NZ) at an estimated cost of $20,000-$30,000 per annum.

Recommendation 20

The revised *HRT Act* includes provisions that would enable linkage between the RT Register data with other WA registers, including but not limited to the Midwives Notification System, and Births, Deaths, and Marriages registers (noting this is where it is recommended the Donor Conception Register will be held).

Table: Required change and action

Table 4.1 details the changes required that are relevant to the discussion of the Reproductive Technology Register, considering that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended *as a matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 4.1: Recommended Changes to Legislation, Directions and Operations Regarding Reproductive Technology Register

Required Change	Legislation*	Directions**	Operation**
Address significant issues of concern regarding the Reproductive Technology Register, as a matter of priority (/urgency).	Repeal and replace current *HRT Act* 1991 (and subordinate legislation) Include in new Act similar provisions to ss44-46 with any revisions or amendments required to achieve the recommendations in this *HRT Act* review report. (See further above and below Chapters 5 and 6).	Repeal and replace current HRT Directions (last revised in 2004). Specifically, in relation to the reporting, storage, and release of data repeal HRT Directions 'Part 2: Recommendations and Reporting' and the Schedules containing Forms. Implement new directions as required to 1. align data collection with the ANZARD process; 2. streamline data reporting to the DoH; 3. provide for annual reporting (utilising ANZARD reporting if required); 4. address issues relevant to the collection and release of identifying and non-identifying information relevant to donor-conception, as per recommendations in this report; 5. provide for data notification requirements relevant to the regulation of ART/registration of clinics, as required.	Attend to internal operational and communications issues between units. Ensure adequate training, understanding of ART data, and resourcing, to enable liaison with clinics and ANZARD, data management, monitoring, and reporting as required. Do not place overly prescriptive requirements/ forms within the new directions/regulations that may quickly become outdated such as a reference to how data must be provided (e.g. electronically, in paper form) or administrative forms. Rather, provide any details regarding such requirements to clinics and on DoH website, which can be updated as needed.

Chapter 5

Managing Information – Donor Conception and Current Issues

Chapter 5:
Managing Information – Donor Conception and Current Issues

5.1 Introduction

This chapter focuses on the Terms of Reference regarding access to information about donation, genetic parentage and donor conception; and the Western Australian Voluntary Register (donor-assisted conception). Section 5.2 first provides some background on donor-conception practices with a focus on the issue of secrecy and anonymity, and the evolution in some jurisdictions of laws that require record keeping and the release of information about donor conception. Section 5.3 details the reasons that have been given for seeking identifying information about genetic heritage and/or relations. The discussion then moves to examine the specifics of the *HRT Act* regarding record keeping and access to information via the RT and Voluntary registers. Issues with the current RT Register as outlined in Chapter 4 and specific to donor-conception records are then noted and further examined. The operation of the Voluntary Register is also discussed. Chapter 6 subsequently focuses upon how best to ensure that the rights and interests of those born as a result of donor-conception are upheld and makes recommendations for the future operation of the Donor Conception Register.

5.2 Background

5.2.1 History of secrecy and anonymity

The donation of gametes (sperm or eggs) and embryos has meant that people who may not have otherwise had children have been able to do so. However historically, secrecy surrounding donor-conception has been perpetuated. Such secrecy most often was (and is) related to moral, religious, and socio-cultural concerns about instrumental insemination, whether donation amounts to adultery, the legitimacy of donor-conception as a 'medical treatment' or 'cure' for infertility and the stigma and shame associated with infertility.[266] There were also legal concerns about the status of the child born, its legal parentage, whether the donor had any rights or responsibilities regarding the child, and if the donor-conceived person could inherit from his/her non-biological parent and/or donor reinforced practices that led to donors of gametes being told they must remain anonymous, and the recipients of such gametes being sworn to secrecy.[267] The involvement of third parties such as the medical practitioner served to keep recipients and donors apart and unknown to each other, and was, at the time, said to be in the best interests of all parties.[268]

266 For more in-depth discussion of the history of donor conception please see Sonia Allan, *Donor Conception and the Search for Information: From Secrecy and Anonymity to Openness* (2017) Routledge, Oxford UK.

267 Ibid.

268 Ibid.

However, the rights and interests that donor-conceived people may have in accessing information about their conception, genetic heritage, and blood relations were also discussed from at least as early as the 1950s in the literature. The practice of donor anonymity and secrecy denied them access to such information. There was also little-to-no regard given to the fact that many recipients and donors did not wish to be sworn to secrecy or condemned to anonymity.

Over time it became apparent that secrecy and anonymity were hard to maintain, something that people rejected, and something that for some donor-conceived people, caused significant harm and/or distress. Some parents felt compelled to tell their children the truth surrounding their conception and to be open with them about their use of a donor(s). Sometimes children found out in other ways – in the context of divorce, illness, death, family conflict, and in more modern times via direct-to-consumer genetic testing for ancestry tracing. Donors also wondered about the children they had helped to create. As donor-conceived people grew and became capable of expressing their own views and experiences of being donor-conceived, it became apparent that some desired further information about the donor and/or genetic relatives, including but not limited to siblings. However, whether access to information about the donor(s) was possible, depended upon when and where a donation was made, and/or the child conceived, as laws differed over time and place. Such laws are outlined at 5.3.

5.2.2 Why is access to information important?

The impact upon some donor-conceived people of not having information about their genetic heritage and relatives has been significant. This includes a range of issues regarding identity, the absence of medical information, concern about risks of forming consanguineous relationships, and a desire for openness, honesty, equality and non-discrimination (or in the reverse suffering with a sense of lies, injustice, inequality, and discrimination). Each of these warrants further discussion.

Self-identity

Self-identity relates to the way a person perceives themselves and their relationship to the world. It involves the 'Who am I?' questions that many people ask about themselves at various stages of their life and the strength and confidence with which they may answer such questions. In childhood, this may include questions such as "Where do I come from?', 'Who are my family members?', 'Where do I fit in?' and "Who else am I related to?' In later childhood and adolescence, there is further development of a sense of individual self, while also comparing one's self with others. In adulthood, as relationships are formed, marriage or partnerships occur, and/or children and grandchildren are born, 'Who am I?' questions may become relevant in an inter-generational sense, giving a broader picture of a person and their place within and across generations.[269]

For donor-conceived people, such questions are in this sense similar to those asked by those in the general population. However, such questions are made more complex as donor-conceived people have a parent(s) who rears them but are also the genetic offspring of sperm and/or egg donor(s). The issue of identity was raised in numerous written submissions to the Review.[270]

269 Allan (2017), above n 266.

270 Isabelle Andrews (Jigsaw), Submission 27; Sharon Genovese, Submission 32; Confidential, Submission 49; VANISH, Submission 54; Pauline Ley, Submission 56; International Social Service (ISS) Australia, Submission 55; Ross Hunter, Submission 63; Bridgitte Reynolds, Submission 78; Sherrie-Lee Long, Submission 88; Coalition for the Defence of Human Life, Submission 90; Confidential, Submission 92; Hayley Smith, Submission 102; Richard Egan, Submission 109; Joan

A donor-conceived person from Western Australia described her experience as follows:

> *Even though I was told of my donor conception at a young age and raised with supporting, loving parents, I still feel that I am missing an important part of my identity. I feel a strong desire for information about my ethnicity, family history and medical history that goes beyond mere curiosity. I feel that humans have a fundamental right and an innate need to know about our genetic and biological origins.*[271]

Further compounding the issue is that for some donor-conceived people there may be a strong sense of lost identity when they are denied access to information or told of their donor-conceived status later in life. Some may experience confusion about their identity and feel significantly deceived about who they are.[272] A recipient mother said in the face-to-face interviews:

> *I've seen that it has really ripped some people apart. I think it's the deception, the secrecy, the lies. To think up until a point that Mum and Dad are the people they live with, and then they find out there's an added layer, that they have been lied to, and everything is not as it seemed. It rips them apart. But, if you are open, honest, and they know from the start, things can be very different. They can be good.*[273]

Others seek information for other reasons, not feeling a sense of loss or distress, but still wanting to know about their progenitor. Others are uncertain about whether they want to seek information. For example, in the face-to-face consultations, one donor-conceived girl from Western Australia said:

> *I don't know if I would do it. I don't know if I want to know who he is. What if he's a maniac… or what if I don't live up to expectations. What if I found my half-siblings and they didn't welcome me… Maybe I'd like to know a name… Yeah, I would like to know a name…*[274]

Others do not seek information at all.

Perhaps most clear is that, while the small amount of existing research points to varied feelings regarding donor conception and outcomes for families,[275] when people do decide to search for information, their reasons almost always include the desire to know and understand more about the donor and about themselves. This often also extends to a desire to know and understand more about other genetic relatives, including most frequently, siblings.

Smurthwaite, Submission 124.

271 Confidential, Submission 49.

272 M. Dennison, (2008). Revealing your sources: The case for non-anonymous gamete donation. *Journal of Law and Health, 21*(1), 1–27 at 13; V. Ravitsky, (2010). Knowing where you come from: The rights of donor-conceived individuals and the meaning of genetic relatedness *Minnesota Journal of Law, Science & Technology, 11*(2), 655–684 at 670, referring to Warnock, M. (1987) The good of the child. *Bioethics, 1,* 141 at 151.

273 Recipient mother and egg donor, during face-to-face meeting with Sonia Allan, April 2018.

274 Donor-conceived person, during face-to-face meeting with Sonia Allan, April 2018.

275 R. McNair, (2004). *Outcomes for children born of A.R.T. in a diverse range of families*. Melbourne: Victorian Law Reform Commission; S. Golombok, J. Readings, L. Blake, P. Casey, L. Mellish, A, Marks, & V. Jadva, (2011). Children conceived by gamete donation: Psychological adjustment and mother-child relationships at age seven. *Journal of Family Psychology, 25*(2), 230–239; S. Wise, & G. Kovacs, (2014) Secrecy, family relationships and the welfare of children born with the assistance of donor sperm: Developments in research, law and practice. In A. Hayes & D. Higgins (Eds.), *Families, policy and the law: Selected essays on contemporary issues for Australia* (pp. 81–88). Melbourne: Australian Institute of Family Studies.

Medical history

A recurrent reason given for seeking further information about donors and siblings is that knowing about the familial medical history of heart disease, diabetes, cancer, mental health issues and/or other heritable diseases may enable early intervention, and/or prevention of disease.[276] Donor-conceived people who are denied access to familial medical histories may be placed at increased risk as a result of not having access to information. This becomes very significant as people age.

In addition, despite some receiving medical information about the donor gathered at the time of donation, there are many conditions which develop later in life. A donor may discover a heritable disease many years after donation. Similarly, a donor-conceived person may become aware of a heritable condition, but in an anonymous regime has no way to notify their donor(s) or donor-siblings. This may have ramifications for the person unaware of such information and generations to come.

A number of written submissions to the review emphasised the importance of medical information.[277] Sherrie Lee-Long, a donor-conceived person from Western Australia said:

> *I have numerous medical conditions that are nowhere to be found through my mother's side and due to no right to my biological father's medical information I have to live day to day with no knowledge at all. It is emotionally exhausting not knowing the other half of your genetic makeup. I am concerned about my own health and therefore the health of my three children.*[278]

In her written submission to the review, Bridgette Reynolds,[279] a Western Australian donor-conceived woman, noted the story of her friend, Narelle Grech. Narelle was a Victorian donor-conceived girl who died of bowel-cancer in 2013 at the age of 30. She had searched for her donor for 15 years before special action by the then Victorian Attorney-General led to her meeting her donor shortly before she passed away. The donor, on being contacted, expressed his dismay that he had not been contacted 15 years ago.

Regarding medical issues, Narelle's submission to the Victorian Law Reform Committee in 2011 illustrated the kinds of questions that plagued her:

> *I was diagnosed with Stage 4 bowel cancer following an emergency surgery…The first thing the doctors and surgeons asked me was: is there any family history of cancer in your family? …I am sure there was no family history of illness at the time that [the donor] donated but who is to say he simply didn't know…What if he or someone else has developed cancer since? What if he died from cancer himself? …What if my eight half-siblings are at risk of cancer? What if there are children whose aunty has bowel cancer? It's really quite important that they should know this if they are at risk. It's believed that in most cases where a person is diagnosed with bowel cancer under the age of 30 there is a genetic link.*[280]

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276 Centers for Disease Control and Prevention (CDC). (2004). Awareness of family health history as a risk factor for disease. Morb Mortal Wkly Rep, 53(44) 1044.

277 Damian Adams, Submission 40; Confidential, Submission 49; VANISH, Submission 54; International Social Service (ISS) Australia, Submission 55; Kerrie Fervato, Submission 67; Australian Christian Lobby, Submission 77; Bridgitte Reynolds, Submission 78; Giselle Newton, Submission 86; Sherrie Lee-Long, Submission 88, Family Law Practitioners Association WA (Linda Richardson), Submission 115.

278 Sherrie Lee-Long, Submission 88.

279 Bridgitte Reynolds, Submission 78.

280 Narelle Grech, Transcript of evidence, Melbourne, 12 September 2011, reported in Victorian Law.

The Australian Christian Lobby noted 'Narelle's Law' in Victoria,[281] which is the colloquial name given to Victorian laws subsequently enacted to grant access by donor-conceived people in that state to identifying information about their donors regardless of when the donation took place (see further below).

Medical issues of concern were also apparent for a number of donor-conceived people who contacted me during the Western Australian Review from both within and outside of Western Australia. They had found their donors and/or a half-sibling and were dealing with discovered medical information of importance to them and their siblings. For example, one had discovered her donor has been diagnosed with schizophrenia, which may mean a 13-fold increase in risk for her and her 12 donor-conceived siblings – of whom she has only been able to find two. She was also suffering from another medical condition that increased her and her siblings' risk of developing cancer. She felt very strongly they should be warned about the risk of cancer, as early screening could be beneficial to them. The second has discovered her donor has Asperger's syndrome. He has provided her with a fuller picture of medical history that may be of relevance to her. The third has discovered donor-siblings who have had breast cancer. She is currently undergoing extensive early screening and testing.

The Victorian Law Reform Committee noted in 2012 that as time passes, the number of donor-conceived people who may benefit from medical information will only increase as medical knowledge of the influence of genes on disease develops. They also noted the extreme detriment that may potentially be avoided by sharing information provided a strong case for access to information.[282] Such cases only serve to reinforce this.

Risk and fear of forming consanguineous relationships

Another significant driver in the search for information for some donor-conceived people is the fear or risk of unknowingly forming relationships with siblings or possibly their donor. The review received several written submissions in this regard.[283] The risk may be significant within smaller populations, or where there are high limits or no limits upon the number of families for which the same donor's gametes may be used or children born.

Reform Committee, Inquiry into Access by Donor-Conceived People to Information about Donors (March 2012), p55.

281 Australian Christian Lobby, Submission 77.

282 Ibid, Victorian Law Reform Committee, p 55.

283 Damian Adams, Submission 40; VANISH, Submission 54; Australian Christian Lobby, Submission 77; Emeritus Chief Rabbi of WA (David Freilich OAM), Submission 112; Women and Newborn Health Services, Submission 121.

Both the risk and fear associated with forming consanguineous relationships has long been recognised in Australia and was noted, for example, in 1984 by the New South Wales Law Reform Commission.[284] Entering consanguineous relationships may have negative legal ramifications.[285] There is also the chance that such relationships would bear children, leading to the risk of genetic or chromosomal abnormalities.[286] The fear of this occurring can cause great distress[287] and, in turn, affect the psychological, emotional and social wellbeing of some donor-conceived people.

While one way to avoid half-siblings forming relationships is to restrict a donor to one donation or to one recipient family, this is not and has not been, the practice in donor conception. Nevertheless, some jurisdictions limit the number of families to whom a donor may donate (including his or her own). For example, in Victoria, the maximum number is 10 families;[288] in New South Wales, the limit is five women;[289] in Western Australia, the limit is five families.[290] Limits in other countries vary based upon a calculated actual, or estimated population risk.[291] (Note, other justifications also exist for imposing limits, such as the psycho-social impacts upon donor-conceived people, donors, and their families of having a large number of donor-conceived siblings/offspring spread across numerous other families.[292] It has been raised that having significant numbers of siblings, offspring or families that share donors may have a negative or overwhelming impact upon people.[293])

In Western Australia, there is evidence that multiple half-siblings were born within a small timeframe to a variety of families and live in the same vicinity. For example, the story of Bridgitte Reynolds was published in the press when she discovered she had gone to the same school as her donor-sibling.[294] Also, note that prior to the *HRT Act* there were no practised limits in

284 New South Wales Law Reform Commission. (1984). *Artificial conception: Human artificial insemination,* (Discussion Paper 11). Sydney: New South Wales Law Reform Commission.

285 For example, the *Australian Marriages Act 1961* (Cth), s 23(1)(b), makes marriages involving "prohibited relationships" void. Section 23(2)(a)–(b) states that "marriages between an individual and their parent and an individual and their sibling, including half siblings" are "prohibited relationships". State criminal law also makes sexual intercourse between lineal relatives a crime: see *Criminal Code Act 1913* (WA), s 329(7) and 329(8) (note a key element of the crime is knowledge).

286 R.L. Bennett, A.G. Motulsky, A. Bittles, L. Hudgins, S. Uhrich, D.L Doyle, (2002). Genetic counseling and screening of consanguineous couples and their offspring: Recommendations of the National Society of Genetic Counselors. *Journal of Genetic Counselling, 11*(2), 97–119

287 Commonwealth, Senate Committee, Hansard (3 November 2010), oral evidence of donor-conceived individuals.

288 *Assisted Reproductive Treatment Act 2008* (Vic.), s 29.

289 *Assisted Reproductive Technology Act 2010* (NSW), s 27(1).

290 *HRT Act 1991* (WA) (see "Human Reproductive Technology Directions (WA)", Western Australian Government Gazette (30 November 2004) p. 5434 at [8.1]).

291 See, for example, M Curie-Cohen, 'The Frequency of Consanguineous Matings due to Multiple use of Donors in Artificial Insemination' (1980) 32 *Am J Hum Genet 589*; J Eccleston,'The Probability of a Consanguineous Marriage Occurring as a Result of Artificial Insemination' (1978) 90 *The Australian Mathematical Society Gazette* 91.

292 J E Scheib and A Ruby, 'Beyond Consanguinity Risk: Developing Donor Birth Limits that Consider Psychosocial Risk Factors' (2009) 91 *Fertil Steril* 12; E Blyth, M Crawshaw, J Haase, and J Speirs, 'The Implications of Adoption for Donor Offspring Following Donor-assisted Conception' (2001) 6(4) *Child and Family Social Work* 295.

293 Scheib and Ruby, above n 292.

294 See, James Purtill, "A Daughter's Search for her Anonymous Sperm Donor", RMR1084, JJJ Hack, www.abc.net.au/triplej/programs/hack/a-daughter's-search-for-her-anonymous-sperm-donor-

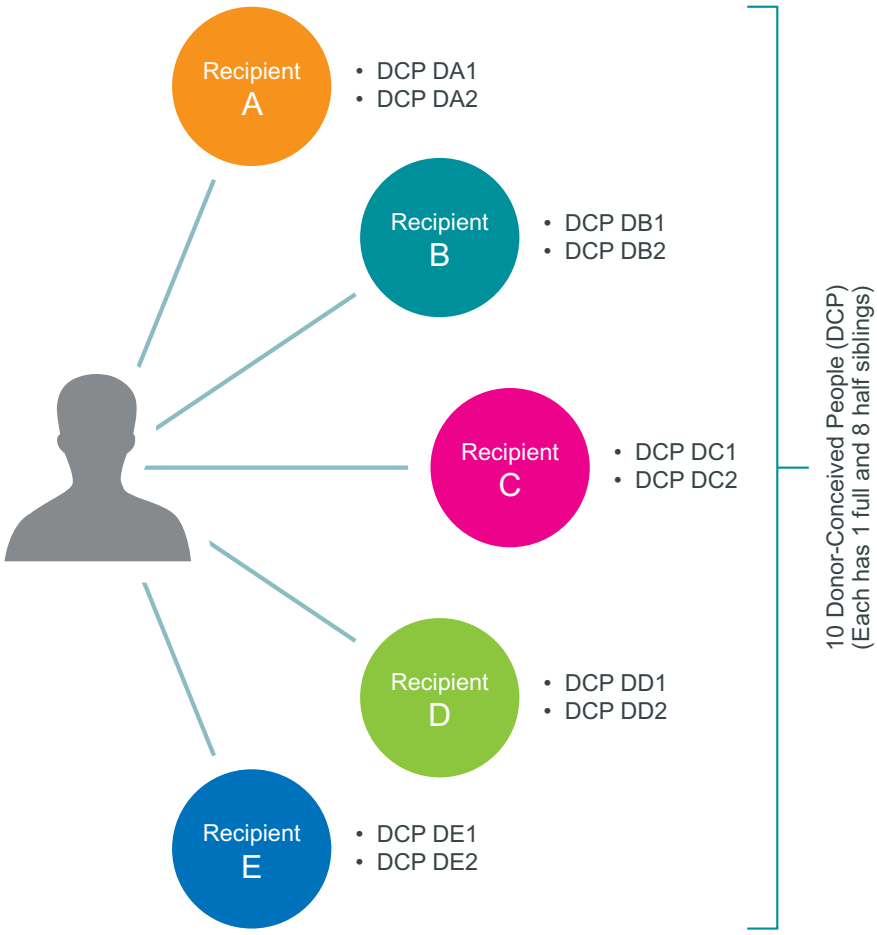
Western Australia. During the review I was informed that donor sperm was sent to clinics, GPs, and interstate. In one case, there was a record that the donor's sperm was sent to 35 different locations; in another, it was mentioned that there could have been 65 or more locations for a single donor. This may not have resulted in a live birth in every case, but there is a chance that there are high numbers of offspring and siblings who may not know they are related to each other.

While the risk of consanguineous relationships has been calculated to be very small, the psychological impact of not knowing who one might be related to can be great. This would be greatly reduced if donor-conceived people were able to obtain information about the identity of their donors and donor siblings. Early disclosure to recipient parents regarding donor siblings who may live in close proximity is also called for.

Figures 5.1 and 5.2 below provide some visual examples of the number of siblings that may result from family limits of five and 10 respectively.

Figure 5.1 Example of five family limit – Donor used to create two children per family

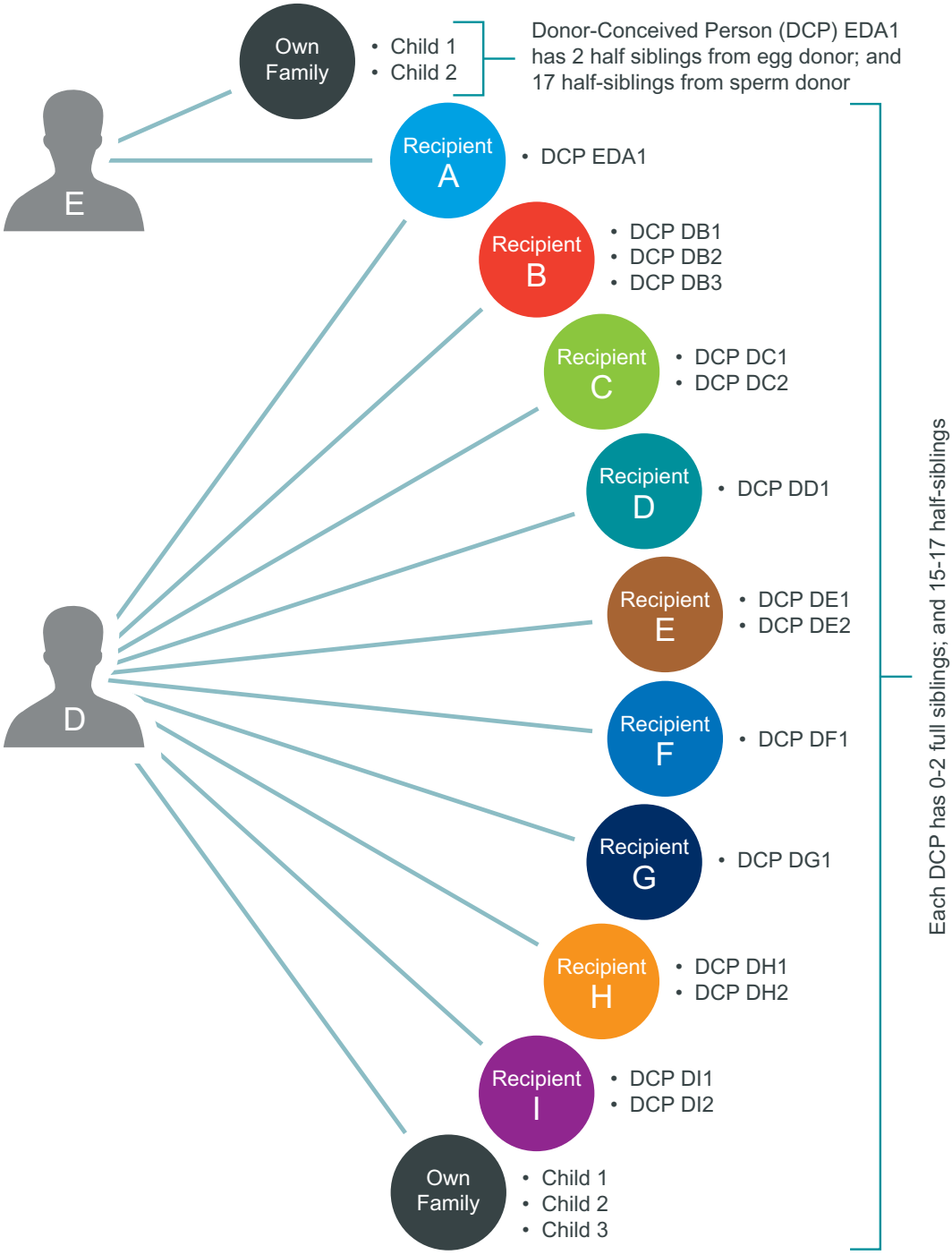
In this diagram, the donor is used for five families, each of whom has two children. There are 10 children that result. Each donor-conceived person has one full sibling and eight half-siblings.



father/7201012 accessed 04 August 2018).

Figure 5.2: Example 10 Family Limit

In this example, a donor is used to create one to three donor-conceived people per recipient family (4 x 1; 4 x 2; 1 x 3). The donor has three children of his own. An egg donor is used for Recipient A. The egg donor has two children of her own. Each donor-conceived person has 0–2 full siblings and 15-17 half-siblings.



Note, Figures 5.1 and 5.2 provide relatively straightforward examples of five and 10 family limits for one donor (and in Figure 5.2 the use of one egg donor for one family). The relationships can become more complicated if recipients have children using different donors, who in turn may be used by other recipient families. For example, in Figure 5.2 if Recipient I had her two children using two different sperm donors, DCPI1 would have 17 half-siblings including DCPI2. DCPI2 would also have half-siblings from their donor who can be used for up to 10 families. This would link family I to up to 19 other families via the two donors. Where there are no family limits, the number of families to which a donor-conceived person may be linked is very high. Some donors have been reported to have been used to create between 150-300 children. Some donor-conceived people, donors and their partners reported feeling overwhelmed by this.

It is noted that during the review some clinics asked that the five-family limit in Western Australia be raised to 10.[295] Donor-conceived people were opposed to this, as were the donors (and their partners, if any) who participated in the Review. The Womens and Newborn Health Service submitted that *the number of families conceived using ART procedures from a single donor should be restricted to four to prevent siblings forming consanguineous relationships given the size and density of Western Australia's population*.[296]

Openness, honesty, equity, and non-discrimination

There were many other reasons that were reported to drive some donor-conceived people to search for information. Many who participated in the review mentioned wanting to know the name of their donor. Some reported this was very important to them as having a code was depersonalising or made them feel the *'stigma of being created in a lab'*. Some donor-conceived people and their parents said they wanted to be able to say thank you regarding how he/she had helped build their families. Several donor-conceived people want to know whether they have any half-siblings.[297] The RTC submission acknowledged that *'parents and DCPs have an interest in basic information about those to whom the DCP may be related (e.g. the number of potential siblings or half-siblings, as well as potential consanguinity)'*.[298]

Cutting across all of these reasons is a desire for openness, honesty and an end to secrecy and lies that some donor-conceived people felt had formed the foundation of their life. The maintenance of secrecy and anonymity was shown to cause a number of people distress.[299] During the review donor-conceived people called for an end to secrecy and anonymity, and an opportunity to choose for themselves whether to pursue access to information about their donor and/or further contact. Several written submissions also explicitly pointed to discrimination against donor-conceived people in that they were not able to access information about their genetic heritage that others in society have a right to and are supported in doing so.[300]

295 PIVET, Submission 114; Concept Fertility and Fertility North during face-to-face consultations. The AMA submission also supported this. AMA, Submission 96.

296 Maternal and Newborn Health Services, Submission 121.

297 Damian Adams, Submission 40; Confidential, Submission 49; VANISH, Submission 54; Confidential, Submission 92; Katherine Vowles, Submission 100; such views were expressed at the community forums.

298 Reproductive Technology Council, Submission 122.

299 Damian Adams, Submission 40; VANISH, Submission 54; Ross Hunter, Submission 63; Confidential, Submission 92, International Social Services (ISS) Australia, Submission 105.

300 Damian Adams, Submission 40; VANISH, Submission 54; Ross Hunter, Submission 63; Confidential, Submission 92.

Some people emphasised that there was stigma around donor-conception and wanted the secrecy to end. One mother who had used donor sperm (and had also been an egg donor) noted:

> *I still think there is an element of secrecy. My daughter has five half-siblings that we know of, but we don't know who they are. I still don't think that people talk about it. There must be more around, but it still seems a little secret. I certainly haven't made a secret of it for a long time, but when I tell people around me, they'll acknowledge it, but then move on. They don't want to know any more about it. I think it's time people were more open. I mean we have been doing this for a long time now. I have always been open.*

Her daughter agreed:

> *Yes...I still think there is a stigma around it. My best friends know about it and they are OK, maybe curious more than anything. It doesn't affect the way they think about me. But I have told some people and they feel really sorry for me. People don't understand. I don't think it should be that way.*

Ross Hunter emphasised in his written submission:

> *We are not a secret that needs to be 'kept' anymore. Society has moved on from this. Continued 'anonymity' perpetuates the idea that we are shameful and need to be secret. This is damaging and demeaning to both parties. Review and reform of these Acts will help remove that stigma, promote openness and equality and help us to get on with our lives.*[301]

Recipients and donors wish to share information

Many recipient parents and donors have also called for the release of information and an end to secrecy. In Western Australia most people on the voluntary register, for example, are recipient parents and donors who are open to contact.[302] Donor views have also been demonstrated in past inquiries and evidenced in other states, illustrating it is not necessarily the case that past donors wish to remain anonymous.[303] For example, in 2010 the Donor Conception Support Group quoted to the Senate Committee Inquiry into Donor Practices a former sperm donor who stated:

> *I was a sperm donor during 1997-1998. My donations were during the period when donors had to sign away any future contact. This was a condition of participation and I only wanted to help people – but at the back of my mind was the hope that the rules would change to allow the resultant children to trace their donor fathers if they wished to do so.*[304]

301 Ross Hunter, Submission 63.

302 At June 2017 there were 39 donor-conceived people (16%), 87 donors (36%), and 114 recipient parents (48%).

303 Senate Legal and Constitutional Affairs References Committee, Submission 73 (Rainbow Families Council) p 2 and Submission 122 (Donor Conception Support Group) p 139.

304 Senate Legal and Constitutional Affairs References Committee, Submission 122 (Donor Conception Support Group) p 74.

Similarly, the Victorian Assisted Reproductive Treatment Authority (VARTA) has long recognised that the belief that secrecy was paramount to protect all parties was based on myths. They have said such myths included the view that donors would not want to be contacted, that parents would not want to know more about their donor, and that donor-conceived individuals would not want information about their donor if they really loved their parents.[305] VARTA reports further that:

> *Donors do not forget they have donated and often wonder about the people they helped to create. Who are they? Are they healthy? Are they happy? Are they loved?*[306]

5.3 Comparative view of laws and practices regarding access to information

In some jurisdictions from the early 1980s laws have been enacted to provide access to information about donor-conception, genetic heritage and/or relations. This now includes legislation in the Australian states of New South Wales,[307] Victoria,[308] Western Australia;[309] and the countries of Austria;[310] Argentina[311] Croatia;[312] Finland;[313] the Netherlands;[314] New Zealand;[315] Norway;[316] Swede[317] Switzerland;[318] the United Kingdom,[319] and Uruguay.[320] Ireland has also introduced laws but some provisions have not yet commenced.[321] In these jurisdictions the law provides that a donor-conceived person who knows of their status and wishes to obtain

305 Victorian Assisted Reproductive Treatment Authority, Time to Consent? Information Pamphlet (2008).

306 Ibid.

307 *Assisted Reproductive Technology Act 2010* (NSW).

308 *Infertility (Medical Procedures) Act 1984* (Vic) (Repealed); *Infertility Treatment Act 1995* (Vic) (Repealed); Infertility Treatment Regulations 1997 (Repealed); *Assisted Reproductive Treatment Act 2008* (Vic).

309 *HRT Act 1991* (WA).

310 Fortpflanzungsmedizingesetz. 275 Bundesgesetz, 1992.

311 Código civil y comercial de la nación (Civil and Commercial Code of the Nation), Title V, Ch2, approved by Law 26,994.

312 ZAKON O MEDICINSKI POMOGNUTOJ OPLODNJI (Law on Medically Assisted Reproduction, 12 July 2012) (Croatia), No: 71-05-03 / 1-12-2, Article 15(2).

313 Act on Assisted Fertility Treatments (1237/2006).

314 Wet donorgegevens kunstmatige bevruchting, 2002.

315 Human Assisted Reproductive Technology (HART) Act 2004 (NZ).

316 Act on Biotechnology 2003.

317 Lag om insemination (Law on Insemination) 1984 (replaced by Genetic Integrity Act 2006).

318 Federal Act on Medically Assisted Procreation of 18 December 1998 – FF 1996 III, 197 (LPMA).

319 Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (UK).

320 Law Regulating Human Assisted Reproductive Techniques (22/11/2013 No 19.167)

321 Children and Family Relationships Act 2015 Act No. 9 of 2015. NB. Relevant sections have not yet commenced. See http://www.irishstatutebook.ie/eli/isbc/2015_9.html accessed 16 August 2018.

information about their donor(s) may turn to a special register,[322] to the clinic[323] or hospital[324] that assisted in their conception, or apply for judicial approval[325] to access information about their donor(s), and possibly siblings. In Australia, the NHMRC Ethical Guidelines have also required non-anonymous donation since 2004 (requiring that before donation takes place a person must consent to identifying information being released to a donor-conceived person upon request). In Queensland, South Australia, Tasmania, and the Northern Territory a person conceived with sperm donated after this date may approach the clinic to request such information. Table 5.1 summarises the law in Australia and how it has changed over time. (Note, donors and recipient parents in some jurisdictions may also be able to obtain information).

Table 5.1: Australian laws regarding recording and release of information

Jurisdiction	Legislation	Date of implementation	Access
Victoria (Australia)	1. *Infertility (Medical Procedures) Act 1984*; 2. *Infertility Treatment Act 1995; Infertility Treatment Regulations 1997*; 3. *Assisted Reproductive Treatment Act 2008*	1. 1985 (with consent); 2. 1 January 1998 (consent required under law prior to donation); 3a. 2010 (new Act –); 3b. amended 2015; 3c. amended 2016	Central Register 1. Non-identifying from 1988 2. Identifying information prospectively from 1998 (consent required); 3a. provided for an addendum to birth certificates notifying the person of donor-conceived status 3b. Amendments 2015 – Retrospective release of identifying information with consent for those conceived with sperm, eggs or embryos donated pre-1998 3c. Amendments 2016 – Full retrospective release for all donor-conceived people, contact veto/preference system from 1 March 2017. Voluntary Register also operates – important for sibling matches and further information sharing. NB. Some early records may have been destroyed.

322 Australian states of New South Wales, Victoria, Western Australia; countries of Croatia; Finland; The Netherlands; New Zealand; Switzerland; United Kingdom. Note in Ireland while the legislation has since 2015 provided for a register, the law is not yet operational.

323 Austria; Switzerland (pre-2001). Note in Ireland due to the legislative provision for a register not yet being operational (and donors being used from outside of Ireland), records are kept for 30 years pursuant to the Health Products Regulatory Authority and EU legislation by fertility clinics. Fertility clinics state that information is available to all donor- conceived children, or their parents, upon request, but this may not include identifying information.

324 Sweden.

325 Argentina, Uruguay.

Jurisdiction	Legislation	Date of implementation	Access
Western Australia	*Human Reproductive Technology Act 1991* (WA)	Recording of information on RT Register from 1993 Amended 2004	Access to information • Prospective from 2004 • With consent pre-2004 Voluntary register also operates (See further below)
New South Wales (Australia)	*Assisted Reproductive Technology Act 2007*	1 January 2010	Central Register: • Prospective from 2010 • With consent pre-2010 NB. Evidence that some records were tampered with or destroyed – donor-codes ripped out.
South Australia	*Assisted Reproductive Treatment Act 1988* (SA); *Assisted Reproductive Treatment Regulations 2010* (SA).	1988- Identifying information cannot be released without consent Amended 1 July 2010 – enshrine NHMRC Guidelines	Clinic-Based: • Identifying information can be obtained via clinics subject to the consent • Consent must have been given post-2004 donations under NHMRC Guidelines NB. Some records not held by clinics and therefore fall outside of the Act. 2017 recommendations for central register and release of information to all donor-conceived people, subject to parties being able to place a contact veto.
Northern Territory, Australian Capital Territory, Queensland, Tasmania	Currently, follow NHMRC Guidelines.	Have required non-anonymous donation since 2004.	Clinic-Based NB. No monitoring or enforcement; practices appear to vary.

Table 5.2 summarises other jurisdictions around the world that make legislative provision requiring the recording and release of identifying information.

Table 5.2: Legislation around the world requiring recording and release of information

Jurisdiction	Legislation	Date of implementation	Access
Sweden	Lag om insemination (Law on Insemination) 1984 (replaced by *Genetic Integrity Act 2006*)	18 March 1985	Prospective (hospital/clinic-based)
Austria	Fortpflanzungsmedizingesetz. 275 Bundesgesetz	1 July 1992	Prospective (clinic-based)
Switzerland	Federal Act on Medically Assisted Procreation of 18 December 1998 – FF 1996 III, 197 (LPMA)	1 January 2001	Retrospective (register-based post-2001; clinic-based pre-2001)
The Netherlands	Wet donorgegevens kunstmatige bevruchting, 2002	1 June 2004	Retrospective with consent (register based)
Norway	Act on Biotechnology 2003	1 January 2005	Prospective (clinic-based)
United Kingdom	Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004; and *Human Fertilisation and Embryology Act 2008*	1 April 2005	Prospective (but donors who donated 1991-2005 can 're-register' to consent to release) (register based)
New Zealand	*Human Assisted Reproductive Technology (HART) Act 2004*	22 August 2005	Prospective (register based)
Finland	Act on Assisted Fertility Treatments (1237/2006)	1 September 2007	Prospective (register based)
Washington State (United States)	Wash Rev Code Ann §26.26.750	July 2011	Prospective (clinic Based) NB. Subject to veto by the donor
Croatia	ZAKON O MEDICINSKI POMOGNUTOJ OPLODNJI (Law on Medically Assisted Reproduction, 12 July 2012) (Croatia), No: 71-05-03 / 1-12-2	12 July 2012	Prospective (Register Based)
Uruguay	Law Regulating Human Assisted Reproductive Techniques (22/11/2013 No 19.167):	22 November 2013	Based on application to the Court
Argentina	Código civil y comercial de la nación (Civil and Commercial Code of the Nation), Title V, Ch2, approved by Law 26,994.	1 October 2014	Prospective (Birth registration, and medical records)
Ireland	*Children and Family Relationships Act 2015* Act No. 9 of 2015	6 April 2015	Prospective (Register) (*Yet to commence)

In Germany, while there is no legislative provision for access to information, there have been a number of German Court judgements that have supported a donor-conceived person's right to know their genetic heritage.[326] In 2015 the German Supreme Court (Bundesgerichtshof) held that all children have a right of access to information, regardless of age, and that right trumps any right the donor has to privacy.[327] The Court derived the right of the child to know his or her heritage from Articles 2(1), 1(1) of the German Constitution, which was held to found the right to a claim for information between two private individuals if a civil claim exists between the parties.[328] The German Civil Code § 242 was also seen as important as it established such a civil claim. The contract entered into by the parents and the doctor constituted a third-party beneficiary contract for the benefit of the child and this contract could be the basis of the right of the child to know the donor's identity.[329] It further determined that 'the right of the sperm donor to informational self-determination, that is, deciding himself which details about his private life to disclose to the wider public, based on Articles 2(1), 1(1) of the German Constitution, was trumped by the right of the child to know his or her heritage'.[330] The Court amongst other things argued that in the balancing test between the fundamental rights of the child and the donor, it had to be taken into account that the donor had willingly participated in the procreation of the child and that he had to accept a certain social and ethical responsibility towards the child. In addition, the Court reasoned that the donor's economic interests were insignificant as part of the balancing test.[331] The right of the child to know his or her heritage was seen by the Court as also surpassing the right of the doctor not to disclose information about his patients as part of his or her professional freedom derived from Article 12(1) of the German Constitution.[332]

Four jurisdictions – Victoria, Ireland,[333] Croatia and Argentina – have also made legislative provision for entry of information about the method of conception on the birth register to ensure that a donor-conceived person knows they are donor-conceived and then may seek further information if desired. Victoria and Ireland[334] explicitly state that such information will be provided to the donor-conceived person on an application for their birth certificate at age 18. Croatia mandates disclosure by parents to the child regarding its donor-conceived status no later than age 18. Argentina lists information on the birth record, but it is unclear as to how this information will be conveyed.

Other nations, including the United States, Canada and Denmark, have seen the increased offering of 'open-identity gamete donation', albeit still also offering anonymous donors.[335]

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326 See for example, Oberlandesgericht Hamm, I-14 U 7/12. Available at http://www.justiz.nrw.de/nrwe/olgs/hamm/j2013/I_14_U_7_12_Urteil_20130206.html accessed 27 August 2018; and BGH, Urteil vom 28. Januar 2015 - XII ZR 201/13.

327 BGH, Urteil vom 28. Januar 2015 - XII ZR 201/13.

328 Child rights international network, Supreme Court of Germany decision XII ZR 201/13, summary, available at https://www.crin.org/en/library/legal-database/supreme-court-germany-decision-xii-zr-201/13, accessed 27 March 2018.

329 Ibid.

330 Ibid.

331 Ibid.

332 Ibid.

333 Note again that the relevant sections within the Irish legislation have not yet commenced and have thus not been operationalised. See http://www.irishstatutebook.ie/eli/isbc/2015_9.html accessed August 2018.

334 Ibid.

335 For detailed discussion of all the above jurisdictions and their laws, Allan (2017), above n 266.

Some other countries such as Belgium, Denmark, France, Portugal, and Spain continue to provide only for donor-anonymity (and in some countries, this is supported by the law).

5.4 Jurisdictions that provide for access regardless of when a donor-conceived person was born

While generally laws recognising the right to access information have acted prospectively, some jurisdictions have recognised the right to access information for all donor-conceived people, regardless of whether donor anonymity was required and/or 'guaranteed' by clinicians at the time of donation.[336] Specifically, Switzerland recognised such rights to access to information in 2001. There a register of donor information for children born post-2001 was established, but the law also provides that those born before 2001 can apply for information to clinics, which are obliged to release it. However, due to other laws that permitted the destruction of records after 10 years, some donor-conceived people have not been successful in accessing information via the clinics. As above-mentioned, in Germany Supreme Court recognition has been given to donor-conceived people's constitutional and human rights to access identifying information about their donor, at any age.[337] In 2017 Victoria, adopted laws recognising the right of all donor-conceived people to equal access to information, regardless of when they were born, subject to a contact veto/ preference system.[338]

In Western Australia, there has been long-term historical reference to the fact that opening records from the past was likely to happen in the future, with consent forms including such statements and/or practitioners required to discuss this with their donors.

5.5 Ancestry tracing via direct-to-consumer DNA testing

It is also important to recognise that access to information about biological heritage and relations has become increasingly possible via direct-to-consumer DNA testing. Such testing allows people to commission genetic tests directly from the internet via ancestry tracing websites such as AncestryDNA, 23andMe, and Family Tree DNA. In recent times, such testing has proven to reveal connections between donor-conceived people and their donors and siblings.

From about the year 2000 some males used Y-chromosome testing to find matches with their paternal relations and then searched for clues regarding the surname of their biological father. Information on ancestry sites, surname, geographical location, public records, and other non-identifying information (e.g. provided by clinics) was then triangulated to identify the donor. The success of such methods, however, was estimated to be low at around 10-18%.[339] Family Tree DNA is now the only commercial company offering a Y-DNA matching database having over 550,000 Y-DNA records with representation from nearly 400,000 unique surnames. (Note, the

336 G. Pennings, (2012). How to kill gamete donation: Retrospective legislation and donor anonymity. *Hum. Reprod. , 27*(10), 2881–2885. doi:10.1093/humrep/des218; Sonia Allan, Donor identification kills gamete donation: A response. *Hum. Reprod. , 20*, 1–5.

337 Supreme Court of Germany decision XII ZR 201/13, summary, available at https://www.crin.org/en/library/legal-database/supreme-court-germany-decision-xii-zr-201/13, accessed 04 August 2018.

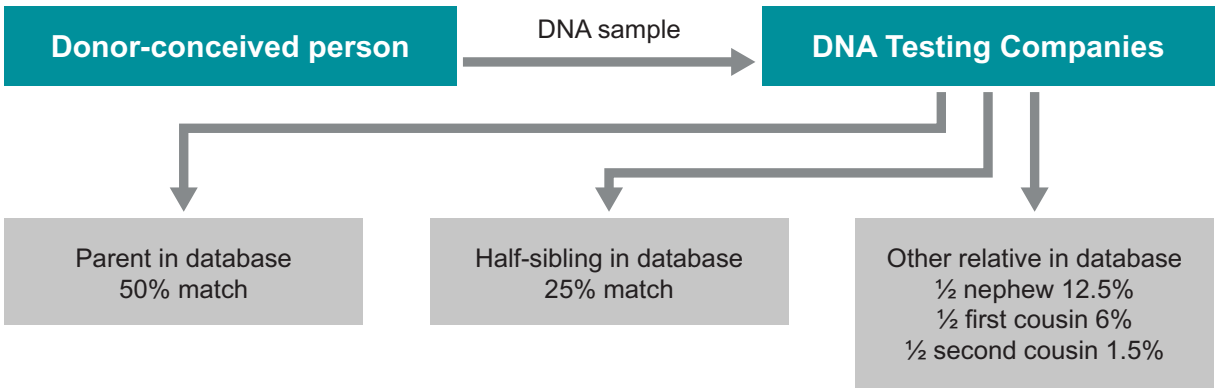
338 For detailed discussion of the Victorian laws see Sonia Allan, 'Donor Identification: Victoria gives Rights to all Donor-Conceived People' 98 Family Matters, November 2016.

339 Gymrek M, McGuire AL, Golan D, Halperin E, Erlich Y. Identifying personal genomes by surname inference (2013) 339 *Science* 321–324.

company also undertakes autosomal testing, which is discussed below and hosts a Donor-Conceived Project, which states its main goals are to provide a central location for donor-conceived individuals to locate half-siblings; and for former and current donors to locate their biological children).

More recently both males and females have been using autosomal DNA testing, with greater success. Autosomal testing via direct-to-consumer ancestry sites allows relationships to be predicted based on the amount of DNA shared with other people who have placed their DNA on such sites, and the size and number of shared DNA segments on the 22 autosomal chromosomes. The ancestry sites provide customers with a list of matches with a prediction of the relationship based on a percentage (as per Figure 5.3) and/or information regarding the number and length of shared DNA segments (further discussed below):

Figure 5.3: DNA percentage match indicating relationship type



Relationships may also be determined by examining the centimorgan (cM) distance between the first and last single nucleotide polymorphisms, which are the most common type of genetic variation among people (these are frequently called SNPs – pronounced 'snips'). The more closely related two individuals, families, or populations are, the more SNPs they typically share.[340] That is, the longer the shared segment between two people is, the higher the probability that it was inherited from a common ancestor – meaning the two people are genetically related. All 22 pairs of chromosomes add up to a total of about 7000 cMs. Half is inherited from a person's mother, and the other half from their father. The length of shared segments between a person and their relatives falls, on average, within the following ranges:

- Identical twin: 7000cM
- Parent: 3350 – 3600cM
- Full siblings: 2300 – 2900cM
- Half siblings, grandparents, aunts/uncles, niece/nephew: 1300 – 2200cM
- First cousins: 600 – 1200cM.

The above values represent average ranges. In some cases, matches can have lower or higher cM values.

340 NIH, National Library of Medicine *What is genetic ancestry testing?* Available at https://ghr.nlm.nih.gov/primer/dtcgenetictesting/ancestrytesting accessed 18 August 2018.

Donor-conceived people may also use ‘mirror trees’, which involve creating a replica of another user’s family tree (that is someone with whom the searcher shares ancestors such as a cousin) upon which the person seeking information then places their DNA. Algorithms within the ancestry website then operate to identify people who share common ancestors. In this way, a person may be able to work out who their genetic ancestors were, and then trace back down to identify their biological parent. In more complicated searches people may also search for surnames to locate other family trees, use message boards to contact people to learn more about their relatives, and email or leave shared notes on ancestry sites about suspected relationships, which are often answered by people willing to share information and to help the person searching find out more about their relatives.

Notably, there are donor-conception groups and networks to assist. For example, the Facebook group called ‘DNA Detectives’ has over 30,000 active members varying from beginner to advanced genetic genealogists, including search assistants who have already solved their own cases. A specific group exists for donor-conceived people (DNA for the Donor Conceived). Such groups provide self-education files to help people interpret their DNA, but also a significant support network. There are also Australian-based groups such as the Australian Donor Conceived Persons Network, and DNA Detectives Down Under. (Note, support networks are not just focused on DNA or ancestry tracing but serve to provide significant peer support for donor-conceived people via a community of people who may share and discuss experiences of being donor conceived.)

All of the above has led to an increase in donor-conceived people identifying siblings and donors, a number of whom are now in contact and are building relationships, including in Western Australia. One donor-conceived person who made a submission to the review described her experience as follows:

> *I was donor-conceived in Perth, Western Australia in 1986 and my brother was conceived from the same sperm donor in 1989. Last year through DNA testing we were thrilled to discover and make contact with a half-sister donor conceived in Christchurch, New Zealand in 1987. Finding a half-sister has been one of the happiest discoveries in my life and I only wish we had been able to make contact earlier.*[341]

Four other Western Australian donor-conceived people participated in face-to-face meetings and/or made written submissions to the Review who had found their donor via DNA testing. All were in touch with their donor and were building relationships. These donor-conceived people talked of their great sense of relief at having found their donor.

Another participant in the review, who had found a sibling via the Voluntary Register, had found their donor via DNA testing and was in contact with him and his wife. The donor and his partner, also participated in the Review, providing insight into how they felt it would have been good to have had somewhere that they could have turned to for support. They also called for somewhere people can go if they need help or advice and stressed how important it is to think about the donors and their families as well.

There were also examples presented to me of donor-conceived adults who were not informed of their status but had found out that they are donor-conceived when they have placed their DNA on ancestry websites for other reasons such as curiosity, genealogy tracing/family tree building, or having received a membership as a birthday present. A number of such people have then joined the support groups and may search for more information.

341 Confidential, Submission 49.

In 2016 an article published in *Human Reproduction* concluded that as a result of DNA testing donors can no longer be told their anonymity is guaranteed.[342] This is so even in countries in which anonymous donation is alleged, or where laws currently only give certain people access to information – like Western Australia. Recipients also need to be fully informed that their children's DNA will identify that they are donor-conceived, and disclosure that they have used donor gametes or embryos should be encouraged.[343] It is also necessary to consider changes that may need to be made to the law and donor-conception registers to recognise that such technology has opened up access to information that was once restricted to someone having a donor-code. This is discussed further below when making recommendations regarding a new Donor Conception Register in Western Australia.

Some donor-conception registers and/or support services (in Victoria, the Netherlands, and the United Kingdom) currently use DNA testing to supplement information or confirm connections.

5.6 Western Australian donor-conception registers

The *HRT Act* currently provides for the recording and release of information concerning donor conception via the RT Register. There is also a Western Australia Voluntary Register which, as further discussed below, operates on a policy basis. The following considers the operation and effectiveness of such registers.

5.6.1 The RT register: Information about donor conception

The Western Australian *HRT Act* has required the collection and reporting of information about donor-conception since the inception of the RT Register in 1993. This includes identifying information about donors, recipients, and children born as a result. Prior to this the main sperm bank (Keogh) and the clinic (PIVET) that were practising in the early days of ART in Western Australia reported having also kept their own records, many of which they still hold, albeit in paper form or notebooks in some cases.

From 2004 the *HRT Act* has also provided for access to identifying information by donor-conceived people about their donors when they turn 16 – which means the first group of people who have a right to such access will be able to apply to the RT Register from 2021.

However, as detailed in Chapter 4, the review revealed concerning issues regarding the current state of the RT Register. A significant concern is that the data custodians confirmed to me during the review that they are not currently confident that data held on that register could reliably be conveyed to donor-conceived people in 2021. This was due to concerns over the state of the data held on the RT Register and concern that they may not be able to match recipients, donors and donor-conceived people with confidence. (I subsequently confirmed with all clinics practising in Western Australia that they had kept their own records and could reliably match recipients, donors, and births if required – albeit in some instances this would require accessing archived files.)

342 Harper, Joyce Catherine, Debbie Kennett and Dan Reisel. 'The end of donor anonymity: how genetic testing is likely to drive anonymous gamete donation out of business.' (2016) 31(6) *Human reproduction* 1135-40.

343 Ibid.

There was also significant concern that, even when the data is rectified, holding it in the Data and Information Unit or another policy unit within the DoH, such as the RTU, was not the appropriate place for a donor-conception register. A number of donor-conceived people communicated to me that given the nature of the information and its direct relevance to their biological parentage and relations that such data should be kept with all other birth record data, that is, at Births, Deaths and Marriages. They also raised concern that people currently responsible for the data did not have the expertise to be the point of contact for people seeking information about donor-conception, and that it can be distressing and stigmatising to approach a health department to access information about their genetic heritage and relations as it treats them differently because of their parent's infertility or sexual orientation and use of donor-conception.

Such concern about record keeping, interaction with, and support of those seeking information, and where the donor-conception register should be located was further reflected when examining the operation of the voluntary register. The discussion thus turns to that register before consideration of what should occur in relation to the recording and release of information regarding donor conception in Western Australia.

5.6.2 The Voluntary Register

Background

The Voluntary Register was established in 2002 by the then Western Australian Minister for Health. It was not established via legislation being enacted but rather was established via a departmental policy decision with the original intention that people donor-conceived before 1 December 2004 would be able to have access to information if their donor also joined the register. This recognised that laws providing a legal right to access identifying information about donors would operate prospectively from that date, and thus only gave a right of access to information to people donor-conceived after that date and was meant to enable access retrospectively provided all parties agreed.

Subsequently, at a time unable to be exactly determined, access to the Voluntary Register was extended to allow parents of donor-conceived children (under 18 years of age) to register on behalf of their child. This is believed to have been in response to complaints from two women who wanted to meet as their children were half-siblings by the donor.

Later again, access to the Voluntary Register was extended to allow parents of donor-conceived children and donors to voluntarily share identifying information with each other.

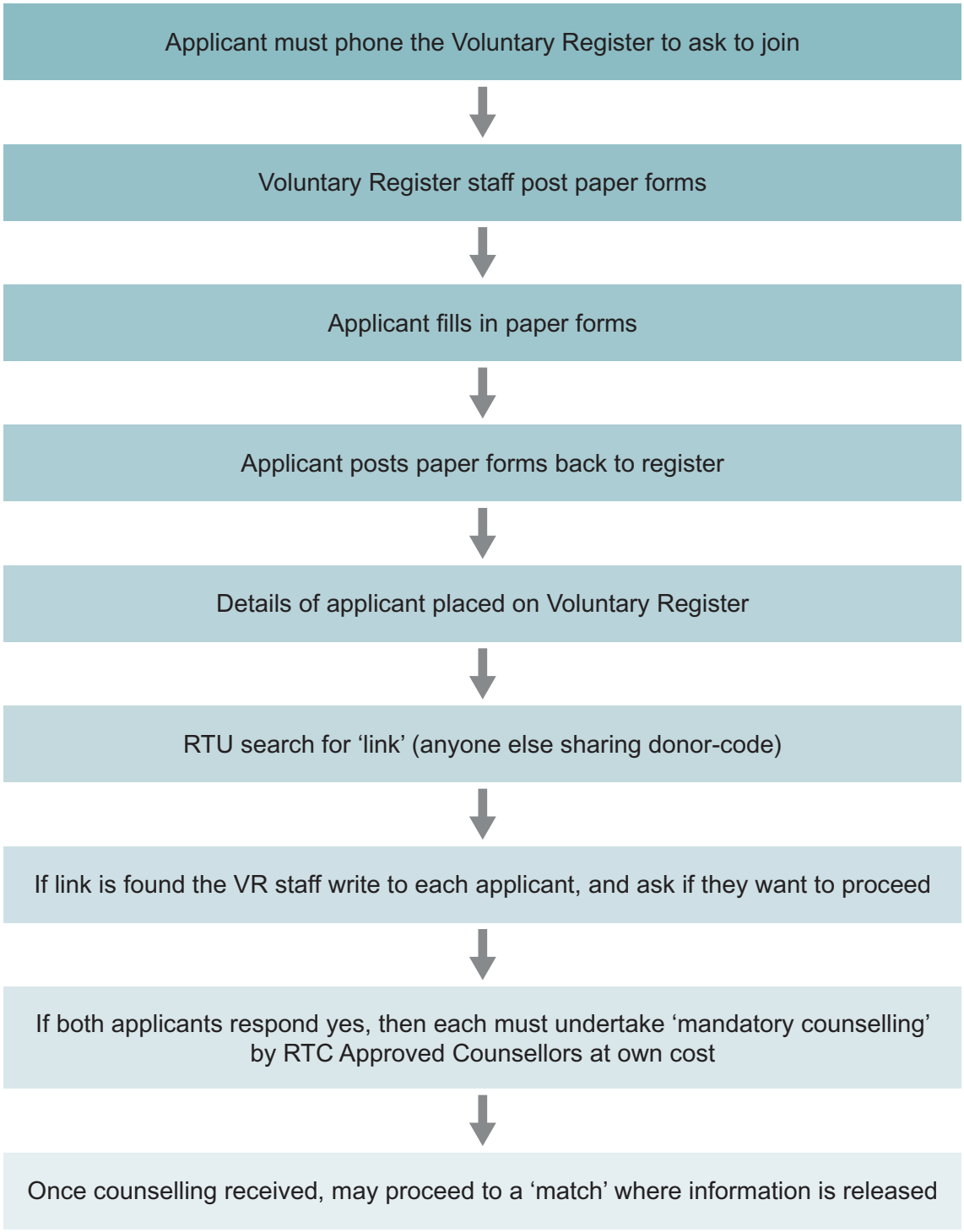
Operation of the voluntary register

The Assistant Director General Clinical Excellence is the Data Steward for the Voluntary Register. The Manager of the RTU and two policy officers in the RTU currently look after the day-to-day management of the Voluntary Register. Both policy officers have a background working as scientists/embryologists at a number of clinics in Western Australia and are knowledgeable about the technical aspects of donor-conception practices, donor-codes, and record keeping practices.

Up until recently, the Voluntary Register database was located in the Data and Information Unit, which is responsible for the reproductive technology register (RT Register) discussed in Chapter 4 and above at 5.5.1. It was, however, reported by the RTU that the dislocation of the Voluntary Register *database* from the RTU who manage the Voluntary Register had contributed to errors, omissions, failure to follow up with applicants (over several years), and lack of adequate risk mitigation strategies. In June 2017 it was thus agreed that the Voluntary Register database should be transferred from the Data and Information Unit to the RTU. (This means that the Voluntary Register and the RT Register are currently situated in different locations and units within the DoH).

The process of making an application to be placed on the Voluntary Register is phone and paper-based. The RTU currently requires that if a person is interested in placing their name on the register they must telephone the RTU. The person will usually speak to one of the two policy officers in the Unit although people may be referred to the Manager of the RTU if there are particular issues or complaints. They will then be posted paper forms to fill in, which they must post back to the RTU to be registered on the Voluntary Register. Once the paper application is received by the RTU it searches the Voluntary Register database for other Voluntary Register applications who share the same donor-code. If a 'link' is established (i.e. two people have the same donor-code) the applicants are notified, again via a letter being sent by the RTU, and asked if they wanted to proceed. If both consent, before the information is exchanged, they are required by the RTU to undertake 'mandatory' counselling which can only be supplied by the RTC 'approved counsellors' (see above discussion at 3.4.5). Applicants must pay for such counselling themselves. It is noted again that this has no legislative basis, but rather is what the DoH/RTU currently requires. If the people concerned give mutual consent, undertake the counselling, and then provide proof of such counselling to the Voluntary Register, they are then permitted to share information, and are considered a 'match'. This is depicted in the following flowchart.

Flowchart 5.1: Current Procedure Regarding Voluntary Register



Since 2002 there have been 370 enquiries to the Voluntary Register, and 65% of people had been sent application forms.[344] Currently, there are 240 people active on the register including 114 recipient parents (48%), 87 donors (36%), and 39 donor-conceived adults (16%). There were approximately 57 deactivated records. As of early February 2018, there were 55 identified 'links' (i.e. identified as having the same donor-code) and 23 of these have proceeded to 'matches' (i.e. have shared identifying information). Applicants with one or more links between participants included 11 donor-conceived people, 24 donors, and 59 parents. The most frequent matches were between parent and donor (21); half-siblings (21); and parent to parent (13). There were only five matches between donor-conceived adult half-siblings, and fewer than five reported matches between donor-conceived adults and their donors.

The Voluntary Register distinguishes between links (Donor Codes are shared) and matches (where people proceed to exchange information). Reasons for not proceeding to matches included (noting there may be more than one reason):

One party did not want to proceed	9
Still planning to proceed	9
Already known to each other	< 5
Wanted only donor contact	< 5
Financial constraint for counselling	< 5
Deactivated before proceeding	< 5
Unknown	< 5

An example of a person planning to proceed in the future was presented in the face-to-face forums by a mother of a donor-conceived person who said that she had put her name on the register when her daughter was very young. She had been contacted that a link had been made with the donor when her daughter was 12 years old. She and her daughter felt that it was too soon to contact the donor and were going to wait until the daughter was an adult. It was not clear to them whether this information had been shared with the donor.

Issues raised concerning the Voluntary Register

The Data and Information Unit noted that the Voluntary Register was not a data collection in the normal sense of the term, but rather a register of forms used for confirming the bona fides of a registrant making an application. In the past, when the Data and Information Unit held the database and an application was received, the donor-code would be reported to the Data and Information Unit who would search for a match. However, as with the RT Register generally, the review was informed that the database had not been reliably maintained over time. Issues identified included for example, that there had been donor-code omissions which meant applicants who were related by donor were overlooked for several years; and failure to identify people who were already registered and shared the same donor-code.

344 Communicated by Department of Health staff in the RTU. These figures are based on information provided by a Department of Health policy officer.

The RTU reported that over time there had also been several undocumented and iterative changes made by prior staff in relation to the operation of the Voluntary Register, raising concern that the Voluntary Register had been managed in a 'piecemeal fashion'. They also expressed concern that 'no attention [had been given to] Government policy initiatives, legal frameworks, risk management, systems development or strategic intent' over time.[345]

More recently work had been undertaken to improve RTU record-keeping and processes. For example, a designated policy officer had undertaken focused work on auditing all records on the Voluntary Register and correcting all the previous errors from the database. In addition, there have been form letters established, and the Register's functioning has been improved. While such work has made a marked difference to the state of the current Register, such work was reportedly still to some extent constrained by internal policies and processes, the lack of legislative framework, and/or internal fear concerning the level of risk the register carries. Staff reported ongoing issues to include the lack of use of technology (for example, requiring people to engage with postal correspondence only) and lack of qualified personnel that could provide appropriate support services to those seeking information.

In addition it was reported that the prior convention of requesting information from clinics about donors and their recipients, and from the RT Registers, ceased in 2016 due to a departmental view that this may not comply with privacy laws or the *HRT Act*. Applicants have since instead been required to approach the clinics themselves to obtain their donor code on a standard proforma (again a paper form), which is then required to be submitted to the RTU with the Voluntary Register application form. The view of the RTU was that *'this mitigates risks of breaching legislation and streamlined the whole process'*. The Manager also said that the clinics sometimes did not provide the requested information for months. However, some staff within the RTU acknowledged that this meant that information that once may have been obtained by them, could no longer be obtained, and had hindered the operation of the Register. In addition, donor-conceived people perceived having to get their donor-codes from the clinics as *'just another hurdle which makes it harder to access information'*. Some complained about being required to directly approach clinics stating *'this can be really difficult for us'*.

Experiences of donor-conceived people

There are relatively few donor-conceived people on the Voluntary Register. This is of concern given that it was specifically donor-conceived people for whom the Register was initially established. Several donor-conceived people complained to me during the review that the process they had been subjected to in relation to the Voluntary Register. Several complaints were also made regarding their experiences in interacting with staff at the RTU, stating such interactions had caused them distress. It was reported that there was a reluctance to engage with the RTC/RTU by the donor-conception community.

345 Communicated by Department of Health staff in the RTU.

One donor-conceived person said during a face-to-face meeting:

> *I mean what do the people at the RT[U] do exactly other than make it hard for us? We have to ring them and tell them why we want information, even though that's really personal. We are adults and they treat us like children. Then they say they will send us forms in the post, which I never received and was supposed to call them again to chase them up. It was hard enough to get up the courage to decide to look for my donor, let alone having to ring the health department and tell a stranger over the phone why, and then I had to chase them when the forms didn't arrive. I didn't feel that I could go through that. Why don't they use computers? Why isn't there an online form? It just seems bizarre…Anyway, then when I finally did receive the forms, I realized I had to get information directly from the clinic. I mean why? Isn't that what the register is supposed to help with? I don't know, it seems I have to jump through a lot of hoops. I think it is wrong that we are also told we have to go and see a counsellor and that counsellor can only be one of the few they have on a list of counsellors they have approved. I don't think fertility counsellors know anything about being donor-conceived or searching for information. The icing on the cake is that we are also expected to pay for the whole process and otherwise we don't get anything. If you question them [the RTU] they are really rude. They don't really seem to know what they are doing. I know many donor-conceived people just don't want to deal with those people and so they don't even put their name on the register.*[346]

Bridgitte, another donor-conceived person, described her experiences as follows:

> *I joined the WA Voluntary Register in 2007, when I was 21 and was only provided with… minor pieces of non-identifying information…My story took an interesting turn when in December 2014 I was contacted by the WA Voluntary Register and provided with new information…that there were seven other confirmed offspring [siblings]…including five other girls and two boys, all born the same year as myself (1986) or in 1987, with one of the boys being born in 1990…One of them had also signed up to the register and was wanting to undertake information sharing with me in the hope of meeting up. To do this we both had to undertake a mandatory counselling session with one of the RTC's approved counsellors, of whom only one would meet with me as the rest turned down my request for a session as I was not a patient of theirs receiving fertility treatment. I…attempted to get this counselling session subsidised, as money is not something that I have just lying around, and if this is a mandatory part of a government process then surely it could be funded… but …every response I received…was a dead end… I eventually had to concede defeat...and proceed with counselling… I met my half-sibling…in August 2015. She is six months younger than me and went to the same school as me. If I was born in January instead of December, then we would have been in the same grade at school and would have known each other. How lucky …we both have parents that told us the truth about being donor-conceived…both felt the desire to find out more and discovered the WA Voluntary Register… We are trying not to think of the years that we have missed out on knowing each other…*[347]

346 Donor-conceived person, face-to-face forum, April 2018.

347 Bridgitte Reynolds, Submission 78.

Bridgitte also met with me personally and described how difficult her interactions had been with the RTC/RTU during the above time. She also described how she felt mandatory counselling was not acceptable and described that when she did finally engage with the one counsellor who would see her, the counsellor said that she would just sign the form. She said she believes that donor-conceived people should not have to undergo counselling unless it was their choice and they felt they needed it, let alone pay for such counselling. She advocated for the law to change so that all donor-conceived people could have access to information regardless of when they were born, and without all the hurdles she had faced. Bridgette and her sister also subsequently engaged with direct-to-consumer genetic testing on Ancestry.com and located their donor.

The Review also received a written submission from a donor-conceived person who lives overseas. It was said:

> *It should be possible to join the register through an online application form (as in Victoria) rather than a phone call (the current process for joining the voluntary register in WA.) Making an international phone call and attending a counselling session is difficult for those who no longer live in Australia and would likely discourage many people from joining the register.*[348]

As mentioned above in Chapter 3.4.4, another donor-conceived adult, Beth, who had made a written submission and attended face-to-face forums, also contacted me during the review distressed about interactions with the staff responsible for the Voluntary Register. She subsequently made a formal complaint to the DoH and forwarded the complaint and responses to me, asking that they form part of the Review. The complaint included matters related to how her initial inquiry had been handled, the lack of clear policy and processes concerning what she was told was required of her, the way in which she was treated, and the expectation that she would then have to pay 'approved counsellors' for 'mandatory counselling'. Beth also noted:

> *I do not feel that the list of ANZICA approved counsellors understand the needs and concerns of donor-conceived persons. These counsellors are largely representatives of the fertility industry and they have inadequate experience dealing with the perspectives of donor-conceived people…. Upon receiving this list of seven approved counsellors and looking into them individually, I have become aware that two of the counsellors are on the RTC counselling committee and this was not disclosed to me.*

Following the lodgement of a complaint, Beth received several responses that also proved unsatisfactory. I found that her case highlighted significant issues regarding the Voluntary Register's current operation. Her experiences appeared in common with a number of other donor-conceived people who conveyed to me how difficult dealing with the Voluntary Register had also been for them. Other issues highlighted by the cases presented to me during the review include:

- The Voluntary Register has no legislative framework.
- Although staff refer to policies related to what they require of people, they do not appear to be able to produce some policies or guidelines to which they refer. It appeared that at times the reference to 'policy' is used because there is no ability for staff to answer the questions asked and/or to address complaints.

348 Confidential, Submission 49.

- The current requirement for mandatory counselling in relation to the Voluntary Register is based on a 'policy decision' and is not legally enforceable. Yet, if donor-conceived people state they do not wish to undergo such counselling, they are prevented from linking with their donor/siblings (likewise for donors and siblings who are also told they must undergo counselling). Further, that people are required (on a policy basis) to pay for the 'mandatory counselling' themselves prevented access to information as it proved cost prohibitive.
- The list of mandatory counsellors given to people applying to the Voluntary Register were fertility counsellors, two of whom were on the RTC, and all of whom work for commercial clinics:
    - There is a possible conflict of interest in having members of the RTC on a list of approved counsellors, who will benefit financially from supporting the status quo.
    - The apparent view that infertility counsellors were best placed to counsel donor-conceived people was not shared by donor-conceived people who participated in the Review. It appears insensitive to communications from donor-conceived people, who state they do not see fertility counsellors as the most suitable people to assist them, to continue to assert that this is the view of the RTC/DoH.
    - Donor-conceived people had reported difficulty in finding a fertility counsellor who would engage with them even if that counsellor was on the list.
- Prior clinical experience with ART clinics did not in itself mean that RTU staff understood, nor were they trained in relation to, the needs of donor-conceived people searching for information about genetic heritage and relations. The people at the RTU recognised and conveyed to me that they did not have the training to deal with some of the complexities they were faced with and were not trained lawyers nor counsellors; they reported also finding some interactions to be very stressful/distressing which sometimes impacted their own well-being and responses.
- Donor-conceived people, donors, and recipients engaging with the Voluntary Register were required to obtain information from clinics without assistance from the Voluntary Register. This was distressing, particularly for donor-conceived people, and appeared to be a result of an internal decision that the RTU's contact with the clinics was a breach of privacy. This was perhaps due to the lack of a legislative framework to support the voluntary register, however, it did not appear to best to support people seeking information.
- The data held by the DoH has over time faced significant issues regarding its integrity (as discussed above in Chapter 4, and at 5.5.1 and 5.5.2). While steps have been taken to improve the data held on the Voluntary Register, the current Register still appears vulnerable to issues regarding staffing and internal 'policy'/procedural decisions over time. Into the future, wherever the registers are held, high standards of data integrity are essential.
- The Voluntary Register does not have current capacity or protocols to deal with people who have linked with relatives via direct-to-consumer DNA testing. It is necessary to consider further how the Register should function into the future given that direct-to-consumer DNA testing has rapidly become the way many people are identifying their donor or siblings. Notably, a number of other donor-conceived people contacted me or attended face-to-face sessions during the Review who had found and contacted their donor via DNA testing. Some had decided not to place their details on the Register.

- The Voluntary Register does not operate in a manner that utilises up-to-date technology. The requirement for telephoning and subsequent use of only paper-based forms provides yet another barrier to people engaging with the Register (noting the operation of the Voluntary Register appears to have led some donor-conceived people to decide not to engage with it at all, leaving them absent of information).
- Current processes of requiring only postal communications did not appear to 'protect privacy' as asserted to those seeking information. For example, it was reported that letters have 'gone astray' and/or were reported never to have been received. It is also noted that staff at the RTU working on the Voluntary Register sit in open plan areas where telephone conversations may be overheard.

5.7 Discussion

The discussion in this chapter has highlighted the history of secrecy and anonymity surrounding donor conception and why access to information is of such importance to donor-conceived people, drawing on extensive research as well as lived experiences of people from Western Australia. It has also provided an overview of laws in other jurisdictions that support access to information and has noted those who do not. An overview of other ways donor-conceived people are finding information via direct-to-consumer DNA testing, ancestry tracing, and triangulation with other data, was also provided. This highlighted not only new ways of accessing information but also the importance of considering and providing support to all parties if they require it, including the families of donor-conceived people and donors.

The chapter then moved to a detailed examination of the current operation and effectiveness of both the 'RT Register' and the 'Voluntary Register'. Both are found to have significant flaws and issues that need to be addressed. While some staff at the RTU/DoH have made significant efforts to correct some such things, they have not always had the autonomy or power to do so. Nevertheless, in commissioning this independent review the Minister and Department of Health staff have shown a willingness to be open and transparent in relation to all matters listed in the Terms of Reference, including the operation and effectiveness of the Registers and the problems faced. This, coupled with the information put to the review by members of the public and those in the industry, must be acknowledged as a significant step toward enabling robust recommendations to be made – with the view that this will lead to improvements for all people. This is of particular importance to donor-conceived people who are born as a result of ART, and who have been left searching for information about their genetic heritage and relations.

Chapter 6 moves to discussing the future of the Donor Conception Register, including where it should be located, and how it should operate. However, findings and recommendations regarding the discussion thus far are noted below.

Findings

1. Donor-conceived people seek information about their donors and siblings for many varied reasons including, but not limited to, understanding their biological heritage, a sense of self and identity, to obtain or share medical information, fear and risks of forming consanguineous relationships, concern for each other's well-being, and a desire for openness, honesty and equality.
2. While there is legislative provision for access to information by donor-conceived people in Western Australia, this does not apply to all people. The *HRT Act* provides that donor-conceived people born after 2004 have a right to access identifying information about their donor at age 16.
3. Several jurisdictions around the world provide via legislation or the common law the right for donor-conceived people to access identifying information about their donor. Some such jurisdictions have moved to allow access to all donor-conceived regardless of when they were conceived, and regardless of whether there was a promise of anonymity made to the donor.
4. At the time of writing, there was not a stand-alone donor-conception register held at the DoH. Rather data is held on the RT Register, which is a database that holds a variety of data collected from licensed clinics in Western Australia. The data custodians of the RT Register have reported that they are not confident, given the current state of data on the RT Register, that they could provide information to donor-conceived people without risk of error. The RT Register was reported to 'not be fit for purpose'.
5. A Voluntary Register was established in 2002 in Western Australia to enable donor-conceived people born prior to 2004 to access identifying information about their donor and siblings if the donor/siblings also place their name on the Register. The Register has no legislative framework and has developed over time based on a number of iterative and undocumented changes. Its current operation is based on 'policy' and processes that have been determined by RTU staff and the DoH. Processes, limitations, restrictions, and operational issues at times hinder access to information and have led to the distress of those seeking information.
6. Requirements for mandatory counselling imposed by the Voluntary Register are not meeting the needs of donor-conceived people. At present such counselling may only be provided by the RTC Approved Counsellors (which involves a limited list of fertility counsellors, two of whom sit on the RTC); people are required to pay for such counselling themselves, and release of matched information will not be provided until all parties have undertaken such counselling. This creates unnecessary barriers for donors and donor-conceived people to exchange information.

Recommendations

Recommendation 21

An audit should be undertaken of the data held on the RT Register as a matter of priority to ensure that all data held in relation to donors, recipients, and donor-conceived people is accurate and reliable, and may be linked with confidence.

Recommendation 22

New legislative provisions be drafted that provide for a Donor Conception Register that operates in a manner that will best serve access to information by donor-conceived people, donors, and recipients.

Please see further findings, recommendations, and table for the required change and action relevant to the recording and release of information relevant to donor conception, biological heritage and relations at end of Chapter 6.

Chapter 6

Managing Information – Future Operation of the Donor Conception Register

Chapter 6:
Managing Information – Future Operation of the Donor Conception Register

6.1 Introduction

Chapters 4 and 5 highlighted that there exist significant issues of concern in Western Australia regarding the RT Register and the operation of the Voluntary Register. This includes that the RT Register has been reported as being 'not fit for purpose', and that the Voluntary Register faces significant operational issues. This chapter continues that discussion by examining the future operation of the Donor Conception Register. It is written with the welfare and interests of people born as a result of donor conception and surrogacy as the central consideration, mindful of the issues raised in Chapter 5 concerning why many seek information about their biological heritage and relations. The interests of recipient parent(s) and donors are also considered, noting however, that their interests necessarily must not outweigh those of the people who are born as a result of ART, donor-conception, and/or surrogacy. The following focuses on matters such as where the Donor Conception Register should be held, the provision of intermediary and support services, access to information by all donor-conceived people in Western Australia, access by donors to information, voluntary registration, and notification of donor-conceived status. It also provides consideration of costs in relation to the Donor Conception Register, before the final discussion, findings and recommendations for change.

6.2 Where should the Donor Conception Register be held?

While it is imperative that clinics maintain their own records concerning donor-conception, it is preferable that there is one central register from which access to information by donor-conceived people about their donors and siblings may occur. This would provide for access in one central location, consistency of practice, and security of data, for example by protecting it if a clinic closes, or changes business owner or structure. Chapter 5, however, highlighted that the current situation in which data is held on the RT Register (with no separate Donor Conception Register) and Voluntary Register gives rise to significant issues in relation to the management of information about donor conception, and the support offered to people seeking access to information.

Three options of where the register should be held were presented to me during the review:

1. internally at the DoH (in one location, or spread across two locations as is currently the situation)
2. by a stand-alone authority, which would have to be established
3. at Births, Deaths and Marriages, where all other birth information is recorded.

In examining which would be most suitable, I considered factors such as the size of the population in Western Australia, the number of donor-conceptions per year, the number of operational clinics, the need to preserve the records in perpetuity, the level of expertise and focus of work in various government departments, preferences expressed by the Western Australian donor-conception community, and the system of co-regulation that is recommended in this report in Chapter 3.

6.2.1 Population size

At December 2017 the Australian Bureau of Statistics population count demonstrated that Western Australia is significantly smaller in population size (2.6 million) when compared to the Eastern states in Australia where New South Wales has a population of 7.915 million, Victoria: 6.285 million, and Queensland: 4.96 million. The Western Australian population exceeds that of South Australia, which is 1.7 million but is most closely aligned with that State.[349] Tasmania had approximately 524,000 people in December 2017; the Australian Capital Territory 415,000 and the Northern Territory 215,000.

6.2.2 Number of donor conceptions per year

The National Perinatal Epidemiology and Statistics Unit reported in 2015 that there were 613 live births resulting from egg and embryo donation in that year, and 334 live births resulting from sperm donation – a total of 947 live births.[350]

I was unable to ascertain with confidence how many donor-conceived people have been born in Western Australia, nor how many are currently being born each year. The RTC Annual Reports contained yearly birth outcomes from 1994 to 2002 as per the following Table 6.1, noting that since the 2003-2004 report the yearly birth outcomes have not been included in the annual reports.

Table 6.1 Donor conception birth outcomes from 1994 to 2002

Source RTC annual report	Year of outcome	Donor births
1995-1996	1994	74
1996-1997	1995	60
1997-1998	1996	74
1998-1999	1997	64
1999-2000	1998	65
2000-2001	1999	61
2001-2002	2000	71
2002-2003	2001	76
2003-2004	2002	49
2004-2005 *	2003	-

The RTC reports up until 2004-2005* stated the birth outcome information was obtained from linkage with the Midwives Notification System. It appears to be around this time that questions

349 Australian Bureau of Statistics, Australian Demographic Statistics, December 2017, http://www.abs.gov.au/ausstats/abs@.nsf/mf/3101.0 accessed 28 August 2018.

350 National Perinatal Epidemiology & Statistics Unit Assisted reproductive technology in Australia and New Zealand 2015 (October 2017).

were raised internally regarding the legality of linking the RT Register with other databases, including the Midwives Notification System, and as a result, such linking stopped.

No further information about the number of donor-conceived people in Western Australia could be confidently determined during the review, due to the issues that were identified in relation to the management of information and record keeping related to the RT Register (see above discussion at Chapter 4 and Chapter 5.6). The number was roughly reported to me by clinics as being around 100-150 per year.

In Victoria, the only state that currently publishes state-specific data, a total of 565 donor births were registered in 2015-2016.[351] In 2016-2017 VARTA reported 516 donor births registered in Victoria, 338 from sperm donation, 116 from egg donation, and 62 from both egg and sperm donation.[352] It was also reported that there are 9,206 registered births on the Victorian central donor-conception register, which has operated since 1984.

Other states and territories do not publish data regarding the number of donor-conceived people born each year. New South Wales is likely to have similar numbers as Victoria, although an inquiry to their state Central Register yielded no information. Clearly less populous states would have fewer donor-conception births. It is noted, for example, that in South Australia the four operational clinics indicated that in 2016, 60 to 100 donor-conceived people were being born per year in that state.[353] Nevertheless, with increased use of donor-conception by single women and same-sex couples it is likely that donor conception will continue to increase.

The ANZARD 2018 report stated that in 2016, nationally, there were 666 live births resulting from oocyte/embryo donation and 415 live births resulting from donor insemination.[354]

6.2.3 Number of operational clinics

There are eight licensed clinics in Western Australia. One reported not providing donor conception.

6.2.4 Options

In considering options about where the Donor Conception Register should be held I consulted with post-adoption support services in Western Australia, met with the registrar from Births, Deaths and Marriages (BDM), met with the staff working in the Data and Information Unit, met with staff working in the RTU, and consulted with consumers, donors, and donor-conceived people. Three options were presented:

1. maintain the Register internal to the Department of Health
2. establish a stand-alone authority
3. maintain the Register at Births, Deaths, and Marriages, providing external intermediary and support services.

351 VARTA Annual Report 2016-2017 (2017).

352 Ibid.

353 Sonia Allan, *Report of the Review of the Assisted Reproductive Treatment Act 1988* (SA) (2017).

354 Fitzgerald O, Paul RC, Harris K, Chambers GM. Assisted reproductive technology in Australia and New Zealand 2016. (2018) Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales Sydney.

Internal to Department of Health

Options for where the Donor Conception Register would be held internal to the DoH included 1) the Data and Information Unit, where the current RT Register sits 2) the RTU, where the current Voluntary Register sits.

The Data and Information Unit is a data and statistics unit and is not set up for contact by the public regarding the data held by it. There was also no current expertise within the unit regarding assisted reproduction, nor establishing or running a Donor Conception Register. At present, a separate central Donor Conception Register from the general RT Register data collection has not been established. The Data and Information Unit's lack of confidence in the data currently held on the RT Register (see above at Chapter 4 and at 5.5.1), nd the issues the RT Register has faced for at least the last 15 years makes a strong case that this is not where the Donor Conception Register should be held. In addition, the Data and Information Unit is not a unit that could liaise with the public or provide support services that would enable family linking.

Staff in the RTU did have experience in having worked on the Voluntary Register and had undertaken significant steps to improve its functions. However, significant issues with the Voluntary Register remain, as noted above at 5.7. Staff in the RTU also expressed that they did not have the appropriate training nor did they feel equipped at times to be able to deal with some of the highly emotive issues and complexities that arose for people seeking information. Inability to provide adequate support (see above at 5.6.2) alongside current policies and procedures that create barriers to access to information did not indicate that this was a suitable location for the central Donor Conception Register either. Further, some donor-conceived people had expressed having chosen not to engage with the Voluntary Register because of its location and the current operation of the register including processes required of them.

The RTU is also a small unit (of three people) which supports the functions of the RTC and the implementation of the *HRT Act*. Both the nature of the work and the workload associated with this indicate that this unit is not the best place for the donor-conception register to be held. The proposed changes to the regulatory system in this report, if implemented would see the RTU/RTC focus on supporting the public by providing education and information about ART and the related ethical, legal and social issues that arise, registration of clinics, and supporting compliance with the *HRT Act* (amongst other things). The RTU should be able to focus on these functions and should not also have the responsibility for the central Donor Conception Register. In particular, access to birth and genetic information should be treated separately from the regulation and oversight of clinics, and operations and functions that support the treatment of people who require ART. The management of data relevant to birth and genetic heritage requires particular sensitivities and expertise. Further, intermediary and support services need to be available in a manner that is supportive and sensitive to the needs of those seeking information – with the ability to focus on those needs. The RTU is not staffed to provide such services.

In order to establish and maintain a functioning central Donor Conception Register that will serve people into the future it will be necessary to invest in and to ensure the appropriate infrastructure (for example, modern IT systems and procedures); it is also imperative that the data integrity and operational issues faced by the RT Register and the Voluntary Register be addressed. Donor-conception information must be held in a location that is secure and stable over time, where the data can remain in perpetuity (recognising it has value for generations to come), and where its integrity can be assured. Neither unit was found to be the suitable location for this to occur.

Stand-alone authority

The United Kingdom Human Fertilisation and Embryology Authority (HFEA) and the Victorian Assisted Reproductive Treatment Authority (VARTA) operate stand-alone regulatory authorities related to ART, which both also operate donor-conception registers as part of their functions. There are no other jurisdictions in the world that adopt this model. The HFEA and VARTA differ in the size of the populations they serve, both compared to each other and compared to Western Australia. Relative to Western Australia, both serve much larger populations. Both are highly funded and have significant costs associated with their operations. Neither is guaranteed to exist in perpetuity.

It is noted that in Victoria the donor-conception registers have been moved several times, including that they were held by the former Infertility Treatment Authority (ITA), where the register(s) was established in 1984; moved to Births, Deaths and Marriages in 2010; and are now managed by VARTA (which replaced the ITA) in 2017. The move to VARTA managing the registers followed the most recent changes to the law which have given the right of access to information by all donor-conceived people in that state, subject to the contact-veto/preference system (discussed further below at 6.4). In the 2017 financial year, VARTA received funding totalling $1,758,401 from the Victorian Government ($1,386,253), Commonwealth Government ($320,000), Department of Health and Human Services ($26,376) and Other Sources ($25,772). This compared with funding in 2016 of $984,399.

VARTA in addition to its functions regarding clinic registration and oversight and public education was given additional funding to employ personnel to manage the registers and provide support services (counselling and intermediary services). Employees at VARTA include counselling staff who have worked in adoption information, search and find services, as well as staff that have worked in infertility services. VARTA does not, however, carry out all tasks related to the registers. Via a memorandum of understanding with the Secretary for Health, the Victorian Adoption Network for Information and Self Help (VANISH) was nominated as the search agency to undertake searches for people who are the subject of inquiries (donors, donor-conceived people). This involves additional costs.

Some submissions to the Review praised the Victorian system in relation to its 'one door in service' meaning people could seek information and be provided support services in the one location.[355] Others expressed that they would not like to see 'a VARTA' in Western Australia concerned about it being both the regulatory authority and provider of donor-conception information and services.[356] Others thought that Western Australia should follow the recommendations in the South Australian legislative review that took place in 2017,[357] which among other things recommended the donor-conception register and information services be located at Births, Deaths, and Marriages (BDM), with support, intermediary and search services offered by a single external agency experienced in such practices.

On consideration of all of these views, the establishment of an independent authority in Western Australia appeared neither practical nor cost-effective. This was particularly so having taken into account the size of the population in Western Australia, the estimated numbers of donor-conceived people being in the low hundred range per annum, and that regulatory functions will

355 Bridgitte Reynolds, Submission 78, Confidential, Submission 92.

356 Face-to-face meeting, April 2018.

357 Damian Adams, Submission 40; Confidential, Submission 49; Katherine Vowles, Submission 100; Women & Newborn Health Services, Submission 121.

continue to be carried out by the DoH, albeit recommended that that occur in a more streamlined co-regulatory fashion (see Chapters 2 and 3 above). It was also found to be important to separate regulatory functions from the provision of support services offered to donor-conceived people, donors, and recipients seeking information about biological heritage and relations. Doing so enables the respective regulatory functions and support services to be located where appropriate skills and expertise can be utilised. It would also avoid any actual or perceived conflicts of interest arising. This was deemed very important given that many donor-conceived people were opposed to those who regulate or provide fertility and associated services also being the people who donor-conceived people are required to see in regard to access to information.

Births, Deaths, and Marriages (with external support service provider)

During the Review, I met with the Registrar from BDM to discuss the suitability of having the Donor Conception Register at BDM. Subsequently, the Manager of the RTU also met with the Registrar to further discuss this option. The outcome of this discussion was then submitted to me to form part of my considerations for the Review.

BDM collects and manages data relevant to birth and parentage. They maintain the birth register and issue birth certificates. BDM also engages in linking records and does so in relation to births and deaths. The main arguments for placing donor-conception information on the BDM Register include that it:

- involves data that is integral to a person's genetic heritage
- is where everyone else's birth data is recorded
- is a location where birth records are most likely to be kept securely in perpetuity
- would enable linkage of records to a person's birth registration data as well as the recipient, donor and sibling records.

In addition, the recording and release of donor information are for the benefit of the donor-conceived person and the parents' infertility should not prevail upon the child throughout his or her life, whether such 'infertility' is a medical condition or due to social reasons, relationship status, or any other factor.[358] Centralising all information about a child's birth at BDM may help to normalise donor conception (recognising that it is another way in which families are formed) and allows donor-conceived people to access information about their genetic parentage in the same way as others born to families created in other ways.

There are also complexities around running a donor-conception register given that linkages for donor-conceived people can be complex (see for example above at 5.2.2) as they cross multiple families. It was found that BDM has capacity and experience in this regard in relation to supporting access to biological heritage relevant to adoptees, which provided insight into how the donor-conception services may work. Nevertheless, it is recommended that a person should be employed to work at BDM on the donor-conception information who understands reproductive technology, donor-conception, and donor-codes. This has served the RTU where the current Voluntary Register is held in being able to understand what codes mean and would build capacity at the BDM in relation to the data that it would hold.

358 Victorian Law Reform Commission, *Assisted Reproductive Technology & Adoption: Final Report* (2007), p 52.

I was informed that in further follow-up with BDM by the RTU Manager after I had met with them, BDM was given more details about the types of information that would need to be recorded and asked to assess their capacity to run the Register. They responded that subject to start up and ongoing costs, BDM may provide a suitable location for the establishment and ongoing operation of the Register in conjunction with a third-party body, such as the post-adoption services, that would engage in the face-to-face client liaison, intermediary and support services for those people wishing to meet or forge relationships (that is, 'donor-linking').

In the examination of all options available, BDM proved to be the preferred option for the establishment of the Donor Conception Register, *provided that adequate funding was provided to establish it and a system for providing intermediary and support services*. Legislation and/or directions will need to be drafted to enable the Donor Conception Register to be held there and to provide the framework for such a system to operate effectively.

The following discussion is premised on the assumption that the recommendations of this report will be adopted, and that the Donor Conception Register will move to the BDM in order to further discuss how the donor register may operate effectively into the future.

6.3 Intermediary and support services

Intermediary services are those provided by a third party who acts as a 'go-between' between two other parties. They may, for example, undertake search and find services (locating where individuals are), contact the relevant parties, and implement any contact veto/preference systems. Such services may be particularly relevant to donor conceptions that occurred under anonymity regimes, or when there are children under the age of 18 involved.

Support services are those provided where some form of counselling is necessary or desired. For example, support services may be necessary when information is not available such as when past records have been destroyed, or following donor conception (for recipients), or donation of gametes (for donors). They may be desired by parties who are seeking information or needing support in relation to donor-conception.

There are different views and practices around the world in relation to the provision of intermediary and support services relevant to accessing information about, and/or contacting genetic relatives. For example, Wendy Kramer, who runs the largest voluntary donor-conception register in the world situated in the United States[359] has communicated to the reviewer previously that:

> *With almost 13,000 people connected on the [Donor Sibling Registry], we are certain that a counsellor doesn't need to be present at these initial meetings. We don't have a counsellor present when a child meets their visiting cousins, right? I think some look at donor families as different than "normal" families. We're not though, we meet new relatives just like anyone else.*[360]

In other jurisdictions, a variety of approaches were found.

359 The Donor Sibling Registry, is a Voluntary Register operated in the United States, which was established by Wendy Kramer and her son, Ryan who is donor-conceived. See https://www.donorsiblingregistry.com/ accessed 8 January 2017.

360 Wendy Kramer, email to me dated 30 January 2016. Wendy noted that of their 48,000 members (from all over the world), they have more than 800 Australian families on the register and have helped to connect more than 320 people in Australia.

Some jurisdictions provide for donor-conception registers but do not mandate support services. These jurisdictions include Switzerland, New South Wales, Finland and Croatia. In New Zealand, counselling is not required but is recommended. The view in these nations is that while information should be made available, it is up to the person accessing such information, who in most cases will be an adult, to decide whether he or she needs support services and to seek them out themselves if that is the case.[361]

Other jurisdictions provide for donor-conception registers and mandate intermediary services. The Netherlands requires intermediary support as the first point of contact with donors when contact is desired. In Victoria counselling prior to access to information is required.[362] In Victoria and the Netherlands the state funds services.

In the United Kingdom intermediary and support services are available on an optional and free basis to donor-conceived people and some donors. Family members (such as parents, non-donor-conceived siblings, or spouses) and friends can also pay to access services. Professional support services are available to anyone affected by post-donation issues, in cases where a donor-conceived person is seeking (or considering seeking) information about a donor or donor-conceived genetic sibling. Intermediary services are available to facilitate contact between an identifiable donor and a donor-conceived person or between donor-conceived siblings.

In Argentina and Uruguay approval by a judicial authority is required before information will be released, and it does not appear any further counselling or intermediary services will be required.[363]

6.3.1 Submissions regarding intermediary and support services

During the Western Australian Review, all donors, recipient parents, and donor-conceived people who participated in face-to-face meetings or forums or telephone conversations were asked whether they thought intermediary and/or support services should be available, and if so whether they should be mandatory or optional, who should provide such services, and who should pay them. All responded that intermediary and/or support services should be *available, optional, and free* (i.e. subsidised by the government or clinics).

It was the general view that such services should be engaged if one or both parties wanted to use them, but that they were of no benefit if forced upon people. In relation to who should provide such services, several donor-conceived people emphasised they did not believe fertility counsellors were best placed to provide them. Damian Adams, a donor-conceived adult, said:

> *In enabling contact between parties an organisation that specialises with reunions such as those agencies that assist adopted people to reconnect with their birth families should be used to facilitate contact and offer counselling, if and only if parties wish to undergo counselling and use a third party mediator. Counsellors from clinics have a vested interest in the running of a clinic and cannot provide completely unbiased counselling.*[364]

361 Allan (2017), above n 266.

362 Ibid.

363 Ibid.

364 Damian Adams, Submission 40.

As noted above, Beth, a donor-conceived adult said:

> *I do not feel that the list of ANZICA-approved counsellors understand the needs and concerns of donor-conceived persons. These counsellors are largely representatives of the fertility industry and they have inadequate experience dealing with the perspectives of donor-conceived people…*[365]

Beth and Damian's views exemplified other comments made to the reviewer by donor-conceived people, donors and recipients.

In relation to who should deliver services, Isabell Andrews from Jigsaw, and adoption support service, said:

> *…it is essential that the agency conducting the interview and outreach is neutral and have a background in either social work or psychology. This is not information/work that should be undertaken by administrative people. The role of an intermediary is to support all parties; thus, it is important they not be allied to another stakeholder service.*[366]

In the written submission received from the Western Australian branch of ANZICA counsellors it was submitted:

> *We strongly support the current model for mandatory counselling prior to donor linkage. However, we recommend that counselling be provided at no cost to the individuals seeking information from the Voluntary Donor Register or Donor Register. The current model of requiring donors to pay for their counselling is a barrier to the connection being established with the recipient and/or the children born as a result of the donation and works against the best interest of donor offspring and their right to access identifying donor information.*[367]

6.3.2 Services should be available, optional, and free (subsidised)

In considering the evidence and submissions put to the Review, it was found that mandating *counselling* support services should not occur. There may be little if any therapeutic benefit in requiring a person to undergo counselling they do not wish to engage in. Such support services should, however, be available to donor-conceived people, recipients, and donors *as required and desired by them*.[368] The availability of such services should also be extended to families (e.g. the spouse and children of a past donor) who need them, with the reviewer having spoken to a number of extended family members who were also impacted by donor-conception, and required support.

Intermediary services should also be available but not mandatory unless special circumstances exist. Such special circumstances may arise in cases that apply to access to information about donors who donated when anonymity was generally practised or when recipient families are applying for access to information prior to a person reaching the age of 16. Intermediary services in such cases would act for example, to inform a person that an inquiry has been made about

365 See above at 5.6.2.

366 Isabelle Andrews (Jigsaw), Submission 27.

367 ANZICA WA Fertility Counsellors, Submission 61.

368 See further Premier's Women's Council, submission 62; Kim Buck, submission 41. A call for follow-up support was also made by donors during the donor consultation, 21 April 2016.

them, provide information about the information release process, and discuss the contact veto system if one is put into place (see further discussion below at 6.4).

The option or requirement to engage with support or intermediary services should be free for donor-conceived people, recipients and donors. This is particularly so as making people pay for such services has been a barrier to their accessing information and/or the support they may require. Options regarding how to fund such services are discussed further below.

In listening to the people who would benefit from intermediary and support services agency and acknowledging that they are best placed to determine who they would feel comfortable with in relation to support services, it was also apparent that it was not their view that fertility counsellors were best placed to provide such services. As such, the option to utilise an agency/counsellor with expertise in delivering services to people who are searching for genetic relatives, such as those that function in the adoption area, would be most beneficial. The provider of such services should have 'trusted agency' status and be enabled to operate in an effective manner in terms of conducting search and find and family linking services (including but not limited to being able to access necessary records via BDM and otherwise as required). It is noted that this is a proven method in Western Australia for engaging in intermediary and support services in other contexts.

6.4 Access to information by all donor-conceived people?

6.4.1 Current limitations in Western Australia

While the above-discussed issues and recommended changes may serve donor-conceived people into the future, it is important to recognise that a significant concern and focus of the review was that the *HRT Act* only provides for access to identifying information by donor-conceived people about their donor by those born as a result of a donation made after 1 July 2004. Western Australia has, however, long since recognised that developments in policy and legislation may occur that would make available to donor-conceived people identifying information about their biological heritage in the future regardless of when the donation took place (that is, retrospectively). For example, the original HRT Directions promulgated in 1993 (Direction 4.2) required that the person responsible for providing donor-conception (e.g. clinician) **must** ensure that prior to consent being given to donation:

> *All donors and recipients are given oral explanations, supported by written information in a form approved by Council, including information…about the possible developments in policy and legislation making identifying information about their biological parentage available to children of donors.*

In 1999 the Select Committee on the *HRT Act* 1991 (WA) members (other than the member for Joondalup) recommended that if there was clear evidence that donors, who donated after the *HRT Act* came into effect, had been notified of the possibility of being identified in the future, it should *'now [in 1999] be possible for offspring to access donor identifying information retrospectively'*. The member for Joondalup agreed in principle but was of the view that such access should be available per se – that is, intrinsically to all donor-conceived people without condition. Examples of some pre-*HRT Act* consent forms used in Western Australia for donors of semen to unknown recipients included a statement that *'legislation may be introduced in the future to allowing the release of information to the offspring'*. In the past, such statements have also appeared on the Western Australian Department of Health's website and documents.

In considering other jurisdictions, as was noted above at 5.4, Switzerland granted rights to access to information to all donor-conceived people in 2001. In 2015 the German Supreme Court recognised that it is all donor-conceived people's constitutional and human right to access identifying information about their donor, at any age.[369] In 2017 Victoria adopted laws recognising the right of all donor-conceived people to equal access to information, regardless of when they were born, subject to a contact veto/preference system.[370]

In the present day many people and the ART industry recognise that anonymity is no longer guaranteed due to the advances in DNA testing and its use in ancestry tracing (see above at 5.5). Many of the donor-conceived people who had participated in the Review had, in fact, identified their donor in this way and were now in contact. A donor-conceived person further submitted:

> *I feel that the legislation regarding anonymity for donors was written primarily with the interests of the donors and parents in mind, rather than according to the wishes and wellbeing of the donor-conceived offspring. I do not believe there were adequate long-term studies of the health and wellbeing of donor-conceived offspring undertaken before the legislation was put in place. With the advancements in DNA testing and recent large increases in the size of DNA databases, it is unrealistic for donors to remain anonymous much longer. Even if the donor has not undertaken a DNA test, it is possible to identify them by examining shared matches and building family trees based on shared ancestors. You only need to view the personal stories posted on Facebook groups such as DNA Detectives to see that adopted and donor-conceived people around the world are discovering their biological parents every day through DNA testing.*[371]

In this sense, systems that granted rights of access to identifying information subject to having intermediary services and/or a contact veto, such as that in Victoria, were seen to provide greater protection to donor-conceived people and their donors than the status quo.[372]

369 Supreme Court of Germany decision XII ZR 201/13, summary, available at https://www.crin.org/en/library/legal-database/supreme-court-germany-decision-xii-zr-201/13, accessed 04 August 2018.

370 For detailed discussion of the Victorian laws see Sonia Allan, 'Donor Identification: Victoria gives Rights to all Donor-Conceived People' 98 *Family Matters*, November 2016.

371 Confidential, Submission 49.

372 See for example, Ross Hunter, Submission 62 and Bridgitte Reynolds, Submission 78.

6.4.2 Balancing 'competing interests'

The question, however, then arises as to how to address concern over removing the secrecy and anonymity that was promised to donors at the time of donation. The problem is most often presented as being one in which the interests of the donor-conceived person in knowing who their donor is competes with those of the donor who may wish to remain anonymous. First, it is therefore important to recognise that the direct juxtaposition of donor versus donor-conceived people's interest is often not correct in that it fails to consider that many donors also call for information release and an end to anonymity. Nevertheless, this is not to deny that some donors may be concerned about their privacy, and it remains very important to consider how to balance the respective interests of parties when interests do compete. Two questions arise. First, whether changes to the law that relate to past practices providing for 'retrospective release of information' are possible, and second, how to ensure any such changes are fair, just and reasonable. This section, therefore, considers these questions.[373]

Changes to the law that relate to the past as well as present practices

In general, laws in all jurisdictions operate from the day they were enacted onwards, that is, prospectively. This is seen as particularly important in criminal law contexts as it would be unjust to expose people to criminal sanctions and penalties for behaviour already committed that was legal at the time.[374] In addition, a retrospective law that interferes with judicial functioning by altering the laws of evidence or removing judicial discretion regarding sentencing of certain

373 In the interests of openness and transparency I note again that I have spent much of the past 15 years researching and writing about such issues and have drawn on such work for the purposes of this report. These arguments were similarly canvassed in the review of the South Australian legislation conducted by me in 2015-2017, the report of which was known to the Western Australian government. See further: S. Allan, 'Psychosocial, Ethical and Legal Arguments for and Against the Retrospective Release of Information about Donors to Donor Conceived Individuals in Australia' (2011) 19(1) *Journal of Law and Medicine* 354; S. Allan, 'Donor conception, Secrecy, and the Search for Information' (2012) 19(4) *Journal of Law and Medicine* 631; S. Allan, 'Donor Identification: Victoria gives Rights to all Donor-Conceived People' 98 *Family Matters*, November 2016S; Allan (2017), above n 266; S. Allan *Report on the Review of the Assisted Reproductive Treatment Act 1988* (SA) (2017). I have also referred to other literature that has considered relevant issues, including but not limited to D. Adams and C. Lorbach, 'Accessing Donor conception Information in Australia: A Call for Retrospective Access' (2012) in 19(4) *Journal of Law and Medicine* 704; Naomi Cahn, 'Legal parent versus biological parent: The impact of disclosure' (2012) 19(4) *Journal of Law and Medicine* 790; R. Chisholm 'Information rights and donor conception: Lessons from adoption?' (2012) 19(4) *Journal of Law and Medicine* 722; The Victorian Law Reform Committee Report, *Access by Donor-conceived people to Information about their Donors* (2012) (available at http://www.parliament.vic.gov.au/57th-parliament/lawreform/article/1468); Victorian Government, *The Right to Know Your Identity: Giving Donor-Conceived People the Right to Access Information Identifying their Donor* (Discussion Paper, Victorian Government, 29 June 2015). In addition, I refer the Minister to the Victorian parliamentary consideration of laws that from 17 March 2017 will implement a contact preference system in that state. See Parliamentary Debates (Hansard) Legislative Assembly Fifty-Eighth Parliament First Session Book 2 23, 24 And 25 February 2016, available at http://www.parliament.vic.gov.au/images/stories/daily-hansard/Assembly_2016/Assembly_Weekly_Feb-Jun_2016_Book_2.pdf.

374 *Director of Public Prosecutions (Cth) v Keating* (2013) 248 CLR 459, 479 [48] (French CJ, Hayne, Crennan, Kiefel, Bell, Keane JJ). Many jurisdictions therefore have express provisions in their Constitutions or law that prohibit 'ex post facto' criminal laws or penalties: See for example, Brazilian Constitution, Art 5 Sect XL; Canadian Charter of Rights and Freedoms, s11(g); French Penal Code, Art 112-1; Constitution of Ireland, Art. 15.5.1; Wetboek van Strafrecht (Criminal Law) (Netherlands), Art 1; Portugese Constitution, Art 29. In Australia the general presumption against ex post facto criminal laws is found at common law.

offenders may be unconstitutional.[375] On occasion, however, laws are acceptably passed that relate to actions undertaken in the past. In Australia there has been judicial recognition of the power to pass 'retrospective' legislation'[376] that applies to situations where no law existed at the time, or the prior law is seen to give rise to an injustice that needs to be corrected.[377] This is so, even if such laws 'might be considered to work some injustice to one party, but are clearly required to rectify a manifest injustice to others'.[378]

In Western Australia an example of laws that had retrospective effect in the context of ART includes the recognition of the mother of a child *and her female or male partner* as the legal parents of a child born as a result of donor-conception. This in effect meant that the birth certificate shows the child's legal parentage and not their genetic parentage. It is also relevant to note that on the 30 April 2018 the Western Australian Attorney-General provided written submissions in support of the State of Victoria in the High Court case of *Craig William John Minogue v State of Victoria* [2018] HCA 27 in which it was stated:

> *…(a) there is nothing in the Constitution to prevent a State Parliament from enacting a law that has a retrospective or retroactive effect. Indeed, quite the opposite. This Court has held that Chapter III of the Constitution does not preclude the Commonwealth Parliament from enacting retrospective [laws]…; a fortiori a State Parliament could do so; ….*[379]

In the same case the South Australian Attorney-General submitted that State parliaments 'remain competent to enact retrospective legislation';[380] and the Queensland Attorney-General submitted: *the orthodox principle regarding retrospective laws [is] that: provided Parliament has evinced its intention with sufficient clarity, there is no constitutional impediment to passing retrospective laws*.[381]

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375 *Liyanage v The Queen* [1967] AC 259; approved in Australian Building Construction Employees' and Builders Labourers' Federation v Commonwealth (1986) 161 CLR 88, 96

376 *See R v Kidman* (1915) 20 CLR 425 per Isaacs, Higgins, Gavan Duffy, Powers and Rich JJ (Griffith CJ dissenting); *Millner v Raith* (1942) 66 CLR 1; *Polyukhovich v Commonwealth* (1991) 172 CLR 501; and *Tuitupou v Minister for Immigration and Multicultural Affairs* (2000) 60 ALD 361.Noting that where such laws deprive someone of a property right they must do so 'on just terms'. See *Georgiadis v Australian and Overseas Telecommunications Corp* (1994) 179 CLR 297; Australian Constitution Act 1901 (Cth), s 51(xxxi).

377 DC Pearce and RS Geddes, *Statutory Interpretation in Australia* (6th ed, Butterworths, Sydney 2006) p 314.

378 *Doro v Victorian Railways Commissioners* [1960] VR 84, Adam J at 86. In the United Kingdom several retrospective Acts have been passed based on Parliamentary sovereignty: See for example, *Statutory Instruments (Production and Sale) Act 1996; Caravans (Standard Community Charge and Rating) Act 1991; Domestic Rates Etc (Scotland) Act 1987; The Scotland Act 2012; The Wireless Telegraphy (Validation of Charges) Act 1954*. For discussion see Oonagh Gay, Retrospective legislation Standard Note: SN/PC/06454 Last updated: 14 June 2013 (Section Parliament and Constitution Centre).

379 *Craig William John Minogue v State of Victoria* [2018] HCA 27 Annotated submission of the Attorney-General of the State of Western Australia (intervening) [30(a)] (30 April 2018) available at http://www.hcourt.gov.au/assets/cases/06-Melbourne/m2-2017/Minogue_AGWA.pdf, accessed 30 August 2018.

380 *Craig William John Minogue v State of Victoria* [2018] HCA 27 Annotated submission of the Attorney-General of the State of South Australia (intervening) [33], (30 April 2018) available at http://www.hcourt.gov.au/assets/cases/06-Melbourne/m2-2017/Minogue_AGSA.pdf, accessed 30 August 2018.

381 *Craig William John Minogue v State of Victoria* [2018] HCA 27 Annotated submission of the Attorney-General of the State of Queensland (intervening) [6.b] (30 April 2018) available at http://www.hcourt.gov.au/assets/cases/06-Melbourne/m2-2017/Minogue_AGWA.pdf, accessed 30 August 2018.

The passing of law permitting access to information by donor-conceived people regarding donor conception that occurred before or after the commencement of the *HRT Act* is thus possible. In regard to the release of identifying information, the argument in favour of doing so is that it would rectify the manifest injustice that exists in denying people access to information based upon the date of gamete donation and the state in which that donation took place. Any such retrospective laws, however, should be fair, just and reasonable, for example, minimising the impact as much as possible on those whose positions may be changed. In considering how this might be done, it is useful to consider the analogous situation of the opening of adoption records to allow access to identifying information before considering the case of donor-conception.

Ensuring laws are fair, just and reasonable: The analogous situation of adoption

That laws may be changed retrospectively does not mean that they should, unless such a change will address the injustice done, and do so in a fair, just and reasonable way. While a number of written submissions spoke about a donor-conceived person's rights and interests 'trumping' that of the donor, there are approaches that rather seek to balance interests to provide all parties with some sense of security and control, while also requiring compromise by all. A particularly relevant approach may be found by considering the analogous situation of adoptees searching for information about their biological heritage.

Throughout much of the 20th century, many Western countries had legislation intended to prevent adoptees and adoptive families from knowing the identities of birth parents and vice versa.[382] Then after a decline in the social stigma surrounding adoption and increased understanding of the impact that denial of identifying information about their biological heritage was having upon adoptees, a number of jurisdictions changed laws with retrospective effect to allow for the release of formerly 'sealed' birth records. The changes to the laws were, however, subject to some limitations in some jurisdictions, such as contact or information vetoes which were intended to balance the interests of the parties involved.[383] Information vetoes allowed people to 'veto' the release of identifying information, while the contact veto system operated to protect people from unwanted contact by another person, while still allowing the release of identifying information. Such systems were implemented in some states of Australia, the United Kingdom, and some states in the United States.

Notably, over time the veto system, which allowed relinquishing parents or adopted children to 'opt out' of the retrospective system, has slowly been removed across jurisdictions. In 1992 the New South Wales Law Reform Commission detailed the reasoning for the retrospective release of information about adoptees in that state, reiterating there is no legal principle preventing legislation from having retrospective operation.[384] They recognised that the law relating to information about adoption needed to deal fairly with many different people and situations and that adoptions had taken place over a long period of time (from the 1920s-1970s) during which there were major changes to adoption law and practice.[385] However, in recommending retrospective laws in New South Wales that allowed identifying information release to adoptees the New South Wales Law Reform Commission concluded:

382 Allan (2017), above n 266.

383 Ibid.

384 New South Wales Law Reform Commission, *Review of the Adoption Information Act 1990*, Issues Paper 7 (1992), Chapter 3, [3.14].

385 Allan (2017), above n 266, Chapter 3.

The view that prevailed was that the law should enable adopted persons and birth parents to have the right to information, even though this did mean a change from the position as it was when the adoption order was made. The interests of those who felt threatened by the new law were acknowledged by a number of measures, notably the contact veto system.[386]

In 2010 Queensland enacted the *Adoption Act 2009* (Qld), which retrospectively removed the option of placing an information veto on identifying information that related to adoptions that occurred prior to 1991. The then acting Child Safety Minister, Karen Struthers said at the time:

No longer will we have the most restrictive adoption laws in the country…Under the new Act, which will come into force on February 1, 2010, adopted people and birth parents will have the right to identifying information regardless of when the adoption took place. The new laws balance people's right to information about their birth parents or son or daughter who was adopted, with the right of others to maintain their privacy. Currently, more than 3000 Queenslanders affected by an adoption that occurred before 1991 are prevented from obtaining identifying information about their birth parents or son or daughter who was adopted. The new Act will give these people the right to access information about their own identity or that of a son or daughter for the first time. The new laws will make it possible for people to access identifying information about themselves and their birth parents but still requires them to respect another person's privacy if they do not wish to be contacted.[387]

The explanatory memorandum of the Queensland bill details that peoples' privacy would be protected via enabling contact vetoes and placing fines for breach of such vetoes. It states that 'retrospective removal of their rights must be balanced with the benefits that arise by allowing other parties to those adoptions access to information about their identity, family and heritage. The change in the law also ensures that parties … are treated equally, regardless of when the adoption occurred, as there is no longer any entitlement to object to the release of identifying information.'[388]

Western Australia previously allowed for both contact and information vetoes. Contact vetos placed prior to 1 June 2003 are still valid; no further vetos have been accepted from this date. All information vetos were removed on 1 June 2005. This means every adopted person can obtain her/his original birth certificate and birth mothers can obtain their child's adoptive details. A person seeking access to information where a contact veto is in place is required to be interviewed by an approved counsellor and to sign an undertaking not to contact the person who has placed the contact veto. Breach of the undertaking imposes penalties of $10,000 and 12 months in prison. The purpose of counselling in these instances is to ensure that the rights of all involved parties are fully understood and that people are made aware of some of the issues which may arise in the search and reunion process.[389]

386 Ibid.

387 Queensland Government, Department of Child Safety statement (archived) reported at http://www.mysunshinecoast.com.au/articles/article-display/new-adoption-laws-for-queensland,16035 accessed 8 January 2017.

388 Adoption Bill 2009 (Qld), Explanatory Memorandum, pp 19-20. http://www.legislation.qld.gov.au/Bills/53PDF/2009/AdoptionB09Exp.pdf accessed 30 August 2018.

389 The Australian Institute of Health and Welfare, Adoptions Australia 2006-2007, (2008).

The Victorian Adoption Network for Information and Self-Help Inc. (VANISH) notes that despite the initial anxiety surrounding the retrospective release of identifying information to adoptees it is now well accepted that it is normal for adopted people to want information about their birth parents, and information release has proceeded well.[390] Consideration of what has occurred in other jurisdictions also highlights this point.

United Kingdom

Since 1930 in Scotland, adopted persons aged 17 and older have had the right to access to their adoption records and original birth records.[391] In England and Wales laws have been adopted and changed over more than 40 years regarding disclosure and contact.[392] Debates followed the same course as has been seen in Australia, including that there was support for access to past records, but opponents worried that opening records would violate promises to birth mothers that children would not be able to trace them, and lead to unwanted contact or people full of resentment 'landing' on the mother's doorstep. Compulsory counselling prior to being able to access birth records was thus required.[393]

Approximately 225,000 people (55 per cent of 550,000 people adopted in the United Kingdom) have now sought genealogical information and/or established contact with a birth relative. Carp notes, *'no cases have been reported of blackmail or vindictiveness being displayed on the part of adopted people… Studies have demonstrated that searches for birth family members by adopted adults have been highly successful'*. He notes further that *97 per cent of the searchers state that meeting their birth relatives made no difference in their feelings for their adoptive parents*.[394]

United States

In the early 1980s in the United States, voluntary mutual consent adoption registries and intermediary services were established in a number of states to assist adoptees searching for information and/or contact. However, complaints that such registries and intermediaries were 'cumbersome, expensive, and ineffective' led to calls that adoptees deserved equal rights to information. In response in 1998 Oregon passed laws that enabled access to information, subject to a contact preference form.[395] By May 2018 there had been 12,201 records issued and 702 contact preference forms submitted by birth parents – 577 asked for contact with the adoptee, 37 asked for contact through an intermediary, and 88 asked for no contact.[396] There have been no reported adverse events or harm to any party reported, including birth parents.[397]

390 Commonwealth, Senate Committee Hansard, 3 November 2010, 65-70, Mr. Cole (from VANISH).

391 *The Scottish Adoption Act 1930* (UK).

392 See for example, *Children Act 1989* (UK); *Adoption and Children Act 2002* (UK)

393 E. Wayne Carp, 'Does Opening Adoption Records Have an Adverse Social Impact? Some Lessons from the U.S., Great Britain, and Australia, 1953–2007' (2007) 10(3-4) *Adoption Quarterly*, 29-52.

394 Ibid, p. 43.

395 Ibid.

396 Oregon Health Authority, Measure 58 History, http://public.health.oregon.gov/BirthDeathCertificates/GetVitalRecords/Pages/58update.aspx#05312010 accessed 30 August 2018.

397 American Adoption Congress, State Legislation Website, http://www.americanadoptioncongress.org/state.php#OR accessed 30 August 2018.

Many other states in the United States now also have laws that allow access to identifying information, with or without contact vetoes. A number have seen the progressive removal of such vetoes. States that allow access to identifying information noting the use of such vetoes include:

- Alabama uses contact preference forms
- Alaska provides the original birth certificate (OBC), no contact vetos/preferences
- Colorado, access to records and birth certificates has been available for some time but different rules applied dependent on when the adoption took place. Amendments to the law in 2014 eliminated different standards of access. The law also removed prior ability to place a contact preference as it was no longer seen as necessary
- Kansas, adoption records were never sealed and adoptees could always access information once they turned 18
- Maine, access legislation was enacted on January 1, 2009, allowing adults, age 18 and older, to get their OBC, with more than 1,280 OBCs having now been released. Of the limited number of birth parents completing Contact Preference Forms, only eight have requested no contact
- New Hampshire, since June 2005, OBC have been available to adoptees age 18 and older. As of January 2012, over 1,572 OBCs were released. Only 12 birth parents have indicated they do not want contact. No harm has been reported
- Rhode Island, since 1 July 2011 adult adoptees 25 years of age or older may obtain a non-certified copy of their original birth certificate. Since July 2, 2012, 759 adoptees have received their OBC with 10 birth mothers indicating a preference for no contact.[398]

I could find no official reports in the above jurisdictions of the biological parents' lives having been destroyed, as had been repeatedly predicted by those who opposed the release of identifying information. In the years that have followed such release, there have been no reports of privacy violations, nor the break-up of families as a consequence of unwanted contact. Very few people placed 'no contact' preferences on their form.[399]

Ensuring laws are fair, just and reasonable: Applying the analogy to donor conception

While circumstances surrounding their conceptions and births are clearly different, the analogy between adoptees and donor-conceived people can be drawn in relation to their search for information about their biological heritage.[400] In particular, it has been shown that donor-conceived and adopted people may share common feelings and impacts of being denied information about their status, being denied access to information about their biological parent(s) and or siblings, and about the secrecy that has shrouded such practices.[401]

398 S. Allan (2017) above n 266

399 Ibid.

400 R. Chisholm, 'Information rights and donor conception: Lessons from adoption?' (2012) 19(4) JLM 722.

401 A. Turner and A. Coyle 'What does it mean to be Donor Offspring? The Identity Experience of Adults Conceived by Donor Insemination and the Implications for Counselling and Therapy' (2000) 15(9) *Hum. Reprod.* , 2041.

Like adoptees, an increased call for identifying and non-identifying information has occurred globally as donor-conceived people have grown. Many have called for similar treatment as that accorded adoptees, in which records have been opened with or without an option for a contact veto/preference to 'balance rights'. In the Senate Committee Inquiry into donor conception practices in 2010, Mr Egan of Family Voice Australia commented:

> *if legislation establishing a national register was retrospective, contact vetoes could be put in place the way they are in adoption cases. No-one wants to force themselves on someone else, but they do have a right to know where they come from, who they are, who their relatives are and so on. That should include the ability to track donor siblings, so you know who your brothers and sisters are. That seems to me a fundamental human right.*[402]

After many years of research, consultation, and reflection, and again in relation to the review of current laws, practices, and beliefs in Western Australia, I have also reached the conclusion that contact vetoes or preference forms are a way to balance competing interests when they exist, while allowing for release of information to all donor-conceived people who seek it.[403] The donor's privacy is protected by allowing him/her to control the intimate sphere of their daily lives from intrusion.[404] Simultaneously, the donor-conceived person's privacy[405] is respected by allowing access to information necessary to uncover the truth about an important aspect of his or her personal identity. However, there is also a compromise. If the donor refuses contact via a contact veto/preference statement, then the donor-conceived person's 'rights' do not go so far as to be able to act to establish a relationship with the donor.[406] (Similarly, if a donor-conceived person wishes to place limits on contact, they may).

The Victorian Law Reform Committee accepted this approach in its 2012 inquiry into access to information by donor-conceived people in Victoria. That Committee subsequently recommended release of information to all donor-conceived people pursuant to the contact veto system. The Chair, Mr Clem Newton Brown said:

> *While the release of identifying information to donor-conceived people may potentially cause discomfort and distress to donors (although this will not always be the case), it is certain that donor-conceived people are actually suffering from their lack of knowledge about donors. Although debates about the consequences of releasing identifying information often focus on the suffering that donors may experience, the fact is that many donor-conceived people are already suffering, in some cases quite profoundly, from not having access to this information.*[407]

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402 Commonwealth, Senate Committee Hansard, 29 October 2010, pp 19-20, Mr. Egan (Family Voice Australia).

403 See for example, S. Allan (2011) above 372.

404 As noted by *Lord Mustell in R v Broadcasting Standards Commission; Ex parte British Broadcasting Corp* [2001] QB 885 at [48].

405 In the context of 'rights' in the United Kingdom a donor-conceived person's right to privacy has been recognised as a 'right to obtain information about a biological parent who will inevitably have contributed to the identity of his child'): *Rose v Secretary of State for Health and Human Fertilisation and Embryology Authority* [2002] EWHC 1593 (Admin).

406 In European Court of Human Rights this was recognised in the early decision of *X v Iceland* (Application 6825/74) (1976) 5 DR 86 at 87 to be part of the concept of 'respect for private life' now protected by Art 8 of the European Convention on Human Rights.

407 Victorian Law Reform Committee, *Inquiry into Access by Donor-conceived people to Information about*

As noted above, laws that adopted this approach came into force on 1 March 2017. Breach of a contact preference will result in a significant fine (of approximately $7000). Recommendations for the same approach to be adopted in South Australia were shown bi-partisan support during the review of their legislation and await implementation.

Note, this approach does not mean that identifying information about a person should be released without sensitivity and support. A system that allows the release of identifying information should be respectful to the person(s) about whom such information relates. It should require a reasonable attempt to contact them *prior* to any such release. In contacting them, the process of information release should be explained, and they should be offered support services. The person would also be given the opportunity to lodge a contact veto/preference statement, and to access intermediary services if wanted if they are open to contact. The release of such information should not occur until the donor has been contacted, or after a reasonable period of time during which a donor cannot be located (or if the donor is deceased). If a contact veto/preference is lodged, a donor-conceived person should have to meet with the appropriate support services and undertake not to breach the veto/preference prior to being able to access information. Breach of any contact veto/preference statement should be subject to an appropriate penalty.

Although in the adoption context such contact veto systems have been removed over time, donor conception differs from adoption due to the potential for high numbers of offspring and the number of families. For some people who donated gametes in the past, the thought of contact with all such people may be overwhelming. The right to control whether, and if so to what extent, such contact occurs may serve to ensure a person feels in control and that they are supported in light of changes to the law.

Submissions regarding the retrospective release of information

The review received numerous written submissions from a variety of stakeholders that supported the retrospective release of identifying information to all donor-conceived people, regardless of when the donation took place.[408] A number of submissions also supported such release being subject to parties having the option to place a contact veto and the availability of intermediary and support services, as has occurred in Victoria.[409]

the Donors (March 2012) p 73.

408 SQC Family Planning Association of Australia, Submission 6; Rodino & Clissa, Submission 8; Sharon Genovese, Submission 32; Damian Adams, Submission 40; Marilyn Crawshaw, Submission 46; Trevor Harvey, Submission 47; Confidential, Submission 49; Myfanwy Cummerford, Submission 50; Brenda Harvey, Submission 51; Peter Tavi-Pinto, Submission 53; VANISH, Submission 54; International Social Service (ISS) Australia, Submission 55; ANZICA WA (Fertility Counsellors), Submission 62; Ross Hunter, Submission 63; Kerri Farvarato, Submission 67; Hollywood Fertility, Submission 74; Australian Christian Lobby, Submission 77; Bridgitte Reynolds, Submission 78; LJ Goody Centre for Bioethics, Submission 85; Giselle Newton, Submission 86; Sherrie-Lee Long, Submission 88; Coalition for the Defence of Human Life, Submission 90; Confidential, Submission 92; FINRRAGE, Submission 92; Australian Medical Association (WA), Submission 96; Katherine Vowles, Submission 100; Beth Wright, Submission 102; Hayley Smith, Submission 106; David Freilich, Emeritus Chief Rabbi of Western Australia, Submission 112.

409 Damian Adams, Submission 40; Marilyn Crawshaw, Submission 46; Confidential, Submission 49; International Social Service (ISS) Australia, Submission 55; Bridgitte Reynolds, Submission 78; Giselle Newton, Submission 86; Sherrie-Lee Long, Submission 88; Confidential, Submission 92; Beth Wright, Submission 102.

In consultations with donors, as well as a donor's partner about this option, some said they were open to contact; and some were already in contact with some of the donor-conceived offspring as a result of DNA Ancestry Tracing.[410] They described having always known that there was a possibility that the donor-conceived offspring may one day come to find them, and acknowledged that with DNA testing this was now a reality. They were very supportive of an approach that would give donors the option of placing a contact veto or enable them to express their preferences as to how contact may proceed. They were also in favour of having the option to engage with support and/or intermediary services, saying they felt this would assist them. Some emphasised how important this was and how they felt that it needed to be addressed urgently, as they did not know how many donor-conceived offspring there were, and although open to contact would welcome support in navigating these new relationships.

Consideration of the Victoria implementation of retrospective legislation

I also considered how the system is operating in Victoria, as at the time of reporting on this review the Victorian system had been operational for approximately 18 months. In that state recall that from 1 March 2017 legislation was enacted to provide *all* people conceived in Victoria from donor treatment the right to know their donor's identity. Previously the identities of pre-1998 donors could only be released with a donor's consent while sperm, egg or embryo donors who donated after 1998 were identifiable when the offspring turned 18. Emphasis in the passage of the bill[411] that changed this was given to honouring the guiding principles of the Victorian ART Act, that "the welfare and interests of persons born or to be born as a result of treatment procedures are paramount" and that *"children born as the result of the use of donated gametes have a right to information about their genetic parents."*[412]

Under the current law contact preferences are available to pre-1998 donors and donor-conceived people. Pre-1998 donors can also lodge contact preferences to cover their own children aged under 18 years and parents or guardians of donor-conceived children aged under 18 years can lodge a contact preference on behalf of the child. (Note, donors and parents are also able to apply to the Central Register for information about someone to whom they are connected via donor conception. However, *identifying* information will only be released if the person they want information about provides consent for this to occur.)

In their 2016-2017 Annual Report, VARTA reported that of the 92 Central Register applications received in that financial year, 57 applications were received between 1 March and 30 June 2017, after the new legislation came into force. Of those 57 applications, 42 related to the pre-1998 donor treatment period and 15 to the post-1998 donor treatment period. Of these applications, 42 per cent were received from donor-conceived persons, 41 per cent from recipient parents and 16 per cent from donors. Additionally, there were 45 applications relating to the 2015-16 financial year still in progress in relation to counselling and donor-linking matters. They further report:

410 I speak generally about what these persons said to me during private meetings so as not to publicly identify them.

411 Assisted Reproductive Treatment Amendment Bill 2015 (Vic.)

412 *Assisted Reproductive Treatment Act 2008* (Vic) s 5

> *There have been a variety of outcomes since VARTA started managing applications to the Central Register on March 1. Some pre-1998 donors who could not be previously located have been found and have been open to the exchange of information and contact with donor-conceived applicants. Other pre-1998 donors have lodged contact preferences specifying no contact or a specific means of contact with a donor-conceived applicant. Some pre-1998 donors who have chosen no contact have provided contemporary medical and personal information for the donor-conceived applicant.*[413]

This indicates that the system is working as intended, providing identifying information to applicants, while giving people the choice to control the level of contact they have (if any), and how such contact occurs. In speaking with the VARTA CEO this was confirmed, with her noting that only a small number of donors had placed contact vetoes.[414] It was also noted that counsellors provided information and supportive services associated with applications to the donor conception registers to 151 people over the 2016-2017 financial year, with 89 of those people provided with supportive services since 1 March 2017.[415]

Hayley Smith, a donor-conceived woman living in Victoria, in her written submission to the Review said:

> *…having access to records and information about my biological identity has profoundly impacted my life for the better. The recent law changes allowed me to apply for contact, and despite donating anonymously almost 30 years ago, my biological father has been warm and open to forming an ongoing friendship with me. I deeply feel that I have been given a sense of peace and a sense of self-confidence which I'd been missing due to finally understanding my biological identity. The experience has been mutually beneficial to both my biological father and me, and my parents have been nothing but loving and supportive in this endeavour. Every donor conceived Australian deserves the right to seek this experience and to not be discriminated against based on the State in which they were conceived.*

6.4.3 The 'consent-first' approach

The alternative approach would be to allow for the release of *identifying* information for pre-2004 donations only with the consent of the donor. This would basically maintain the status quo in Western Australia for pre-2004 donations. That is, the current law allows access to identifying information by donor-conceived people only when there is consent by the donor. Currently, this requires a donor to place their information on the Voluntary Register (discussed above at 5.6.2) and thus reflects a passive approach in that it waits for someone to place their details/consent on that register rather than actively seeking consent.

413 VARTA, Annual Report 2016-2017 (2017), p 11.

414 Teleconference with VARTA CEO, 20 July 2018.

415 VARTA, Annual Report 2016-2017 (2017), p 13.

An alternative active approach would require that donors be actively contacted to ask them whether they consent to the release of identifying information. This approach was adopted as an interim measure in Victoria and involved donors being contacted by a third party to seek consent when a request for information was made. That approach was subsequently changed to allow for the release of all information regardless of whether consent had been obtained as the two-tiered system (allowing access to some and not others based on the date of donation) was seen to be inequitable.

The active approach was also adopted in the Netherlands for pre-2004 donors (anonymity being abolished post-2004). There, clinics were required to contact *all* past donors and ask them for their consent, regardless of whether an inquiry had been made. All details of the donors were transferred to the register but identifying information could only be released if consent was forthcoming. My prior research revealed that there was some opposition by clinicians in the Netherlands to this requirement, and it is unknown whether all donors had been contacted.[416]

The Review received one written submission that explicitly supported the consent-first approach currently taken in Western Australia (referred to as 'opt-in') from the Reproductive Technology Council.[417] A policy officer in the RTU also stated her support for maintaining the current requirement for consent for pre-2004 donations. Interestingly, and of note, is that this position does not accord with the many people who participated in this Review and spoke to the issue. Nevertheless, there may be other members of the community, including past donors, who support this approach, but who did not participate in the review.

The argument in favour of the 'consent-first' approach is that waiting for, or actively seeking via a third-party, the donor's consent would not interfere with the donor's right to privacy or previous assumptions about anonymity – albeit active consent approaches still require contact by a third party to ask for the donor's consent.

The argument against the 'consent-first' system is that it is akin to having an information veto. That is, whether identifying information is released depends *solely* upon what the donor decides. The consent first approach, therefore, weighs in favour of a donor who may decide he/she does not wish for such information to be released, rather than the donor-conceived person's interests in having such information. There is no 'balancing of rights or interests' in the true sense, as one person's interests are permitted to trump another person's interests, without compromise. A contact-veto system, in comparison, enables the donor-conceived person to have the information they seek, while the donor may protect his/her privacy via deciding whether or not to have contact – thus balancing interests.

It is again noted that the reality that identifying information maybe, and is increasingly being, obtained via DNA testing and ancestry-tracing needs also to be considered. Enabling people who have found information, or about whom information has been obtained, to place details on a central register is desirable, as is supporting them to link in with a system that provides intermediary and support services if desired. In fact, this might provide more protections for those who want them than are currently available.

416 Sonia Allan, *A Cross-Jurisdictional Study of Regulatory Requirements and Practice Regarding the Recording of Donor Information and its Release to Donor-conceived people 2012* Report prepared for the Winston Churchill Memorial Trust.

417 Reproductive Technology Council, Submission 122.

6.5 Access to information about siblings

The question of whether people should be able to access information about their donor-siblings was also considered. For many donor-conceived people this is especially important to avoid risks or fears concerning forming consanguineous relationships (see discussion in above at 5.2.2). There is also a desire for openness, honesty, as well as a call for information sharing that recognises and shows acceptance of their family formation and extended kinship. Myfanwy Cummerford, a donor-conceived person from Victoria, shared her experience of connecting with her sister with the review:

> *… I was also very fortunate to be able to make contact with one of my donor-conceived sisters, we have a lot in common and I am loving getting to know her. I am so very grateful that donor-conceived people in my state now have the choice to find out more about their biological family members should they wish to do so. I hope that Western Australia will follow Victoria's lead in legislating to facilitate access to identifying information about donors for donor-conceived people and the services required to support the release of that information.*

When people discuss access to information, they most often refer to both donor and siblings. However, a statutory right to access identifying information has only been recognised in relation to donor and offspring relationships.

In Western Australia recipient parents or donor-conceived people may place their details on the Voluntary Register stating they are seeking matches with a sibling(s). If a match occurs, they will be able to obtain identifying information. Bridgette Reynold's joy at having found her donor-sister in this way was noted above at 5.6.2.[418] Non-identifying information, such as number, year of birth, and sex of donor-siblings, was also previously provided by the Voluntary Register when it was a practice that register staff contacted the clinics to find out information that may assist the inquiry. However, as mentioned above, following a change in policy the Voluntary Register no longer contacts clinics to obtain this information, they also do not access information from the RT Register. Rather donor-conceived people are now required to contact clinics themselves. Donor-conceived people may receive non-identifying information, such as number, year of birth, and sex of donor-siblings in this way, although as discussed above, some found it difficult to contact clinics themselves. That they are asked to do so also diminishes the functions of the register to one that simply holds information provided to it, without enabling outreach or investigation on people's behalf. This is not satisfactory.

In considering how the Donor Conception Register should operate in the future, it is important that recipient parents (if a person is under 18) and donor-conceived people who are of sufficient maturity be able to engage with the Donor Conception Register in order to seek access to information about siblings that share the same donor. This should include not only donor-conceived children but also the donor's own children. At a minimum, the donor-conception register must be able to communicate to a donor-conceived person non-identifying information including, how many siblings they have, their sex, and year of birth.

418 Bridgitte Reynolds, Submission 78.

Beyond this, the release of identifying information may be subject to registration by both parties on the Donor Conception Register of a willingness to exchange such information and liaison with appropriate support/intermediary services if required. Where only one party registers, it is noted, that 'active' outreach may alert siblings to their being donor-conceived if they do not know their status. This may be distressing for some people and thus should be carefully considered. However, active outreach should not be precluded if particular circumstances require it. For example, if a donor-conceived person has discovered a serious heritable disease or another issue that siblings should be advised of, such outreach should be possible. As such intermediary services should be able to determine whether it would be appropriate to contact the sibling and have the authority to do so (or their parent(s) if the sibling is under 18).

6.6 Donors: Access to information

The issue of whether donors should have access to information about the children born as a result of their donations was also considered as part of how to manage information in relation to the donor-conception registers.

In Western Australia currently, identifying information about donors who donated after 2004 can be released to donor-conceived people at the age of 16. Donors (pre- and post- 2004) may also place their details on the Voluntary Register and can be linked/matched to recipient parents and/or donor-conceived people. It is noted that donors may also ask clinics to inform them of non-identifying information about people born as a result of their donation, including sex, year of birth, and number. However, this does not appear to be actively provided to them.

In Victoria, donors may apply to the register for identifying information about any offspring. An inquiry to VARTA leads to the recipient parent(s) or donor-conceived person over the age of 18 being contacted to ask if they consent. This practice has led to some people who did not know they are donor-conceived finding out for the first time. In discussing this with the CEO of VARTA I was informed that of the applications received by donors roughly half of the donor-conceived people contacted did not know that status. She said that 'even so, around half are willing to exchange information'. She emphasised that this is 'incredibly sensitive work' and that only more senior counsellors were engaged in it. When asked why donors made such requests she noted that it was largely for very important reasons, such as medical conditions.

In considering the future operation of the Donor Conception Register, again it is seen as important that at a minimum it must be able to communicate to a donor non-identifying information about how many children have been born as a result of their donation, their sex, and year of birth. Beyond this, the release of identifying information may be subject to registration by both parties on the Donor Conception Register of a willingness to exchange such information and liaison with appropriate support/intermediary services if required. Where only one party registers, it is noted, that 'active' outreach may alert children to their being donor-conceived if they do not know their status, that this may be distressing for some people, and thus should be carefully considered. Nevertheless, active outreach should not be precluded if particular circumstances require it, for example if a donor has discovered a serious heritable disease or illness which the offspring should be warned about. As such intermediary services should be able to determine whether it would be appropriate to contact the donor-conceived person and have the authority to do so (or their parent(s) if the donor-conceived person is under 18).

I also recommend that active notification to donors regarding non-identifying information about the children born as a result of their donation(s) should be required by clinics. This would allow a donor to keep informed of the number, age and sex of children that have been born, who may one day wish to have information about, and contact with, the donor. It may also encourage donors to notify the register if heritable medical conditions are discovered, as they will be aware of living people who may be at risk. Donors have also previously expressed to me that they felt that active notification would demonstrate appreciation for their part in helping conception to occur and help them in not feeling dismissed or forgotten once the donation had been received.[419]

6.7 Voluntary registration on Donor Conception Register

In some situations, clinics or practitioners that were involved in early donor-conception may no longer have records, or the donor-code may have been lost or destroyed. When this is the case, there needs to be an option for past donors and donor-conceived people to register on the donor-conception register on a voluntary basis. This may involve, for example, a donor registering that he was a sperm donor, where he donated, and when; or a donor-conceived person or recipient parent(s) registering information known to them to increase the chances of possible matches to donors and siblings.

It may also involve people registering as a result of DNA testing. Such testing may in the first instance have been a direct-to-consumer test that revealed relatedness, but registration on the Donor Conception Register may require a further test from a service that would be recognised as a legally valid test in establishing relatedness (e.g. from a NATA-accredited facility). This would ensure the integrity of the data held by BDM (albeit a higher standard than that required for natural births, where all that is required is that the mother names someone as the father (other parent) without the requirement to prove biological relatedness.)

If a 'consent-first' approach was taken for pre-2004 donations, all such parties should also be able to register their consent to release of identifying information directly on the Donor Conception Register – that is, rather than maintaining a separate Voluntary Register. It will be important in such instances that the operation of the Register and the linked intermediary and support services will then be able to put in place the requisite processes to assist with the release of information and family linking, as required.

It is not recommended that the Donor Conception Register be able to hold gifts as this raises numerous issues concerning ownership, storage, and deceased estates, and moves beyond the administration and facilitation of information exchange and possible contact between donors, recipients, and donor-conceived people. The intermediary services, however, may wish to facilitate the exchange of letters, photos, gifts or other things, once parties are engaged with family linking.

Where a person wishes to leave something for an unknown genetic relative, it may be more prudent to express such a wish in their own will.

The intermediary and support services may also keep a record of people who are unable to place their name upon the donor conception register (*e.g.* due to an inability to prove donor status), but who are seeking information or open to contact.

419 Sonia Allan, *Review of the Assisted Reproductive Treatment Act 1988* (SA) Donor consultations, 21 April 2016.

6.8 Notification of donor-conceived status, birth registration, and birth certificates

6.8.1 Parental disclosure of donor-conceived status

Potential recipients of donor gametes or embryos are not required in Western Australia (or anywhere else in Australia) to make any formal undertaking prior to treatment that they will tell their child(ren) that they are donor-conceived. Nor is there a legal obligation upon them to do so after birth.[420] However, it is a requirement pursuant to the NHMRC Ethical Guidelines and RTAC Code of Practice, that persons considering the use of donor-conception should be counselled to understand the implications of using a donor(s) to build their family, the importance of disclosure to children that may result, and the right of such children to access information. Accreditation by RTAC is required by law in Western Australia for the purposes of licensing and is recommended above to continue should the system change to one of registration.

The NHMRC Ethical Guidelines, with which all licensed ART providers are required to comply, provide:

> *Clinics should help prospective recipients to understand the significant biological connection that their children have with the gamete donor. Recipients should be advised that their children are entitled to knowledge of their genetic parents and siblings; they should therefore be encouraged to tell their children about their origins.*[421]

The RTAC Code of Practice states *'counselling by a suitably qualified counsellor with training and experience in assisted reproductive technology is mandatory for all donors, recipients and surrogates.'*[422]

It was submitted to the review that more could be done regarding the provision of ongoing information and support to recipient parents about how to tell their children of their status and discuss donor-conception with them as they grow.[423] For example, Marilyn Crawshaw emphasised that *'parents of donor-conceived offspring should be provided with ongoing support, if they wish it, with talking with their children about their origins and associated matters.'*[424]
In 2002 the Western Australia RTC produced a pamphlet on 'Talking to children about donor conception', which was circulated to relevant organisations and groups during the year, with the aim of providing practical assistance to parents of donor offspring in telling their child about the method of his/her conception. The Western Australia RTC has the pamphlet on its website and has on occasion run forums about telling.

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420 Croatia is the only jurisdiction in the world that places a legal obligation upon the parents of a donor-conceived person to inform them about the nature of their conception no later than the age of 18. (See ZAKON O MEDICINSKI POMOGNUTOJ OPLODNJI (Law on Medically Assisted Reproduction, 12 July 2012) (Croatia), No: 71-05-03 / 1-12-2, Article 15(2).) How such a requirement will (or could) be enforced is unknown. Active encouragement and support in telling may be more effective than imposing a legal obligation that would be difficult to enforce.

421 *NHMRC Ethical Guidelines*, [6.1.2]. It is noted that a similar obligation exists for clinics in relation to donors: see *NHMRC Ethical Guidelines* [6.1.1

422 Fertility Society of Australia and the Reproductive Technology Accreditation Committee, Code of Practice for Assisted Reproductive Technology Units (Revised 2015), p13. (Critical Criteria, Section 12. See further discussion of oversight requirements in Chapter 2

423 See for example, Marilyn Crawshaw, submission 46.

424 Marilyn Crawshaw, submission 46.

In Victoria the 'Time to Tell Campaign', which is run by VARTA and has been operating since the previous ITA was in its place, is aimed at encouraging and supporting parents to share information about the method of conception and the donor with their children.[425] Workshops are held on an annual basis for those considering donor-conception, and those who are at different stages following its use. They include talks by other families, donors, and donor-conceived people, and educate people about the issues that they may face. Such events are well attended and are extremely successful. VARTA also maintains an excellent website with information about disclosure (among other things). Such a campaign should be encouraged in Western Australia.

6.8.2 Recording and notification of donor-conceived status

While encouraging parents of donor-conceived people to inform them of their status is the preferred approach, for a variety of intra and interpersonal, social and family life cycle factors, many children born as a result of the use of donor conception are not informed that they are donor-conceived.[426] This is despite it being considered to be in the best interests of children to know.[427] Alongside increased moves toward openness, there has also been a call for mechanisms to be put in place to ensure there are mechanisms to notify a person of their donor-conceived status, as access to information cannot occur without knowing one is donor-conceived.

In considering this, and as noted in Chapter 5, a number of jurisdictions that allow for information release have also moved to legislate to require that donor-conceived people be informed of their status via addendums to birth certificates, recording of status on birth records, or a legal requirement of parents to inform the person of their status.[428]

In Victoria the parent(s) of a child is required to include on the birth registration statement whether the child was conceived by a donor-treatment procedure; and the name and address of the registered ART provider or doctor who carried out the donor-treatment procedure.[429] The Registrar is required to mark 'donor-conceived' against the birth entry.[430] Since 2010 Victoria has also required an addendum to the birth certificate of a donor-conceived person.[431] On applying for a birth certificate at or after age 18, a donor-conceived person in Victoria will be told there is more information about them held on the register. This is intended to encourage parents to be open with their children about the child's origins. The Registrar must not issue the addendum to any person other than the person conceived by a donor treatment procedure named in the entry.

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425 Louise Johnson, Kate Bourne and Karin Hammarberg, 'Donor conception legislation in Victoria, Australia: the "Time to Tell" campaign, donor-linking and implications for clinical practice' (2012) 19(4) *Journal of Law and Medicine* p 803-819. The Time to Tell Campaign has been said to have been modelled on, or to mirror, the very successful workshops run by the United Kingdom Donor Conception Network: 'Telling children about being donor conceived'.

426 A. Indekeu, K. Dierickx, P. Schotsmans, K.R. Daniels, P. Rober, and T. D'Hooghe, 'Factors contributing to parental decision-making in disclosing donor conception: a systematic review' 19 (6) *Hum. Reprod.* Update (November/December 2013), 714-733 first published online June 27, 2013 doi:10.1093/humupd/dmt018

427 A. Barron and R. Pannor Lethal Secrets: The Psychology of donor insemination problems and solutions (2008). Las Vegas, NV: Triadoption Publications.

428 Sonia Allan (2017) above n 266.

429 Births, Deaths and Marriages Registration Regulations 2008, regulation 7(g) & (h).

430 *Births, Deaths and Marriages Registration Act 1996* (Vic) s 17B(1).

431 *Assisted Reproductive Treatment Act 2008* (Vic), s 153; *Births, Deaths and Marriages Registration Act 1996* (Vic), s 17B(2).

In South Australia changes to the *Births, Deaths and Marriages Registration Act 1996* (SA), in September 2016[432], provide for the recording of particulars about the biological parent(s)[433] (if known) on the birth registration statement; and for the inclusion of a biological parent on the birth certificate of the donor-conceived person if they consent, or their legal parent(s) or guardian(s) consent to such inclusion and the donor-conceived person is under the age of 18.[434] Such provisions have been operationalised by including a space on the birth registration statement to include a known donor's details noting a donor must also sign the registration statement to acknowledge they were a donor. Following registration, a standard birth certificate shows the details of the legal parents; a second birth certificate may also be issued that includes details of any donor(s).[435] People will be notified of a second birth certificate existing when they apply for their birth certificate. While these changes were intended to provide an interim measure until the donor-conception register is established in that state,[436] the review of that state's legislation recommended that they remain, as the right given to donor-conceived people to have a second birth certificate issued should not be taken away.

In Argentina information regarding the person born by the use of assisted human reproduction with gametes of a third party must be included in the corresponding base file to birth registration. It appears that donor-conceived people will be made aware of their status when they obtain this document if their parent(s) have not told them previously.[437]

Ireland has also made provision in its legislation for a note to be added to the entry in the register of births that the child is donor-conceived and that additional information is available from the National Donor-Conceived Register.[438] When a person reaches 18 years of age and applies for a copy of his or her birth certificate the Registrar General shall inform the person that further information relating to him or her is available.[439] However, note this legislation has yet to have commenced.

In Croatia, the law requires parents to inform their donor-conceived child about the nature of their conception no later than the age of 18.[440]

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432 *The Family Relationships (Parentage Presumption) Amendment Act (2016) was introduced to amend the Family Relationships Act 1975* (SA) to remove a three-year co-habitation requirement for the recognition of the domestic partner of a person who has used donor-conception to have a child, as a legal-parent of that child. Amendments to the Births, Deaths, and Marriages Act 1996 were included in a Schedule to that Act. The Act was assented to on 23 June 2016 and came into effect three months after that date.

433 *Family Relationships (Parentage Presumption) Amendment Act 2016* (SA), Schedule 1(1), amending section 14 of the Births, Deaths, and Marriages Act 1996 (SA).

434 Ibid, Schedule 1(2), amending section 46 of the Births, Deaths, and Marriages Act 1996 (SA).

435 Communicated to me by the South Australian Registrar of Births, Death and Marriages on 4 January 2017.

436 *Family Relationships (Parentage Presumption) Amendment Act 2016* (SA), Schedule 1(1) and 1(2).

437 Código civil y comercial de la nación, Article 563.

438 *Children and Family Relationships Act 2015* Act No. 9 of 2015 (Ireland), s 39.

439 Ibid.

440 Ibid, Article 15(2).

In Western Australia there is no provision to record on the birth registration statement that the child was conceived as a result of donor-conception. This would assist in notifying the Registrar of a person's donor-conceived status. It is noted that the Director of the Data and Information Unit submitted that *'an alternative for determining donor offspring and managing genetic family contacts would be if it was mandated that Birth Registration Form to include information on births that resulted from [donor conception].'* While such notification should not be used on its own (as some people may not correctly report on birth registration statements), it could be a useful tool for triangulation of data which should also be submitted to the register by the Midwives Notification System and clinics. However, as it requires self-report such data may not always be accurate.

In Western Australia there also is not any provision to notify a donor-conceived person of their status. However, given that the law recognises that donor-conceived people have a right to access identifying information about their donor, it would be consistent with this that they know their status. In this regard, the birth certificates issued to donor-conceived people in Victoria provide a model which protects people's privacy while ensuring they know their biological origins. Their birth certificates are indistinguishable from others but include an 'addendum' (extra page) stating that 'further information' about the person's birth is available. As stated above, this is intended to encourage parents to be open with their children about the child's origins. It will also alert them at age 18 to their status. It is recommended that Western Australia adopt this approach.

In addition, the *option* of placing upon a second birth certificate information about both legal and biological parentage should be possible – with clear provision that in the case of donors, such inclusion does not constitute an acknowledgement of parentage for the purposes of any law; and does not otherwise operate to make that person the legal parent of the child. The maintenance of such an option would provide a right that donor-conceived people have long fought for and would serve the restorative process of addressing the impact of secrecy and anonymity upon them.

6.9 Responsibility for costs related to the register

In relation to all records held by persons, establishments, organisations, ART clinics, or otherwise, consideration was given to how to resource the ongoing operation of, the Donor Conception Register and support services. It was noted that the existence of the Donor Conception Register would not, and should not, negate current operating clinics' responsibility for the collection and recording of information pertaining to donors, recipients, and any child(ren) born as a result of the use of donor gametes or embryos. By enabling the transfer of information onto the Donor Conception Register, the Government provides a service to the clinics by way of maintaining a register upon which information and records relating to donor-conception would be stored in perpetuity. It would also be assisting the clinics in their responsibilities toward donors, recipients, and donor-conceived people to provide for, and to facilitate, information exchange, noting intermediary and support services in relation to release of information would also predominantly be taken over by the Government by way of engaging a third-party provider of such services.

It is recommended that consideration be given to whether an annual fee should be levied upon ART clinics to help to support the functions of the regulatory system, including but not limited to the Donor Conception Register and intermediary and support services. This could be somewhat akin to the charging of fees to clinics in the United Kingdom by the HFEA. Ultimately, such matters are beyond my expertise or remit, and I defer to the Minister for Health and others to determine and direct Government funding and any registration or other fees.

Ideally, other people holding records (for example, General Practitioners, retired ART providers, or otherwise), should also be required to come forward to provide to the Donor Conception Register any information they have on past donors, recipients, and donor-conceived offspring. A fee may be levied in such instances to transfer any records they hold to the register, or the Minister may consider waiving the fee in special circumstances to encourage people to come forward and provide whatever records they have. For example, when a family of a former provider have inherited information/records that they wish to pass to the register.

6.10 Discussion

This chapter has considered numerous issues relevant to the future operation of the Donor Conception Register and associated matters. It has drawn on extensive inquiry, reflection upon submissions, consultation with people in Western Australia, visits and discussions with people across other states, and consideration of various models and systems across the world. Following on from the discussion in Chapters 4 and 5, it examined where the Donor Conception Register should be held, concluding that the office of Births, Deaths and Marriages would be the most appropriate location. This should be coupled with the provision of intermediary and support services provided by a 'trusted agency' that has expertise in supporting people seeking information about their biological heritage, and the provision of search and intermediary services related to family linking. Post-adoption agencies have delivered such services in Western Australia.

The Register's operation was then considered in further detail. Whether the Register should provide access to identifying information to all donor-conceived people was examined. It was noted that since the inception of the *HRT Act* and HRT Directions, clinics have been made aware and required to notify their donors that changes in policy and legislation in the future could result in donor-conceived offspring being given such a right. Evidence was presented that consent forms prior to the 2004 amendments which prospectively granted such a right, included such information. Reference to other jurisdictions and a consideration of how to balance the rights of all parties led to the conclusion that retrospective access to identifying information should be granted to donor-conceived people about their donors, subject to parties being able to register a contact veto.

Consideration of access to information about siblings, and by donors about the donor-conceived offspring born as a result, was also had. It was concluded that registration of consent to release of information upon the Donor Conception Register by donor-conceived people searching for siblings and donors should be possible. In addition, the intermediary services should have the authority to contact the relevant donor-conceived party(ies) if there is a reason to do so (for example, the presence of a serious illness or disease).

Voluntary registration upon the Register should also be possible by people who may not have a donor-code, for example past donors, or people who have identified by other means relationships or their donor-conceived status (such as via DNA testing). This should be subject to any requirements of BDM, such as what additional evidence may be required.

To assist the robustness of information on the Register it was recommended that a parent(s) should be required to provide information on birth registration forms stating if the child was donor-conceived, and noting the clinic where treatment was received. There should also be notification of donor-conceived status via an addendum to the birth certificate, and an option for adult donor-conceived people to request a second birth-certificate be issued that shows their biological progenitors as well as their legal parent(s). (Note, in Part 2 of this report[441] it is recommended that children born as a result of surrogacy also have this right conferred and be able to include their birth mother whether or not she contributed her own eggs).

Finally, it was recommended that consideration should be given to whether an annual fee should be levied upon registered ART clinics to support the ongoing costs of the regulatory system, including, but not limited to, the Register and intermediary and support services. How such services and functions will be funded, however, is ultimately a decision for Government.

Findings

1. One central Donor Conception Register should be established and maintained at the office of Births, Deaths, and Marriages (BDM), which is responsible already for the collection and management of data relevant to the birth of people in Western Australia.
2. To complement the information service that BDM provides and enable search and find functions, and intermediary and support services, an independent agent with the necessary expertise, should be contracted to provide such services. The provider of such services should have 'trusted agency' status and be enabled to operate in an effective manner in terms of conducting search-and-find and family-linking services, including, but not limited to, being able to access necessary records via BDM, the clinics, and otherwise as required. (Such services could also, in the interim, take over the Voluntary Register).
3. Intermediary services should be *optional* except in cases that involve the retrospective release of identifying information. In that case the intermediary service should be involved in initial contact with the donor to advise of an inquiry, explaining the contact veto system, and supporting any further requests to liaise between the parties.
4. Support services (such as counselling) for donor-conceived people, recipients, or donors, and their families, in relation to seeking information about genetic heritage and biological relations should be *optional*. (All mandatory requirements for counselling should be repealed).
5. The option or requirement to engage with support or intermediary services should be free for donor-conceived people, recipients, donors, and their families. In practical terms, this means that such services will need to be subsidised by the Government and/or fees levied upon clinics as determined by the Government.
6. Access to identifying information about donors by donor-conceived people should be available regardless of when a donor-conceived person was born, subject to a contact veto system for those conceived with donated gametes or embryos prior to 2004.
7. Donors should be actively notified of all live births, sex of the child(ren) born, and the year of birth, in relation to their donation by clinics.

441 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Part 2)*, 2019.

8. Donor-conceived people should be notified of any other donor-siblings, including the donor's own children, with regard to the number of siblings, sex, and year of birth, upon request to the Donor Conception Register and/or a clinic.
9. Access to identifying information about donor-conceived people should only be available to donors and siblings of the donor-conceived person if the donor-conceived person (or recipient parents if the donor-conceived person is under 16) has registered their consent to the release of identifying information on the central register. However, outreach to donors and donor-conceived people by the intermediary and support services should be available in special circumstances, for example, if there is a serious heritable illness or matter about which the donor or donor-conceived person should be notified.
10. Voluntary registration should be permitted on the central Donor Conception Register by people for whom records may have been destroyed but are aware of their donor-code; and as a result of DNA testing identifying biological relatedness and subject to the testing being recognised as a legally valid test in establishing relatedness (e.g. from a NATA-accredited facility) and any other requirements of BDM to ensure the integrity of the data held on the Register.
11. An addendum to a donor-conceived person's birth-certificate should be placed on the Register at BDM notifying the person that there is more information held about them on the Register – being that they are donor-conceived. This addendum should be available to the donor-conceived person when they request their birth certificate after the age 16 or when they are of sufficient maturity, aligning with the legal age of access to information about donors in Western Australia and enabling them to decide if they wish to seek further information.
12. Recipient parents should be supported prior to receiving treatment, during pregnancy, and after the birth of a child(ren) with provision of information, education and initiatives, clinics, and fertility counsellors about the importance of disclosure to children about their donor-conceived status, how to have discussions with children about such status, and the law providing the child with rights of access to information about their donor.
13. Donors should be provided information and counselled at the time of donation about the laws in Western Australia and disclosure to children about their donor-conceived status. They should also be informed of a child's right to access identifying information about their donor.

Recommendations

Recommendation 23

Pursuant to section 45 of the *HRT Act*, the DG of the Department should cause a Donor Conception Register to be kept at the office of BDM (in a manner approved by the Minister, and in consultation with other relevant Government departments as required). Noting, any new Act in the future should maintain the provision for the Donor Conception Register and its operation.

Recommendation 24

The Donor Conception Register should be supported by an independent agency which is contracted to provide intermediary and support services to those seeking information about genetic heritage and biological relations, those about whom information is sought, and their immediate families; and relevant search-and-find services.

Recommendation 25

Any necessary provision required to enable such an agency to operate in an effective manner (including, but not limited to, being able to access necessary records via BDM, co-operation by clinics, and otherwise as required) be made.

Recommendation 26

Provision should be made within the new HRT Directions that intermediary services be *optional* except in cases that involve the retrospective release of identifying information in which case the intermediary service should, after locating the donor, make the initial contact to advise of an inquiry, explain the contact veto option, and provide further support if requested.

Recommendation 27

Section 49(2a) and s 49(2d) of the *HRT Act* be amended to remove the requirement for 'approved counselling' prior to release of identifying information to a donor-conceived person about their donor; and in the interim, pursuant to ss 49(2f) the DG include in new Directions that 'approved counselling' means counselling a person chooses to engage in and may include a discussion with the intermediary and support service provider about the implications of access to information.

Recommendation 28

Provision be made for intermediary and support services to be provided *free of charge* to donor-conceived people, donors, recipients, and/or their families in relation to access to identifying information about genetic heritage and relations, via Government subsidy to the providing agency and/or fees levied upon clinics or as otherwise determined by the Government.

Recommendation 29

Section 49(2e) of the *HRT Act* be amended to enable access to identifying information about donors by all donor-conceived people when they reach the age of 16 or sufficient maturity, regardless of when they were born, subject to a contact veto system for those conceived prior to 1 July 2004; and that in the interim the DG provide direction regarding section (2e)(b)(ii) which allows release provided there was adequate information provision before donation that future changes in legislation might enable information to be divulged or communicated without the donor's consent.

Recommendation 30

The DG make provision within the new Directions that clinics notify donors of all live births, sex of the child(ren), and year of birth, resulting from their donation(s).

Recommendation 31

The DG make provision within the new Directions that donor-conceived people should, upon request to the Donor Conception Register and/or a clinic, be provided with non-identifying information regarding the number, sex and year of birth of any donor-siblings, including the donor's own children.

Recommendation 32

Provision should be made for voluntary registration of consent upon the Register by a donor-conceived person (or their recipient parent if the person is under 16) to enable access to identifying information about that person by their siblings or donor.

Recommendation 33

The new Directions make provision for outreach to donors and donor-conceived people by the intermediary and support services in special circumstances, for example, if there is a serious heritable illness or a matter about which the donor/donor-conceived person should be notified.

Recommendation 34

The new Directions make provision for voluntary registration on the central Donor Conception Register by people for whom records may have been destroyed but are aware of their donor-code; and as a result of DNA testing identifying biological relatedness, subject to the testing being recognised as a legally valid test in establishing relatedness (e.g. from a NATA-accredited facility) and any other requirements of BDM (or the relevant Government authority) to ensure the integrity of the data held upon the Register.

Recommendation 35

Legislative provision should be made to require an addendum to a donor-conceived person's birth certificate notifying the person that there is more information held about them on the Register. This addendum should be available to the donor-conceived person when they request their birth certificate after the age of 16 or when they are of sufficient maturity to enable them to decide if they wish to seek further information.

Recommendation 36

The Directions provide that recipient parents should be supported prior to receiving treatment using donated gametes or embryos, during pregnancy, and after the birth of a child(ren) via provision of information, education, clinics, and fertility counsellors about the importance of disclosure to children about their donor-conceived status, how to discuss with children such status, and the law providing the child with rights of access to information about their donor.

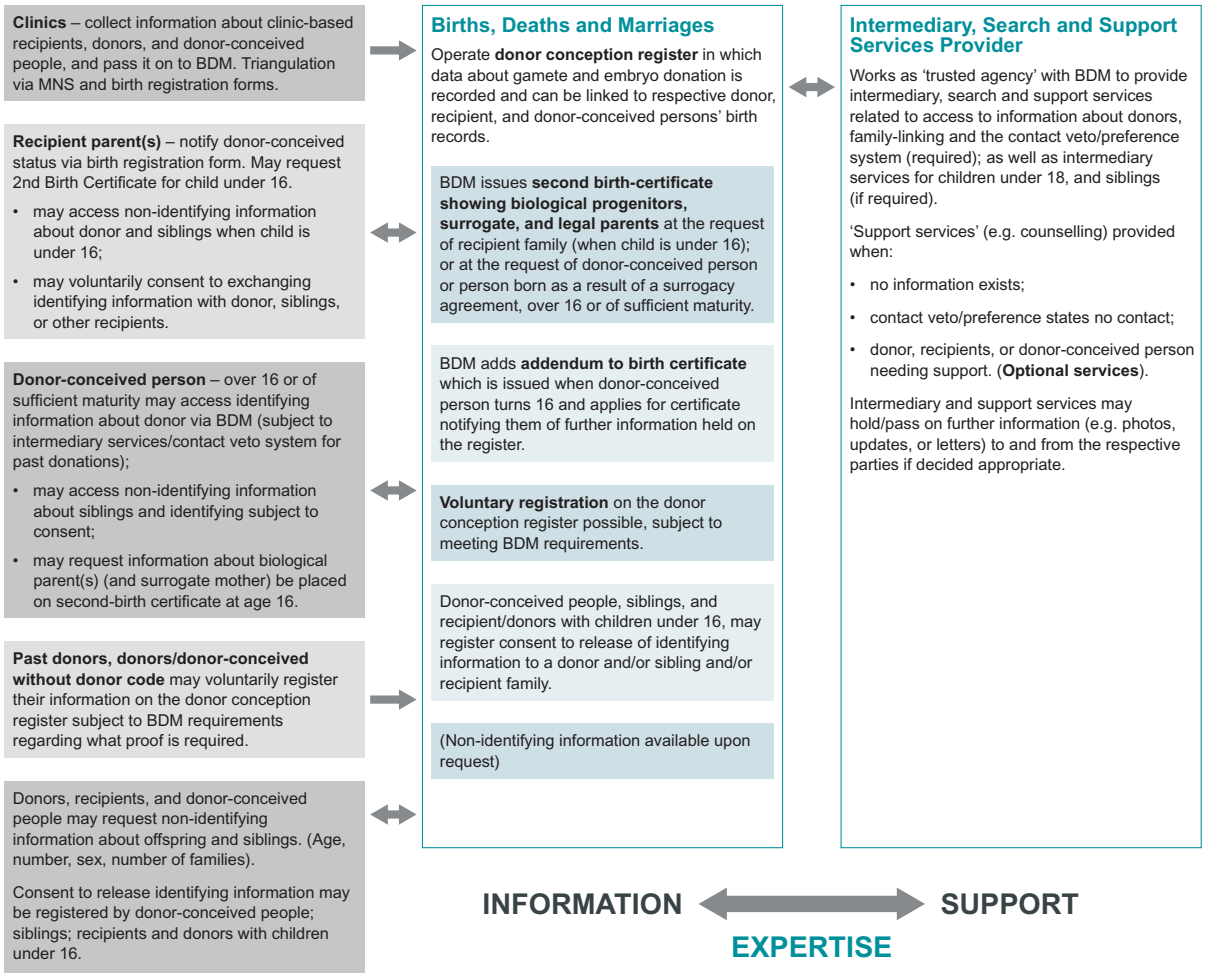
Recommendation 37

The Directions require that donors must be provided information and counselled at the time of donation about the importance of disclosure to children about their donor-conceived status, and the law in Western Australia and that donation cannot be accepted without consent to a person born as a result of such a donation having access to identifying information.

Recommendation 38

Legislative provision be made to allow the issuance of a second birth certificate at the request of a donor-conceived person, or person born as a result of surrogacy, or their legal parent(s) (if the person is under the age of 16) that contains factual information about a person's genetic and birth heritage.

Figure 6.1: Recommendations for Western Australian Donor Conception Register



- System operational now, but also ready for a future in which all donor information has been consented to be released and the requirement for support services declines (donor-conception families are accepted as 'normal families' who are curious about, and meet relatives, like everyone else).
- System will continue to be able to provide a place to consent to release of information and make links between siblings that may otherwise not be known.

Table: Required change and action

Table 6.2 details the changes required that are relevant to the discussion in Chapters 4, 5 and 6 regarding donor conception, the Reproductive Technology Register and the Voluntary Register; including recommendations concerning what should occur regarding a Donor Conception Register into the future. Again, it is noted that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended as a *matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 6.2: Recommended Changes to Legislation, Directions and Operations Regarding the Donor-Conception Register(s)

Required Change	Legislation*	Directions**	Operation**
Provide for a Donor Conception Register *that operates in a manner that will best serve access to information by donor-conceived people, donors, and recipients.*	Pursuant to section 45 of the current *HRT Act*, the DG should cause a Donor Conception Register to be kept at the office of Births, Deaths, and Marriages (BDM) (in a manner approved by the Minister and in consultation with other relevant Government departments as required). NB. any new Act in the future should maintain the provision for the Donor Conception Register and its operation.	Repeal and replace current HRT Directions (last revised in 2004). Within the new Directions and pursuant to section 45 of the current *HRT Act* (or relevant section of the new/revised *HRT Act*), the DG should cause a Donor Conception Register to be kept at the office of Births, Deaths, and Marriages (BDM) (in a manner approved by the Minister and in consultation with other relevant Government departments as required).	Ensure adequate training, understanding of ART data, and resourcing, to enable operation of Donor Conception Register and support services (noting this may become the responsibility of another government department solely or in conjunction with the Department of Health). Voluntary Register – Knowledge transfer to Trusted Agency
Allow for access to identifying information about donors by donor-conceived people, regardless of when a donor-conceived person was conceived, subject to contact veto system for those conceived pre-1 July 2004.	Repeal/revise current *HRT Act* s49(2e) (or provide in new Act) for access for all donor-conceived people to identifying information about their donors regardless of when they were born. Provide for contact vetos to be able to be placed in relation to pre-2004 donations by the donor, donor-conceived person, or relevant others. (Details of the system to be detailed when drafting new legislation).	Provide within Directions a requirement to engage with intermediary support services when requesting identifying information relevant to pre-2004 donations.	Establish intermediary services (see below). Establish processes for delivery of intermediary services relevant to inquiries relevant to pre- 2004 donations, search and find services, and contact veto system.

Required Change	Legislation*	Directions**	Operation**
Intermediary and Support Services	Repeal/amend current legislation: That s 49(2a) and s 49(2d) of the *HRT Act* be repealed/amended to remove the requirement for 'approved counselling' prior to the release of identifying information to a donor-conceived person about their donor. New legislation: provide for intermediary and support services within the new legislation.	While current *HRT Act* 1991 is in place, in the interim, pursuant to ss 49(2f) the DG include in new directions that 'approved counselling' means counselling a person chooses to engage in and may include a discussion with the intermediary and support service provider about the implications of access to information. Provision should then also be made within the new directions that engaging with intermediary services is *optional* except in cases that involve retrospective release of identifying information about pre-2004 donations, in which case the intermediary service should, after locating the donor, make the initial contact to advise of an inquiry, explain the contact veto option, and provide further support if requested. Provision should be made within the new directions that engaging with support services (e.g. counselling) is optional.	Provision should be made to have a contract of services supported by an independent trusted agency who is contracted to provide intermediary, and support services to those seeking information about genetic heritage and biological relations, those about whom information is sought, and their immediate families; and relevant search and find services. Any necessary provision required to enable such an agency to operate in an effective manner (including but not limited to being able to access necessary records via BDM/DoH, co-operation by clinics, and otherwise as required) should be made. That provision be made for intermediary and support services to be provided free of charge to donor-conceived people, donors, recipients, and/or their families in relation to access to identifying information about genetic heritage and relations, via government subsidy to the providing agency and/or fees levied upon clinics or as otherwise determined by the government (via relevant law/directions/policy as required). NB. The contracting of a 'trusted agency' may also be operationalised as an interim measure to address issues raised in relation to the current Voluntary Register e.g. by having trusted agency support/ maintain the Voluntary Register functions in its entirety prior to all register data being moved to BDM. (Subject to the notification of those currently on the register).

Required Change	Legislation*	Directions**	Operation**
Notification to donors regarding non-identifying information about offspring		That the DG make provision within the new Directions that clinics must notify donors of all live births, sex of the child(ren), and year of birth, resulting from their donation(s).	
Notification to donor-conceived people regarding non-identifying information about siblings		That the DG make provision within the new Directions that donor-conceived people should, upon request to the Donor Conception Register and/or a clinic, be provided with non-identifying information regarding the number, sex and year of birth of any donor-siblings, including the donor's own children.	
Provision for active outreach		That the new Directions make provision for outreach to donors and donor-conceived people by the 'trusted agency' that provides intermediary and support services in special circumstances, for example, if there is a serious heritable illness or a matter about which the donor/donor-conceived person should be notified.	
New Donor Conception Register • Registration of consent to allow access to identifying information by siblings and donors	That provision should be made for voluntary registration of consent upon the register by a donor-conceived person (or their recipient parent if the person is under 16) to enable access to identifying information about that person by their siblings or donor.		

Required Change	Legislation*	Directions**	Operation**
Current and new donor-conception registers • Registration by people whose records have been destroyed (but are aware of donor-code) • Registration by people who have identified biological connection via DNA testing		That the new Directions make provision for voluntary registration on the central Donor Conception Register by people for whom records may have been destroyed but are aware of their donor-code; and as a result of DNA testing identifying biological relatedness, subject to the testing being recognised as a legally valid test in establishing relatedness (e.g. from a NATA-accredited facility) and any other requirements of BDM (or the relevant Government authority/agency) to ensure the integrity of the data held upon the register. That provision should be made in the new Directions that such registrants may access the intermediary and support services if they require them.	Develop processes to deal with such registration. Be supportive and understanding. Have clear and accessible procedures. Provide information in a clear and accessible format to the public regarding what is required. Ensure processes/ procedures enable utilisation of current technology (e.g. electronic form submission; etc) Funding
Notification of donor-conceived status	That legislative provision (or Directions) be made to require an addendum to a donor-conceived person's birth-certificate notifying the person that there is more information held about them on the Register. The addendum should be available to the donor-conceived person when they request their birth certificate after the age of 16 or when they are of sufficient maturity to enable them to decide if they wish to seek further information.		
2nd Birth Certificate	That legislative provision be made to allow the issuance of a second birth certificate at the request of a donor-conceived person, or person born as a result of surrogacy, or their legal parent(s) (if the person is under the age of 16) that contains factual information about a person's genetic and birth heritage.		

Required Change	Legislation*	Directions**	Operation**
		That the Directions should provide that recipient parents should be supported prior to receiving treatment using donated gametes or embryos, during pregnancy, and after the birth of a child(ren) via provision of information, education and, clinics, and fertility counsellors about the importance of disclosure to children about their donor-conceived status, how to have discussions with children about such status, and the law providing the child with rights of access to information about their donor.	
		That the Directions require that donors should be provided information and counselled at the time of donation about the importance of disclosure to children about their donor-conceived status, and the law in Western Australia and that donation cannot be accepted without consent to a person born as a result of such a donation having access to identifying information.	

Chapter 7

ART Issues – Storage of Gametes and Embryos

Chapter 7:
ART Issues – Storage of Gametes and Embryos

7.1 Introduction

Both gametes and embryos are accorded a somewhat special status, when compared to other human biological materials, due to the potential that their use will lead to the formation or development of a human life. Connected to such status are many complex ethical issues associated with their storage. The Terms of Reference required consideration of rights to storage of gametes and embryos including:

- the storage of gametes, eggs in the process of fertilisation and embryos (including the duration of storage and procedures for extension of storage periods)
- rights upon separation or divorce, or the death, or the physical or mental incapacity of an individual, or one or both members of a couple
- rights of third parties such as subsequent spouses, and the rights of other relatives.

This chapter addresses these issues in turn.

7.2 Western Australian law regarding the storage of gametes

Section 22(b) of the *HRT Act* provides that the gametes of a person shall not be kept in storage unless there is effective consent by that person to their storage. 'Effective consent' is defined in s 22(8) to mean that it must be given in writing, any condition to which it is subject must have been met, it has not been withdrawn, and the gametes are …kept and used in accordance with that consent. Section 22(9) provides that where consent required by or under the Act is not given, or is not effective, or does not comply, the matter may be the cause of disciplinary action or proceedings for an offence but does not necessarily affect the rights of any person.

The HRT Direction 6.8 then specifies that the licensee must ensure the gametes are not, without the approval of the RTC, stored for longer than 15 years. Direction 6.9 provides that the RTC may approve an extension of the storage period for gametes, on the application of the licensee or the gamete provider if the stored gametes are to be used in the treatment of the gamete provider or for research. The RTC has also approved extensions for donated gametes when families are not complete. Direction 3.1 then provides that the licensee must ensure that consent to store gametes is renewed every five years.

7.3 Western Australian law regarding the storage of eggs in the process of fertilisation and embryos

The *HRT Act* provides that consent to the storage of embryos or eggs in the process of fertilisation must state the primary purpose of storage to relate to the probable future implantation of the embryo or its probable future use under an NHMRC license (for research).[442] Embryos

442 *HRT Act* s24(1).

must not be stored for a period exceeding 10 years except with the approval of the RTC. RTC approval may only be sought before the expiration of the statutory storage period,[443] or if a longer storage period has previously been approved before the end of that period.[444] The RTC will not approve an extension of storage unless there are special reasons for doing so.[445] Applications are currently considered on a case-by-case basis by the Embryo Storage Sub-Committee which consists of four RTC members and the Executive and Deputy Officers.

The Western Australian legislation also prescribes that three months before the end of the storage period, clinics must take reasonable steps to notify each person for whom the embryo is being stored.[446] The HRT Direction 6.10 stipulates that 'the licensee has potential liability to the persons for whom the embryo or egg undergoing fertilisation is stored if the notification requirements in section 24(3) of the Act have not been complied with before the embryo is removed from storage'. It further states that such steps may include writing to the person at the last known address, writing to the person at an address obtained from an electoral roll search, or telephoning or contacting the person's general practitioner or any other suitable third party.

The HRT Direction 6.12 states that the licensee cannot apply for an extension themselves. But rather it must ensure information is provided to the person(s) storing the embryos or egg undergoing fertilisation that they may apply for an extension, using the requisite Form 8, to the RTC at least one month before the RTC meeting that precedes the expiry of the storage period. Licensees may apply for extensions of storage periods for excess ART embryos donated for research before the end of the storage period, and at least one month prior to the RTC meeting that precedes the expiry of the storage period.[447]

7.4 Storage periods: Comparison to other jurisdictions

7.4.1 New South Wales

In New South Wales, the law distinguishes between gametes and embryos stored for a person or couple's own use, and donated gametes and embryos. In relation to the former, an ART provider must not store a gamete or an embryo except with the consent of the gamete provider and in a manner that is consistent with the gamete provider's consent.[448] The period of storage is not stipulated by the law, but rather is determined by agreement between the clinic (based on its policies) and the gamete/embryo provider(s) (based on their stipulated length of storage) – and if there is divergence between the two, the longer period being the one that stands at law.[449] However, a period must be stipulated or the gametes/embryos may not be stored.[450] Contravention of this provision may be subject to a maximum penalty of 800 penalty units in the case of a corporation, or 400 penalty units in any other case.

443 *HRT Act* s24(1c).

444 *HRT Act* s24(1c).

445 *HRT Act* s24(1a).

446 *HRT Act* s24(3).

447 HRT Directions 6.13 and 6.14.

448 *Assisted Reproductive Technology Act 2007 (NSW)* s 25(1).

449 *Assisted Reproductive Technology Act 2007 (NSW)* s 25(3)(a)&(b).

450 *Assisted Reproductive Technology Act 2007 (NSW)* s 25(2).

In relation to donated gametes and embryos: donated gametes collected after 2010 may be stored for a maximum period of 15 years.[451] Similarly, embryos created after 2010 may be stored for a maximum period of 15 years. [452] This period may be extended by authorisation by the Secretary of the Ministry of Health.

7.4.2 South Australia

In South Australia the *Assisted Reproductive Treatment Act 1988* (SA) is silent regarding the length of storage of gametes or embryos. However, the Minister may place conditions of registration on the ART provider.[453] There are two relevant conditions of registration to the storage of gametes and embryos. First, the Assisted Reproductive Technology Regulations 2010 requires that it be a condition of registration that the registrant complies with the NHMRC Ethical Guidelines.[454] NHMRC Ethical Guidelines state that clinical and personal considerations should determine storage periods, and that if there is no evidence of deterioration, decisions about the continued storage of gametes or embryos may depend entirely on the personal preferences of the responsible party(ies). Second, it is a standard condition of registration that *donated gametes* must be destroyed after 15 years from the time of donation unless approval from the Minister is obtained for the ongoing storage and use.[455] There is no such time limit for donated embryos.

7.4.3 Victoria

In Victoria the *Assisted Reproductive Treatment Act 2008* (Vic) provides gametes may be stored for a maximum of 10 years.[456] However, if the gametes have been produced by a child or person who is at reasonable risk of becoming prematurely infertile due to a medical procedure, the gametes may be stored for 20 years.[457] It is an offence for a clinic to continue to store gametes if the gamete provider has asked for their removal from storage. An application can be made to the Patient Review Panel to extend the period of storage, which may give written approval for a longer storage period if it considers that there are reasonable grounds to do so in the particular case.[458]

Embryos may be stored for a maximum period of five years.[459] This period may be extended with the approval of the Patient Review Panel.[460] Note, this time limit has applied since the original ART legislation was enacted in Victoria in 1984, recommended by the Waller Committee as

451 *Assisted Reproductive Technology Act 2007 (NSW)* s 25(3)(c).

452 *Assisted Reproductive Technology Act 2007 (NSW)* s 25(d).

453 Assisted Reproductive Technology Act 1988 (SA) s 9.

454 Assisted Reproductive Technology Regulations (SA) reg .8(2)

455 See Government of South Australia, SA Health, Assisted Reproductive Treatment Provider Register, at http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+services/fertility+services/assisted+reproductive+treatment+provider+register, accessed 02 September 2018.

456 *Assisted Reproductive Treatment Act 2008* (Vic) s 31(1)(b)(i).

457 *Assisted Reproductive Treatment Act 2008* (Vic) s 31(1)(b)(ii). This applies to gametes placed into storage after the 23 April 2013, when changes to the Victorian legislation were made (see sections 2 and four of the Assisted Reproductive Treatment Amendment Act 2012).

458 *Assisted Reproductive Treatment Act 2008* (Vic) ss 31(1)(b)(iv) and 31A.

459 *Assisted Reproductive Treatment Act 2008* (Vic) s 33(2)(b).

460 *Assisted Reproductive Treatment Act 2008* (Vic) s 31(2).

embryo freezing was still new.[461] The Committee also made specific reference to a case in which a couple, who were United States citizens, had stored two embryos in Victoria in 1981 with the view of later transfer to the wife. In early 1984 the couple died in a plane crash. The Committee referred to 'the lengthy period between the beginning of storage and the accident in which the couple died as underlining [its] view that storage shall be for as short a period as possible'.[462]

Embryos may not be stored unless the person who will store the embryos is a registered ART provider, the embryos are intended for use in a treatment procedure, and the persons who have produced the gametes from which the embryo was formed have consented, in writing, to the embryos' storage for the purpose of its later transfer.[463] Penalties of up to 240 penalty units or two years in prison may be imposed if these conditions are not met.

7.4.4 Australian Capital Territory, Northern Territory, Queensland, and Tasmania

There is no legislation governing ART in the Australian Capital Territory, Northern Territory, Queensland, or Tasmania. In these states adherence to NHMRC Ethical Guidelines is required via the RTAC Accreditation scheme and in order to be eligible for Medicare funding.

Chapter 7 of the NHMRC Ethical Guidelines outlines the responsibilities of clinics in relation to stored gametes and embryos. It provides that persons for whom gametes or embryos are stored are entitled to certainty about their safety and identity. Clinics must, therefore, ensure the safety and accurate identification of all gametes and embryos stored, which includes recording the identity and locations of gametes and embryos, the number of embryos stored, and the use of secure labelling methods. As mentioned above, the 2017 NHMRC Ethical Guidelines do not stipulate a length of time for storage. Rather they provide that *decisions about storage periods are determined by clinical and personal consideration, however, if there is no evidence of deterioration, decisions about the continued storage of gametes or embryos may depend entirely on the personal preferences of the responsible party(ies)*.[464]

Nevertheless, the NHMRC Ethical Guidelines require that clinics should have policies that guide the clinical determination for continued storage of gametes and embryos, form the basis of discussion about embryos no longer needed by an individual or couple for their own reproductive purposes, and for discarding stored gametes and embryos (among other policies and procedures).

Chapter 9 of the NHMRC Ethical Guidelines provides further requirements regarding maintaining integrity and privacy of personal information; observing, recording, monitoring, and evaluating procedures and outcomes; recording information about donation, use and storage of gametes and embryos; monitoring the number of embryos created and stored; and ensuring public accountability for all activities and procedures.

461 Committee to Consider the Social, Ethical and Legal Issues Arising From In Vitro Fertilisation Report on the Disposition of Embryos Produced by In Vitro Fertilisation, 1984 at 2.13.

462 Ibid, at 2.14.

463 *Assisted Reproductive Treatment Act 2008* (Vic) s 32(2).

464 *NHMRC Ethical Guidelines*, [7.2].

Table 7.1 summarises whether there are legislated time limits for gamete storage and/or a requirement for committee, panel or other approval for extensions across Australia.

Table 7.1: Gamete Storage Period and Extension Approval Requirements

Jurisdiction	Gamete Storage Period Legislation		Approval for Extension	
Australian Capital Territory	✗		✗	
Northern Territory	✗		✗	
Queensland	✗		✗	
Tasmania	✗		✗	
New South Wales	✔ Patient's own: time agreed b/w patient and clinic	✔ Donated materials: 15 years	✗	✔ Donated materials: The Secretary
South Australia	✗	✔ Donated gametes: 15 years	✗	✔ Donated gametes: The Minister
Victoria	✔ 10 years (under review) 20 years if stored for child or person at risk of premature infertility due to a medical procedure		✔ Patient Review Panel	
Western Australia	✔ 15 years with five yearly re-consent		✔ RTC	

✗ = no legislated requirement, NHMRC Ethical Guidelines apply (no stipulated period; storage determined by clinical determinations and personal preferences of person storing the gametes).

Table 7.2 summarises whether there are provisions regarding time limits for embryo storage and a requirement for committee, panel or other approval for extensions across Australia.

Table 7.2: Embryo Storage Period and Extension Approval Requirements

Jurisdiction	Embryo Storage Period Legislation		Approval for Extension	
Australian Capital Territory	✗		✗	
Northern Territory	✗		✗	
Queensland	✗		✗	
South Australia	✗		✗	
Tasmania	✗		✗	
New South Wales	✔ Patient's own: time agreed b/w patient and clinic	✔ Donated materials: 15 years	✗	✔ Donated materials: The Secretary
Victoria	✔ five years (under review)		✔ +five years with gamete provider's consent the Patient Review Panel	
Western Australia	✔ 10 years		✔ Embryo Sub-Committee	

✗ = no legislated requirement, NHMRC Ethical Guidelines apply (no stipulated period; storage determined by clinical determinations and personal preferences of the person(s) storing the embryos).

7.5 Consultation

In the public forums, several consumers reported feeling uncomfortable that their ability to extend storage of their gametes or embryos had to be 'approved' by the RTC. They stated that such decisions were very personal and should be made between them, their partner (if any), and their clinician.[465] Several said they thought it was important that a record of the number of embryos that are stored be kept and reported, but again did not see why they would need to apply for special approval if they were adhering to legal requirements and had provided informed consent. One woman said in relation to storage periods *'if there is a legal requirement or agreement that says you can't go beyond this time, then everyone would know that. We don't want to break the law'*.[466]

The Womens and Newborn Health Service submitted that … *the Act should be amended to allow individual clinics to maintain storage for the period of time agreed between the parties involved*.[467] They noted the United Kingdom Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 provide for successive 10-year extensions of storage, up to a maximum of 55 years, and supported clinics and patients making the decision subject to documented consent.[468]

Face-to-face consultation with the clinics revealed that staff were supportive of having 'some limit' on storage periods, as otherwise they may find themselves storing gametes and/or embryos indefinitely, but that this might be agreed depending on patient condition and needs. The clinics were of the view that the provisions in the current *HRT Act* and HRT Directions, alongside RTC Committee processes, were not suitable. It was reiterated that they should be trusted to make decisions with their patients and that the RTC should not be involved, provided they were adhering to the law. They also noted RTAC and the NHMRC Ethical Guidelines do not set limits but require safe management, and consent regarding the duration of storage; and the use, storage or discard of gametes or embryos if either or both the person(s) for whom they are stored die(s), become(s) incapable of varying or withdrawing consent, or fail(s) to give further instructions at the expiry of the period of storage specified in the consent form.[469]

A number of clinicians referred particularly to the requirement under the HRT Directions that requires re-consenting people who had stored gametes every five years when they had already consented to storage for a period of 15 years. They described the heavy burden such a requirement placed on clinics, who had to try to locate the person who had stored the gametes and that doing so often took much time and expense. Locating people was found to be particularly difficult. For example, this could be particularly difficult in cases in which the people who had stored the gametes had done so before undergoing chemotherapy. It was noted that 'many of these men are young, sometimes in their late teens when they store sperm, and the 15-year limit may only last until their early 30s when they have not yet even considered to start a family'. Moreover, it was noted that many of them are 'mobile, move addresses, cities, states, and even countries within the 15-year timeframe'.

465 Public Forum, April 2018.

466 Female attendee at Perth Community Forum, April 2018.

467 Women and Newborn Health Services (Jenny O'Callaghan), Submission 121.

468 Ibid.

469 NHRMC Ethical Guidelines, para 4.6.3 and 4.6.4.

I was provided with one licensee's procedure for trying to find uncontactable patients, which is set out in Box 7.1.

Box 7.1: Example procedure for uncontactable patients (gamete storage)

1. Patient sent an email to current email address (if recorded) with a read receipt. If read receipt returned, contact is assumed to be initiated.
2. If no read receipt, a letter is sent to the last known address. The letter includes renewal and discards form and reply-paid envelope. Response requested within two weeks.
3. If the letter is returned, or no reply within two weeks, phone calls are made to all recorded numbers.
4. If these numbers are disconnected or messages are not returned, cemetery records are checked to see if the patient is deceased.
5. If this is unsuccessful, the patient is transferred to the accounts department who verify address using the following methods:
    a. Checking current address on the electoral roll
    b. Checking the house sales/rental history online
    c. Checking with referring doctor for updated address
    d. Checking bank records if the patient has a direct debit arrangement.
6. If this process yields a different address the process is reinstated using the new contact information.
7. If this process yields no new information or if the new contact details are also unsuccessful, a registered letter is sent to the last known address.
8. If this is not retrieved, the laboratory manager checks the online history or social media for any records. Due caution should be used to protect the patient's confidentiality and contact details found online are only used to contact the patient if it is possible to independently verify their identity (e.g. by employment history or known relatives).
9. If this is unsuccessful, next of kin is contacted and/or their referring doctor is contacted and informed stored samples will be discarded once the period of current consent has expired. Each letter again encloses a renewal of consent form, a self-addressed envelope, and a covering letter explaining the process and its importance.

…

- If a patient who is storing and is not contactable, gametes should not be automatically discarded. The details of storage history, age, and the reason for storage (if known) is conveyed to the RTC. It is expected they will make the decision to discard or not under the legislation.

I was also provided with examples of attempts to locate people which illustrated how difficult this could be. The following are two examples of the many I was given.

Example 1:

Reason for storage: Pre-chemotherapy (Cancer); storage date: 2009:

- Contact attempts in 2015 and 2017 were unsuccessful
- 2017 mobile phone disconnected, no email address, messages left on home phone, no response; registered letter sent and delivered
- 2018 registered letter sent, and returned to sender unclaimed; sent SMS reminder; checked health record obtained new phone number and next of kin number; mobile disconnected; left voice message on home phone; father returned call and is not on speaking terms with the son, removed as next of kin; sent reminder letter to confirmed address asking to contact urgently; message on Facebook, no response.

Example 2:

Reason for storage: Pre-chemotherapy Hodgkin's Lymphoma; storage date: 2013:

- Contact history: has never responded to contact attempts
- 2018 letter sent; unable to contact by phone; partner not responding on their phone; checked health record and obtained number of father; spoke to father who supplied postal address; letter express posted; called father to check receipt, told son was there; son said he had seen the letter, then said not to call again and issued threat of violence.

It was noted above at 3.4.4 that one licensee had, during the review, reported that the regulatory burden imposed and resultant costs were too great to bear and withdrew from providing any services that fell under the auspices of the *HRT Act* and Directions (as well as RTAC). This decision was significantly influenced by matters regarding difficulties the licensee had in meeting requirements of the HRT directions regarding the requirements for the additional five-yearly consents (amongst other things). The gametes stored were predominantly (99%) those of cancer patients. The inability to contact some of them, despite multiple attempts, and the reluctance to discard sperm when the person could not be contacted at the 15-year mark, had resulted in a 'breach' of the Act, and subsequent disciplinary action. At another clinic a laboratory director informed me:

> *The big one comes for me being the embryo cryopreservation storage…We spend a lot of time trying to track these people down. How we work is we charge the patients every six months. We send out a consent every six months, asking them what to do, and whether they want to re-consent. We might do this for a few years and get nothing back. The letters are sent back, and this may go on for years. Often they just disappear. Then according to the Act, we need to make reasonable attempts to contact the patient when the storage period is coming to an end. We send a letter by registered post, which comes back; we phone them; we contact their GPs; we used to access the electoral roll but, we can't do that anymore. The issue for me is that it is not clear what a reasonable attempt involves. We would be very reluctant to discard anyone's embryos without their consent. But, the Act doesn't tell us what to do in such circumstances. Where does our responsibility lie? Of course, once 10 years is up, we become liable, and we have to discard. I understand that, but I don't think it is clear as to when we can say we have done everything we needed to do. It would be better to have some guidance on this rather than just feel we are facing getting sued by the person who stored the embryos or punished by the RTC.*

Another clinic submitted:

> *…There is a big issue with Direction 3.1 which is the need to get consent every five years if we have gametes stored. We don't charge an annual storage fee. This requirement creates a massive workload for us, it is a huge administrative task and has high costs. On the consent form, the patients sign a 15-year maximum storage period. We question having to contact them every five years. Why would they have to re-consent what they have already consented? Then the other issue is that while we need a clear ability to be able to discard after a period of time, we also need to have some ability to keep some samples longer for some people. Some are so young when they have the gametes stored, and really, the 15-year limit is too early for them. We really should be able to decide with our patients what is appropriate to their needs, and not have an arbitrary time imposed upon us. We should be able to decide with our patients what the limit needs to be. Then there is a limit, but, it is a suitable one that meets the patient's needs. … and... on the embryo storage extension, we send a letter at nine years, and then at three months before expiry. If they want to extend at nine years, we are not allowed to submit that extension until three months before the expiry. It seems to be a procedure that the RTC/RTU have decided on internally. It makes no sense that we have to wait, while it creates the possibility that it gets lost under someone's pile of work because we can't send it at the time. Honestly, there is no logic in this.*

At that clinic, another person noted regarding extensions,

> *There is an advantage in being able to have a limit and variable extensions. Sometimes it helps. Otherwise it might go on forever. It is good for everyone, including for the patient, to know that there is an end-point.*

7.6 Extension applications and approvals

In order to understand the results of extension applications to the RTC in Western Australia I also consulted the Annual Reports for a period of 10 years from 2015-2016 back to 2006-2007. Table 7.3 outlines the results of applications to the RTC concerning embryos and gametes.

Table 7.3: Numbers of applications for extension of storage period for embryos and gametes and RTC approvals

YEAR	No. of Applications EMBRYOS	No. Approved by RTC	No. of Applications GAMETES	No. Approved by RTC
2015-2016	25	25	< 5	Not reported
2014-2015	27	26	16	16
2013-2014	21	21	9	9
2012-2013	30	30	1	1
2011-2012	16	16	20	20
2010-2011	25	25	1	1
2009-2010	20	20	0	0
2008-2009	15	15	0	0
2007-2008	29	29	0	0
2006-2007	23	23	0	0

Over a 10-year period, of 231 applications for extension of the embryos storage period, the RTC approved 230 applications. The approvals contained variable lengths of time, ranging from six months to five years for the extension. In three cases, the extension approved was for a short period of time (two-three months) to enable further information to be provided. In relation to extension applications for gametes in the same 10-year period, the RTC reported 47 applications, all of which were approved.

7.7 Storage periods: Discussion

As a result of current provisions in the *HRT Act* and HRT Directions, much administrative time is spent trying to find people who have stored gametes or embryos. The costs associated with trying to contact people to get them to 're-consent' were high. This was particularly so in relation to gamete storage which requires re-consent every five years, in addition to the requirement that such gametes be destroyed at the 15-year mark if an extension has not been granted. The costs do not just relate to the financial costs associated with the administration of the scheme. There were also costs in relation to the level of stress it created for those trying to locate people, what to do when contact had been made but forms had not been returned, and what to do when people could not be located. Licensees also felt uncertain about destroying gametes or embryos even when the cut-off date had been reached, without the permission of the person who had stored them. If they did not, they were, however, subject to disciplinary procedures by the RTC.

It should also be acknowledged that contact regarding re-consent for some people for whom gametes have been stored may be stressful. For example, a young person, who is not yet old enough to be considering future reproduction or who may still be dealing with the illness that led them to store in the first place, may not yet be in the position to engage with having to re-consent.

When considering laws and guidelines in other jurisdictions, again it was found that these varied across the country in relation to storage periods for gametes and embryos. The majority of states impose *no limits for gametes or embryos derived from the person(s) who will undergo treatment*. This was the case in the Australian Capital Territory, Northern Territory, New South Wales, Queensland, South Australia, and Tasmania. Instead, the storage period is agreed between the clinic and the patient subject to clinic policies and patient preference and consent. In the Australian Capital Territory, Northern Territory, Queensland, and Tasmania no distinction is made in relation to donated gametes or embryos. New South Wales differs for donated gametes and embryos, imposing a 15-year limit for both, with extension possible if approved by the Secretary of the Ministry of Health. South Australia imposes a 15-year limit for donated gametes, with extension possible by the Minister for Health.

In Victoria there is a 10-year limit for storage period for all gametes (personal use or donated), which may be extended by application to the Patient Review Panel; and a five-year limit for embryos (personal or donated), which can be extended by consent for another five years, and then afterwards by application to the Patient Review Panel. Victoria is the only state that makes some provision for people who have stored as a result of medical treatment that may render them infertile, allowing a 20-year initial period of storage in such cases, and extension via the application.

Western Australia has a 10-year storage limit for embryos and a 15-year storage limit for gametes, with extension possible via application to the RTC. Of 231 extension applications made over a 10-year period related to embryos, only one has been rejected. Of 47 applications for the extension of the storage period, none had been rejected. While the granted extension period varied, the process was seen by many consulted during the review as a bureaucratic one, which ultimately ‘rubber stamped’ the application. There is no differentiation between gametes or embryos created for personal use and those that are donated. There is no distinction made for people who store at a young age as a result of medical treatment that may render them infertile for use sometime in the distant future, and people storing for immediate use.

On conducting further research into the reasoning that lies behind storage limits it was found that it is a historical matter, stemming from early uncertainty regarding whether the ability to freeze eggs, sperm, and embryos posed biological and/or social risks.[470] Later there have also arisen considerations concerning the costs to clinics involved in maintaining the storage of gametes and embryos for long periods of time. Early versions of the NHMRC Ethical Guidelines thus included maximum storage periods (for example, in the 2007 guidelines the maximum period of storage was five years, with the opportunity to increase the storage period for an additional five years). However, in the 2017 review of the guidelines, this was seen to be *'arbitrary and not based on evidence'*.[471] The NHMRC states that in making changes to remove the limits it was *'acknowledged that the suitability of continued storage depends on both personal and clinical considerations and requires clinics to have policies in place to support the clinical decisions'*.[472]

There was not any evidence put to the review as to why an external committee needs to be involved in this decision. It also did not appear that scrutiny of people's decisions about the storage of their gametes and embryos, or an arbitrarily imposed time limit, was serving any protective function in relation to the patients or their own gametes or embryos or the child(ren) that may be born as a result (donated gametes and embryos are discussed below). While the Review received one oral submission during face-to-face meetings that the committee approach may serve to reinforce to people that there 'needs to be an end-point', imposing an arbitrary time limit on every patient, without considering their circumstances, appeared contrary to upholding patient autonomy and supporting people in seeking access to ART to create their families.

It was seen above that gametes collected from young (or very young) cancer patients may need to be stored for a long period of time. For others, it may be that storage is necessary for the period in which they discover they need ART and are building their family. In relation to embryos, strict imposition of rules about how long they may be stored and when they should be 'disposed of' or taken out of storage to 'succumb' may also fail to acknowledge and respect the woman or couple undertaking treatment and their individual relationship with their embryo(s), and the special status they have for people. For example, in research conducted by Millbank it was found:

> *Many women said that they did not want their embryos to be wasted or treated as waste …and expressed distress at the prospect of them being 'flushed' or 'shoved' down the sink or toilet…, or 'chucked' in a bin …. [A participant in the study,] articulates her embryos as 'deserving' of 'something better' than an imagined and abject ending—a waste product left on a bench and 'flushed down the sink'.*[473]

470 Committee to Consider the Social, Ethical and Legal Issues Arising From In Vitro Fertilisation Report on the Disposition of Embryos Produced by In Vitro Fertilisation, 1984 at 2.13. & 2.14; UK Department of Health and Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cmnd. 9314 (1984); See also discussion in Anita Stuhmcke & Eloise Chandler, *Storage Limits of Gametes and Embryos: Regulation in Search of Policy Justification*, 22 J. L. MED. 121, 123–125 (2014).

471 National Health and Medical Research Council, Summary of the major revisions to the 2007 ART guidelines (2017) available at https://www.nhmrc.gov.au/health-ethics/ethical-issues-and-further-resources/assisted-reproductive-technology-art/development accessed 02 September 2018.

472 Ibid.

473 Jenni Millbank; Reflecting the 'human nature' of IVF embryos: disappearing women in ethics, law, and fertility practice, *Journal of Law and the Biosciences*, Volume 4, Issue 1, 1 April 2017, p 87.

In this sense, it is most important to acknowledge that people will have different needs and views about how long they wish to store their embryos, and what happens to them afterwards.[474]

The costs to clinics that unlimited storage may involve (whether the clinic provided such storage for free or because people didn't pay the storage fee) should also be considered. However, it does not support the setting of an arbitrary time limit of 10 or 15 years for storage that applies to all people who are storing gametes or embryos for personal use regardless of their age, circumstances, or reasons for storage. Rather it may support having an agreed upon endpoint based on personal circumstances and discussion with the clinic. Thus for example, a young cancer patient may decide to store gametes at age 15 prior to chemotherapy for a maximum of 35 years, a woman freezing her eggs at age 25 might store for up to 25 years, a couple accessing treatment where the youngest is aged 40 might store gametes/embryos for a period of 10 years. The agreement with the clinic would also be able to be subject to any policies in place that the clinic has regarding lack of contact by the person(s) storing the gametes/embryos, failure to pay storage fees, or a failure to provide further consent to storage after the agreed upon period expires.

Provision should then be made to support clinics/storage facilities to be able to lawfully remove the gametes or embryos from storage (to allow them to succumb) after the agreed period expires, when accounts have not been paid after a certain time (if issued), and/ or when no further consent if the initial agreed time period for storage has expired and reasonable attempts to contact the person(s) have failed. This should be coupled with guidelines issued by the Minister regarding what 'reasonable attempts' to contact the person involves. All gametes and/or embryos stored for personal use should be allowed to succumb upon a person's death unless subject to the intention for posthumous use by their spouse (see Chapter 8).

Finally, one must consider whether to differentiate between donated gametes and embryos, and those stored for personal use. This approach has been taken in both New South Wales and South Australia to prevent the use of donated embryos and/or gametes over a very long period of time in accord with principles that people who will be born as a result of donor-conception may seek identifying information about their donor, and some, contact. As donors relinquish their relationship or intention to use their gametes/embryos, it is reasonable to consider how long such donations should be stored. Given the considerations about donor-conceived children it would not be acceptable to store donated gametes or embryos for a period of time that would mean that the donated gametes or embryos may be used when the donor(s) is very aged or deceased, or that result in a situation in which the progenitor and/or siblings are more than one generation apart.[475] It would be consistent with the other states to have a time limit upon the storage and/or use of donated gametes or embryos as being 15 years from the date of donation or a date before that if the donor stipulates/consents to an earlier cut-off date or if the donor dies. (It might also be considered as to whether there should be an upper age limit for the donor, for example, not beyond when the donor reaches the age of 50 unless the Minister grants authority to extend that period).

474 Be this donation to another couple, donation for research, or allowing them to succumb (and how). In relation to the latter, Millbank, for example, describes a woman having taken the containers in which the embryos were stored home, knowing they were no longer viable, but preferring this to leaving them on a shelf in the laboratory.

475 Note, the use of donated gametes posthumously is also different to the issue of posthumous use of gametes by the spouse or partner of a deceased person who would have parented the child if not for their early death. The posthumous retrieval, storage, and use of gametes is discussed in the next chapter.

7.8 Rights upon separation or divorce, death, or physical or mental incapacity, subsequent spouses, and other relatives

7.8.1 Disagreement about use or storage

A couple may, upon separation or divorce, disagree in relation to the use or continued storage of an egg undergoing fertilisation or a human embryo. In 2002 section 23(2) of the *HRT Act* 1991 (WA) was amended to provide for this situation presently stating:

Where rights in relation to a human egg undergoing fertilisation or a human embryo are vested in a couple and the couple disagree about its use or continued storage, the DG shall, on application by a member of that couple, direct the licensee storing the egg or embryo to ensure that the storage is maintained subject to:

- payment of the proper charges of the licensee for the storage
- any limitation as to the time of storage prescribed or determined in accordance with (the Act)
- any order made by a court of competent jurisdiction which otherwise requires.

This provides for the ongoing storage of an egg undergoing fertilisation or a human embryo until such time as the couple comes to an agreement, ceases paying any storage fees, reaches the time limit for storage, or a Court order stipulates what should happen.

The NHMRC Ethical Guidelines require that when discussing storage with a couple a clinic must discuss any circumstances under which the clinic may dispose of the gametes or embryos before the end of the consent period, including the clinic's policy for managing disputes that may arise between a couple for whom an embryo is stored (paragraph 4.6.4). Paragraph 7.4 of the Ethical Guidelines further provides in relation to the management of disputes between members of a couple for whom an embryo is stored that:

> 7.4.1 Clinics must have clear policies for managing disputes that may arise between individuals for whom an embryo is stored.
>
> 7.4.2 When a dispute arises, a clinic may suspend the expiry of the period of storage specified in the consent form (see paragraph 4.6.4) at the request of either party. Such a suspension should be notified in writing to both parties and should be reviewed by the clinic every five years. Any subsequent discard of the embryos, without the consent of both parties, must be in accordance with the clinic's policy, which should have been clearly articulated to the responsible couple before the storage initially occurred.

The *HRT Act* should be consistent with the NHMRC Ethical Guidelines in stipulating discussion should take place at the time embryos are being stored about the clinic's policy in relation to disputes (as well as discussion regarding what the law provides). The *HRT Act* should also be consistent with the NHMRC Guidelines that a decision to suspend the agreed time period should be reviewed every five years, and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and clinic's policies.

7.8.2 Rights when there is physical or mental incapacity

The *HRT Act* does not speak to what should occur when a person becomes physically or mentally incapacitated and has gametes or embryos in storage. However, this does not seem to be an issue if a person is physically incapacitated as, provided they still have the cognitive capacity, they will still be able to direct what happens to their stored gametes or embryos.

If the incapacity results in lack of cognitive function or inability to consent and is impermanent, then any storage limit should be suspended until the person recovers. If the incapacity is permanent (e.g. the person is in a continuing vegetative state) or due to brain death, then the person's wishes as expressed prior to this state should be considered. This should include if there was any explicit consent in writing as to what should happen to any gametes or embryos the person has stored for their personal use, which should have been discussed at the time of storage, or other evidence as to what the person would have wanted in relation to continued storage and the possibility of posthumous use (which is discussed in Chapter 8).

7.8.3 Death

Section 26(1)(b) provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman… in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death would then be directed by the law on posthumous use of gametes/embryos, which is discussed further in Chapter 8. (Note, Chapter 8 recommends that gametes or embryos stored for a person's personal use with their spouse should not be stored (or used) beyond a person's death if they have objected to such storage (or their use) (See Chapter 8).) If both members of a couple die (for example in a car accident), the clinic should allow any stored gametes/embryos to succumb, following approval by the Minister/DG.

7.8.4 Rights of third parties

Subsequent spouses of the partner, or the relatives, of a deceased person, should not have a 'right' conferred upon them to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1). Their continued storage or use then should be determined as per the discussion in Chapter 8 regarding posthumous storage and use of gametes/embryos.

Findings

1. Current provisions regarding time limits for storage of embryos and gametes intended for personal use, and associated required periods of consent, in Western Australia are unsatisfactory and inconsistent with practices across Australia. Arbitrary time limits for storage imposed upon patients in relation to their gametes/embryos intended for their personal use are not evidence-based, and do not respect patient autonomy to consent to a period of storage that meets their personal needs and circumstances.

2. Time limits for storage of gametes or embryos for a person/couple's personal use would best be decided upon by that person/couple in consultation with their clinician, as per the requirements of the NHMRC Ethical Guidelines. They should not be stored after a person's death other than where there is evidence they have consented to the posthumous use of such gametes/embryos by their surviving spouse.
3. A distinction should be made for donated gametes/embryos, due to the implications for donor-conceived people. As such, and consistent with the states of New South Wales and South Australia, donated gametes/embryos should not be stored for more than 15 years after the date of donation, unless granted authority to extend that period by the Minister. Preferably, a maximum cut-off-age should also be agreed upon (for example, a storage period that does not go beyond the donor's 50th birthday or a lesser time if stipulated by the donor), and not for a period beyond the donor's death.
4. Section 26(2) of the *HRT Act*, provides for the maintenance of storage where a couple for whom an egg in the process of fertilisation or an embryo disagree about its continued storage. Further clarification regarding this matter is needed. The *HRT Act*/HRT Directions should be consistent with the NHMRC Ethical Guidelines by requiring that discussion take place *at the time embryos are being stored* about the clinic's policy in relation to disputes, any pre-agreement by the parties, and discussion regarding what the law provides and requires.
5. The *HRT Act* should also be consistent with the NHMRC Guidelines that a decision to suspend the agreed time period should be reviewed every five years, and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and the agreement made at the time of storage.
6. If a person is physically incapacitated, provided they still have the cognitive capacity, they will still be able to direct what happens to their stored gametes or embryos.
7. If a person suffers incapacity that results in lack of cognitive function or inability to make decisions or give consent, but such incapacity is impermanent (the person is expected to recover), then any storage limit should be suspended until the person recovers.
8. If the cognitive incapacity of a person that results in them losing decision-making capacity is assessed by a medical practitioner as permanent (such as they are in a persistent vegetative state from which they will not recover) or is due to brain death, then the person's wishes as expressed prior to this state should be taken into account in relation to the storage of their gametes or embryos. This should include consideration of if there was any explicit consent in writing as to what should happen to any gametes or embryos the person has stored for their personal use, which should have been discussed at the time of storage, or other evidence as to what the person would have wanted in relation to continued storage and the possibility of posthumous use by their surviving spouse (see further Chapter 8).
9. Section 26(1)(b) provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman… in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death would then be directed by the law on the posthumous use of gametes/embryos.
10. Gametes or embryos stored for a person's personal use with their spouse should not be stored (or used) beyond a person's death if they have objected to such storage (or their use).

11. Subsequent spouses of the partner, or the relatives, of a deceased person, should not have a 'right' conferred upon them to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1), and then will be subject to provisions relevant to the posthumous use of gametes/embryos.
12. If both members of a couple die (for example in a car accident), the clinic should allow any stored gametes/embryos to succumb, following approval by the Minister/DG of the Department.

Recommendations

Recommendation 39

The Minister repeal s24 of the *HRT Act* and Direction 6.8 which stipulate time limits for storage of embryos and gametes respectively, and provide in the new *HRT Act*/Directions that a person or couple, for whom gametes or embryos will be stored for their personal use in assisted reproduction, and the clinic must discuss and agree upon in writing:

a. the storage period for the person's or couple's gametes/embryo(s) that suits their circumstances;
b. the conditions and period of time upon which the gametes/embryos will be stored and will cease to be stored; and
c. the gametes/embryos not being stored beyond death of a person unless there is consent regarding the posthumous use of such gametes or embryos by the surviving spouse.

Recommendation 40

The Minister/DG provide in the (new) HRT Directions the conditions pursuant to which a clinic may lawfully remove the gametes or embryo(s) from storage and allow them to succumb. Such conditions should include the failure of a person or couple to pay the storage fees (if any) for a period of more than five years and/or the failure of a person or couple to consent to a further storage period after the previously agreed storage period has expired, and there has been an inability to contact or trace the person or couple after reasonable attempts to do so have been made in relation to non-payment of storage fees or during the three months preceding the end of the storage period.

Recommendation 41

The new HRT Directions detail what constitutes a 'reasonable attempt' in relation to seeking contact with a person or couple who have stored gametes/embryos where storage fees have not been paid for a period of five years, or the expiry date of agreed storage is about to be/ has been reached.

Recommendation 42

A section be drafted for inclusion in the (new) *HRT Act*/Directions that *donated* gametes/embryos should not be stored for a period of more than 15 years from the date of donation, and not after a) the gamete donor (donor of ova or sperm) has reached the age of 50 or is deceased; or b) in relation to a donated embryo, the donor(s) (or any gamete provider where the embryo has been created using both donated eggs and sperm) has reached the age of 50 or is deceased; unless authorisation has been granted by the Minister/DG. Such authorisation must not be given unless the Minister/DG is satisfied that there are reasonable grounds for extending the storage period having regard to any relevant guidelines issued by the Minister/DG.

Recommendation 43

Section 26(2) of the *HRT Act* be maintained (in the current or any new legislation) in that it provides for the maintenance of storage where a couple for whom an egg in the process of fertilisation or an embryo disagree about its continued storage. Further clarification should be provided in the HRT Directions consistent with the NHMRC Ethical Guidelines by requiring discussion to take place (at the time embryos are being stored) about the clinic's policy in relation to disputes, any pre-agreement by the parties and discussion regarding what the law provides. The HRT Directions should also specify that a decision to suspend the agreed time period should be reviewed every five years and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and agreement made at the time of storage.

Recommendation 44

The HRT Directions provide that persons who are physically incapacitated maintain the right to direct what happens to their stored gametes or embryos.

Recommendation 45

The HRT Directions provide that if a person suffers incapacity that results in lack of cognitive function or decision making capacity, but such incapacity is not expected to be permanent (i.e. the person is expected to recover), then any storage limit should be suspended until the person recovers (or if it is decided by a medical professional that they will not recover at which point their prior wishes, and any agreement regarding storage should be taken into account, as well as any legislative provisions or directions relating to the vesting of rights in any spouse/survivor, to determine if or when such gametes/embryos may be permitted to succumb).

Recommendation 46

Section 26(1)(b) of the *HRT Act* be maintained (in the present Act and any new legislation) in that it provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman… in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death should then be directed by the law on the posthumous use of gametes/embryos.

Recommendation 47

The HRT Directions provide that if both members of a couple die (for example in an accident), the clinic must allow any stored gametes/embryos to succumb, following approval by the Minister/DG of the Department.

Recommendation 48

The HRT Directions provide that subsequent spouses of the surviving partner, or the relatives, of a deceased person, do not have the 'right' to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1), which is subject to provisions relevant to the posthumous use of gametes/embryos.

Table: Required change and action

Table 7.4 details the changes required that are relevant to the discussion regarding the storage of gametes and embryos. Again, it is noted that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended *as a matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 7.4 Recommended Changes to Legislation, Directions and Operations Regarding Storage of Gametes and Embryos

Required Change	Legislation*	Directions**	Operation**
Provide for agreement between a person(s) who store gametes or embryo(s) for personal use to agree the time period for storage in consultation with clinics (and counsellors if required). (Consistent with NHMRC Ethical Guidelines).	Repeal s24 of the *HRT Act* regarding storage periods for embryos (10 years).	Repeal HRT Direction 6.8 (which stipulates a 15-year time limit for storage of gametes); and HRT Direction 3.1 (requiring consent to store gametes be renewed every five years). Repeal and amend other Directions relevant to storage and consent. Provide new Directions as per the recommendations in this report including, but not limited to: that a person or couple for whom gametes or embryos will be stored for their personal use in assisted reproduction and the clinic must discuss and agree in writing upon: a. the storage period for the person or couple's gametes/embryo(s) that suits their circumstances; b. the conditions and period of time upon which the gametes/embryos will be stored and will cease to be stored; and c. the gametes/embryos not being stored beyond death of a person unless there is consent regarding the posthumous use of such gametes or embryos by the surviving spouse.	RTC/RTU to provide information and support to clinics/ public, as required. (But are no longer to be responsible for 'approvals' that exist under the current regime).
Provide for the conditions pursuant to which a clinic/storage facility may lawfully remove gametes or embryos from storage.		That the Minister/DG provide in the new HRT Directions the conditions pursuant to which a clinic may lawfully remove the gametes or embryo(s) from storage and allow them to succumb. Such conditions should include: a. the failure of a person or couple to pay the storage fees (if any) for a period of more than five years and/or b. the failure of a person or couple to consent to a further storage period after the previously agreed storage period has expired, and there has been an inability to contact or trace the person or couple after reasonable attempts to do so have been made in relation to non-payment of storage fees or during the three months preceding the end of the storage period.	RTC/RTU to provide information and support to clinics/ public, as required.

Required Change	Legislation*	Directions**	Operation**
Provide guidance on what constitutes a 'reasonable attempt' to seek contact with a person or couple about the storage of gametes/embryos and non-payment of fees or the expiry of the agreed storage period.		That the new HRT Directions detail what constitutes a 'reasonable attempt' in relation to seeking contact with a person or couple who have stored gametes/embryos where storage fees have not been paid for a period of five years, or the expiry date of agreed storage is about to be/has been reached.	Provide information and support as required.
Provide for a limited storage period in relation to donated gametes or embryos.		That the new HRT Directions include provision that donated gametes/ embryos should not be stored for a period of more than 15 years from the date of donation, and not after: • the gamete donor (donor of ova or sperm) has reached the age of 50 or is deceased; or • in relation to a donated embryo, the donor(s) (or any gamete provider where the embryo has been created using both donated eggs and sperm) has reached the age of 50 or is deceased; unless the Minister/DG has granted authorisation. Provide that such authorisation must not be given unless the Minister/DG is satisfied that there are reasonable grounds for extending the storage period having regard to any relevant guidelines issued by the Minister/DG.	Provide information and support as required.
Provide for what should occur in the case of a couple for whom an egg in the process of fertilisation or an embryo is stored disagree about future storage.	Maintain section 26(2) of the *HRT Act* in the current or any new legislation in that it provides for the maintenance of storage where a couple for whom an egg in the process of fertilisation or an embryo disagree about its continued storage.	Provide further clarification in the HRT Directions consistent with the NHMRC Ethical Guidelines to require that discussion should take place at the time embryos are being stored about the clinic's policy in relation to disputes, any pre-agreement by the parties, and discussion regarding what the law provides. The HRT Directions should also specify that a decision to suspend the agreed time period should be reviewed every five years and that any subsequent discard without the consent of both parties should be in accordance with the *HRT Act* and the agreement made at the time of storage.	Provide information and support as required.
Make clear provision that persons who are physically incapacitated maintain the right to direct what happens to their stored gametes or embryos.		Provide that persons who are physically incapacitated maintain the right to direct what happens to their stored gametes or embryos.	Provide information and support as required.

Required Change	Legislation*	Directions**	Operation**
Make clear provision that if a person that suffers incapacity that results in lack of cognitive function or decision-making capacity, but such incapacity is not expected to be permanent (i.e. the person is expected to recover), then any storage limit should be suspended until the person recovers or the situation is assessed differently.		That the HRT Directions should provide that if a person that suffers incapacity that results in lack of cognitive function or decision making capacity, but such incapacity is not expected to be permanent (i.e. the person is expected to recover), then any storage limit should be suspended until the person recovers, or if it is decided by a medical professional that they will not recover at which point their prior wishes, and any agreement regarding storage should be taken into account, as well as any legislative provisions or directions relating to the vesting of rights in any spouse/ survivor, to determine if or when such gametes/embryos may be permitted to succumb.	Provide information and support as required.
Maintain provision for the vesting of rights in surviving spouse/ partner.	Section 26(1)(b) of the *HRT Act* should be maintained (in the present Act and any new legislation) in that it provides that in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing fertilisation or human embryo that is outside of the body of a woman… in the event of one member of a couple in whom the rights are vested, those rights vest solely in the survivor. What happens after death should then be directed by the law on the posthumous use of gametes/embryos.		Provide information and support as required.
Make provision regarding removal from storage of gametes/ embryos should both parties to a couple die.		That the HRT Directions should provide that if both members of a couple die (for example in an accident), the clinic must allow any stored gametes/embryos to succumb, following approval by the Minister/DG of the Department.	Provide information and support as required.
Make provision to limit the vesting of rights solely in the deceased person's surviving spouse/partner.		The HRT Directions should provide that subsequent spouses of the surviving partner, or the relatives, of a deceased person, do not have the 'right' to make decisions about the continued storage of gametes or embryos. The right vests solely in the person's surviving spouse as per s 26(1), which is subject to provisions relevant to the posthumous use of gametes/embryos.	Provide information and support as required.

Chapter 8

ART Issues – Posthumous Use of Gametes

Chapter 8:
ART Issues – Posthumous Use of Gametes

8.1 Introduction

The possibility that an individual might be conceived following the death of one of their parents is understandably controversial. This situation might arise via the use of gametes or embryos collected and stored prior to the death of a spouse or partner; or the collection of gametes from a deceased person, or a person who is dying and their subsequent use. This chapter addresses the Terms of Reference in relation to issues surrounding the posthumous collection, storage and use of gametes and embryos, including the consent required, conditions for use, and any impact on other legislation. In such situations, a number of considerations must be had. This includes reference to relevant state or territory legislation; respect for the deceased or dying person; respect for the desire of the surviving spouse or partner to have a child; possible (and unknown) effects on the welfare of the person to be born having been conceived following a parent's death; and possible (and unknown) effects on the welfare of existing children within the family unit who may be affected by that birth.

In Australia laws exist in each state and territory that are relevant to the posthumous use of gametes and embryos. Across the country the ability *to remove* tissue from the body of a person may be provided for in the respective state or territory human tissue and transplantation Acts, is referred to in the NHMRC Ethical Guidelines, and has been subject to the consideration of the respective state Courts. The ability *to use* the gametes is governed in some states by specific ART legislation (Western Australia, New South Wales, South Australia, Victoria) and/or the NHMRC Ethical Guidelines (Australian Capital Territory, Northern Territory, Queensland, and Tasmania).

In the following sections an overview of the law in Western Australia concerning posthumous collection, storage and use of gametes, and the laws of other jurisdictions in Australia, is provided. Examination of recent judicial decisions when an issue has reached the Courts is then had. In considering such matters recommendations are then made concerning how Western Australian law should address the posthumous use of gametes and embryos.

8.2 Current law in Western Australia

In relation to posthumous collection of gametes after a person's death, section 22 of the *Human Tissue and Transplant Act 1982* (WA) provides that a designated officer for a hospital may authorise the *removal* of tissue from the body of a person who has died in hospital or whose dead body has been brought into the hospital for the purpose of the transplantation of the tissue to the body of a living person; or for use of the tissue for other therapeutic purposes or for medical or scientific purposes where, after making inquiries, the designated officer is satisfied that:

- the deceased person during his lifetime expressed the wish for, or consented to, the removal after his death of tissue from his body for the purpose or a use and had not withdrawn the wish or revoked the consent

- where, after making inquiries, the designated officer has no reason to believe that the deceased person had expressed an objection to the removal after his death of tissue from his body for the purpose or a use and the designated officer is satisfied that the senior available next of kin consents to the removal of tissue from the body of the deceased person for the purpose or a use referred to in subsection.

In *Re Section 22 of the Human Tissue and Transplant Act 1982 (WA); Ex Parte C* [2013] WASC 3 (2 January 2013), Edelman J applied the above provisions to a case in which an urgent application was heard for removal and storage of spermatozoa and associated tissue from Ms C's husband who had died the previous day. The evidence was that Ms C and her husband had been trying for her to conceive for nearly two years. They had commenced a program of in vitro fertilisation. Her husband consented throughout to the plan of having a baby. On 28 December 2012 he committed suicide. He had previously encountered several bouts of depression. Ms C wanted to extract spermatozoa from his body for the possibility of future in vitro fertilisation. She was told by officials at the hospital at which her husband's body had been present that she needed a court order. By the time that Ms C contacted the court there were only hours remaining for: (1) the hearing of the matter; (2) the making of a formal order; (3) the provision of the order to the doctor; and (4) the removal of the spermatozoa from Ms C's deceased husband. Edelman J noted Ms C was the senior available next-of-kin of the deceased, and the effect of s 22 is that the designated officer for the hospital had the power to authorise the removal of tissue from Ms C's deceased husband because:

1. *his dead body had been brought into the hospital*
2. *the power of the authorised officer to remove spermatozoa for the purposes of storage for later assistance for another person to become pregnant tissue falls within 'medical purposes' (terminology used in s 22(1)(b))*
3. *the word 'tissue', as defined by the Act includes spermatozoa*
4. *if the designated officer, or his delegate, had made inquiries of Ms C then those inquiries would have revealed to the designated officer that there is no reason to believe that the deceased person had expressed an objection to the removal after his death of tissue from his body for 'medical purposes' as described above and the designated officer would have been satisfied that Ms C consented to the removal of the spermatozoa for that purpose. Nor was there any suggestion of any possible objection by any of the persons listed in the definition of 'senior available next-of-kin'.*

Because the husband's death had been a suicide, there was one additional qualification. Section 23 of the *Human Tissue and Transplant Act 1982* (WA) provides that if the designated officer for a hospital has reason to believe that the death of a person is or may be a reportable death, the designated officer shall not authorise the removal of tissue from the body of the deceased person unless: the coroner has given his consent to the removal, or the coroner has given a direction either before or after the death of a person that his consent to the removal of tissue from the body of the person after the death of the person is not required. Section 23(4) provides that the consent of the coroner can be given orally and, if so given, shall be confirmed in writing. Edelman J had his associate call the coroner and the coroner gave such consent. The sperm was, therefore, able to be removed. However, Edelman J noted that in the future the hospital should act expediently and not require a court order for such action where the senior next of kin has given consent.

Use of gametes posthumously to conceive a child is a separate issue in Western Australia.

The *HRT Act 1991* (WA) (*HRT Act*) provides that gametes of a person or embryos created with gametes cannot be used without their consent, and such consent must be in writing.[476] However, directions given by the Commissioner of Health pursuant to the *HRT Act*, further provide that any person to whom a licence applies must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider.[477] This effectively prohibits the posthumous use of gametes in Western Australia, whether they were collected prior to or after death.

However, in cases that have lawfully engaged in the *removal* of gametes posthumously pursuant to the *Human Tissue and Transplant Act 1982* (WA),[478] or where gametes or embryos have been stored prior to death, permission has been granted on occasion by the RTC, and more recently it has been held by the Supreme Court, that the person wishing to use the gametes may remove them interstate to a jurisdiction in which their *use* is permissible.[479] Importantly, the Supreme Court has also held that such removal to another state by a spouse/partner does not require the approval of the RTC under the current directions. The current law as interpreted by such common law decisions is discussed further below at 8.4.

8.3 Current law in other jurisdictions of Australia

New South Wales

The *Human Tissue Act 1983* (NSW) permits *removal* of human tissue after death for transplantation or other therapeutic or medical use in another person provided written consent of the deceased was given prior to death, and not revoked.[480] Like Western Australia, the senior next of kin may also give such approval when the designated officer has no reason to believe that the deceased person during his lifetime had neither expressed consent nor objection to the removal of tissue after death. Unlike Western Australia, the provisions also include wider decision-making powers by the designated officer in section 23(3) of the *Human Tissue Act* in which the designated officer is unable to ascertain the existence or whereabouts of the next of kin, the designated officer may authorise the removal of tissue from the body of the deceased person.

The *Assisted Reproductive Technology Act 2007* (NSW) provides that use of gametes or embryos is not permitted after death unless the gamete provider has given *written consent prior to death*; that the woman who is to use the gametes has been notified of death; and that the woman provides written consent to use the gametes.[481] (Note, New South Wales legislation does not specify that use must be by the partner, and therefore may be read to include the posthumous use of gametes collected from a donor.) The *Assisted Reproductive Technology Act 2007* (NSW) also prohibits storage or export of the sperm in the absence of *written consent of the donor*.[482] The posthumous removal, storage and use of gametes in New South Wales may thus occur provided there is written consent.

476 *HRT Act 1991* (WA) s 22.

477 Western Australian Government Gazette No 201, 30 November 2004, Dir 8.9.

478 See, for example, *S v Minister for Health* (WA) [2008] WASC 262; *Re Section 22 of the Human Tissue and Transplant Act (WA)*; *Ex parte M* [2008] WASC 276.

479 See *GLS v Russell-Weisz* [2018] WASC 79.

480 *Human Tissue Act 1983*, Pt 4 ss 23 and 24.

481 *Assisted Reproductive Technology Act 2007 (NSW)* ss 17, 18, 19 and 23.

482 *Assisted Reproductive Technology Act 2007 (NSW)* ss 22 and 25.

Notably, the s 23(3) ability for the senior next of kin or designated officer to allow such removal when written consent is absent has been viewed as making the legal position unclear as it is contrary to the prohibition on storing them without written consent pursuant to the New South Wales ART legislation. [483] In the 2018 case of *Chapman v South Eastern Sydney Local Health District*[484] which concerned an application to export sperm from New South Wales which had already been removed from a deceased man who had not given prior written consent, Fagan J thus called for the legislature to clarify the issue. He said there is 'the need for an unequivocal statutory rule' regarding sperm recovery from unconscious patients and from dead bodies. He said:

> *It is undesirable that hospital staff should be left to fathom what Parliament may have intended by first providing that a designated officer may authorise removal of human tissue, generally and including sperm, from a dead body, notwithstanding the absence of written consent …and then enacting in the Assisted Reproductive Technology Act a prohibition upon storing or doing anything else with the material [if such written consent is absent]. It is likewise undesirable that such professional staff, or the next of kin of a deceased person, should be put to the task of finding a report of this or any other judicial decision which might be thought to resolve the relationship between the two statutes or that they should need to make an application to the Court to clarify the position.*

In granting the application for the export of the sperm to a state in which it could be used (the Australian Capital Territory, Northern Territory, or Tasmania), Fagan J then followed the line of authority stemming from the New South Wales case of *Re Estate of Edwards*. As discussed below, that case held that the applicant spouse had a right to possession, enabling the release of the gametes to her for their export out of the state to a jurisdiction in which they may be used.

South Australia

The *Transplantation and Anatomy Act 1983* (SA) provides that a designated officer for a hospital may authorise the removal of tissue from the body of a person who has died in the hospital or whose dead body has been brought into the hospital for the purpose of the transplantation of the tissue to the body of a living person; or for use of the tissue for other therapeutic purposes or for medical or scientific purposes.[485] There must be a reasonable belief that the deceased person had, during his lifetime, expressed the wish for, or consented to, the removal after his death of tissue from his body for the purpose or a use referred to above, and had not withdrawn the wish or revoked the consent.[486] The South Australian legislation also includes a similar provision to New South Wales regarding the designated officer's ability to authorise the removal of tissue from the body of the deceased person for the purpose or a use referred to above, in the absence of written consent.

483 *Chapman v South Eastern Sydney Local Health District* [2018] NSWSC 1231.

484 Ibid.

485 *Transplantation and Anatomy Act 1983* (SA) s 21.

486 *Transplantation and Anatomy Act 1983* (SA) s 21.

In the 2012 case of *Re H, AE*,[487] which involved an application for removal and storage of gametes from a deceased male who had not provided written consent, Gray J considered that it was not necessary in the case before the Court to determine whether the removal was within the provisions of the *Transplantation and Anatomy Act 1983* (SA), but noted the Act did not prohibit an order for the removal of the sperm. He further considered that orders for removal could be made within the inherent jurisdiction of the Court. His Honour held that given that state legislation envisaged the use of sperm of the deceased person for the purposes of artificial insemination, there was no reason why the ordinary principles relating to the preservation of the subject matter of litigation did not apply. There needed to be an order for extraction to enable preservation to be affected.

Regarding the use of gametes or embryos posthumously, the *Assisted Reproductive Technology Act 1988* (SA) provides that when semen of a donor was collected or used to fertilise an ova or create an embryo before the donor died, and written consent was given to use the semen after the donor's death, the semen (or resultant embryo) may be used after the donor's death for a woman who was living with the donor on a genuine domestic basis.[488]

The *Transplantation and Anatomy Act 1983* (SA) is silent regarding the posthumous use of ova and the use of sperm collected *after* death. However, in *Re H, AE (No 3)* (2013) 118 SASR 259 where sperm had been collected posthumously, and written consent to use the sperm did not exist, the Supreme Court approved an application to transport the sperm to the Australian Capital Territory.

Victoria

The *Human Tissue Act 1982* (Vic) permits the *removal* of human tissue after death for transplantation or other therapeutic or medical use in another person subject to written or oral consent (in front of two witnesses for the latter).[489] In *AB v Attorney-General* (2005) 12 VR 485 Hargrave J stated that, if it had been relevant for him to decide, he would have found that the purpose of removing the sperm was for 'medical purposes' within the meaning of the relevant tissue and transplant legislation. Similarly, Habersberger J in *Y v Austin Health* (2005) 13 VR 363 considered that the obtaining of sperm for use in reproduction would be for 'medical purposes'.

The *Assisted Reproductive Technology Act 2008* (Vic) provides that gametes or embryo(s) may be used by the deceased person's partner, or if the deceased is a woman, for use in a surrogate mother, with the deceased's written consent, and with the consent of the Patient Review Panel. The person who will undergo treatment must have counselling.[490] Such counselling must cover the grieving process and the possible impact on the child to be born as a result of the treatment procedure.[491] Victoria is the only jurisdiction that explicitly provides for the posthumous use of gametes or embryos in a surrogate mother.

487 *Re H, AE*, (2012) 113 SASR 560.

488 *Assisted Reproductive Technology Act 1988* (SA) s 9(1)(iv).

489 *Human Tissue Act 1982* s 26.

490 *Assisted Reproductive Technology Act 2008* ss 46–48.

491 Assisted Reproductive Treatment Regulations 2009, r 11.

Australian Capital Territory, Northern Territory, Queensland, and Tasmania

In the Australian Capital Territory,[492] Northern Territory,[493] Queensland,[494] and Tasmania[495] the respective 'tissue and transplantation acts' permit the *removal* of tissue posthumously upon similar terms to those in Western Australia, New South Wales and South Australia.

In Queensland, whether the *Tissue and Anatomy Act 1979* (Qld) applies to the removal of gametes posthumously was queried in judgements handed down in the early 2000s (see below discussion of Re Gray). Subsequent judgements have permitted such removal subject to an interlocutory Court order (see below discussion of Re Denman). More recently in the 2018 case of *Cresswell v Attorney General for the State of Queensland*[496] Brown J considered that the Transplantation Act did apply to the removal of the sperm. Her Honour further noted in that case that she did not agree with a Queensland Government document 'Guidelines for removal of sperm from deceased persons for IVF: consent, authorisation and role of IVF organisations' which provides that a court order for removal is required for such removal to occur.

The Northern Territory, Queensland, Australian Capital Territory or Tasmania do not have legislation concerning the posthumous *use* of gametes. In the Northern Territory, it is generally the case that South Australian laws are followed. In Queensland, in *Cresswell*, a right to possession and use of gametes was recognised by the Court (see further discussion below).

The NHMRC Ethical Guidelines

In all jurisdictions, the NHMRC Ethical Guidelines provide guidance on the posthumous use of gametes. Adherence to them is a requirement of RTAC Accreditation, and they, therefore, apply in all states and territories to the extent that they do not conflict with the law. (That is, the law takes precedence). The NHMRC Ethical Guidelines provide that court authority is required before a clinician may facilitate the collection of gametes from a person who is deceased or is dying and lacks the capacity to provide valid consent. In the case of posthumous collection, this may be relevant when provisions of the above human tissue and transplantation Acts have not been met – however, note the decision of *Re Section 22 of the Human Tissue and Transplant Act 1982 (WA); Ex Parte C* [2013] WASC 3 in Western Australia permits the senior next of kin to make such a decision without recourse to the Courts, and that such a view was also recently echoed in the Queensland case of *Cresswell*.

492 *Transplantation and Anatomy Act 1978* (ACT).

493 *Transplantation and Anatomy Act (NT)* (as in force at April 2017).

494 *Transplantation and Anatomy Act 1979* (Qld).

495 *Human Tissue Act 1985* (Tas).

496 *Cresswell v Attorney-General for the State of Queensland* [2018] QSC 142

With such authority, clinics[497] may then facilitate the collection of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent if: the request to do so has come from the spouse or partner of the deceased or dying person, and not from any other relative; the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction; there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur; the surviving spouse or partner provides valid consent for the collection and storage of the gametes; the proposed collection and storage has been approved by an appropriate court authority.[498]

Regarding the posthumous use of stored gametes or embryos to achieve pregnancy the NHMRC Ethical Guidelines state that where permitted by law, clinics may facilitate such use, if:

- the deceased person left clearly expressed directions consenting to such use following their death
- the request to do so has come from the spouse or partner of the deceased person, and not from any other relative
- the gametes are intended for use by the surviving spouse or 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) is 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
- the surviving prospective parent (the spouse or partner) has undergone appropriate counselling
- an independent body has reviewed the circumstances and supports the proposed use.[499]

Note, in states that have legislative provisions the NHMRC Ethical Guidelines may be used as guidance to the extent to which they do not conflict with the law.[500]

8.4 Common law decisions concerning the posthumous collection, storage, and use of gametes

In examining the law relevant to the posthumous collection, storage, and use of gametes it is also relevant to consider further the case law. In particular there are three divergent lines of authorities as to the Court's power to order removal of gametes that have been followed in various states of Australia. In relation to storage and use, the Western Australian Supreme Court has followed a line of authority that has found a right to possession by the spouse/partner. These are discussed in turn.

497 Note that the ethical guidelines apply to the use of ART in clinical practice or research. It may be that it is not a clinic that is removing the gametes, but rather a hospital. Whether these guidelines apply in that case should be considered.

498 *NHMRC Ethical Guidelines* (2017) at [8.21].

499 *NHMRC Ethical Guidelines* (2017) at [8.22]–[8.23].

500 For further discussion in the context of posthumous use of gametes see *Re YZ and Infertility Treatment Authority* (2005) VAR 1; and *Re H, AE (No 3)* [2013] SASC 196.

Court has no power to make an order for removal

An early line of authority established in 2001 by the case of *Re Gray*[501] considered that the Court has no power to make an order for removal at all. In *Re Gray*, a woman's husband had died unexpectedly in his sleep. Chesterman J was of the view that the *Transplantation and Anatomy Act 1979* (Qld) had no application as the removal of tissue under the statutory regime must be for the transplantation into the body of a living person or for some therapeutic or other medical or scientific purpose, and the applicant's purpose was none of those purposes. He further stated:

> *The deceased's personal representative or, where there is none, the parents or spouse, have a right to possession of the body only for the purposes of ensuring prompt and decent disposal has, I think, the corollary that there is a duty not to interfere with the body or, to use the language found in Pierce, to violate it. These principles are inimical to the proposition that the next of kin or legal personal representative may remove part of the body.*

In considering the situation in which even if the Court had some general overriding power to permit a party to remove reproductive tissue from a deceased person Chesterman J said such a power would be discretionary. He said he would have declined the application in the case to hand as:

- the deceased had not in his lifetime indicated his consent to such a procedure, such that there was no reason to think that he would have wished his wife to be impregnated posthumously even though he may have wanted another child during his lifetime
- the Court could have no confidence that the applicant's desire was a result of careful and rational deliberation given the time between her husband's death and having to make an urgent application
- the interests of any child born as a result of the procedure must be of particular importance in the exercise of the discretion, and he did not see how it could be in the best interests of the child to grow up fatherless and because the Court can never know in what the circumstances the child would be born or brought up it would be impossible to know what is in its best interests.

Chesterman J's reasoning in *Re Gray* was followed in the 2003 Queensland case of *Baker v State of Queensland*.[502]

The court may order the posthumous collection of gametes by way of an interlocutory order

The second line of authority stems from cases in the United Kingdom, the United States and Victoria,[503] that have permitted the removal or use of the sperm of a deceased person. It is one that has predominantly been followed in Queensland regarding orders for the removal of gametes, the principle case being *Re Denman*.[504]

501 *Re Gray* [2001] 2 Qd R 35.

502 *Baker v State of Queensland* [2003] QSC 002.

503 *R v Human Fertilisation and Embryology Authority; ex parte Blood* [1997] 2 All ER 687; *Hecht v Superior Court* (Kane) 20 Cal Rptr 2d 275 (Cal App 2 Dist 1993); *AB v Attorney-General* (Supreme Court (Vic), Gillard J., 23 July 1998, unreported).

504 *Re Denman* [2004] 2 Qd R 595.

In *Re Denman*, the couple concerned had lived together for five years and had discussed their desire to have two children. They had been married four months prior to the application in order to have children. The husband died unexpectedly and without a will. In deciding whether sperm could be collected from the deceased, Atkinson J did not follow *Re Gray* and *Baker* on the basis that she considered the Court had an inherent jurisdiction to allow behaviour which is not unlawful. She followed the above-mentioned cases from the United Kingdom, the United States and Victoria. She also considered that it would not offend the criminal law if the deceased's widow wished to have the sperm removed in circumstances where the couple had discussed their keen desire to have children. Atkinson J thus granted permission to remove the sperm from the deceased relying on the inherent power of the Court to permit the making of an order which is in the nature of an interlocutory order, pending a determination of whether there is any jurisdiction for the Court to make orders as to the future use of the sperm.

Posthumous removal of sperm may be regarded as 'for medical purposes' under the transplant and tissue legislation.

In other states, courts have considered whether the removal of sperm was for 'medical or scientific purposes' as required under the respective transplant and tissue legislation discussed above.

In Victoria, in *AB v Attorney-General* (2005) 12 VR 485 Hargrave J stated that, if it had been relevant for him to decide, he would have found that the purpose of removing the sperm was for medical purposes within the meaning of the relevant legislation. Similarly, Habersberger J in *Y v Austin Health* (2005) 13 VR 363 considered that the obtaining of sperm for use in reproduction would be for 'medical purposes'.

In New South Wales, in Hulme J in *Edwards; Re Estate of Edwards* (2011) 81 NSWLR 198 found that the removal of sperm could be regarded as 'for medical purposes'.

In Western Australia, in *Re Section 22 of the Human Tissue and Transplant Act 1982 (WA); Ex Parte C* [2013] WASC 3 Edelman J held that the power of the authorised officer to remove spermatozoa for the purposes of storage for later assistance for another person to become pregnant tissue falls within 'medical purposes' referred to in s 22(1)(b)); and the word 'tissue', as defined by the Act includes spermatozoa.

In Queensland, in *Cresswell v Attorney General for the State of Queensland* [2018] QSC 142, Brown J considered that 'medical purposes' was wide enough to encompass the removal of sperm, the transplant and tissue legislation therefore applied, and it was necessary to determine whether it had been complied with.

Property law as relevant to storage, direction, and use

In relation to the storage and use of sperm, there has also developed a line of authority that while there is generally the view that there is no property in the human body or its parts, in some circumstances, tissue or part of a human body removed from a corpse can be the subject of property rights. Such cases are generally described as falling within the 'work or skill' exception by reference to the words used by Griffith CJ in the *Doodeward v Spence*:

> *[A] human body, or a portion of a human body, is capable by law of becoming the subject of property. It is not necessary to give an exhaustive enumeration of the circumstances under which such a right may be acquired, but I entertain no doubt that, when a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it.*[505]

The cases that have led to such a 'line of authority' are discussed below in the order of the date they were decided, noting that while decisions from Courts in one state are not binding on another state, they are often referred to as 'persuasive'.

Bazley v Wesley Monash IVF Pty Ltd (Queensland)

The Doodeward 'work or skill' exception was first applied in a case concerning posthumous storage of sperm in the 2011 Queensland Supreme Court decision in *Bazley* v *Wesley Monash IVF Pty Ltd.*[506] In that case, sperm collected prior to the death of a Mr Bazley was stored with the respondent IVF clinic. Mr Bazley's wife requested the clinic to continue to store the sperm, but it refused pursuant to a lack of written consent existing and stating that this was required by the NHMRC Ethical Guidelines. The court considered whether the stored sperm could be considered part of Mr Bazley's estate (and therefore regarded as property). While the court recognised that a human body or corpse is not generally regarded as property in law, White J noted the exception created by *Doodeward v Spence*[507] and said:

> *The conclusion, both in law and in common sense, must be that the straws of semen currently stored with the respondent are property, the ownership of which vested in the deceased while alive and in his personal representatives after his death. The relationship between the respondent and the deceased was one of bailor and bailee for a reward because, so long as the fee was paid, and contact maintained, the respondent agreed to store the straws. The arrangement could also come to an end when the respondent died without leaving a written directive about the semen, but plainly the bailor, or his personal representatives, maintained ownership of the straws of semen and could request the return of his property. Furthermore, it must be implied into the contract of bailment, that the semen would, if requested, be returned in the manner which it was held, which preserved its essential characteristics as frozen semen capable of being used. Any extra costs associated with that redelivery would be at the applicant's expense. Such conditions may be imposed by r 250, if necessary.*[508]

505 *Doodeward v Spence* (1908) 6 CLR 406 at [40].

506 *Bazley v Wesley Monash IVF Pty Ltd* [2011] 2 Qd R 207; [2010] QSC 118.

507 *Doodeward v Spence* (1908) 6 CLR 406.

508 *Bazley v Wesley Monash IVF Pty Ltd* [2011] 2 Qd R 207; [2010] QSC 118 at [33].

An order was made for the continued storage of the sperm. The order did not, however, indicate that the sperm could be used as this was not at issue in this case.

Re Edwards (New South Wales)

In the 2012 New South Wales case of *Re Edwards*,[509] while the focus again was upon whether stored sperm could be viewed as property, issues of required written consent, and the ability to take sperm to a jurisdiction in which it could be used absent of such consent, were also considered. In that case, posthumous extraction of sperm from a man who had died in a workplace accident had been approved and the sperm stored at an IVF clinic. Subsequently, his wife petitioned the court for the sperm to be released to her. R A Hulme J granted the application citing Bazley and the *Doodeward* exception. He noted that the application was for 'release' of the sperm, and not for its use in New South Wales. It could be released to Mrs Edwards as she had an *entitlement to possession*.

While not the subject of the application, the judge noted it was unlikely that Mrs Edwards could use the sperm in New South Wales as whether Mr Edwards had contemplated that the child might be born as a result of ART after he had died was not at all clear and there existed no written consent for its use posthumously, as required by law in New South Wales. The judge noted that Mrs Edwards may travel interstate to a jurisdiction in which the sperm could be used and that if she did so the clinic's releasing the sperm to her would not be an operative cause for its export, 'it might enable it to happen, but it did not cause it to happen'.

Hulme J said in relation to the consideration of the 'best interests' of the child to be born that on the evidence before the Court in Edwards it was clear that any child who would be conceived as a result of the posthumous use of sperm would be born to a loving mother and with a supportive extended family. Beyond this, he was of the view that 'it would be inappropriate to engage in speculation about a variety of indeterminable matters.' In referring to earlier authority that had recognised that conception with children born as a result of reproductive technology was well accepted in 2000, Hulme J also said, 'it seems safe to assume that this is, even more, the case in 2011.'[510]

Re H, AE (No 2) and Re H, AE (No 3) (South Australia)

In *Re H, AE (No 2)* [2012] SASC 177 Gray J held that where the sperm had also been extracted pursuant to court order, work and skill had been performed upon the sperm by the laboratory staff in order to preserve it, and it, therefore, could be considered property. He viewed the laboratory staff in exercising the skill had been agents of the wife and found that she had a prima facie entitlement to the sperm, pending her submissions on whether she was able to be lawfully provided with IVF under the State legislation. In the subsequent *Re H, AE (No 3)* (2013) 118 SASR 259 Gray J granted the Applicant possession of the sperm even though she was unable to obtain treatment within the State due to the absence of written consent which is required under the SA ART legislation.

509 *Jocelyn Edwards; Re the Estate of the Late Mark Edwards* (2012) 86 ALJ 234.

510 Ibid, at [144]-[145].

GLS v Russell-Weisz (Western Australia)

In the 2018 Western Australian case of *GLS v Russell-Weisz* [2018] WASC 79, the plaintiff GLS, was the de facto partner of the late GWAG. Shortly after his death, the plaintiff arranged for sperm to be extracted in order that it might be used at some time in the future to enable her to conceive a baby. Permission was granted for the extraction of the sperm pursuant to s 22 of the *Human Tissue and Transplant Act 1982* (WA) and the sperm was stored by the holder of a licence issued pursuant to the *HRT Act* (WA).

In deciding the case, Martin CJ noted the three decisions in the Supreme Courts of Queensland, New South Wales and South Australia (*Bazley, Re Edwards, and Re H, AE*) in factual circumstances very similar to the case before him, in which the binding authority of *Doodeward v Spence* has been applied to produce the conclusion that rights of property can exist in relation to samples of sperm removed posthumously;[511] and that such rights will generally be enjoyed by the person who caused the sperm to be extracted rather than the deceased, or the relevant medical personnel, or the administrator of the deceased estate.[512] He noted the issues before him did not require him to determine the entire ambit or content of the Plaintiff's rights with respect to the sperm samples, but rather her right to direct the clinic currently storing the sperm samples to transfer them to another clinic in the Australian Capital Territory. Martin CJ held that such direction was *'entirely consistent with the purpose for which the sperm was removed pursuant to the authority conferred by s 22 of the HTT Act'*, which was *'…for a therapeutic or medical purpose being for later use in an IVF procedure undertaken to enable the plaintiff to conceive a child'* and that there was no reason why the plaintiff should not be held to enjoy that right.[513]

Of relevance to the review of the *HRT Act* was that Martin CJ said that the precise circumstances in which proprietary rights in human tissue will be recognised at law remain to be elucidated by decisions of the courts, and that one could not infer that the Western Australian legislature had intended to exclude the existence of any rights other than those expressly recognised by the statute as the *HRT Act* was enacted well before the Australian decisions recognising the existence of proprietary rights in stored sperm samples to which he had referred.[514] It was also noted that the *HRT Act* and HRT Directions apply only to licensed providers, and in the context of the case, did not confer any rights or impose any obligations upon persons who are not licence holders, such as the plaintiff, or upon the donors or recipients of human gametes.[515]

Cresswell v Attorney-General for the State of Queensland (Queensland)

In 2018, in *Cresswell v Attorney General for the State of Queensland*,[516] a decision was made against the background of an earlier order for the removal of sperm in August 2016, from the late Mr Davies who had committed suicide, following suffering from depression. Ms Cresswell, who had the support of Mr Davies' parents and her own, sought orders that she was entitled to possession and use of the sperm. As noted above, there is no statutory regime in Queensland which applies to the use of posthumous sperm.

511 *GLS v Russell-Weisz* [2018] WASC 79 at [125].

512 *GLS v Russell-Weisz* [2018] WASC 79.

513 *GLS v Russell-Weisz* [2018] WASC 79 at [126].

514 *GLS v Russell-Weisz* [2018] WASC 79 at [128].

515 *GLS v Russell-Weisz* [2018] WASC 79 at [198].

516 *Cresswell v Attorney-General for the State of Queensland* [2018] QSC 142

Brown J concluded that sperm taken from a deceased cannot be property and does not form part of the assets of the deceased. However, once work and skill are applied to the sperm in the form of preserving it, a right of permanent possession is held by those who performed the work, or the principal on whose behalf the work was performed. In making this decision she said:

> *In my view, the weight of authority in the most recent cases in Australia and England supports the fact that the common law recognises that sperm removed from an individual, to which work and skill is applied so it can be preserved, is capable of being property. That recognition has developed as an exception to the principle that there is no property in a corpse and as an extension of the principles in Doodeward…The law has developed significantly since the decision of Chesterman J in Re Gray. I consider the reasoning of Re Estate of Edwards, Re H, AE (No 2), and GLS v Russell-Weisz while not binding, to be highly persuasive.*

Brown J then turned to consider discretionary factors, such as the deceased's wishes, the likelihood that the sperm would be used, the best interests of the prospective child and community standards. She had regard to Mr Davies' wishes considering them as still relevant, noting there was evidence that the couple had discussed having children, that he and Ms Cresswell had medical check-ups with respect to the prospect, and that his friends and family believed he would support the Application. Brown J also noted that Ms Cresswell had undergone counselling in which she discussed her decision and was willing to engage in any further counselling that might be required.

Brown J agreed with the observations of Hulme J in *Re Estate of Edwards* that a consideration of the 'best interests' of a child is difficult to talk about sensibly. She nevertheless, had regard to evidence that the child would be loved, cared for and able to be financially and emotionally supported, not only by Ms Cresswell but by the extended family. Regarding community standards as another discretionary factor, her Honour concluded that there was nothing suggesting that the making of the declarations sought would be contrary to public policy. She otherwise noted that the broader issues raised by such cases were a matter for Parliament.

8.5 Submissions to the Review

The Review received 21 submissions regarding the posthumous collection, storage and use of gametes or embryos. The submissions were divergent in their view of whether posthumous use should be permitted. Eight submissions were of the view that the posthumous collection, storage and use of gametes should be prohibited.[517] Such submissions argued that the posthumous creation of a child is against the best interests of any child that may be born as a result. Most of these submissions emphasised that it was in the best interests of the child to have a relationship with their father. Ten submissions expressed the view that posthumous collection, storage and use of gametes and/or embryos should only occur where there has been consent by the person from whom the gametes will be removed, or embryos have been stored.[518]

517 Rodino & Clissa, Submission 8 (noting this submission expressed that opposition to posthumous collection, storage or use of gametes, but also made recommendations if legislation did permit such use); Damian Adams, Submission 40; VANISH, Submission 54; Kerri Favarato, Submission 67; Australian Christian Lobby, Submission 77; LJ Goody Bioethics, Submission 85; Defend Human Life (Richard Egan), Submission 109, Reproductive Technology Council, Submission 122. (Note, Rodino & Clissa are also members of the RTC).

518 Dr Melanie Walls, Submission 26; Dr Vincent Chapple, Submission 28; Trevor Harvey, Submission 47;

Several submissions called for Western Australia to pass legislation that was consistent with the law in other jurisdictions and/or NHMRC Ethical Guidelines.[519]

The Australian Christian Lobby qualified their opposition to the posthumous collection, storage and use of gametes to note their view that 'stored embryos may be implanted into the mother even after the death of the father, but that such issues should have been part of pre-ART counselling'.[520] Rodino and Clissa, approved RTC counsellors, similarly submitted that there should have been previous consent for the use of existing stored embryos, and called for a requirement of written evidence of such consent, as well as adjunct counselling by an approved counsellor.[521]

Two submissions were from the respective grandparents of a child conceived as a result of the posthumous use of sperm (the mother and father of Ben, who had passed away from aggressive cancer; and the mother of his partner, Annette).[522] One submission was from Annette. Ben had stored sperm in his teens when he had previously faced cancer before being rendered infertile as a result of treatment. Prior to his death, Annette and Ben had been trying to conceive using IVF. The submission by Annette's mother describes the distress the situation in Western Australia had caused. Annette had been informed after her husband's death by the clinic that she could not continue with treatment under the Western Australian law. She then spoke to the RTC and was initially told she could not use the gametes or take them out of the state. Subsequently, she was told that she could make an application to the RTC for approval, which after some time she was granted. She incurred legal costs as a result. Following such permission being granted she had to register with a new clinic in Queensland, paid approximately $2,500 for the transport of the frozen sperm, and costs associated with flights, accommodation, and treatment fees on more than one occasion. It is noted that in the most recent decision of the Western Australian Supreme Court it was held that RTC approval is not required.

All three submissions regarding Annette's situation asked for changes to the law to allow Ben's name to be placed on his daughter's birth certificate. Note, in the United Kingdom a law preventing such registration was held by the United Kingdom High Court to be 'incompatible' with Article 8 of the European Convention of Human Rights (ECHR) (which concerns the right to 'private and family life'). The United Kingdom Government was obliged to amend the law. In September 2003, the *Human Fertilisation and Embryology (Deceased Fathers) Act* was passed by the House of Lords and given Royal Assent – it came into force on 1 December 2003. Women who had already given birth to children conceived posthumously were given a six-month window to re-register the birth of their children.

Brenda Harvey, Submission 51; ANZICA (WA) Fertility Counsellors, Submission 61; Hollywood Fertility, Submission 75; Australian Medical Association, Submission 96; Genea Limited, Submission 107; Family Law Practitioners Association (WA), Submission 115; Women and Newborn Health Services, Submission 121

519 Dr Melanie Walls, Submission 26; WANZICA (WA) Fertility Counsellors, Submission 61; Hollywood Fertility, Submission 75; Genea Ltd., Submission 107; Family Law Practitioners, Submission 115; Women and Newborn Health Services, Submission 121.

520 Australian Christian Lobby, Submission 77.

521 Rodino & Clissa, Submission 8.

522 Gaye Gelok, Submission 15; Alison and Michael Lane, Submission 80; Annette Gelok, Submission 98.

8.6 Discussion

Western Australia is the only jurisdiction in Australia that prohibits the posthumous use of gametes. Despite such prohibition, the Western Australian Supreme Court has held that it is lawful to collect gametes posthumously, pursuant to the *Human Tissue and Transplant Act 1982* (WA) and that an application to the Court is not necessary if the consent has been given by the senior next of kin.[523] Edelman J, who made that decision, is now a Justice of the High Court of Australia. In 2018, in *GLS v Russell-Weisz* the Supreme Court of Western Australia ruled that once gametes have been collected pursuant to the *Human Tissue and Transplant Act 1982* (WA) the partner of the deceased has a right to possession of such gametes by which they may direct them to be transferred to a jurisdiction where they can be used.[524]

It is anomalous to allow the posthumous collection of gametes for reproduction, their transfer to another state for use, but not to allow such use in Western Australia.

The Review received a submission from the RTC including a position paper it wrote in 2014 opposed to the posthumous retrieval and use of gametes. However, it was of the view that in individual cases involving gametes and embryos collected prior to death that in 'exceptional circumstances' it may be reasonable to use them subject to the RTC's approval. There was evidence via two submissions to the review that the RTC has approved at least one application to allow the transport of gametes collected prior to death to a jurisdiction in which they could be used. In contrast, the application made in the first instance to the RTC by GLS, which involved retrieval posthumously, was denied by the RTC. It is inconsistent to allow the posthumous use of gametes stored prior to death for assisted reproduction, but not the posthumous use of gametes collected after death. The rejected application by GLS resulted in an application to the Supreme Court which held the applicant had a right to possession and a right to direct the transport of the sperm to a state in which she could use it in an IVF procedure to create a child.[525] Notably, that ruling also held that RTC approval was not required for such transfer.[526]

The Review received a number of submissions that opposed the posthumous use of gametes. The primary argument presented in such submissions was that it was against the best interests of the child who would be born as a result. However, judicial authority across the country has not taken this view. Rather, it has recognised that children are born into many different types of families in the modern era, including via ART, and that this has become increasingly socially acceptable. The Courts have also taken the view that in making decisions in such cases it is 'difficult to talk sensibly about the best interests of the child' beyond confirming whether the child will be loved and cared for. Anecdotally, the children born to Diane Blood in the United Kingdom as a result of the posthumous use of gametes 20 and 14 years ago, do not report having suffered detrimental effects.[527] Other research that has been conducted has shown positive health and

523 *Re Section 22 of the Human Tissue and Transplant Act 1982 (WA); Ex Parte C* [2013] WASC 3 (2 January 2013),

524 *GLS v Russell-Weisz* [2018] WASC 79 at [126].

525 *GLS v Russell-Weisz* [2018] WASC 79 at [126].

526 *GLS v Russell-Weisz* [2018] WASC 79 at [126].

527 Victoria Lambert, 'Exclusive: Diane Blood on family life 20 years after she won the right to use her dead husband's sperm' The Telegraph, 10 February 2017 available at https://www.telegraph.co.uk/family/relationships/exclusive-diane-blood-family-life-20-years-won-right-use-dead/ accessed 02 September 2018.

developmental outcomes for children born as a result of the posthumous use of gametes.[528]

The Review also received a number of submissions that the law should be changed to allow the posthumous use of gametes, subject to evidence of the deceased's wishes and consent, an adequate grieving period, and appropriate counselling. Such submissions were consistent with what is required in other jurisdictions of Australia. They were also consistent with the most recent judgments and reasoning of the Supreme Courts of Queensland, New South Wales, South Australia, and Western Australia referred to above.

When considering other jurisdictions of Australia, all permit the posthumous use of gametes subject to meeting certain requirements. The difference among them lies in states that have legislation requiring prior *written* consent from the deceased for the collection or use of such gametes, versus the requirement for express or oral consent and/or evidence of the deceased' wishes in states that do not have ART legislation. In those states the NHMRC Ethical Guidelines are relevant.

When written consent has *not* been present in states with or without ART legislation recent judicial authority in Queensland, New South Wales, South Australia, and Western Australia has permitted retrieval pursuant to the relevant human tissue and transplantation legislation, and have followed the line of authority that the spouse has a right to possession and may direct their transfer to a state/territory in which the gametes may be used (i.e. to a state that does not require such written consent). In making such judgements, the Courts' discretionary powers have been exercised to consider the deceased's wishes as far as can be determined, the best interests of the future possible child (only in so far as whether there is evidence it will be loved and supported), and community standards. It has been held that such use does not offend public policy. Such judgements have been made by judges that serve the highest Courts in each state. Nevertheless, there is a call for the legislature to clarify its position, including by some such judges, particularly regarding whether prior written consent by the deceased should be required.

In considering this question it is important to acknowledge that the majority of people do not seriously contemplate the possibility of an untimely or unexpected death particularly when they are young and in their reproductive years. As such, while discussion may be had about future wishes to have children or for their spouse/partner to be able to do so should they die, few may write their views down. It may be more likely that written consent could be obtained from a person suffering from a terminal illness, however, even then, it appears that such consent is not always available (see above case of Ben and Annette). Perhaps this is because of the illness the person, their spouse, and extended family are dealing with an absence of an active inquiry by health professionals concerning such preferences or thought to include such directions in a will. Here it is, therefore, useful to consider research that has asked people of reproductive age to actively consider posthumous conception, which has found that the majority support their partners' use of their sperm posthumously. For example:

- In a 2014 study 2064 people in the United States were contacted using random-digit dialling and were asked "Suppose you were to experience an early death and your spouse wanted to have a biological child with you. Would you or would you not want your spouse to be able to use your sperm/eggs following your death to have a child

528 Stephen J. Robson, Simone Campbell, Janelle McDonald, Kelton Tremellen, Emily Carlin, Genevieve Maybury; Pregnancy and childhood health and developmental outcomes with the use of posthumous human sperm, *Hum. Reprod.* , Volume 30, Issue 10, 1 October 2015, Pages 2259–2262; Joi Ellis, 'Four Fathers and Four Families: A follow up report of the use of posthumous sperm' (2006) ANZICA Newsletter (November 2006) 9, 12.

with you?" Among reproductive age respondents (18-44 years), 70% of males and 58% of females wanted their spouse to be able to use their gametes. It was also found that religiosity was the best predictor of attitudes – those who described themselves as more religious were less likely to desire posthumous gamete retrieval. Nevertheless, 58% of respondents who were very religious still approved of retrieval.[529]

- A 2013 retrospective review of medical records and consents for 361 male patients presenting for sperm banking from 2009-2011 also found the majority agreed to the posthumous use of their sperm. The men were grouped based on the reason for banking, which included fertility problems ('Infertility') and malignancy prior to treatment ('cancer'). Of the 361 men, 85.9% said that they would agree to the posthumous use of their sperm. In the infertility group, 87.4% of men consented. Of these, 92.9% of men in a relationship and 62.5% single men provided affirmative consent. Within the cancer cohort, 83.8% men consented. Of these, 65.2% of men under 18 years old consented and 85.8% of men 18 years and older consented. Relationship status yielded 93.2% of men in relationships and 79.4% single men consenting.
- In a 2011 study of 106 couples presenting at a fertility clinic for initial evaluation, Nakhuda et. al found approximately 78% of individuals stated they would permit posthumous assisted reproduction. Couples expressed concordant attitudes about 75% of the time. Statistically, women and men were equivalent in correctly predicting their partner's attitudes (79% vs. 71%).[530]

A requirement for *written* consent may thus preclude the posthumous use of gametes as an option for most spouses while not reflecting what the majority of deceased partners would have wanted or consented to. This does not, however, suggest that some evidence of consent should not be required. Rather, it supports a broader perspective of the form evidence of the person's wishes should take. Thus, the Courts have also accepted evidence of conversations, actions, and gifts, which are illustrative of consent.

On balance, the law weighs in favour of allowing people, who may have lost a spouse or partner to terminal illness or sudden and unexpected causes, to decide as to whether or not to continue with their and their partner's plans to have a child(ren) (or other children). Note, all such people will not necessarily act to do so, and such action is not commonplace. Rather the law does not foreclose what is a very private and personal decision that the widow/er may wish to make, in light of their and their deceased partner's wishes, only after the grieving process is over and they have had the opportunity to engage in counselling. Such a decision is surely not one to be taken lightly, but nor is it one that anyone else may make.

In giving consideration to the law, the debates concerning its implementation, and judicial interpretation and decisions across the country, it would be consistent for Western Australia to address the anomaly of allowing the posthumous retrieval of gametes, but not their use (and the past inconsistency in the RTC having allowed some people to transport gametes out of the State to engage in posthumous reproduction, but not others). To this end, it is recommended that posthumous retrieval of gametes continue to be permitted in Western Australia pursuant

529 Hans, J.D. (2014). Posthumous gamete retrieval and reproduction: would the deceased spouse consent? *Social science & medicine, 119*, 10-7.

530 Nakhuda G.S., Wang J.G., Sauer M.V. Posthumous assisted reproduction: a survey of attitudes of couples seeking fertility treatment and the degree of agreement between intimate partners. *Fertil. Steril.* 2011;96(6):1463–1466

to current provisions in the *Human Tissue and Transplant Act 1982* (WA). Further, it is recommended that in redrafting the *HRT Act* (and repealing and redrafting Directions), as recommended in Chapter 3 of this report, that new provision should be made that:

- retrieval of gametes from a person who is unconscious and near death, or after their death may occur only when the requirements of s 22 of the *Human Tissue and Transplant Act 1982* (WA) have been met, and only for the purpose of storage for the purposes of future use by the surviving spouse or partner of the person, or a surrogate mother, for the purposes of bearing a child(ren) who will be cared for by the surviving spouse or partner.
- that the posthumous use of gametes or embryos collected before or after a person's death may occur only when:
    - 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
- court approval should not be required where the above conditions have been met unless there is a dispute among family members as to whether the deceased objected to the posthumous use of their gametes
- where there is evidence that a person has expressly objected to the posthumous use of their stored gametes or embryos, or the posthumous collection and/or use of gametes, the posthumous collection/use of the stored gametes or embryos to achieve pregnancy should be prohibited.

Such recommendations are in accordance with the current state of law across Australia.

As a consequence of such recommendations, it should be possible for the birth certificate of a child(ren) born as a result of the posthumous use of gametes to include the deceased person's name listed as a parent on that birth certificate, with a possible annotation that the parent is deceased.

It is also necessary to consider further, any consequential amendments that may need to be made regarding succession laws. The review did not receive any submissions in this regard, and it is recommended that further focused research and consultation take place.

Findings

1. The posthumous collection, storage and/or use of gametes and embryos collected either before or after a person's death is a sensitive and complex issue. Over many years laws and guidelines have been developed across Australia that permit such collection, storage and/or use subject to the deceased and the surviving spouse/partner having met certain requirements.
2. The current provisions in the *Human Tissue and Transplant Act 1982* (WA) permit the posthumous retrieval of gametes and have been held by the Court to provide valid criteria under which such retrieval may occur.
3. The posthumous retrieval of gametes should continue to be permitted in Western Australia pursuant to current provisions in the *Human Tissue and Transplant Act 1982* (WA) (*HTT Act*), and added provision being made in the *HRT Act*. However, as per the *HTT Act* the posthumous collection, storage and/or use of gametes should not occur when the deceased person, in their lifetime, objected to such collection, storage or use.
4. The current HRT Direction that effectively prohibits the posthumous use of gametes in Western Australia is inconsistent with:
    - the law that allows their collection
    - the recent Western Australian Supreme Court decision recognising the surviving spouse's/partner's right to possession of such gametes and right to direct the transfer of such gametes to a jurisdictions where they may be used
    - state and territory laws and guidelines across Australia.

    It also creates unnecessary distress and cost burdens on the surviving spouse (for example, via requiring court action) and does not ultimately prevent the posthumous use of gametes (or embryos).
5. Posthumous use of gametes collected before or after a person's death should be permitted subject to meeting requirements that:
    - 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 as a result.

6. Provision should be made in such circumstances for the deceased to be listed on the birth certificate as the parent of any child that is born as a result.

Recommendations

Recommendation 49

In redrafting the *HRT Act* and repealing any current Directions that provision be made that: 'retrieval of gametes from a person who is unconscious and near death, or after their death may occur only when the requirements of s 22 of the *Human Tissue and Transplant Act 1982* (WA) have been met, and only for the purpose of use by the surviving spouse or partner of the person, or a surrogate mother, for the purposes of bearing a child(ren) who will be cared for by the surviving spouse or partner.'

Recommendation 50

In redrafting the *HRT Act* (and repealing any current Directions) that provision be made that: 'The posthumous use of gametes or embryos collected before or after a person's death may only occur when:

- 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.

Recommendation 51

In redrafting the *HRT Act* (and repealing any current Directions) that provision be made that: 'Court approval is not required where the above conditions have been met.'

Recommendation 52

In redrafting the *HRT Act* and repealing any current Directions that provision be made that: 'Where there is evidence that a person has expressly objected to the posthumous use of their stored gametes or embryos, or the posthumous collection and/or use of gametes, the posthumous collection/use of the stored gametes or embryos to achieve pregnancy is prohibited'.

Recommendation 53

In cases in which a child(ren) has been born as the result of posthumous use of a deceased partner's gametes or an embryo made with such gametes, that provision in the *Births, Deaths and Marriages Registration Act 1998* be made to enable the deceased to be listed on the child(ren)'s birth certificate as a parent of that child.

Recommendation 54

Further research, consideration, and targeted consultation be undertaken in relation to any other necessary consequential amendments to the Western Australian *Administration Act 1903* and *Family Provision Act 1972*.

Table: Required change and action

Table 8.1 details the changes required that are relevant to the discussion regarding the posthumous use of gametes. Again, it is noted that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended *as a matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 8.1 Recommended Changes to Legislation, Directions and Operations Regarding Posthumous Use of Gametes

Required Change	Legislation*	Directions**	Operation**
Amend legislation to provide for the posthumous use of gametes in Western Australia	That in redrafting the *HRT Act* provision be made that: 'retrieval of gametes from a person who is unconscious and near death, or after their death may occur only when the requirements of s 22 of the *Human Tissue and Transplant Act* (WA) have been met, and only for the purpose of use by the surviving spouse or partner of the person, or a surrogate mother, for the purposes of bearing a child(ren) who will be cared for by the surviving spouse or partner.'		
Amend legislation to provide for the posthumous use of gametes in Western Australia	That in redrafting the *HRT Act* (and repealing any current Directions) that provision be made that: 'The posthumous use of gametes or embryos collected before or after a person's death may only occur when: • 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.' That in redrafting the *HRT Act* (and repealing any current Directions) that provision be made that: 'Court approval is not required where the above conditions have been met.'		

Required Change	Legislation*	Directions**	Operation**
Amend legislation/ Directions to provide that: 'where there is evidence that a person has expressly objected to the posthumous use of their stored gametes or embryos, or the posthumous collection and/or use of gametes, the posthumous collection/use of the stored gametes or embryos to achieve pregnancy is prohibited'.	That in redrafting the *HRT Act* and repealing any current Directions that provision be made that: 'where there is evidence that a person has expressly objected to the posthumous use of their stored gametes or embryos, or the posthumous collection and/or use of gametes, the posthumous collection/ use of the stored gametes or embryos to achieve pregnancy is prohibited'.		
Consequential amendments to *Births, Deaths, and Marriages Registration Act 1998* to enable the deceased to be recorded as a parent	In cases in which a child(ren) has been born as the result of posthumous use of a deceased partner's gametes or an embryo made with such gametes, that provision in the *Births, Deaths and Marriages Registration Act 1998* be made to enable the deceased to be listed on the child(ren)'s birth certificate as a parent of that child. (May consider annotation of 'deceased').		
Further consideration and consultation regarding issues relevant to succession.			That further research, consideration, and targeted consultation be undertaken in relation to any other necessary consequential amendments to the *Western Australian Administration Act 1903 and Family Provision Act 1972.*

Chapter 9

ART Issues – PGD, PGS and Saviour Siblings

Chapter 9:
ART Issues – PGD, PGS and Saviour Siblings

9.1 Introduction

Pre-implantation Genetic Diagnosis (PGD) is a procedure for testing early embryos to find out if a genetic disorder affects them. It involves removing a cell from an IVF embryo to test it for a specific genetic condition (for example, cystic fibrosis) before transferring the embryo to the uterus. As testing is undertaken prior to any embryos being transferred to the woman, it is possible to discard affected embryos and to select those embryos that do not have the particular condition for implantation. The term PGD is often used loosely to refer to any testing performed on an embryo prior to it being transferred to the uterus. However, the distinction should be made between the terms PGD (*diagnosis*) and Pre-implantation Genetic Screening (PGS).

Pre-implantation Genetic Screening (PGS) is the term used to refer to screening embryos for overall chromosomal normalcy. It involves screening embryos for aneuploidy (missing or additional numbers of chromosomes) or for unspecified and multiple genetic or chromosomal abnormalities where the gamete providers are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. (It has thus, more recently, been referred to as PGT-A – pre-implantation genetic testing for chromosomal abnormality). PGS is undertaken with the aim of improving live birth rates (by improving pregnancy rates from embryo transfer and reducing the incidence of miscarriage) and is argued to be suitable in cases of advanced maternal age and repeated implantation failure by selecting those that have a normal chromosome copy number. However, its benefit as an adjuvant treatment in IVF has remained controversial, mainly because the weight of evidence in support of improving delivery rates is still considered questionable (see further discussion below).

PGD/S may also be used for the purposes of sex selection, in order to avoid a sex-linked disorder (by screening embryos to choose XX embryos (girls) instead of XY (boys), for example), and PGD may be used together with human leukocyte antigen typing (HLA typing) to create a 'saviour sibling'.[531]

As such, PGD services are offered in the community on the basis of improving the chance of conception for patients with genetic abnormalities, and to make it likely that their offspring will not suffer from the genetic defect carried by the family. As PGS is used strictly to screen embryos for normal chromosome numbers, PGD is the only method that tests for specific genetic conditions at the embryonic stage. Alternatively, couples may choose to try for a natural pregnancy, followed by prenatal diagnosis and the possibility of termination of pregnancy, or pursue another pathway to have a family such as pregnancy with donor egg or sperm, or adoption. Some couples may choose not to have children.[532] PGD and PGS are not currently funded via Medicare, it having been found approving such funding may lead to a decrease in the use of 'natural pregnancy with prenatal diagnosis (or postnatal diagnosis) for the proposed population and an increased uptake

531 For a good discussion of the various uses of the technology, see P Braude, 'Pre-implantation Genetic Diagnosis: Safely Born but not Designed' in S McLean and S Elliston (eds), *Regulating Pre-implantation Genetic Diagnosis: A Comparative and Theoretical Analysis*, Routledge, Oxford, 2013.

532 Elhassen D, Coleman K, Mernagh P, Campbell S, Fodero L, Scuteri J. (2015). *Preimplantation genetic diagnosis. MSAC Application 1165, Assessment Report.* Commonwealth of Australia, Canberra, ACT.

of PGD without evidence that it is a better method than other methods, should the service be publicly funded'.[533]

The Terms of Reference for the Western Australian Review of the *HRT Act* included an examination of PGD, PGS and 'saviour siblings'. These are each examined in turn below.

9.2 PGD screening for disease of illness in Western Australia

The acceptability of PGD screening may depend upon the type of disease or illness, and the reasoning behind such screening. For example, there are ongoing debates about whether the use of PGD reflects an underlying assumption that not only will those born with a disability lead a dissatisfying life, but they are unwelcome in society.[534] Whether provisions that enable PGD to devalue the lives of people who have a disability, or value them unequally to the lives of others, is also often the subject of debate. Others have questioned whether the use of PGD for the purpose of avoiding disability means 'society has a reduced imperative to find cures for these conditions.'[535] On the other hand, for some people with severe inheritable disorders, PGD may be the only means for them to conceive a child that will survive pregnancy and result in a live birth; for others it means the child will live beyond the first few days after birth.[536]

Current NHMRC Ethical Guidelines expressly prohibit the use of PGD for the prevention of conditions that are not 'seriously harmful' to the person to be born.[537] The guidelines also recognise that the use of these technologies raises a number of difficult ethical issues including that what counts as a serious genetic condition is controversial; that there are different perceptions of disability; and that the practice of selecting against some forms of abnormality may threaten the status and equality of opportunity of people who have that form of abnormality.[538] Given the significance of these and other matters, the NHMRC Ethical Guidelines state that careful evaluation is required prior to the use of PGD. Clinics in Western Australia must adhere to the NHMRC Guidelines for RTAC accreditation.

The *HRT Act* allows a couple or a woman to access IVF if they are likely to have a child who would otherwise be likely to be affected by a genetic abnormality or a disease.[539] Section 7 of the *HRT Act* makes it an offence:

- [for] a diagnostic procedure to be carried out upon or with a human egg undergoing fertilisation, or any embryo, not being a procedure, which is:
  - authorised by the Code; or
  - specifically approved by the Council.

533 Ibid.

534 See for example, A Lippman 'Bottom Line Genetics' (2001) 4(2) Community Genetics 87-89; Ana Siltis, 'Prenatal screening and prenatal diagnosis: contemporary practices in light of the past' (2016) *J Med Ethics* 42:6, pp 334-339. Published Online First: 9 May 2016 doi:10.1136/medethics-2016-103623.

535 R Deech and A Smajdor, *From IVF to Immortality: Controversy in the Era of Reproductive Technology,* Oxford University Press, Oxford, 2007, p 57.

536 Allan & Blake, *Australian Health Law*, pp 403-409.

537 National Health and Medical Research Council, *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research* (2007), [12.2].

538 Ibid, [12.1].

539 *HRT Act 1991*, s 23(1)(iii).

As such, prior to using PGD, RTC approval is required.[540] In addition, because PGD usually requires the testing of several embryos to increase the likelihood of identifying an unaffected embryo, and licensees currently require Council approval to store more than three embryos of the same biological parentage (Direction 8.7), Western Australian clinics must also apply for a waiver for this requirement.

In Western Australia, before an application for approval of PGD goes to the RTC, the following steps must be taken:

1. GP, specialist or self-referral of the person/couple to a genetic counsellor and clinical geneticist.
2. The consultation with the genetic counsellor and clinical geneticist covers a wide range of issues, including the experience and understanding that a person/couple have of the condition, the risk of passing the condition onto a child, the impact of the condition on a child and the family, and reproductive options for the couple, including PGD.
3. Consultation with a fertility clinic that offers PGD services. (A GP or specialist referral to undertake IVF will be needed.) At this appointment, the person/couple receives information about the IVF process, the risks, how embryos will be tested for the genetic condition and the costs associated with each step of the process. The clinic will also provide access to an RTC 'Approved Counsellor' for which one counselling session will be included in the cost of each IVF cycle to support the patient in relation to the physical and emotional impact of IVF treatment and to discuss ways to manage this.
4. A feasibility test, which involves complex laboratory testing to find out if it will be possible to test embryos for the genetic condition in question. In most cases, a new test will have to be developed specifically. The person and their partner will have to provide a small sample of blood for this test and other family members may also be asked to provide a blood sample. If the test is not feasible, PGD cannot be done. The feasibility test may take some time – three to six months, depending on the genetic condition it is testing for.

Only once steps one to four have been completed may an application to the RTC be made for approval. For single gene disorders and translocations, the fertility clinic applies to the RTC on the patient's behalf to undertake PGD. The RTC states that the approval process usually takes a month but can take longer for more complex applications. It requires a report from the clinical geneticist to accompany an application sent to the RTC to undertake PGD.

540 The RTC notes that General approval may be provided in the Directions or specific approval may be given in a case (Sections 7(1)(b), 14(2b), 53(W)(2)(d) and 53(W)(4) of the HRT Act).

9.3 PGS in Western Australia

PGS was first proposed 20 years ago based on the hypothesis that elimination of aneuploid embryos prior to transfer will improve implantation rates of remaining embryos during IVF, increase pregnancy and live birth rates and reduce miscarriages. This hypothesised improved outcome was reportedly based on five essential assumptions:

1. most IVF cycles fail because of aneuploid embryos
2. their elimination prior to embryo transfer will improve IVF outcomes
3. a single trophectoderm (TE) biopsy at the blastocyst stage is representative of the whole TE
4. TE ploidy reliably represents the inner cell mass (ICM)
5. ploidy does not change (i.e. self-correct) downstream from blastocyst stage.[541]

However, in recent times, these assumptions and the practice of PGS has increasingly been questioned.[542]

In a literature review of 55 study publications, Gleicher and Orvieto found that various reports over the 18 months up until 2017 have *'raised significant questions not only about the basic clinical utility of PGS but the biological underpinnings of the hypothesis, the technical ability of a single trophectoderm (TE) biopsy to accurately assess an embryo's ploidy, and suggested that PGS actually negatively affects IVF outcomes while not affecting miscarriage rates.'* Moreover, due to high rates of false positive diagnoses as a consequence of high mosaicism rates in TE, it was found that PGS leads to the discarding of large numbers of normal embryos with potential for normal euploid pregnancies if transferred rather than disposed of. Gleicher et. al concluded that all five basic assumptions (above-mentioned) underlying the hypothesis of PGS were unsupported and that clinical use of PGS for the purpose of IVF outcome improvements should, therefore, be restricted to research studies.[543]

In 2018, Verpoest et. al. reported on a randomised controlled trial conducted at the Vrije Universiteit in Brussels, Belgium, which followed 396 women aged 36 to 40 years undergoing treatment at fertility centres in seven countries from 2012. About half the patients received PGS (pre-implantation genetic testing for aneuploidy) prior to embryo implantation, while the other half received IVF only.[544] After one year and the first cycle of IVF, the percentage of women from both groups who had had a baby was identical at 24 per cent. The second endpoint of the study

541 N. Gleicher and R. Orvieto, Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review. 2017. 10(1) *Journal of ovarian research*, p.21.

542 Ibid. See also N. Gleicher, A. Weghofer, D. Barad. Preimplantation genetic screening, 'established' and ready for prime time? (2008) 89(4) *Fertil Steril* 780-788; N. Gleicher, A. Vidali, J. Braverman, VA Kushnir, DF Albertini, DH Barad., Further evidence against use of PGS in poor prognosis patients: report of normal births after transfer of embryos reported as aneuploid. (2015) 104(Suppl) 3 *Fertil Steril*, e9; RJ Paulson. Preimplantation genetic screening: what is the clinical efficiency? (2017) 108(2) *Fertil Steril* 228-230.

543 Gleicher and Orvieto, above n 541.

544 Willem Verpoest, Catherine Staessen, Patrick M Bossuyt, Veerle Goossens, Gheona Altarescu, Maryse Bonduelle, Martha Devesa, Talia Eldar-Geva, Luca Gianaroli, Georg Griesinger, Georgia Kakourou, Georgia Kokkali, Jana Liebenthron, Maria-Cristina Magli, Monica Parriego, Andreas G Schmutzler, Monica Tobler, Katrin van der Ven, Joep Geraedts, Karen Sermon; Preimplantation genetic testing for aneuploidy by microarray analysis of polar bodies in advanced maternal age: a randomized clinical trial, (2018) 33(9) *Hum. Reprod.* 1767–1776.

looked at the rate of miscarriages and embryo transfers and found that with PGS (PGT-A) both were reduced, with miscarriages decreasing from 14 per cent in the IVF only group, to seven per cent in the PGS (PGT-A) group. However, the researchers noted that

> *Whether these benefits outweigh drawbacks such as the cost for the patient, the higher workload for the IVF lab and the potential effect on the children born after prolonged culture and/or cryopreservation remains to be shown.*[545]

Richard Kennedy, President of the International Federation of Fertility Societies and Medical Director of the Birmingham and Solihull Local Maternity System, notes *'the debate concerning PGS is fluid because of emerging technologies such as next-generation sequencing and the falling cost of diagnostics, but for now its place in routine practice remains to be determined.'*[546] He raises the concern, however, that additions to standard ART, which have no strong evidence base to support their use, have added substantially to the cost of treatment, typically borne by the patient – but this has not been matched by increased pregnancy rates. He writes:

> *Some of these add-ons pose risk to the patient. The consequence of the widespread use of add-ons, far from benefitting the infertile, is in fact decreasing access to treatment. For some couples it may contribute to catastrophic financial consequences.*[547]

Fees to patients for PGS (PGT-A) in Western Australia are not advertised publicly and may vary depending on whether the testing is done in-house, sent to another laboratory, and other factors. On the east coast of Australia, one clinic advertises its fees for PGS to be $700 per embryo biopsied, with biopsies capped at 10 embryos.

The RTC 2016-2017 Annual Report states that *'PGS does not require specific Council approval when there are known risk factors for aneuploidy. However, PGS may also be indicated when there are other factors, and these are considered by Council on a case-by-case basis.'*[548]

9.4 Reproductive Technology Council approval process for PGD and PGS

Examination of the past five year's Annual Reports of the RTC found that in:

- 2016-2017, the RTC reported that 33 applications were approved for PGD
- 2015-2016, the RTC reported a total of 31 applications for PGD were approved and of those 25 had PGS
- 2014-2015, a total of 32 applications for preimplantation genetic testing were approved (20 for PGD; 11 for both PGD and PGS; one for PGS only)
- 2013-2014, a total of 43 applications for genetic testing were approved (18 for PGD; 20 for both PGD and PGS five for PGS)

545 Ibid.

546 Richard Kennedy, 'Back to basics: Improve access to fertility care by subtracting the 'add-ons'' BioNews, *19 March 2018,* available at https://www.bionews.org.uk/page_134885 accessed 13 September 2018.

547 Ibid.

548 WA Reproductive Technology Council, *Annual Report*, 2016-2017 (2017), p 11.

- 2012-2013, a total of 34 applications for genetic testing were approved (20 for PGD; 11 for both PGD and PGS; three for PGS).

There were no rejected applications reported.

In speaking with the clinics, I was informed that the vast majority of applications to the RTC to do PGD and to waive HRT Direction 8.7 (regarding the ability to create more than three embryos) have been approved, noting most applications to waive HRT Direction 8.7 are on behalf of patients planning PGD. Clinics reported that the RTC approval process delayed treatment and saw the process as unnecessary 'rubber stamping'. One health practitioner said:

> *We have only had one application rejected. One lady who had one miscarriage, but they require that someone has had multiple miscarriages. She was also young. The RTC said no. We have never had any other application rejected. So, it's just time and a rubber stamp. It seems so wrong.*

In regard to seeking approval for PGD specifically, the process of having to seek RTC approval and waivers was seen to be outdated by those who participated in the review. It was again emphasised that it hindered patient ability to engage with techniques that could assist them in achieving the birth of a child. The review received written submissions that the application to the RTC was 'a bureaucratic delay holding up patient treatment, and unnecessary given the process that patients had to go through'[549] (see steps one-four above). It was put to the review that:

> *Given a couple have had appropriate genetic counselling, a medical consultation and counselling, and the opportunity to discuss their situation with a trained counsellor …this obviates the need for a formal submission to the Reproductive Technology Council.'*[550]

It was also submitted that the process of requiring PGD is stressful and emotionally and financially draining for the patients, and the extra time to wait for treatment was reported to contribute further to this stress.[551]

Another clinician said during face-to-face consultation:

> *Some of it seems crazy. Our patients have seen a doctor, then a genetic counsellor, it's gone to an ethics committee, but we need to have the RTC rubber stamp it. Explaining that to the patient, you see their reaction. They just don't understand why. It does seem particularly crazy to me.*

Further investigation revealed that no other jurisdiction in Australia requires special approval when PGD is used to screen for genetically linked disease or disorder. Victoria requires that an application be made to its Patient Review Panel for PGD if it is to be used for sex selection, but not related to screening for disease.[552] Table 9.1 illustrates the approach taken in other jurisdictions across Australia. Approval for PGS was not required anywhere.

549 PIVET Medical Centre, Submission 114. See also Fertility Specialists Western Australia/Fertility Specialists South, Submission 7; Dr Melanie Walls, Submission 26; ANZICA Fertility Counsellors (WA) Joint Submission 61; Hollywood Fertility, Submission 75.

550 Fertility Specialists Western Australia/Fertility Specialists South, Submission 7 See also other submissions noted above n 545.

551 Dr Melanie Walls, Submission 26.

552 Assisted Reproductive Treatment Act 2010 (Vic), ss 31-34A.

Table 9.1: PGD Approval Requirements

Jurisdiction	The requirement for PGD Approval by a Regulator or Government Panel
Australian Capital Territory	✗
New South Wales	✗
Northern Territory	✗
Queensland	✗
South Australia*	✗
Tasmania	✗
Victoria	✗ ✔ PGD for sex selection not related to disease (Patient Review Panel)
Western Australia	✔ RTC

✗ = no legislated requirement for approval by a regulator or Government panel

The NHMRC Ethical Guidelines specify that PGT (PGD/S) may only be used to:

- select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born;
- select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or another relative;
- increase the likelihood of a live birth.[553]

They further state that such testing may not be used to preferentially select in favour of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born.

It appears unsatisfactory to require RTC approval for PGD when the patients have already undertaken significant steps to determine its use, and the RTC approval process appears to add little if anything to the process. The review also received submissions that it is unreasonable in these circumstances to limit patients to only three embryos, without RTC approval, noting again that such approval appears always to be given. The RTC concurred in their written submission recognising that

> *Neither the NHMRC Ethical Guidelines, nor the legislation in other states and territories, place a limit on the number of embryos patients may have in storage prior to commencing treatment to create additional embryos; and that ANZARD data published in 2017 reports an average of 1.9 fresh and or thaw cycles per woman in 2015 which suggests that women are not routinely undergoing multiple embryo batching cycles. For these reasons, the Council supports the removal of Direction 8.7.* [554]

553 *NHMRC Ethical Guidelines* 2017, [8.15.1].

554 WA RTC, Submission 122.

Setting the bounds of when such screening/testing may take place, however, does appear necessary. This is especially important in terms of ensuring that patients are not offered 'add-ons' to their IVF procedures that do not have a sound evidence base but add significant cost onto treatments. This applies not only to PGS but also to other additional treatments that may be offered. False or misleading advertising is against the Australian Consumer Law. In obtaining informed consent, it is also incumbent upon clinicians to explain to their patients, in clear and understandable terms when a practice or technique that is being offered lacks supporting evidence, and/or has been widely questioned for its usefulness in increasing the likelihood of live birth. In addition, there is some persuasive authority from the New South Wales Supreme Court that providing unnecessary treatment (i.e. where the medical practitioner is solely motivated by an unrevealed non-therapeutic purpose such as making money), even when consent has been given, may result in liability for trespass to person (assault and battery) – as the fact that the treatment is unnecessary may negate consent by a patient who is led to believe otherwise.[555]

9.5 PGD and sex selection

As above mentioned, PGD may also be used to screen for the sex of an embryo in order to avoid the transmission of a sex-linked disorder. When such screening occurs, embryos are selected that are of a sex that will not carry the condition. Such screening is generally uncontroversial if the sex-linked disorder with which a child might be born will be severe. The use of PGD to avoid the transmission of a sex-linked disorder is thus generally seen to be consistent with upholding the welfare of the child that will be born as a result, noting that similar 'careful evaluation' as that regarding PGD generally is required.

Beyond sex selection for medical reasons, the use of sex selection for other reasons, such as to select an embryo of the opposite sex to those that already exist in the family (sometimes referred to as 'family balancing'),[556] or of a particular sexed child due to personal or cultural preference, has been the subject of much recent debate.

Research reveals that opponents of 'social sex selection' are concerned about widespread discrimination against a particular sex and long-term population imbalance. Such imbalance is seen in certain regions of the world where 'social sex selection' is believed to have been practised widely.[557] It has also been argued that 'entry to life should not be conditional upon being a particular sex'.[558] Social sex selection may, in addition, reinforce gender stereotypes, and or pose a psychological risk to a child (person) who knows s/he has been selected for being a particular sex, particularly if s/he has a differing gender identity.[559] The Victorian Law Reform Commission found in 2008 that it 'is difficult to identify ways in which the best interests of the child are served by permitting sex selection for a non-medical reason' in the context of ART.[560]

555 *Dean v Phung* [2012] NSW CA 223. See also *White v Johnson* [2015] NSWCA 18 at [2], [17] & [61]-[73].

556 For an example of family balancing see *JS and LS v Patient Review Panel* [2011] VCAT 856.

557 For example, sex-ratio imbalances in favour of boy children have grown in a number of South Asian, East Asian and Central Asian countries.

558 Victorian Law Reform Commission, *Assisted Reproductive Technology & Adoption: Final Report* (2007), p 82.

559 NHMRC, Draft Ethical guidelines on the use of assisted reproductive technology in clinical practice and research: Public consultation – 2015, p 56, available at https://consultations.nhmrc.gov.au/public_consultations/assisted-reproductive-tech accessed October 2018.

560 Ibid.

A joint interagency statement made by the Office of the Commissioner for Human Rights, the United Nations Population Fund, the United Nations Children's Fund, UN Women, and the World Health Organization (WHO) in 2011, reaffirmed the commitment of United Nations agencies to address the multiple manifestations of gender discrimination including the problem of imbalanced sex ratios caused by sex selection, which was recognised to occur at pre-implantation phase (via sperm sorting or PGD), via abortion, or infanticide.[561] WHO noted further that prohibiting the use of technologies alone may be ineffective in preventing gender-biased sex selection, without broader social policies to encourage social norms that value and empower girls and women.[562] While not all social sex selection may prefer boys to girls, a policy that explicitly permits social sex selection may be counter to these goals.

There have been no long-term studies regarding whether children born following a non-medical sex selection procedure have been harmed, or have suffered negative consequences, as a result of their parents' choice. Obviously, such a study would be hard to conduct, as it may be difficult to find such children or to establish if their life lived is a direct result of their selection. Further, even if it could be proven that a child selected because of their sex lived a favourable life within the family, the broader social implications of sex-selection for non-medical reasons must be considered.

A 2013 poll of Australians showed that they overwhelmingly opposed sex selection for non-medical social reasons. While 91% of people supported the use of IVF to help infertile couples, only 20% supported gender selection using PGD within IVF or for family balancing. When it came to the use of IVF only for gender selection, only 17% were in favour.[563]

Consideration of other jurisdictions revealed that sex selection for non-medical purposes is prohibited in numerous countries around the world.[564]

In Victoria laws provide that if PGD is intended for sex selection, an application to the State's Patient Review Panel for approval is required.[565] The Patient Review Panel must adhere to the Act's prioritising of the welfare of any child who may be born following the process. In an application made in 2010, by a couple who had three sons but had lost their daughter at birth, and wished to use sex selection to have a daughter, it was held that family balancing was *'not a sufficiently grave reason to approve a procedure that would otherwise be a criminal offence'*.[566] The couple appealed to the Victorian Civil and Administrative Tribunal, arguing that having a daughter would improve their 'emotional wellbeing', help them complete their family and have a beneficial impact on their sons.[567] The Tribunal rejected these arguments stating they focused

561 WHO, Preventing gender-biased sex selection: an interagency statement OHCHR, UNFPA, UNICEF, UN Women and WHO, (2011) (World Health Organisation), available at http://www.genea.com.au/my-fertility/i-need-help/fertility-treatments/sex-selection accessed October 2018.

562 Ibid, pp 7, 11-12.

563 Gab Kovacs, Julian McCrann, Michele Levine, and Gary Morgan, 'The Australian Community Does Not Support Gender Selection by IVF for Social Reasons' (2013) 13 *International Journal of Reproductive Medicine*, Article ID 242174, http://dx.doi.org/10.1155/2013/242174.

564 Austria, Australia, Belarus, Bulgaria, Canada, China, Croatia, Cuba, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, India, Latvia, Lebanon, Macedonia, Malaysia, Malta, Montenegro, Morocco, Netherlands, New Zealand, Norway, Oman, Romania, Russia, Saudi Arabia, Singapore, South Africa, South Korea, Sri Lanka, Sweden, Switzerland, Syria, Taiwan, Tajikistan, Thailand, Tunisia, United Arab Emirates, United Kingdom, Vietnam, Yemen.

565 *Assisted Reproductive Treatment Act 2008* (Vic), s 28(2)(b).

566 Cited in *JS and LS v Patient Review Panel* [2011] VCAT 856 [54].

567 *JS and LS v Patient Review Panel* [2011] VCAT 856 [53], [81].

on the needs of the parents and the existing children, rather than focusing on the welfare of the future child. The application was dismissed.

While there is no explicit prohibition on sex selection for non-medical purposes in Western Australia, as the law stipulates that PGD can only be provided in limited circumstances it cannot be accessed solely for such purposes. The law also requires RTAC accreditation, which in turn requires adherence to the NHMRC Ethical Guidelines under which sex selection for non-medical purposes is currently prohibited.[568] Clearly, it would be inconsistent to allow social sex selection because someone is using PGD/PGS for another medical reason that is not sex-linked but not to allow social sex selection in other circumstances. The evidence and arguments currently available regarding non-medical sex selection, on balance, do not favour its use. This is especially so as prohibitions on 'social sex selection' accord with concerns that the practice may negatively impact upon children. In contrast, arguments that favour social sex selection tend to focus on the adults who wish to use PGD for family balancing or, personal or cultural preferences, which does not align with placing the interests of children as paramount above all others.

9.6 PGD with HLA typing for tissue matching

9.6.1 'Saviour Siblings'

PGD may be used together with human leukocyte antigen (HLA) typing[569] to create a child with a tissue type that matches that of an existing sibling who is sick with a particular disease or disorder that may require stem cell therapy. The child created with the matching tissue type may be referred to as a 'saviour sibling'. It may be considered when no suitable related or unrelated donor is available for a child requiring a transplant, the requirement is non-urgent (as it will involve waiting for the future child's birth), and the parents are of reproductive age.

PGD for HLA typing is contentious as a child is being created for the benefit of an existing person. An examination of the literature found that it may be argued that this offends the Kantian principle that a person should not be treated merely as a means to an end.[570] However, Jonathon Herring[571] asserts that it is unlikely that the saviour sibling would simply be considered a source of tissue and 'that parents would "discard" a saviour sibling once treatment of the existing child had been

568 *NHMRC Ethical Guidelines* (2007), [11.1] and [12.2].

569 Human leukocyte antigen (HLA) typing is used to match patients and donors for bone marrow or cord blood transplants. HLA are proteins -- or markers -- found on most cells in the body. A person's immune system uses these markers to recognise which cells belong in your body and which do not. People have many HLA markers, half inherited from their father, and half from their mothers. Each brother and sister who shares the same parents has a 25% chance (one in four) of being a close HLA match. Extended family members are not likely to be close HLA matches. But about 70% (seven out of 10) of patients who need a transplant won't have a fully matched donor in their family. Research has found that a donor must match a minimum of six HLA markers. Many times, a closer match is required. A best match is found through detailed testing. Because some HLA types are more common than others, some patients may face a greater challenge in finding a matching donor. Some HLA types are found more often in certain racial and ethnic groups. HLA matching is important for transplant. A close match between a donor's and a patient's HLA markers is essential for a successful transplant outcome. HLA matching promotes the growth and development of new healthy blood cells (called engraftment) and reduces the risk of a post-transplant complication called graft-versus-host (GVHD) disease.

570 I Kant, *Foundations of the Metaphysics of Morals* (1785) p 429. An old but valuable discussion is contained in J E Atwill, *Ends and Principles in Kant's Moral Thought*, Nijhoff International Philosophy Series, Vol 22, 1986, especially Ch VI.

571 Johnathon Herring is a Fellow at Law at Oxford University, UK.

effective. The child is being created to be loved in his or her own right as well as assisting the sibling'.[572] Similarly, Katrien Devolder[573] notes that it would be a mistake to 'presuppose that the desire of the intention to have a child determines the attitudes of the parents toward the child once born'.[574] Nevertheless, concerns have also been directed at whether the saviour sibling would be called upon to donate bone marrow or even an organ at a subsequent time during their life.[575]

9.6.2 The regulation of PGD for HLA typing

As noted above, current legislation in Western Australia restricts PGD to a woman or couple whose child would otherwise be likely to be affected by a genetic abnormality or a disease, which precludes testing for the purposes of tissue matching. Currently, the *HRT Act* does not provide for a person or couple to access ART in circumstances in which they are able to conceive a child but wish to access IVF to have a child whose tissue matches that of a parent, sibling or another relative.

In contrast, the NHMRC Ethical Guidelines state that the use of PGT (i.e. PGD/PGS) for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or another relative may be ethically acceptable as this practice recognises biological relatedness, is beneficial to the recipient and the subsequent collection of stem cells from umbilical cord blood does not cause physical harm to the person who would be born. The NHMRC Ethical Guidelines also require that such techniques only be used to select an embryo with compatible tissue for subsequent stem cell therapy for the planned treatment of an intended parent, sibling or another relative. In addition, clinicians must seek advice from an independent body before undertaking PGT to select an embryo with compatible tissue for subsequent stem cell therapy. The independent body should be satisfied:

- there is no evidence to suggest that the person who would be born would not be a welcomed, respected member of the family unit
- the use of PGT will not significantly affect the welfare and interests of the person who would be born
- 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.

All other states and territories follow such guidelines, noting that the requisite independent body includes an independent ethics committee in all states and territories except Victoria, where reference would be had to the Patient Review Panel.

572 J Herring, *Medical Law and Ethics*, 4th ed, Oxford University Press, Oxford, 2012, p 396.

573 Katrien Devolder is a researcher affiliated with the Department of Philosophy and Moral Sciences at Ghent University.

574 K Devolder, 'Preimplantation HLA Typing: Having Children to Save Our Loved Ones' (2005) 31 *Journal of Medical Ethics* 582 at 583.

575 S Wolf, J Kahn and J Wagner, 'Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits' (2003) 31 *Journal of Law, Medicine and Ethics* 327. See also B Bennett, 'Symbiotic Relationships: Saviour Siblings, Family Rights and Biomedicine' (2005) 19 *Australian Journal of Family Law* 10.

9.6.3 Submissions to the review

The review received several submissions that addressed this matter. Some expressed concern about the potential for trauma if a child is brought into existence to be used for body parts for their already existing sibling and was concerned about the child being pressured to donate tissue or an organ (e.g. a kidney) and/or being subjected to invasive surgical procedures.[576]

The Australian Christian Lobby stated that the creation of saviour siblings should not be permitted as it, alongside PGD generally, is a eugenic practice that contributes to the commodification of children.[577]

The LJ Goody Centre for Bioethics called for consistency with the NHMRC Ethical Guidelines, which restricts 'saviour sibling' practice to the collection and use of stem cells derived from umbilical cord blood, and only when these practices protect the 'donor' child from physical harm and are subject to other scrutiny and protections.[578]

Dr Nick Pachter from the Genetic Services of Western Australia noted that:

> *While the issue of saviour siblings is not specifically related to genetics, GSWA as a group would support PGD for saviour siblings in the context stated in the 'NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017'. Specifically preimplantation genetic testing may be used to select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or another relative.* [579]

The RTC also submitted that they supported consistency with the NHMRC Guidelines.[580]

9.7 Discussion

Overall, in considering the literature, the submissions, and the NHMRC Ethical Guidelines, it would be consistent with the practice of other states and territories to support amendment of the *HRT Act* to permit PGD for the purpose of tissue matching in line with the NHMRC Ethical Guidelines, which set parameters for when the use of PGD for such tissue matching would be appropriate. This would allow, what are generally rare and very personal cases, to be considered in their particular circumstances while also requiring that any child born as a result is a welcomed and respected family member. Like other states an independent ethics committee should be utilised as best suited to make such assessments.

576 Damian Adams, Submission 40; Defend Human Life (Richard Egan), Submission 109.

577 Australian Christian Lobby, Submission 77.

578 LJ Goody Center for Bioethics, Submission 85.

579 Genetic Services of WA, Submission 110.

580 Reproductive Technology Council, Submission 122.

Findings

1. The acceptability of PGD screening may depend upon the type of disease or illness, and the reasoning behind such screening.
2. The *HRT Act* allows a couple or a woman to access IVF if they are likely to have a child who would otherwise be likely to be affected by a genetic abnormality or a disease. PGD is permitted, subject to RTC approval. However, a person or couple would not be able to access ART in circumstances in which they are in fact able to conceive a child but wish to access IVF to have a child whose tissue would match that of a parent, sibling or another relative.
3. The NHMRC Ethical Guidelines provide further guidance concerning when PGD would be acceptable, and what is required, including an express prohibition on the use of PGD for the prevention of conditions that are not 'seriously harmful' to the person to be born.
4. Examination of the past five year's Annual Reports of the RTC and consultation found that the RTC rarely, if ever, rejects such applications. However, the requirement for RTC approval and related processes were seen as outdated, bureaucratic, and hindered patient ability to engage with techniques that could assist them in achieving the birth of a child, causing stress for people seeking treatment.
5. It is unsatisfactory to require RTC approval for PGD when the patients have already undertaken significant steps to determine its use, and the RTC approval process adds little if anything to the process. It is also unreasonable in the circumstances to limit patients to creating only three embryos without RTC approval. Such requirements should be repealed.
6. PGD for sex-selection to avoid sex-linked disease or disorder is accepted in Western Australia pursuant to the access provisions of the *HRT Act*. PGD for sex selection for social reasons (for example, 'family balancing') is not possible in Western Australia, and this position should be maintained.
7. Regarding the use of PGD for the purpose of tissue matching, it would be consistent with the practice of other states and territories to support amendment of the HRT Act in line with the NHMRC Ethical Guidelines which set parameters for when the use of PGD for such tissue matching would be appropriate. Like other states, an independent ethics committee should be utilised as best suited to make such assessments.
8. The use of PGS (PGT-A) has been questioned internationally with recent studies finding it does not result in any difference to live birth outcomes. It remains yet to be determined whether benefits in reduced miscarriage and/or embryo transfer outweigh the costs for the patient, higher workload for the IVF laboratory, and the potential effect on the children born.
9. The above raises a further issue in regard to ensuring patients are not offered 'add-ons' to their IVF procedures that do not have a sound evidence base but add significant cost onto their treatments. Clinics and health practitioners need to be aware of their obligations under Australian Consumer Law in relation to false and misleading conduct and advertising, as well as their obligations in relation to informed consent, including not providing unnecessary treatments to patients that have no therapeutic value.

Recommendations

Recommendation 55

Provisions in the *HRT Act* and HRT Directions requiring RTC approval for PGD and related matters be repealed, subject to a condition of registration that clinics adhere to the NHMRC Ethical Guidelines regarding the use of PGD, including the restriction that PGD be used only to screen embryos for conditions that will be seriously harmful to a child born with such a condition.

Recommendation 56

Provision should be made either via the *HRT Act* or HRT Directions (as required) that PGD for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or other relative is acceptable subject to meeting the requirements of the NHMRC Ethical Guidelines.

Recommendation 57

It be a condition of registration that clinics do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or that are not supported by research to improve birth outcome.

Recommendation 58

It be a condition of registration that clinics obtain informed consent from patients in relation to all ART treatments, including but not limited to any 'add-on' treatments offered to the patient undergoing ART or to the gametes/embryos that will be used in the patient's treatment, and that clinics do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.

Table: Required change and action

Table 9.2 details the changes required that are relevant to the discussion in this chapter. Again, it is noted that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended *as a matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 9.2: Recommended Changes to Legislation, Directions and Operations Regarding PGD, PGS, and 'Add-On' treatments

Required Change	Legislation*	Directions**	Operation**
Repeal unnecessary requirements for RTC approval of PGD.	That provisions in the *HRT Act* and HRT Directions requiring RTC approval for PGD and related matters be repealed, subject to a condition of registration that clinics adhere to the NHMRC Ethical Guidelines regarding the use of PGD, including the restriction that PGD only be used to screen embryos for conditions that will be seriously harmful to a child born with such a condition.	That provisions in the *HRT Act* and HRT Directions requiring RTC approval for PGD and related matters be repealed, subject to a condition of registration that clinics adhere to the NHMRC Ethical Guidelines regarding the use of PGD, including the restriction that PGD only be used to screen embryos for conditions that will be seriously harmful to a child if born with such a condition.	NB. In the meantime could have pre-approval for a listed conditions – like the United Kingdom HFEA.
Make provision to permit PGD for tissue typing an embryo for subsequent stem cell therapy for a parent, sibling, or relative.	That provision should be made either via the *HRT Act* or Directions (as required) that PGD for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or other relative is acceptable, subject to meeting the requirements of the NHMRC Ethical Guidelines.	That provision should be made either via the *HRT Act* or directions (as required) that PGD for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or other relative is acceptable, subject to meeting the requirements of the NHMRC Ethical Guidelines.	
Provide for a condition of registration/ licensing that explicitly prohibits false or misleading advertising and/or practices.			That it be a condition of registration that clinics do not engage in false or misleading advertising or practices in relation to treatments or practices that may be considered experimental, do not have a sound evidence-base, or that are not supported by research to improve birth outcome. (ACCC)

Required Change	Legislation*	Directions**	Operation**
Provide for a condition of registration/ licensing that explicitly requires informed consent in relation to all ART treatments, including but not limited to 'add-on' treatments applied to the patient or gametes/embryos.			That it be a condition of registration that clinics obtain informed consent from patients in relation to all ART treatments, including but not limited to any 'add-on' treatments offered to the patient undergoing ART or to the gametes/embryos that will be used in the patient's treatment.
Provide for a condition of registration/ licensing that explicitly requires that clinics do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.			Provide for a condition of registration/licensing that explicitly requires that clinics do not provide treatments that are unnecessary or motivated by interests that are non-therapeutic.

Chapter 10

ART Issues – Research Involving Human Gametes or Embryos

Chapter 10: ART Issues – Research Involving Human Gametes or Embryos

10.1 Introduction

The history of the regulation of research involving human embryos and cloning is closely aligned with the early regulation of assisted reproduction. Early NHMRC Ethical Guidelines on ART[581] allowed the use of excess[582] ART embryos for research that may damage or destroy the embryo, under exceptional circumstances. Such 'exceptional circumstances' primarily involved research to understand human reproduction and ART.[583] A call for further regulation of such matters was made after the 1997 cloning of Dolly the Sheep,[584] and the 1998 production of human embryonic stem (ES) cell lines.[585] More recently, research involving mitochondrial donation, and research involving gene editing using CRISPR-Cas9, has also been debated (see Chapter 11). Such research has moved rapidly in its search for cures to diseases, allowing people to have children unaffected by heritable disorders, and/or its potential application for better treatments. However, it has also proven controversial due to it involving embryos deemed 'surplus' (or 'excess') to the needs of people undergoing ART or created specifically using 'cloning' (SCNT) techniques. The implications for children born as a result of techniques is also always at the forefront of considerations about what should be permissible.

This chapter examines research and experimentation on gametes, eggs in the process of fertilisation and embryos, and in particular the current disparity between the *HRT Act* and relevant Commonwealth legislation; the need to adopt nationally consistent legislation regarding excess ART human embryo research and prohibited practices. It begins by outlining the Australian Commonwealth legislation that was introduced in 2002 to govern research involving human embryos and cloning for reproductive purposes. It then considers the current inconsistency in the Western Australian *HRT Act* with such laws, and the implications this has for research and practice in Western Australia. Chapter 11 then examines the emerging research concerning mitochondrial donation and gene editing.

581 National Health and Medical Research Council, Ethical Guidelines on Assisted Reproductive Technology *(*1996). (Since repealed and replaced).

582 That is embryos 'excess' to the needs of the people for whom they were created during ART.

583 John Seymour and Sonia Magri, *ART, Surrogacy and Legal Parentage: A Comparative Legislative Review,* Victorian Law Reform Commission, 2004.

584 Ian Wilmut et al, 'Viable Offspring Derived from Fetal and Adult Mammalian Cells' (1997) *Nature* 385 at 810–813. Such 'cloning' involved the transfer of the nucleus from the somatic cell of one sheep to be fused with an enucleated egg cell of another ('somatic cell nuclear transfer' (SCNT) also referred to as cell nuclear replacement.

585 James A Thomson, Joseph Itskovitz-Eldor, Sander S Shapiro, Michelle A Waknitz, Jennifer J Swiergiel, Vivienne S Marshall, and Jeffrey M Jones, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145–7. Such research took place in the United States and was legal.

10.2 The enactment of Commonwealth legislation to govern research involving human embryos and cloning

Following extensive national public consultation, legislation governing research involving human embryos and cloning was introduced at a Commonwealth level in 2002. That legislation contains prohibited and permitted activities subject to a licensing system, and includes the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition on Human Cloning for Reproduction Act* (2002).

Section 13 of the *Research Involving Human Embryos Act 2002* (Cth) established the NHMRC Licensing Committee.[586] To obtain a licence to conduct research involving human embryos, a person must apply to the NHMRC Licensing Committee.[587] When applying for a licence that authorises use of an excess ART embryo that may damage or destroy the embryo, the Licensing Committee must be satisfied that appropriate protocols are in place: (1) to enable proper consent to be obtained before an excess ART embryo is used under the licence; and (2) to enable compliance with any restrictions on such consent.[588] In determining an application the NHMRC Licensing Committee must consider:

- the HREC's approval
- compliance with the NHMRC guidelines
- the number of excess ART embryos likely to be necessary to achieve the goals of the activity or project proposed in the application
- the likelihood of significant advance in knowledge, or improvement in technologies for treatment, as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means
- any other additional matters (if any) prescribed by the regulations.[589]

The Acts have seen two reviews since their inception. The outcome of such review was to retain existing prohibitions on the following activities:

- placing a human embryo clone in the human body or the body of an animal
- importing or exporting a human embryo clone
- creating a human embryo by fertilisation of a human egg by human sperm, for a purpose other than achieving pregnancy in a woman
- creating or developing a human embryo by fertilisation of a human egg by human sperm which contains genetic material provided by more than two persons
- making heritable alterations to a human genome; collecting a viable human embryo from the body of a woman; creating or developing a chimeric embryo
- placing a human embryo in an animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human

586 *Research Involving Human Embryos Act 2002* (Cth) s 13 (also see s 15 for the details of the persons who make up the NHMRC Licensing Committee).

587 *Research Involving Human Embryos Act 2002* (Cth) s 20.

588 *Research Involving Human Embryos Act 2002* (Cth) s 21.

589 *Research Involving Human Embryos Act 2002* (Cth) s 21(4).

- importing, exporting or placing in the body of a woman, a prohibited embryo
- the development of an embryo outside the body of a woman beyond 14 days, unless a shorter time is specified. In no circumstances can any embryo be developed, outside the body of a woman, beyond 14 days
- human cloning for reproductive purposes (punishable by 15 years imprisonment).

Amendments led to the following activities being permitted, subject to strict licensing conditions administered by the NHMRC Licensing Committee:

- create and use human embryos other than by fertilisation of a human egg by a human sperm
- create and use human embryos (by a process other than fertilisation of a human egg by a human sperm) containing genetic material provided by more than two persons
- create and use human embryos using precursor cells from a human embryo or a human foetus
- undertake research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training
- create hybrid embryos by the fertilisation of an animal egg by a human sperm, and develop such embryos up to, but not including, the first mitotic division provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre
- create embryos under licence using somatic cell nuclear transfer (sometimes called therapeutic cloning)
- research under licence on egg maturation and freezing by redefining a human embryo as an entity coming into existence upon the first cell division, the time when fertilisation is complete and when a fertilised egg becomes an embryo. This allows the viability of thawed or immature eggs to be tested by sperm fertilisation, without contravening the prohibition on the creation of an embryo for research.

Note, these activities are not currently permitted in Western Australia (see discussion below).

In addition, the amendments strengthened the investigative powers of inspectors appointed under the Commonwealth Acts and require the relevant Commonwealth Minister to report to Parliament regarding the establishment of a national stem cell bank, the feasibility of a national approach to non-blood human tissue-based therapies and to cause a further independent review of the legislation in three years.

Some key prohibited and permitted activities pursuant to the *Research Involving Embryos Act 2002* (Cth) include:

Section 10: Use of excess ART embryo — prohibited except when:

- authorised by licence; or
- exempt use (includes storage, removal, transport, observation, allowing embryo to succumb, use by ART provider for diagnostic purposes for women for whom it was created, or implantation in another woman).

Section 10A: Use of other embryos prohibited except subject to a licence:

- a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or
- a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than two persons; or
- a human embryo created using precursor cells taken from a human embryo or a human foetus; or
- a hybrid embryo.

Section 10B: Research or training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART is prohibited unless subject to a licence.

Section 11: Use of a human embryo that is not an excess ART embryo outside of the body of a woman for a purpose not relating to the ART treatment of a woman by an accredited ART centre is prohibited unless subject to a licence.

*Offences include penalties up to five years in prison.

Some key provisions from the Prohibitions on *Human Cloning for Reproduction Act 2002* (Cth) include:

Division 1 – Practices that are completely prohibited

- placing a human embryo clone in a human body or the body of an animal (s 9)
- importing or exporting a human embryo clone (s 10)
- creating a human embryo for a purpose other than achieving pregnancy in a woman (s 12)
- creating or developing a human embryo by fertilisation that contains genetic material provided by more than two persons (s 13)
- developing a human embryo outside the body of a woman for more than 14 days (s 14)
- heritable alterations to the genome (s 15)
- collecting a viable human embryo from the body of a woman (s 16)
- creating a chimeric embryo (s 17)
- developing a hybrid embryo for more than 14 days (s 18)
- the placing of an embryo in an animal; or in a human body other than in the reproductive tract (s 19)
- importing, exporting or placing a prohibited embryo (s 20)
- commercial trading in human eggs, human sperm or human embryos (s 21)
- Note, no defence that human embryo clone could not survive (s 11).

Division 2 – Practices that are prohibited unless authorised by a licence

- creating a human embryo other than by fertilisation, or developing such an embryo (s 22)
- creating or developing a human embryo containing genetic material provided by more than two persons (s 23)
- using precursor cells from a human embryo or a human foetus to create a human embryo, or developing such an embryo (s 23A)
- creating a hybrid embryo (s 23B)

(Note, embryos created under a research licence cannot be used for the purpose of achieving pregnancy in a woman).

*Offences include penalties up to 15 years in prison.

States and territories except for the Northern Territory and Western Australia currently all have mirroring legislation.[590] The Northern Territory does not have any legislation. Western Australia maintained the early position that banned SCNT. The law in Western Australia is discussed in the next section.

10.3 Regulation of embryo research in Western Australia

10.3.1 Inconsistency with Commonwealth legislation

Amendments to the *HRT Act* in 2004 involved the addition of Parts 4A and 4B to align the Western Australian legislation with the original 2002 Commonwealth legislation. The Western Australian and Commonwealth legislation remained consistent until, following the Lockhart review, the Commonwealth Acts were amended in December 2006 to expand the range of research activities involving embryos that may be licensed (as described above). In 2007, the Human Reproductive Technology Bill 2007, which was aimed at achieving corresponding legislation in Western Australia, was defeated in the Legislative Council on 6 May 2008 via conscience vote. Debate on the Bill in the Upper House included news of induced pluripotent stems cells (iPS) being generated from skin cells. Opponents of the Bill indicated there was no ongoing justification for the amendments, on the basis that these iPS cells were likely to have the same qualities as human embryonic stem cells derived.

590 *Human Cloning and Embryo Research Act 2004* (ACT); *Research Involving Human Embryos Act 2003* (NSW); *Assisted Reproductive Technology Act 2007*(NSW): *Consent from gamete provider required prior to an ART provider using a gamete or embryo for research* (s20); *Research Involving Human Embryos Act 2008* (Vic); *Research Involving Human Embryos Act 2003* (SA); *Prohibition of Human Cloning for Reproduction Act 2003* (SA); *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (Qld).

10.3.2 Inoperative embryo research licensing and monitoring system

The result of the defeat of the 2007 Bill was that while Parts 4A and 4B of the *HRT Act* were inserted in 2004 to adopt a uniform approach to embryo research across Australia, this has not been achieved. Western Australia's laws are now inconsistent with the Commonwealth and with all other states and the Australian Capital Territory. Further, because Western Australian legislation differs to that of the Commonwealth, this has led to legal uncertainty regarding the authority of the NHMRC to license and monitor research on excess ART embryos in Western Australia.

In particular, under the *HRT Act*, the licensing scheme for research on excess ART embryos in Western Australia relies on the Commonwealth agreeing to undertake the licensing function, through the NHMRC Licensing Committee. As the declaration of the *HRT Act* as a 'corresponding state law' was revoked on 12 June 2007 following amendments to the Commonwealth Acts in 2006, the relevant section of the *Research Involving Human Embryos Act* (section 43) does not apply. There is no authority for the State law to confer powers on Commonwealth officers and the Licensing Committee. The Licensing Committee cannot grant a licence for embryo research under the *HRT Act*. There is also no authority for the Chair of the NHMRC Licensing Committee to appoint officers to inspect and monitor embryo research in Western Australia. The consequence of this is that currently no embryo research can be licensed under the *HRT Act*, including that which was previously permitted under the 2004 amendments to the Act.

Note, the defeat of the 2007 Bill has not only prevented embryonic stem cell research, it has stopped all research on human embryos in Western Australia that would require an NHMRC licence. In 2009 the WA Chief Scientist expressed concern, calling for Parliament to reconsider legislation to allow the cloning of human embryos for medical research, to help find cures for life-threatening diseases. The Australian Stem Cell Centre has since advised the Department of Health that more research is needed to discover whether the iPS cells will offer the same research value as embryonic stem cells. Research on new and emerging technologies that would require NHMRC Licensing is also not possible. There is ongoing concern that some scientists may consider moving overseas or interstate to access greater opportunities and fear that Western Australia has fallen behind the international research community.

10.3.3 Embryo research licences

Investigation into current licences revealed that there was a limited amount of human embryo research for the purposes of embryonic stem cell research and no licence holders for SCNT. Of the eight current licences in Australia, two pertain to the development of human embryonic stem cells, both of which are held by Genea Limited. Of the remaining licences, one is for the development of methods for pre-implantation genetic and metabolic evaluation of human embryos; one is for the use of excess ART embryos and clinically unusable eggs for validation of an IVF device; one is for the use of excess ART embryos for the development of improved IVF culture media; and three are for the use of excess ART embryos for blastocyst-stage biopsy training. Table 10.1 sets out the licence holders, the purpose of the licence and the dates the licence were first granted and when the licences end.

Table 10.1: Current NHMRC Licences for Research Involving Human Embryos (2018)

Licence Holder	Purpose	Date of licence	Date licence ends
Genea Limited	Development of Methods for Pre-implantation Genetic and Metabolic Evaluation of Human Embryos	16 April 2004	Current to 16 April 2019
Genea Limited	Development of Human Embryonic Stem (ES) Cells	16 April 2004	Current to 16 April 2019
Genea Limited	Derivation of human embryonic stem cells from embryos identified through pre-implantation genetic diagnosis to be affected by known serious monogenic conditions	7 May 2007	Current to 7 May 2019
Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	8 Dec 2011	Current to 8 Dec 2018
Genea Limited	Use of excess ART embryos for the development of improved IVF culture media	28 Mar 2012	Current to 28 Mar 2021
Melbourne IVF Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	19 Dec 2014	Current to 19 Dec 2020
IVFAustralia Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	21 April 2017	21 April 2020
TasIVF Pty Ltd	Use of excess ART embryos for blastocyst-stage embryo biopsy training	1 Sept 2017	1 Sept 2020

10.4 Submissions to the Review

The review received 10 written submissions that called for consistency between State and Commonwealth legislation in relation to research involving human embryos and related matters.[591] The Australian Medical Association noted that 'there is scope for greater levels of research to be conducted in WA, which should continue to be tightly regulated.'[592]

In opposition to adopting the Commonwealth legislation was the submission received from Mr Egan, who called for the repeal of the 2004 provisions.[593]

591 Rodino & Clissa (Counsellors), Submission 8; Dr Melanie Walls, Submission 26; Damian Adams, Submission 40; ANZICA WA Fertility Counsellors, Submission 61; Hollywood Fertility, Submission 75; Edith Cowan University (Professor Moira Sim), Submission 72; Australian Christian Lobby, Submission 77; Australian Medical Association, Submission 96; Women and Newborn Health Services, Submission 121; Reproductive Technology Council, Submission 122.

592 Australian Medical Association, Submission 96.

593 Defend Human Life (Richard Egan), Submission 109.

On the issue of research involving human embryos more broadly, the review received nine written submissions that supported enabling research.[594] It received five written submissions that raised concerns about the future clinical application of such research in that it may lead to heritable alterations of the human genome, to which they were opposed.[595] The Review also received submissions that were opposed to research that destroyed human embryos on the basis of ethics,[596] and/or that such destruction was seen not to respect human embryos, as being against God, their beliefs, and the beliefs of their church.[597]

10.5 Discussion

Debates about research involving human embryos and cloning often reflect a long history of argument and beliefs about the beginning of life and moral status of the human embryo. On these issues there has been no consensus, and some people hold strong beliefs about whether research should or should not be permitted, and if so, under what conditions. However, over time debates have also broadened to include not only moral, but also political, economic, and social rationales regarding whether to permit such research and where the boundaries should lie.

Regulatory responses to research have moved from permitting research aimed initially at understanding life itself, to later assisting in the formation of embryos for reproductive technologies, to allowing research involving human embryos as a means to investigate, avoid, and/or develop potential treatments, or cures, for illnesses suffered by other living humans. These are noble purposes aimed at improving the human condition and easing suffering. Within this context, regulation has served to provide a framework within which those wanting to conduct research could work while striking an arguable balance between opposing views about the ethical or moral concerns raised. Some research may prove fruitful, other research will prove that a particular line of enquiry does not provide the promised results, but without such research, such answers will never be known.

In Western Australia the issue is now much wider. By failing to maintain its status as having a corresponding State law to that of the Commonwealth research involving human embryos legislation, it has in fact been left outside of the regulatory scheme altogether. The ability to conduct research involving human embryos for any purpose in Western Australia has thus ground to a halt – for 11 years.

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594 Dr Melanie Walls, Submission 26; Dr Vincent Chapple, Submission 28; Genetic and Rare Disease Network (Amanda Samanek), Submission 57; Australian Mitochondrial Disease Foundation, Submission 59; Edith Cowan University (Professor Moira Sim), Submission 72; Australian Medical Association, Submission 96; Women and Newborn Health Services (Jenny O'Callaghan), Submission 121; Reproductive Technology Council, Submission 122; Ludlow Mills Sparrow Warren (Monash University), Submission 125.

595 Damian Adams, Submission 40; Centre for Genetics and Society (U.S), Submission 48; Australian Christian Lobby, Submission 77; FINRRAGE, Submission 93; Defend Human Life (Richard Egan), Submission 109.

596 LJ Goody Bioethics Centre, Submission 85.

597 Andrew & Jody Burgle, Submission 23; Janice Burdinat, Submission 45; Trevor Harvey, Submission 47; Brenda Harvey, Submission 51; Julie Waddell, Submission 64. (Four of these submissions mirrored each other in content as form letters).

The written submissions received by the Review were mixed in their views. They represented a variety of people and backgrounds, including professionals, lay people, those affected by disease or disorder and those who are not. A number called for Western Australia to align its legislation to that of the Commonwealth. Some were supportive of research but concerned about clinical applications and some expressed their opposition to all embryo research. In making recommendations for Western Australia, I also note that during the review I had the privilege of meeting many Western Australians who were suffering from a variety of conditions, who had it not been for the assistance of medical research, may not be alive or possibly able to even contemplate building a family. All of those I spoke to supported some research being permitted.

It did not appear that the views held in Western Australia were any different to those across Australia which have been demonstrated in extensive public consultations on these particular matters. That is, there are a variety of views and consensus has never been achieved. In response, the Commonwealth, other states, and the Australian Capital Territory have established a regulatory system that allows some research, subject to authorisation by the NHMRC Licensing Committee. It is my recommendation that Western Australia does the same.

However, another issue that is faced not only in Western Australia, but across Australia, is that any such regulation needs to be flexible and responsive, and subject to regular review. Science and technology progress and change, as do social mores and attitudes. As will be seen in the following chapter, again, what was once not thought possible is now a reality. Legislation that was written at a time before such technology was contemplated may again prove outdated. New debates emerge about what should be permitted and decisions about whether to amend legislation or regulations will again need to be made. In recommending Western Australia align its regulation of human embryo research with the Commonwealth, I also recommend that it consider how best to do so to enable flexibility in regard to future issues and emerging technologies that no doubt will present.

Findings

1. The Commonwealth provides legislation and oversight of research involving human embryos and prohibited practices, including a national NHMRC licensing scheme.
2. New South Wales, Queensland, South Australia, Tasmania, Victoria and the Australian Capital Territory have enacted consistent legislation with the Commonwealth legislation and regulation governing research involving human embryos and prohibited practices.
3. Western Australia no longer has consistent legislation, which as a result, means no embryo research can be licensed under the *HRT Act*, including that which was previously permitted under 2004 amendments to the Act. Consequently, research required to be licensed by the NHMRC is not being undertaken in Western Australia.
4. It is in keeping with Western Australia's COAG commitments to have uniform legislation in this area.

Recommendations

Recommendation 59

Western Australia should enact uniform legislation to the Commonwealth *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition on Cloning for Human Reproduction Act 2002* (Cth), in keeping with its COAG commitments regarding research involving human embryos and prohibited practices.

Recommendation 60

Western Australia should consider how best to incorporate changes to Commonwealth legislation regarding human embryo research and related matters into its own law (for example via legislation, regulations, and/or directions) to allow for future flexibility, responsiveness, and regular review in anticipation of further advances in science and emerging technologies.

Table: Required change and action

Table 10.2 details the changes required that are relevant to the discussion in this chapter. Again, it is noted that:

* Legislative change may take time due to drafting, approval, and Parliamentary processes, but, is nevertheless recommended *as a matter of priority*;

** Changes to directions and operation of the RTU/RTC are recommended to be implemented by the DG of the DoH *immediately*.

Note, the actual wording and contents of recommended changes to legislation, directions, and/or administrative forms will need to be determined after the Government has considered this report, and detailed attention to drafting may be had.

Table 10.2: Recommended Changes to Legislation, Directions and Operations Regarding Embryo Research

Required Change	Legislation*	Directions**	Operation**
Amend *HRT Act* or introduce legislation/ directions to be consistent with *Research Involving Human Embryos Act 2002* (Cth) and *Prohibitions on Human Cloning Act 2002* (Cth).	Incorporate changes to Commonwealth legislation regarding human embryo research and related matters into Western Australian law (for example via legislation, regulations, and/or Directions) to ensure consistency with Commonwealth legislation, while allowing for future flexibility, responsiveness, and regular review in anticipation of further advances in science and emerging technologies.	Incorporate changes to Commonwealth legislation regarding human embryo research and related matters into Western Australian law (for example via legislation, regulations, and/or Directions) to ensure consistency with Commonwealth legislation, while allowing for future flexibility, responsiveness, and regular review in anticipation of further advances in science and emerging technologies.	Consider how best to incorporate changes to Commonwealth legislation regarding human embryo research and related matters into Western Australian law (for example via legislation, regulations, and/or Directions) to allow for future flexibility, responsiveness, and regular review in anticipation of further advances in science and emerging technologies.

Chapter 11

ART Issues – Emerging Technologies and Practices

Chapter 11: ART Issues – Emerging Technologies and Practices

11.1 Introduction

Research involving human embryos that promises to cure diseases, or to assist women to bear children free of heritable disease continues to progress. While the *HRT Act* has not permitted such research in Western Australia, new applications and technologies continue to evolve in other jurisdictions. Most recently, this has included research involving mitochondrial donation, and research involving gene editing using CRISPR-Cas9. The Terms of Reference for the current review require consideration of both. This chapter considers each in turn.

11.2 Emerging technologies: Mitochondrial donation

11.2.1 What is mitochondrial donation

Mitochondria are organelles found in the cells of every complex organism. In addition to supplying cellular energy, mitochondria are involved in signalling cellular differentiation, and cell death, as well as maintaining control of the cell cycle and cell growth. All embryonic mitochondria are derived from oocytes (eggs), meaning that all children of a female carrier for mitochondrial disease will be affected by the condition. Mitochondrial diseases tend to have serious consequences, with the most significantly affected organs being those with high-energy consumption (such as the brain, heart and skeletal muscles); and neurological abnormalities include loss of vision and hearing, seizures, dementia, motor neuron disease. Symptoms may appear at birth or have a late onset.

Mitochondrial donation (or mitochondrial replacement techniques) aims to avoid mitochondrial disease.[598] The procedure may occur via pro-nuclear transfer (i.e. acquiring a donor's egg cell, removing its nucleus, and transferring the nucleus of a fertilised egg into it) or maternal spindle transfer, which involves instead transferring the nucleus of the mother's unfertilised egg into the donor egg cell, and then fertilising it. Because mitochondria hold a small amount of DNA, a resulting baby would have the DNA of both parents (found in the nucleus) as well as some DNA from the donor of the cell that contains the mitochondrial contents. The technique has thus been colloquially referred to as 'three-person IVF'.

598 Mitochondrial disease although rare can be severe, with symptoms including poor growth, loss of muscle coordination, muscle weakness, visual problems, hearing problems, learning disabilities, heart disease, liver disease, kidney disease, gastrointestinal disorders, respiratory disorders, neurological problems, autonomic dysfunction and dementia. It can lead in more severe cases to death.

11.2.2 Ethical debate and concerns

Mitochondrial donation has attracted much ethical debate and controversy. Proponents argue that mitochondrial donation offers women with mitochondrial disease an opportunity to have healthy, genetically related children. However, concerns have been raised about the possible psycho-social impacts upon children, including potential impacts concerning identity (for example, the cell donor may not be identified as sperm and egg donors are);[599] about the impact mitochondrial DNA may have on a range of traits and functions such as fertility, cognitive ability, ageing, and personality;[600] and about the lack of understanding and knowledge regarding the long-term impacts of the technique on children born and as a consequence of altering the germline which will be passed down through generations. There exists ongoing debate about whether Australia should permit mitochondrial donation in limited circumstances as a method to avoid mitochondrial disease.

11.2.3 Regulation of mitochondrial donation

United Kingdom

At the time of writing, the United Kingdom was the only nation that had legislation/regulation that allows mitochondrial donation to proceed. Since 29 October 2015, fertility clinics may apply to the Human Fertilisation and Embryology Authority (HFEA) for a licence to use the technique. This position was arrived at after 12 years of reviews and consideration of whether the technique was suitable for clinical implementation and subject to licensing by the HFEA. In the United Kingdom, any clinic that applies for such a licence must provide evidence that they have adequately experienced staff and the necessary equipment. Consideration will also be given to the clinic's plans for follow-up of the children born. Each application is considered on a case-by-case basis, during which the potential patient's specific circumstances will be considered.[601] The first licence to administer mitochondrial donation as a treatment was granted to a fertility clinic in 2017. To date, no children have been born using this process in the United Kingdom.[602]

599 Francois Baylis 'The ethics of creating children with three genetic parents' *26 Reprod Biomed Online* 2013 pp 531–4.

600 Ted Morrow, 'Three person IVF: Science shows ethical questions remain unanswered' (2015) The Conversation, available at https://theconversation.com/three-person-ivf-science-shows-ethical-questions-remain-unanswered-36992 accessed September 2018.

601 Human Fertilisation and Embryology Authority, 'World First Mitochondrial Donation Regulations Come into Force', Press Release 29 October 2015 http://www.hfea.gov.uk/9946.html accessed 18 February 2018.

602 The MITO Foundation notes the following: 'After an extensive process involving many years of consultation and three separate expert reviews, regulations to allow mitochondrial donation have been approved by the UK Parliament. On Tuesday 3 February 2015 MPs in the House of Commons voted by 382 to 128 to allow mitochondrial donation. On Tuesday 24 February 2015 peers in the House of Lords voted by 280 to 48 to allow mitochondrial donation to be licenced for use. On Friday 16 December 2016 the UK Human Fertilisation and Embryology Authority (HFEA) approved the use of mitochondrial donation in specific cases. On Friday 17 March 2017, the HFEA granted the first clinical mitochondrial donation licence to the Newcastle Fertility Centre at the International Centre for Life in Newcastle-upon-Tyne, United Kingdom. On Tuesday 6 February 2018, two UK women carrying mtDNA mutations were granted permission to undergo mitochondrial donation, giving them the opportunity to have children free of mitochondrial disease. See https://www.mito.org.au/mitochondrial-donation/.

United States

In the United States in February 2016, US Food and Drug Administration (FDA)-sponsored study was published by the National Academies Press[603] in which a distinction was drawn between the heritable genetic modification represented by 'mitochondrial replacement techniques' (MRT) and the heritable genetic modification of nuclear DNA. The committee concluded that it would be ethically permissible to conduct clinical investigations of MRT as long as they were subject to the strict conditions and principles outlined in the report which included that any initial MRT clinical investigations focus on minimising the future child's exposure to risk while ascertaining the safety and efficacy of the techniques. They further recommended that restrictions and conditions for initial clinical investigations include: limiting clinical investigations to women who are otherwise at risk of transmitting a serious mtDNA disease, where the mutation's pathogenicity is undisputed, and the clinical presentation of the disease is predicted to be severe, as characterised by early mortality or substantial impairment of basic function; and transferring only male embryos for gestation to avoid introducing heritable genetic modification during initial clinical investigations.[604]

The FDA Report recommended that only following successful initial investigations of MRT in males, that the FDA could consider extending MRT research to include the transfer of female embryos if clear evidence of safety and efficacy from male cohorts, using identical MRT procedures, were available. (Note, this was considered by the HFEA for mitochondrial donation in the United Kingdom but was ultimately rejected due to concerns this would require another intervention, in this case PGD, in an embryo that had already been subject to heavy manipulation and would also halve the number of suitable embryos and reduce the chance of achieving a pregnancy.)

Federal restrictions on funding and research 'in which a human embryo is intentionally created or modified to include a heritable genetic modification' mean that clinics in the United States cannot currently conduct research in this area if they seek public funding.

Birth in Mexico

In 2016, John Zang, a medical director at the New Hope Fertility Centre in New York, and his colleagues used the spindle transfer technique to help a woman who had Leigh Disease to give birth to a baby boy in Mexico. The mother had suffered four miscarriages and two children who had died of the disease, for which the first signs included vomiting, diarrhoea and difficulty with swallowing, followed by progressive loss of movement and deterioration of mental function, resulting in death within two to three years usually due to respiratory failure.

There are no laws governing the technique in Mexico.

603 Anne Claiborne, Rebecca English, and Jeffrey Kahn (Eds); *Committee on the Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases; Board on Health Sciences Policy; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine, Mitochondrial Replacement Techniques: Ethical, Social, and Policy Considerations* (2016).

604 Claiborne et al, above n 603, p xv.

Births in the Ukraine

In June 2018, Valery Zukin, director of the Nadiya clinic of reproductive medicine in Kiev, Ukraine, reported in the media that doctors there had used pronuclear transfer for mitochondrial replacement to help four women give birth (three boys and a girl), three women to become pregnant, and had 14 failed attempts.[605]

Again, there are no laws prohibiting mitochondrial donation. It was reported that the doctors were granted approval from an ethical committee and a review board of the Ukrainian Association of Reproductive Medicine and the Ukrainian Postgraduate Medical Academy.

Australia (Commonwealth Laws)

In Australia, pursuant to the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), the use of mitochondrial donation for clinical application is prohibited. Specifically, section 13 prohibits the creation of a human embryo outside the body of a woman which contains genetic material from more than two persons. Section 15 prohibits the alteration of the genome of a human cell where that alteration is inheritable. Section 20 prohibits placing prohibited embryos into a woman. Contravention of these provisions carries a penalty of up to 15 years in prison. The current understood position is thus that mitochondrial donation for human reproduction cannot occur in Australia.[606]

Research is also prohibited unless authorised by an NHMRC licence (See discussion in Chapter 10 and Table 10.1). Section 23 of the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), provides that it is an offence to create a human embryo containing genetic material provided by more than two persons unless authorised by a licence. Contravention of the provision carries a penalty of up to 10 years imprisonment. There are no such current NHMRC licences.

11.2.4 Senate committee inquiry

On 21 March 2018, the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report:

- the science of mitochondrial donation and its ability to prevent transmission of mitochondrial disease
- the safety and efficacy of these techniques, as well as ethical considerations
- the status of these techniques elsewhere in the world and their relevance to Australian families
- the current impact of mitochondrial disease on Australian families and the healthcare sector
- consideration of changes to legal and ethical frameworks that would be required if mitochondrial donation was to be introduced in Australia
- the value and impact of introducing mitochondrial donation in Australia; and
- other related matters.[607]

605 Rob Stein, Clinic Claims Success in Making Babies with three parents' DNA (heard on Morning Addition) June 2018, available at https://www.npr.org/sections/health-shots/2018/06/06/615909572/inside-the-ukrainian-clinic-making-3-parent-babies-for-women-who-are-infertile accessed September 2018.

606 The Senate Community Affairs References Committee, Science of mitochondrial donation and related matters, Commonwealth of Australia 2018.

607 Ibid.

The Committee received 60 submissions and held public hearings in which it received oral submissions. The submissions, details of the inquiry, and the Committee's report may be found on the Commonwealth Government's website.[608] The Committee made the following recommendations:

- **Recommendation 1:** The committee notes the strong potential of mitochondrial donation to address the debilitating effects of inherited mitochondrial disease. The committee recommends that public consultation should be undertaken regarding the introduction of mitochondrial donation to Australian clinical practice. To facilitate this consultation, the committee further recommends the Australian Government prepare a consultation paper, including options for legislative change that would be required. The Minister for Health should seek advice from the National Health and Medical Research Council on the most appropriate timing and format for this consultation.
- **Recommendation 2:** The committee recommends that the Australian Government task the National Health and Medical Research Council with advising on the following questions:
  - Whether mitochondrial donation is distinct from germline genetic modification.
  - Is there any new information to indicate from research findings from the United Kingdom, that the science of mitochondrial donation is safe for introduction into controlled clinical practice, cannot be applied in an Australian context?
  - Whether other approaches to inheriting mitochondrial disease should also be the focus of Australian research.

The committee recommends the findings be used to inform the future legislative process.

- **Recommendation 3:** The Committee recommends the Minister for Health take the findings of this report to the Council of Australian Governments (COAG) Health Council to progress the implementation of this report's recommendations with the states and territories.
- **Recommendation 4:** The Committee recommends, noting the need for community consultation and scientific review, the urgency of treatment for current patients and the small number of patients seeking this treatment, that the Australian Government initiate dialogue with the relevant authorities in the United Kingdom to facilitate access for Australian patients to the United Kingdom treatment facility as an interim measure.

In making its recommendations the Committee noted that mitochondrial donation should not be introduced without allowing for wider public consultation. It also remained of the belief that it did not have the required expertise to decide about a number of scientific matters that had been raised including whether mitochondrial donation amounted to germline modification and noted a formal determination must be taken by an appropriate body with the relevant expertise. It said that if this view is confirmed, then appropriate amendments should be made to Australian law to keep it up-to-date with science and to allow for, and only allow for, mitochondrial donation. In such circumstances, it considered that a limited clinical trial should be considered before the full introduction of mitochondrial donation and that additional research could be simultaneously conducted. Medical trials would require a change of legislation before they could proceed.

608 See https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation accessed September 2018.

11.3 Emerging technologies: Gene editing

Genome editing (also called gene editing) is a group of technologies that give scientists the ability to change an organism's DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome. Research on gene editing aims to determine whether it is possible to correct mutations at precise locations in the human genome in order to treat genetic causes of disease.

Several approaches to genome editing have been developed. Most recently 'CRISPR' (pronounced 'crisper')[609] and 'CRISPR-Cas9'[610] systems have been programmed to target specific stretches of genetic code and to edit DNA at precise locations. The potential is that using such techniques, researchers may permanently modify genes in living cells and organisms to modify disease-causing genes and ultimately combat human disease and disability. Other potential purposes include the development of new diagnostic tools and understanding of early embryo development. Other systems, such as CRISPR-Cas13's, that target RNA are also being researched to provide alternative avenues.

Research on gene editing using the CRISPR-Cas 9 technique has been conducted on non-viable embryos in China,[611] and has been approved by the United Kingdom HFEA to modify the genes of viable human embryos provided the embryos are not permitted to grow beyond seven days. The aim of the United Kingdom research is to study early embryo development.

However, such technology has again been the subject of debate. Some have expressed 'grave concerns' regarding the ethical and safety implications of research that applies gene-editing techniques to sperm, eggs, or embryos.[612] Unlike when editing is limited to somatic cells, where changes affect only certain tissues and are not passed from one generation to the next, changes made to genes in egg or sperm cells (germline cells) or in the genes of an embryo could be passed to future generations.

In December 2015, discussion of using germline modification at the International Summit on Human Gene Editing indicated that far too much is unknown about issues including off-target mutations (unintentional edits to the genome), persistent editing effects, genetic mechanisms in embryonic and foetal development, and longer-term health and safety consequences. The discussion also focused upon the often-raised concern that in allowing one kind of germline modification it may lead to market-based eugenics which emphasises certain kinds of 'enhancement' and may exacerbate already existing discrimination and inequality.[613] It was also argued that embryo screening techniques such as PGD are already widely available and preferable.

609 Which stands for 'Clustered Regularly Interspaced Short Palindromic Repeats'.

610 Used loosely to refer to the various CRISPR-Cas9 and -CPF1, (and other) systems that can be programmed to target specific stretches of genetic code and to edit DNA at precise locations.

611 P. Liang, Y. Xu, X. Zhang, et al. 'CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes' (2015) 6 *Protein Cell* 363.

612 Edward Lanphier, et al. 'Don't edit the human germline' *Nature Comment* 12 March 2015.

613 National Academies of Science, Engineering and Medicines, International Summit on Human Gene Editing: A Global Discussion, 1-3 December 2015 available at http://www.nationalacademies.org/gene-editing/Gene-Edit-Summit/index.htm, accessed September 2018.

The controversy surrounding germline editing has also raised concern that such research may negatively impact upon work using gene-editing techniques in somatic (non-reproductive) cells, which holds promise for treatment of diseases such as HIV/AIDs,[614] hepatitis,[615] haemophilia, sickle-cell anaemia and several forms of cancer.[616]

At present numerous countries have laws against altering the human genome, including Australia.[617] While at the time of writing there appeared to be no support for the clinical application of germline gene editing, and there does not appear to be any demonstrable high unmet medical need for germline editing, there is clearly some support for basic research to continue (illustrated for example by the United Kingdom approvals for the above-mentioned CRISPR research). Where this will lead is as yet unknown but debate continues.

11.4 Western Australia

11.4.1 Current law

Mitochondrial donation and heritable alteration of a genome for research or clinical application are not possible in Western Australia. Section 53I of the *HRT Act* prohibits the creation of embryos with genetic material from more than two people. Section 53L of the *HRT Act* prohibits heritable alteration of the genome of a human embryonal cell, human foetal cell and human gametes. As discussed in Chapter 10, Western Australia is also currently in the position in which its legislation falls outside of the Commonwealth scheme regulating research involving human embryos and various other technologies, which would permit mitochondrial donation research subject to the NHMRC granting a licence. The consequences of the current state of the law is that at present no embryo research can be licensed under the *HRT Act*, including that which was previously permitted under the 2004 amendments to the Act. Consequently research required to be licensed by the NHMRC is not being undertaken in Western Australia.

11.4.2 Submissions

The review received 15 written submissions that commented on mitochondrial donation and/or gene editing.[618] Nine supported enabling further research.[619] Six raised concerns about the

614 P Tebas, D Stein, WW Tang, I Frank, SQ Wang, G Lee, et al. 'Gene editing of CCR5 in autologous CD4 T cells of persons infected with HIV' (2014) 370(10 *N Engl J Med*. 901–10.

615 V Ramanan, A Shlomai, DB Cox, RE Schwartz, E Michailidis, A Bhatta, et al. 'CRISPR/Cas9 cleavage of viral DNA efficiently suppresses hepatitis B virus' (2015) 5 *Sci Rep*. 10833.

616 DB Cox, RJ Platt, F Zhang. 'Therapeutic genome editing: prospects and challenges'. (2015) 21(2) *Nat Med*. 121–31.

617 *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 15.

618 Dr Melanie Walls, Submission 26; Dr Vincent Chapple, Submission 28; Damian Adams, Submission 40; Genetic and Rare Disease Network (Amanda Samanek), Submission 57; Centre for Genetics and Society, Submission 48 (U.S); Australian Mitochondrial Disease Foundation, Submission 59; Edith Cowan University (Professor Moira Sim), Submission 72; Australian Christian Lobby, Submission 77; Coalition for the Defence of Human Life, Submission 90; FINRRAGE, Submission 93; Australian Medical Association, Submission 96; Defend Human Life (Richard Egan), Submission 109; Women and Newborn Health Services (Jenny O'Callaghan), Submission 121; Reproductive Technology Council, Submission 122; Ludlow Mills Sparrow Warren (Monash University), Submission 125.

619 Dr Melanie Walls, Submission 26; Dr Vincent Chapple, Submission 28; Genetic and Rare Disease Network (Amanda Samanek), Submission 57; Australian Mitochondrial Disease Foundation,

future clinical application of such research in that it may lead to heritable alteration of the human genome, to which they were opposed, and/or their opposition to human embryo research.[620] The Review also received three submissions that did not mention mitochondrial donation or gene editing but that were opposed to research that was seen not to respect human embryos.[621] Some such submissions were very comprehensive. Some were from people with particular expertise and knowledge of these technologies, and/or some were from people who represented affected communities. However, the Review did not attract enough comment on such issues, nor was I able to consult broadly enough, to make recommendations specific to mitochondrial donation or human genome editing.

11.5 Discussion

I have recommended (in Chapter 10) that Western Australia should enact uniform legislation to the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition on Cloning for Human Reproduction Act 2002* (Cth), in keeping with its COAG commitments regarding research involving human embryos and prohibited practices. It will be important for Western Australia to continue to engage with that system and anticipate that there may be further amendments in the future as emerging technologies continue to present themselves, including, for example, amendments regarding mitochondrial donation and/or gene technologies.

Beyond this, I defer to and concur with the recommendations made by the recent Senate Community Affairs References Committee (discussed above), which specifically inquired into mitochondrial donation and, having received 60 written submissions on the matter, conclude that further public consultation and scientific advice is needed. Its report recommended that this happen at a national level, led by the NHMRC, followed by the results being taken to the Council of Australian Governments (COAG) Health Council to progress the implementation of any recommendations with the states and territories. I recommend that Western Australia engage with that process, as well as exploring such issues further in State via the recommended new advisory body.

Similarly, in relation to human genome editing, I find that much wider consultation and scientific advice is needed than was possible in this review. Again Western Australia should engage with wider national and international discourse on such research, as well as examining State-based understanding and attitudes further.

Submission 59; Edith Cowan University (Professor Moira Sim), Submission 72; Australian Medical Association, Submission 96; Women and Newborn Health Services (Jenny O'Callaghan), Submission 121; Reproductive Technology Council, Submission 122; Ludlow Mills Sparrow Warren (Monash University), Submission 125.

620 Damian Adams, Submission 40; Centre for Genetics and Society (U.S), Submission 48; Australian Christian Lobby, Submission 77; Coalition for the Defence of Human Life, Submission 90; FINRRAGE, Submission 93; Defend Human Life (Richard Egan), Submission 109.

621 Janice Burdinat, Submission 45; Trevor Harvey, Submission 47; Brenda Harvey, Submission 51; Julie Waddell, Submission 64. (These submissions mirrored each other in content).

At the same time, I note a recent editorial published in the Lancet:

> *Human genome editing is no longer a concept confined to the pages of futuristic science fiction novels – modifying genetic code is here now and is advancing rapidly. Globally, regulators and investigators must work together to ensure oversight of the development of gene editing technologies. Regulations must not only keep up and anticipate future applications, but also facilitate swift and safe implementation of the technology in the clinic.*[622]

This Review has found that the *HRT Act*, having been drafted in 1991, and last having seen amendments in 2004, is not operating in a manner that is responsive to rapidly changing technology. Again, therefore, I note that it will be important, to not only address the issues that have been raised in this Review but to adopt a regulatory approach that remains flexible and responsive into the future.

Findings

1. Research involving human embryos that promises to cure diseases, or to assist women to bear children free of heritable disease continues to progress. While the *HRT Act* has not permitted such research in Western Australia, new applications and technologies continue to evolve in other jurisdictions. Most recently, this has included research involving mitochondrial donation, and research involving gene editing using CRISPR-Cas9.
2. The Commonwealth Senate Community Affairs References Committee has recommended that further public consultation and scientific advice is needed in relation to mitochondrial donation, at a national level, led by the NHMRC.
3. Western Australia should engage with that process via COAG if and when it proceeds, as well as explore its own stance on such issues further via the recommended new formulation of its Reproductive Technology Council.
4. Similarly, in relation to human genome editing, **much** wider consultation and scientific advice are needed than was possible in this Review. Western Australia should engage with wider national and international discourse on such research, as well as examining State-based understanding and attitudes further.
5. It will be important to not only address the issues that have been raised in this Review but to adopt a regulatory approach that remains flexible and responsive into the future.

Recommendations

Recommendation 61

Western Australia should engage with any national/COAG led public consultations and seeking of scientific advice regarding mitochondrial donation, gene technology or other relevant emerging technologies, as well as exploring its own stance on such issues further via the recommended new formulation of an advisory body.

622 Editorial, Editing the human genome: balancing safety and regulation, 391 *The Lancet*, 3 February 2018.

Chapter 12

ART Issues – Other Matters that require further Consideration or Action

Chapter 12:
ART Issues – Other Matters that require further Consideration or Action

12.1 Introduction

There were a number of other matters concerning the *HRT Act* and the regulation of assisted reproduction in Western Australia that people raised in their submissions. Some such issues are discussed in Part 2 of this report.[623] In this final chapter, matters that were raised, but for which the Review did not receive sufficient submissions/input to be able to address the issue in depth are noted. This included matters regarding:

- age limits regarding access to treatment
- the ability for clinics to refuse treatment in certain circumstances
- egg sharing by same-sex female couples
- the creation of embryos surplus to a patient's needs.

While a comprehensive discussion of each of these issues was not possible within the scope of the Review, the issues raised and recommendations for further action are noted below. Where possible, such recommended actions included reference to laws of other jurisdictions to inform the law and practice in Western Australia as required in the Terms of Reference, and/or what further considerations might be had. Note, these issues are important and should be considered further prior to and when drafting the new *HRT Act* and/or any regulations, directions, or conditions of registration. There is also the opportunity for the recommended new advisory body to play a role in further considering such issues, and advising the Minister.

12.2 Eligibility for ART (IVF) and age limits

Under the current *HRT Act*, section 23 prescribes criteria for when IVF procedures may be carried out, including but not limited to a requirement that persons, as a couple, or a woman, are unable to conceive a child due to medical reasons, but that *'the reason for infertility is not age…'*.

A number of clinicians and the ANZICA Fertility Counsellors suggested that age restrictions for access to ART should be revised and/or clarified.[624] The clinics noted that the RTC has been inconsistent regarding when it has viewed a woman's age as acceptable and that the age of menopause is unclear. They also raised that there is a need to consider other factors such as the ability for women to use an egg donor, and thus being able to conceive provided medically fit to do so. Some clinics were of the view that age limits should apply for men also. For example, one clinic raised the concern that they had been approached by a number of men who were 60 or 70 years of age seeking treatment with 30-45-year-old partners. They questioned whether they

623 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Report: Part 2),* 2019.

624 PIVET Medical Centre, Submission 114; Dr Vincent Chapple, Submission 28; ANZICA WA Fertility Counsellors (Joint submission), Submission 61; Hollywood Fertility, Submission 74.

should treat in such circumstances and raised the inconsistency of applying age limits to women, but not to men. One clinic suggested that a combined age limit should apply.

In contrast, the submission of Rodino and Clissa (fertility counsellors) supported age restrictions.[625]

The review found that there had been some inconsistency over time in how age limits were applied and that issues regarding access based on age in modern times need to be further considered. In the first instance, it is incumbent upon the Minister for Health and his Department to provide clear and consistent communication regarding how the current age limits should be interpreted and applied. This may occur via the recommended new Directions, conditions of registration and/or education of clinics and community.

Beyond this, further research and consultation should be conducted regarding the current limitation on women not being able to receive treatment by way of s 23(1)(d) having been interpreted as post 'average age of menopause'. Such research and consultation should consider whether a cut-off age or stage of life such as 'post-menopause' or otherwise continues to be appropriate, and, if so, the RTC should provide guidance on this matter to clinics. Consideration should also be had as to whether such limitations should apply only to women (as it appears is current practice) or whether age limitations should also be applied to men, or whether a combined age cut off (for example, 110 years as suggested by one clinic) would be justified. If a cut-off age or stage of life such as 'post-menopause' or otherwise is deemed appropriate, then the limit should be explained and justified, based on evidence that such limitations are, for example, in the best interests of children who may be born as a result of ART. Any matters relevant to age discrimination should also be considered.

12.3 Ability to refuse treatment

It was raised with the review that in South Australia the ART Regulations (Reg 4) provide that *'nothing in the Act requires a registered person to provide ART to another person'* (subject to non-discrimination regarding sexual orientation, marital status, gender identity, etc) as a condition of registration. It was submitted by a number of clinicians that there should be an equivalent statement in the Western Australian legislation, regulations or directions. That is, that there should be a clear provision in the Western Australian law that there is no obligation upon clinics to provide ART or surrogacy treatment subject to ensuring non-discrimination and, when appropriate, a requirement to refer the person to appropriate other services that would assist with the issue of concern. The review found that it would be suitable to include equivalent provision to the South Australian provision in the Western Australian *HRT Act*, regulations or directions. This is further discussed in Part 2 of this report.[626]

12.4 Egg / Embryo sharing by same-sex female partners

The review received a small number of submissions that expressed support for egg sharing or the implantation of an embryo formed with a partner's egg, in female same-sex relationships. This is currently not possible in Western Australia unless the receiving partner meets the access criteria and would in such cases be treated as a donation or surrogacy situation.

625 Rodino & Clissa (Fertility Counsellors), Submission 8.

626 Sonia Allan, *The Review of the Western Australian HRT Act 1991 and the Surrogacy Act 2008 (Part 2)*, 2019.

Dr Melanie Walls submitted that:

> *One partner may not wish to become pregnant or cannot carry a pregnancy but may wish to use their gametes in the relationship. This is similar to a male partner providing the sperm in a heterosexual relationship. Not permitting this is gender discriminatory.*[627]

Others thought that current law would make the egg providing partner a donor, and therefore not a legal parent, and argued that this is unacceptable.[628] The RTU said that this was not correct as when the partner signs for consent to treatment she is deemed the parent of any child.

It was also submitted that requirements for the recipient partner to meet infertility criteria is unsatisfactory, and not up to date with modern relationships.[629]

The ANZICA WA Fertility Counsellors stated they did not support egg sharing but did not provide further explanation as to why.[630] The Hollywood Fertility Clinician Submission endorsed the ANZICA submission.[631]

The use of ART to retrieve eggs from one member of a female same-sex couple, to be used by the other member of the couple, would require the first women to undergo ovarian stimulation for egg retrieval, and the second woman to undergo an ART procedure to implant an embryo formed with her partner's egg, albeit neither woman may have fertility issues. The procedure, as such, would not arguably be consistent with a heterosexual couple undergoing IVF, which would be medically indicated. When not medically indicated such procedures are not be covered by the Commonwealth Medicare Benefits Scheme funding for ART.

Should the legislation change to allow people to access ART for wider circumstances, such as being unable to become pregnant in their circumstances including as a result of their relationship status (as is the case in other states), then this would enable either female partner in the couple to access ART without having to be medically infertile. However, this still would not resolve the issue of whether a person should be provided treatment that is not medically indicated or of higher risk in the circumstances. For example, artificial insemination or IUI using a person's own eggs would carry fewer risks than IVF. However, as the issue was put to the review, it appears that the reason for wanting to 'share eggs' is so that both members of the couple will feel they have contributed to their future child's creation – one contributing the egg, the other carrying the pregnancy and birthing the child.

With so little information presented to the review on this issue, I was unable to draw a conclusion on this matter. Further consultation and consideration by the new advisory body with members of the LGBTQI community, ART clinicians, counsellors, people born as a result of ART, legal and ethics experts, and other interested parties, is recommended.

627 Dr Melanie Walls, Submission 26.

628 Danielle Stone, Submission 79.

629 Ibid.

630 ANZICA WA Fertility Counsellors (Joint submission), Submission 61.

631 Hollywood Fertility, Submission 75 – endorsing Submission 61.

12.5 Creation of embryos surplus to needs

The Review received a submission by a patient who reported that she and her husband felt that they had been 'pushed' by a clinic to create embryos surplus to their needs, which she and her partner found upsetting. Specifically, she reported being discouraged to freeze eggs and fertilise each cycle even though that was her and her partner's preference. She also reported that she felt that she and her partner had received inadequate support and information about what to do with the surplus embryos afterwards.

During face-to-face consultations, I also consulted with a woman who had been distressed that she had not been fully informed about what to do with embryos that remained after she and her husband received ART. They had ultimately decided to allow the remaining embryos to succumb but subsequently felt that had they been better informed they would have donated their embryos to a couple who needed them.

This raised issues of a need for education of both clinics and consumers regarding the provision of treatment, treatment options, patient consent, and patient autonomy to decide the nature of their treatment and what they do or do not consent to. There is also a need for education and information regarding options regarding excess embryos and the provision of support in decision making (e.g. counselling). It is recommended that the Minister and DoH commission resources to support the provision of such education and information to clinics and consumers.

Findings

1. There were a number of matters presented to the review that require further consideration, clarification, direction, and/or guidance from the Minister, DG, and/or the RTC regarding:
    - age limits regarding access to treatment
    - the ability for clinics to refuse treatment in certain circumstances
    - egg sharing by same-sex female couples
    - the creation of embryos surplus to a patient's needs.

Recommendations

Recommendation 62

The Minister/DG provide clear and consistent guidance regarding how section 23(1)(d) of the *HRT Act,* stipulating the reason for infertility must not be age, should be interpreted and applied.

Recommendation 63

Further research and consultation be conducted regarding the current section 23(1)(d) requirements having been interpreted as post 'average age of menopause' and whether a cut-off age or stage of life such as 'post-menopause' or otherwise continues to be appropriate.

Recommendation 64

Further consideration should be given to whether such limitations should only apply to women (as it appears is current practice), whether age limitations should also be applied to men, or whether a combined age cut off would be justified.

Recommendation 65

Provision should be made in the Western Australian legislation and/or Directions that there be no obligation upon health practitioners or ART clinics to provide ART treatment.

Recommendation 66

Further consultation and consideration be had with members of the LGBTQI community, ART clinicians, counsellors, people born as a result of ART, legal and ethics experts and other interested parties, on issues related to egg sharing or use of an embryo formed with one partner's ova by the other female partner in a same-sex relationship.

Recommendation 67

The Department of Health provide education and information to clinics and consumers regarding the acceptable provision of treatment, treatment options, patient consent, and patient autonomy to decide the nature of treatment undertaken; as well options regarding what to do with excess embryos, and the provision of support in decision making in this regard (e.g. counselling).

Appendix 1:
Advertising of the Review, including the call for submissions and notices regarding community consultations

Advertising appearances 2018

Call for submissions

Publication	Date
The West Australian	Saturday 27 January
Sunday Times	Sunday 28 January
Out in Perth Magazine	Friday 2 February
Community Newspapers (x17)	Monday 5 February
Albany Advertiser	Thursday 8 February
Augusta Margaret River Times	Friday 9 February
Avon Valley Advocate	Wednesday 7 February
Broome Advertiser	Thursday 8 February
Bunbury Herald	Tuesday 6 February
The South Western Times (Bunbury)	Thursday 8 February
Busselton Dunsborough Times	Friday 9 February
Canning/Victoria Park Examiner	Wednesday 7 February
Collie Mail	Thursday 8 February
Countryman	Thursday 8 February
Esperance Express	Friday 9 February
Examiner Newspapers (Armadale, Gosnells, Serpentine – Jarrahdale)	Thursday 8 February
Fremantle Herald	Saturday 10 February
Geraldton Guardian	Friday 9 February
Midwest Times (Geraldton)	Wednesday 7 February
Great Southern Herald	Thursday 8 February
Kalgoorlie Miner	Saturday 10 February

Publication	Date
Kimberley Echo	Thursday 8 February
Koori Mail	Wednesday 7 February
Mandurah Mail	Thursday 8 February
Mandurah Telegraph	Wednesday 7 February
Manjimup Bridgetown Times	Wednesday 7 February
Midland Kalamunda Echo	Saturday 10 February
Perth Voice (The)	Saturday 10 February
Pilbara News	Wednesday 7 February
Post Newspapers	Saturday 10 February

The below ad featured in the above papers:

Government of **Western Australia**
Department of Health

Review of the *Human Reproductive Technology Act 1991* and *Surrogacy Act 2008*
Call for Submissions

An independent review of the Western Australian *Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008* is being conducted by Associate Professor Sonia Allan. The Department of Health invites comments and submissions from interested parties.

Copies of the legislation, submission instructions and terms of reference for the review can be accessed via:

ww2.health.wa.gov.au/review

Closing date: 5pm Friday 16 March 2018

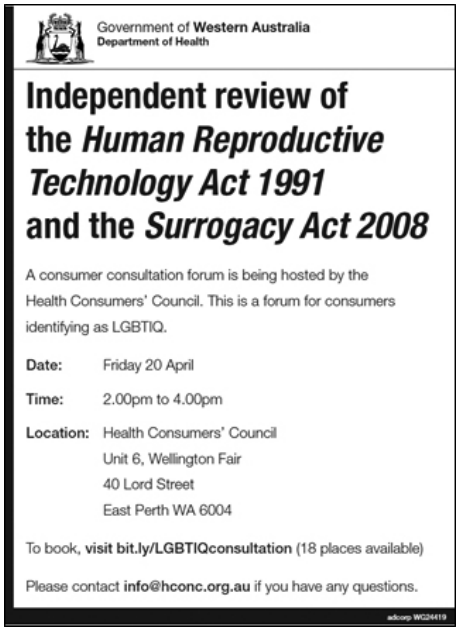
Comments and submissions can be emailed to HRTSR@health.wa.gov.au or posted to:
Program Manager
Reproductive Technology Unit
Patient Safety and Clinical Quality
Clinical Excellence Division
Department of Health
Perth WA 6004

adcorp WG23732

Community consultations

Publication	Date
South Western Times	Thursday 22 March
The West Australian	Tuesday 20 March
The West Australian	Saturday 24 March
Community Newspapers (x17) paper buy WA	Tuesday 20 March
Out in Perth Magazine	Saturday 7 April

This ad promoted the community consultations in Out in Perth Magazine:



Government of **Western Australia**
Department of Health

Independent review of the *Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008*

A consumer consultation forum is being hosted by the Health Consumers' Council. This is a forum for consumers identifying as LGBTIQ.

Date: Friday 20 April

Time: 2.00pm to 4.00pm

Location: Health Consumers' Council
Unit 6, Wellington Fair
40 Lord Street
East Perth WA 6004

To book, **visit bit.ly/LGBTIQconsultation** (18 places available)

Please contact **info@hconc.org.au** if you have any questions.

adcorp WG24419

This ad was used for all the other publications for community consultations (The South Western Times (Bunbury), The West Australian and Community Newspapers):

Government of **Western Australia**
Department of Health

Review of the *Human Reproductive Technology Act 1991* and *Surrogacy Act 2008*

Community consultations

An independent review of the *Western Australian Human Reproductive Technology Act 1991* and the *Surrogacy Act 2008* is being conducted by Associate Professor Sonia Allan.

As part of phase two of the review, A/Professor Allan will be conducting in-person consultations. She would like to meet with consumers; donors; donor-conceived people; and other interested members of the public.

Community consultation sessions are being held at:

Date	Time	Venue
Friday 13 April 2018	2.00pm to 4.00pm	Health Consumers' Council Unit 6/40 Lord St, Perth
Saturday 14 April 2018	1.00pm to 3.00pm	Joondalup Library Meeting room 1, 102 Boas Avenue, Joondalup
Monday 16 April 2018	10.00am to 12.00pm	Bunbury Library Small meeting room, 1 Parkfield St, Bunbury

We invite you to come along to share your experiences or views about assisted reproduction, surrogacy, donor conception, and/or related matters.

No booking is necessary, however, if you wish to register your intention to attend or cannot attend but would like to speak to Associate Professor Allan. Contact:

Program Manager
Reproductive Technology Unit
Department of Health
Email: HRTSR@health.wa.gov.au
Telephone: (08) 9222 4334

For further information about the review see **ww2.health.wa.gov.au/review**

adcorp WG24293

Appendix 2: List of initial contacts to whom letters of invitation were sent inviting participation in the Review

	Contact Person	Organisation/ Department
1.	Des Martin Chief Executive Officer	Aboriginal Health Council of Western Australia
2.	Jenni Millbank	Academic
3.	Kathy Sloan	Academic
4.	Renata Klein	Academic
5.	Ken Daniels	Academic
6.	Naomi Cahn	Academic
7.	Dominique Martin	Academic
8.	Patricia Fronek	Academic
9.	Denise Cuthbert	Academic
10.	Megan Munsie	Academic
11.	Isabel Karpin	Academic, UTS
12.		ACCESS Australia
13.	Chair	ANZICA
14.		Australian Donor Conception Network
15.		Australian Family Association
16.		Australian Human Rights Commission
17.		Australian Medical Association
18.		Australian Mitochondrial Disease Foundation
19.	Secretary	Baha'i Centre of Learning
20.	President	Buddhist Society of Western Australia
21.	Ashley Reid Chief Executive Officer	Cancer Council WA
22.	Marcy Darnovsky Executive Director	Center for Genetics and Society

	Contact Person	Organisation/ Department
23.	Eric Blyth	Centre for Applied Childhood Studies University of Huddersfield
24.	Robyn Lawrence Chief Executive	Child and Adolescent Health Service, Princess Margaret Hospital
25.	Robert Norman	Clinician
26.	Antonia Clissa	Concept Fertility Centre
27.	Iolanda Rodino	Concept Fertility Centre
28.	Bruce Bellinge	Concept Fertility Centre
29.	Executive Officer	Council of Churches of WA
30.	Petra Thorn	Counsellor
31.	Vice Chancellor	Curtin University
32.	Jackie Tang Assistant Director-General	Department of Communities, Child Protection and Family Support
33.	Joanna Scheib	Department of Psychology, University of California
34.	Marilyn Crawshaw	Department of Social Policy and Social Work, University of York
35.	Daphne White Manager	Desert Blue Connect (Women's Health Resource Centre Inc)
36.	Nick Pachter	Director of Genetic Services WA
37.		Donor Conception Support Group
38.	Hans Van Hoof	Donor Register FIOM
39.	Wendy Kramer	Donor Sibling Registry
40.	Liz MacLeod Chief Executive	East Metropolitan Health Service
41.	Vice Chancellor	Edith Cowan University
42.	Phil Matson ERBSWA President	Endocrine and Reproductive Biology Society of WA
43.	Sheryl de Lacey	Faculty of Medicine, Nursing and Health Sciences Flinders University
44.		Family Court of Western Australia
45.		Family Voice Australia
46.		Fay Gale Centre for Research on Gender University of Adelaide

	Contact Person	Organisation/ Department
47.	Elizabeth Webb	Fertility North
48.	Vince Chapple	Fertility North
49.	Michael Chapman President	Fertility Society Australia
50.	Kim O'Dea Secretary	Fertility Society Australia
51.	Louise Black	Fertility Specialists of WA, Bethesda Hospital
52.	Roger Hart	Fertility Specialists of WA, Bethesda Hospital
53.		FINRRAGE
54.	Damien Riggs	Flinders University
55.		Freedom Centre
56.	Diane Snooks Director	Fremantle Women's Health Centre Inc
57.	Amanda Samanek	Genetic and Rare Disease Network WA
58.	Helen Mountain	Genetic Services of WA, King Edward Memorial Hospital
59.	Hugh Dawkins Director	Genomics
60.	Gloria Moyle Coordinator	Goldfields Women's Healthcare Association Inc
61.	Emma Basc CEO	Gosnells Woman's Health Service Inc
62.	Stephen Page	Harrington Family Law
63.	Nigel Laing	Harry Perkins Institute
64.	Rebekah Worthington CEO	Hedland Well Women Centre Inc
65.	Pip Brennan	Health Consumers' Council of WA
66.	President	Hindu Association of WA Inc.
67.	Cailin Jordan	Hollywood Fertility Centre
68.	Simon Turner	Hollywood Fertility Centre
69.	Deborah Foster-Gaitskell	Hollywood Specialist Medical Centre
70.		Human Fertilisation & Embryo Authority
71.		International Social Service

	Contact Person	Organisation/ Department
72.	Andrea Credo Director	ISHAR Multicultural Women's Health Centre Inc
73.	President	Islamic Council of Western Australia
74.	President	Jewish Community Council of Western Australia (Inc)
75.		JIGSAW
76.	Kempton Cowan Chief Executive	Joondalup Health Campus
77.	Bronwyn Stuckey	Keogh Institute for Medical Research QEII Medical Centre
78.		Living Proud
79.	Justin Manuel Manager	M Clinic
80.		Melbourne Anonymous Donors (MADMen) (c/-Mr Ian Smith)
81.	Damian Adams	Member of Public associated w/ ART, Donor Conception, or Surrogacy
82.	Penny Mackieson	Member of Public associated w/ ART, Donor Conception, or Surrogacy
83.	Sarah Dingle	Member of Public associated w/ ART, Donor Conception, or Surrogacy
84.	Kimberley Springfield	Member of Public associated w/ ART, Donor Conception, or Surrogacy
85.	Myfwany Cummerford	Member of Public associated w/ ART, Donor Conception, or Surrogacy
86.	Natalie Parker	Member of Public associated w/ ART, Donor Conception, or Surrogacy
87.	Michael Williams	Member of Public associated w/ ART, Donor Conception, or Surrogacy
88.	Ross Hunter	Member of Public associated w/ ART, Donor Conception, or Surrogacy
89.	Chloe Alworthy	Member of Public associated w/ ART, Donor Conception, or Surrogacy
90.	Kim Buck	Member of Public associated w/ ART, Donor Conception, or Surrogacy
91.	Lauren Burns	Member of Public associated w/ ART, Donor Conception, or Surrogacy

	Contact Person	Organisation/ Department
92.	Linda Alveres	Member of Public associated w/ ART, Donor Conception, or Surrogacy
93.	Adam Quinlivan	Member of Public associated w/ ART, Donor Conception, or Surrogacy
94.	Bridgette Reynolds	Member of Public associated w/ ART, Donor Conception, or Surrogacy
95.	Patsy Molloy General Manager	Midland Women's Health Care Place Inc
96.	Vice Chancellor	Murdoch University
97.	Phillipa Lamont	Neurogenic Unit, Royal Perth Hospital
98.	Wayne Salvage Chief Executive	North Metropolitan Health Service
99.	Kristen Nowak	Office of Population Health Genomics, Department of Health
100.		Office of the Archbishop
101.		Out in Perth
102.		Parents, Families and Friends of Lesbians and Gay
103.	Melanie Honour	Perth City Psychological Services
104.	Suzanne Midford	Perth Psychological Services
105.	John Yovich	Pivet Medical Centre
106.	Darryl Menaglio	Psychologist
107.	David Marryweather	Psychologist
108.	Margaret van Keppel	Psychologist/Fertility Counsellor
109.		Rainbow Families
110.		Rainbow Fertility
111.	Director	Regulation and Compliance Unit NSW Ministry of Health
112.		Robertson Research Institute
113.	Phil Matson	RTAC Chair
114.	Neroli Sawyer	School of Behavioural and Social Sciences and Humanities, University of Ballarat
115.	Debra Gook	Scientist
116.	Alan Trounson	Scientist

	Contact Person	Organisation/ Department
117.	Malcolm Smith	Senior Lecturer, Faculty of Law Queensland University of Technology
118.		Sexual Education and Counselling WA Sexual & Reproductive Health WA
119.		Sexual Health Quarters
120.	President	Sikh Association of WA
121.		SMC Australia.org.au (Single Mothers by Choice)
122.	Penny Webb CEO	South Coastal Women's Health Services Association
123.	Paul Forden Chief Executive	South Metropolitan Health Service
124.		Stop Surrogacy Now
125.		Surrogacy Australia
126.	John Langoulant Chair	Telethon Kids Institute
127.	Michelle Stuckey	The Keogh Institute for Medical Research
128.		The Law Society of Western Australia
129.	James Jarvis CEO	The Ninitirri Centre Inc
130.	Lesley Jackes Manager	The South West Women's Health and Information Centre
131.		Uniting Church Western Australia
132.	Vice Chancellor	University of Notre Dame
133.	Elizabeth Sullivan	University of Technology Sydney
134.	Pilar Blancafort	University of WA
135.	Ryan Lister	University of WA
136.	Vice Chancellor	University of Western Australia
137.		VANISH
138.	Louise Johnson CEO	VARTA
139.		Women's Bioethical Alliance
140.		Women's Community Network WA
141.	Ann Deanus CEO	Women's Healthcare Association Inc

Appendix 3:
Follow-up letter sent to clinics on 7 February 2018

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

Reproductive Technology Unit
Patient Safety & Clinical Quality
Clinical Excellence Division
Department of Health
189 Royal Street
PERTH WA 6004

Dear

As you are aware an independent review of the *Human Reproductive Technology Act 1991* (WA) and the *Surrogacy Act 2008* (WA) is being conducted by Associate Professor Sonia Allan.

Face to Face Meetings/Consultations

A/Professor Allan will be conducting face-to-face consultations and meetings with various key stakeholders from the 9th to 20th April 2018.

If you would be willing, A/Professor Allan would welcome the opportunity to visit [insert NAME of CLINIC/ESTABLISHMENT] for a morning or afternoon during this time, to discuss matters relevant to the terms of reference. It is hoped that she will have an opportunity to speak with the following of your personnel separately (approx. 20-30min per person):

- Medical Director
- Scientific Director
- Nurse Manager
- Senior Counsellor
- Head of Donor Program
- Key personnel responsible for records management
- Managing Director/CEO/authorised officers.

If some of these personnel cannot attend A/Prof Allan could arrange a time to speak to them separately.

A/Professor Allan will be accompanied by a note taker, who will take notes of the discussions. She is also hoping to record the conversations for her to refer back to when writing her final report. Please let us know if people would prefer not to be recorded.

Meetings with Consumers, Donors, and Donor-Conceived People

We also invite you to let your consumers, donors, and donor-conceived people know of the review, and that there is the opportunity for them to make a written submission, attend a consumer meeting, or meet/talk with A/Professor Allan.

To assist you in doing so we enclose a number of flyers and posters, and request that you place them in your rooms to alert people to the review.

You may wish to also reach out to people who you are aware would like to participate in the review, as you think appropriate.

Written Submissions

We encourage and invite you to provide written submissions by 16 March 2018, as per previous correspondence. This will facilitate more productive conversations when A/Professor Allan meets with you in person.

Please call or email the Program Manager, Dr Maureen Harris, to arrange a suitable date and time for the face-to-face meetings (telephone 9222 4334 or email Maureen.harris@health.wa.gov.au. We will follow up with a phone call shortly to discuss the same.

On behalf of A/Professor Allan, I would like to thank you for taking the time to assist with the review and look forward to your feedback.

Yours sincerely

Dr Maureen Harris
Program Manager
Reproductive Technology Unit

7 February 2018

Appendix 4:
Flyer distributed via Twitter, Facebook, and printed flyers placed in clinics notifing the public of the Review

Appendix 5: List of submissions

#	Name
1	Anthony Tassinari
2	Adam Copple-Smith
3	Alicia Young
4	Catherine Lynch (Australian Adoptee Rights Action Group (AARAG))
5	Caroline Mansour
6	SHQ (T/A the Family Planning Association of Western Australia)
7	Fertility Specialists of Western Australia/Fertility Specialists South
8	Iolanda Rodino and Antonia Clissa
9	Confidential
10	Brendan Mahony
11	Daniel Tracy and Mario Tamburri
12	Jenna Farthing
13	Lisa Baker
14	Confidential
15	Gaye Gelok
16	Confidential
17	Confidential
18	Confidential
19	Amy Hodson
20	Confidential
21	Gillian Hodson
22	Confidential
23	Andrew & Jody Van Burgel
24	Kellie Smith
25	Confidential
26	Dr Melanie Walls
27	Adoption Jigsaw
28	Dr Vincent Chapple
29	Daniel Scarparolo
30	Dr Glen Lo
31	Confidential
32	Sharon Genovese
33	ARMS
34	Jo Fraser
35	Martin Bridgman
36	Multicultural women's health centre
37	Telethon Kids Institute
38	Jessica Steele
39	Vanessa Droper

40	Damian Adams
41	Mara Hayler
42	Confidential
43	Confidential
44	Gayle Hall and Petar Spralja
45	Janice Burdinat
46	Marilyn Crawshaw
47	Trevor Harvey
48	Centre for Genetics and Society
49	Confidential
50	Myfanwy Cummerford
51	Brenda Harvey
52	Confidential
53	Peter Ravi-Pinto
54	Vanish
55	International Social Service Australia
56	Confidential
57	Genetic and Rare Disease Network
58	National Council of Single Mothers & their Children
59	Australian Mitochondrial Disease Foundation Belinda
60	Stewart
61	ANZICA WA Fertility Counsellors
62	Adoption Origins Victoria
63	Ross Hunter
64	Julie Waddell
65	Stephen Page
66	Dorothy Kowalski
67	Kerri Favarato
68	Charlotte Adams
69	Anita Bennetts
70	Philip Lillingston
71	Danny Steele
72	Edith Cowan University
73	Feminist Legal Clinic - Anna Kerr
74	Gay Dads WA
75	Genea Hollywood Fertility
76	Confidential
77	Australian Christian Lobby
78	Bridgitte Reynolds
79	Danielle Stone
80	Alison Lane
81	Steve Adams
82	Confidential
83	Rebecca Kalpakoff
84	Confidential

85 L J Goody Bioethics Centre
86 Giselle Newton
87 Fiona Glumac
88 Sherrie-lee Long
89 Confidential
90 The Coalition for the Defence of Human Life
91 Confidential
92 Confidential
93 FINRRAGE
94 Maria Mansour
95 Women's Bioethics Alliance
96 Australian Medical Association (WA)
97 Leigh Hodson
98 Annette Gelok
99 Confidential
100 Katherine Vowles
101 Kate Ranger
102 Beth Wright
103 Alarna & Christopher Richards
104 Ross Jutras-Minett
105 Surrogacy Australia
106 Hayley Smith
107 Genea Limited
108 Embryo Donation Network
109 Defend human life - Richard Egan
110 Nick Pachter - Genetic Services of Western Australia
111 Confidential
112 Rabbi David Freilich OAM
113 Kate Ranger
114 PIVET Medical Centre
115 FAMILY LAW PRACTITIONERS
116 Confidential
117 Melanie Van Der Wilk
118 David Lord
119 Human Rights Law Centre
120 Greg Chang
121 Women and Newborn health service
122 Reproductive Technology Council
123 David and Lidia J
124 Joan Smurthwaite
125 Karinne Ludlow (Monash Uni)
126 John van Bockxmeer

Appendix 6: Written submissions – Qualitative analysis themes and categories

Theme: Assisted reproduction

Categories:

- Artificial insemination
- Birth certificates (posthumous use)
- Commercialisation and trade
- Cryopreservation of embryos/gametes
- Destruction of embryos/gametes
- Donor selection and screening (incl. Donor registers)
- Egg donation
- Embryo/gametes donation
- Family limits
- Harmful effects on birth mother and child
- Infertility
- Limiting the number of donations per donor
- Overseas laws and experiences
- Payment and compensation to donors
- Research
- Rights of the beginning of human life and future children
- Saviour siblings
- Storage of gametes and embryos
- Welfare/rights of the mother

Theme: Assisted reproduction – Access

Categories:

- Access for same-sex couples and single people
- Access Restrictions (Age/BMI/etc)
- Access to Information e.g. success rates, support, etc.
- Counselling
- Egg Freezing
- Female Same-sex Couples
- Posthumous use of sperm/eggs/ embryos
- Pre-Implantation Genetic Diagnosis
- Pre-Implantation Genetic Screening
- Screening Provisions
- Sex selection
- Surrogacy

Theme: Donor conception

Categories:

- Abolish
- The analogy with access to information by adoptees
- Anonymity
- Birth certificate/birth registration
- Commodification
- Consanguinity
- Contacting donors/dc siblings
- Counselling and support
- DNA testing
- Donor linkage
- Education and advocacy
- The effectiveness of current legislation
- Human rights
- Identity issues
- Management of information
- National donor conception register
- Register – central
- Register – voluntary
- Reimbursement
- Removal from biological parents
- Research of impacts
- Retrospective access to donor information (support)
- Rights of the child
- Use of overseas donors

Theme: Record-keeping, data collection and use

Categories:

- Central repository for ART data/donors
- Confidentiality of information
- Eligibility record-keeping
- Lost\destroyed\mismanaged records
- Management of information
- National data collection
- RT registers
- Statutory requirements/regulation of record-keeping
- Suggestions for changes to current record-keeping requirements
- Use of data for research

Theme: Regulation

Categories:

- Abolish
- Advertising
- Approval requirements (RTC)
- Code of practice
- Comment on the licensing regimen
- Data reporting
- DG's powers to issue directions, code of practice, etc.
- Discrimination
- Import/export gametes and embryos
- Independent auditing
- National coordination of laws
- NHMRC guidelines
- Operation of reproductive technology council and committees
- Powers of enforcement/disciplinary provisions under *HRT Act*
- Rights to appeal RTC decisions

Theme: Research and experimentation

Categories:

- The beginning of human life
- Cloning
- Embryos
- Gametes
- Nationally consistent legislation
- New technologies (eg. Mitochondrial donation; gene editing; CRISPR)
- Research

Theme: Surrogacy

Categories:

- Abolish
- Access
- Administration/functions conferred on by Minister, council, DG, etc.
- Advertising
- Agencies
- Alternatives to surrogacy
- Altruistic
- Analogy with adoption
- Arranged/intended parents
- Birth certificates/birth registration
- Breastfeeding
- Commercial
- Commodification
- Consent/anonymity of donors' sperm for surrogacy
- Cooling off period
- Counselling requirements/ psychologists
- Demand
- Discrimination
- Education/awareness
- The effectiveness of current regime, reporting, powers of inspection/ investigation/obtaining information
- Experiences surrogate parents
- Historic concerns
- Human rights
- Import/export gametes and embryos

Theme: Surrogacy (cont.)

Categories:

- Information about laws
- Interaction with the *HRT Act* and other commonwealth/state legislation
- International commercial surrogacy
- Legal parentage
- National coordination of laws/ comparison of overseas laws
- New oversight agency
- Operation of reproductive technology council and committees
- Powers of enforcement/disciplinary provisions under the *Surrogacy Act*
- Regulation
- Reimbursement of costs
- Removal from birth mother
- Reproductive technology council operation
- Research
- Right to be a parent
- Rights of the child
- Rights to access information
- Rights to appeal RTC decisions
- Social media/internet groups or forums
- Stolen generation
- Support
- Surrogacy agreements/contract
- Surrogate families
- Surrogates
- Surrogates – numbers
- Terminology

Theme: Other associated matters

Categories:

- Conduct of the review (terms of reference)
- Cooling off periods
- Federal issues
- Medicare
- Private health insurance
- Other legislation to be reviewed

Independent Review of the HRT and Surrogacy Acts (WA) (Report: Part 1)

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