Regulating assisted reproductive technologies in Victoria: The impact of changing policy concerning the accessibility of in vitro fertilisation for preimplantation tissue-typing

Malcolm K Smith

On 1 January 2010, the Assisted Reproductive Treatment Act 2008 (Vic) came into force. The legislation was the outcome of a detailed review and consultation process undertaken by the Victorian Law Reform Commission. Arguably, the change to the regulatory framework represents a significant shift in policy compared to previous regulatory approaches on this topic in Victoria. This article considers the impact of the new legislation on eligibility for reproductive treatments, focusing on the accessibility of such services for the purpose of creating a “saviour sibling”. It also highlights the impact of the Victorian regulatory body’s decision to abolish its regulatory policies on preimplantation genetic diagnosis and preimplantation tissue-typing, concluding that the regulatory approach in relation to these latter issues is similar to other Australian jurisdictions where such practices are not addressed by a statutory framework.

INTRODUCTION

Victoria was the first common law jurisdiction in the world to enact legislation to regulate assisted reproductive technologies (ARTs). Since the Infertility (Medical Procedures) Act 1984 (Vic) was passed, the legislative framework in Victoria has been updated a number of times in response to scientific and medical advances, and also evolving social attitudes. The enactment of the most recent legislation, the Assisted Reproductive Treatment Act 2008 (Vic), has resulted in some of the most significant changes to the Victorian statutory framework since it was first established. These changes have been implemented as a result of the extensive review of the law conducted by the Victorian Law Reform Commission (VLRC) and the new legislative scheme came into effect on 1 January 2010.

Other commentators have also recently considered how the changes to the Victorian framework have impacted on the provision of ART services in Victoria. Although this article similarly considers the accessibility of in vitro fertilisation (IVF) services following the changes to the statutory scheme, it pays particular attention to the accessibility of such services for families who wish to utilise embryo selection techniques in order to establish the tissue-type (also referred to as human leukocyte antigen) of an embryo before implantation. Focusing the discussion in this way also allows a consideration of another significant change in Victorian policy which came into effect recently concerning the regulation of preimplantation genetic diagnosis (PGD). The reason for this focus should become clear as the discussion progresses, but in summary, it is warranted on the basis of the impact that the changes to the regulatory framework in Victoria have had. Prior to considering this particular issue, this article provides an overview of the changes to the Victorian ART regulatory framework within the context of the national framework of professional guidelines that are currently in place.

Before progressing to the main discussion, it is also worth summarising the practical aspects of the technology that is utilised for the purposes of screening embryos during the IVF process. PGD is a technique that was originally developed to establish which, out of a number of embryos created in the IVF cycle, contain the genetic identifiers for certain hereditary conditions or disorders. This enables an embryo to be implanted in the knowledge that any child born following the technology will be free from the particular genetic condition which her or his parents were at risk of transmitting via natural conception. PGD has advanced significantly since it was first developed and the underlying purpose of the technology’s application has also

* LLB (Hons), LLM, PhD, Lecturer, Health Law Research Program, School of Law, Queensland University of Technology, Brisbane, Queensland.

Correspondence to: mk.smith@qut.edu.au.


begun to change. In addition to being used as a means to test for and prevent transmission of specific genetic conditions, PGD has also been used to positively identify characteristics that are desired within future offspring. One example is where the technique is used to identify and implant embryo(s)8 which are of a matching tissue-type to an existing child (normally a sibling of the child who may result from the IVF process). Any child born following this specific use of PGD may potentially benefit an existing sibling who is suffering from a condition that is potentially curable (or at least treatable) with a transplant of blood stem cells, blood products, or bone marrow (referred to as hematopoietic stem cell transplantation procedures). The success of the procedure is dependent upon the tissue compatibility of the donor and recipient.1 The success rate of an hematopoietic stem cell transplantation procedure is far higher for human leukocyte antigen-identical sibling donations,2 which is why some families elect to conceive a further child who can act as a sibling donor.3

Families seeking access to preimplantation tissue-typing in Australia are, as a minimum, expected to justify their motives to a clinical ethics committee before access to the technology will be granted. As discussed below, prior to the recent regulatory reforms in Victoria, the accessibility of preimplantation tissue-typing was further restricted. Although the recent changes to the Victorian legislation potentially lessen the restrictive nature of the regulatory approach, the result is that some families may be required to have their reproductive decisions subject to the scrutiny of multiple committees before they are able to access tissue-typing techniques. This article argues that there is a need to reconsider this approach.

THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN AUSTRALIA

In short, there is no single regulatory approach in Australia to address the issues raised by ART practices at a national level.10 However, there is Commonwealth legislation addressing human embryo research and cloning which is of some relevance.11 The Commonwealth legislation overseeing human embryo research imposes criminal sanctions on ART clinics for providing any reproductive treatments involving human embryos without accreditation from the Reproductive Technology Accreditation Committee (RTAC) which is overseen by the Fertility Society of Australia (FSA).12 The terms of the accreditation process require clinics to adhere to all relevant legislation and applicable guidelines and the RTAC Code of Practice13 requires adherence to the

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8 The preimplantation genetic diagnosis process used to establish the tissue-type of a couple’s embryos is not, strictly speaking, a “diagnosis” of the embryo’s genetics. However, the term “preimplantation genetic diagnosis” can be used as an umbrella term which encompasses embryo testing techniques such as preimplantation tissue-typing. Thus, the term is used to encompass wider uses of the technology and the physical process involved in the biopsy procedure is the same regardless of whether the purpose is to detect a genetic condition or to establish tissue-type.


6 There is some literature which considers whether the option of using IVF for human leukocyte antigen typing should be considered and discussed with the family by the paediatrician (or paediatric team) treating the existing sick child. For a discussion of these issues see Samuel GN, Strong KA, Kerridge I, Jordens CFC, Ankeny RA and Shaw PJ, “Establishing the Role of Pre-implantation Genetic Diagnosis with Human Leucocyte Antigen Typing: What Place Do ‘Saviour Siblings’ Have in Paediatric Transplantation?” (2009) 94 Arch Dis Child 317; Strong KA, “Informing Patients about Emerging Treatment Options: Creating ‘Saviour Siblings’ for Haemopoietic Stem Cell Transplant” (2009) 190 MJA 506.

10 There have been a number of recommendations arguing in favour of a national approach for regulating assisted reproductive technology in Australia. The Family Law Council of Australia report recommended that a multidisciplinary body oversee matters relating to reproductive technology at a national level: Family Law Council of Australia, Creating Children: A Uniform Approach to the Law and Practice of Reproductive Technology in Australia (AGPS, 1985). The functions of the body were suggested to include advising federal and State governments; monitoring medical research; analysing the implications of assisted reproductive technology for society; providing information for the community; developing clear guidelines for ethics, practice records, access to information and counselling; recommending research on the ongoing effects of reproductive technology; and presenting an annual report. The plans to establish such a body were not followed through fully, but the National Bioethics Consultative Committee (NBCC) was created, which, according to Chalmers, had success in focusing debate and preparing reports, but not in changing public policy. For a detailed review of the development of such issues, see Chalmers D, “Professional Self-regulation and Guidelines in Assisted Reproduction” (2002) 9 JLM 414.


12 The FSA considers the meaning of s 11 of the Research Involving Human Embryos Act 2002 (Cth) to encompass the use of human embryos in any way without RTAC accreditation to amount to a criminal offence under Commonwealth law: Fertility Society of Australia, Reproductive Technology Accreditation Committee, Code of Practice for Assisted Reproductive Technology Units (revised October 2010). That section states that a person who “intentionally uses, outside the body of a woman, a human embryo that is not an excess ART embryo; and the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre”, commits an offence. Section 8 of the Research Involving Human Embryos Act 2002 (Cth) defines an “accredited ART centre” as a “person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia”.

13 Fertility Society of Australia, Reproductive Technology Accreditation Committee, n 12.
National Health and Medical Research Council (NHMRC) Guidelines. Until recently, many Australian States and Territories have relied on this form of regulation alone. Only four States have passed legislation to address the broader issues associated with ARTs, with the Victorian model being the first and most comprehensive regulatory framework in place in Australia.

As outlined above, there are various guidelines that must be adhered to as a condition of RTAC accreditation. The first mentioned is the RTAC Code of Practice, which establishes national standards that apply to all ART providers. The RTAC Code of Practice mainly addresses aspects of clinical practice. The code also overlaps with some other regulatory aspects relevant to the provision of ART services and addresses issues relating to consent, storage of gametes and embryos, and counselling.

The second relevant set of guidelines is the NHMRC’s Ethical Guidelines on Assisted Reproductive Technology. The NHMRC Guidelines aim to address a number of social and ethical concerns relating to ART practices and have been described by some commentators as national standards of acceptable practice. The provisions address, among other things:

- the use and storage of gametes and embryos (including donated gametes and embryos);\(^\text{19}\)
- the level of information that clinics must give to those seeking treatments;\(^\text{20}\)
- the counselling and consent requirements for participants undergoing treatments;\(^\text{21}\)
- the requirement for the keeping of records and data by clinics;\(^\text{22}\) and
- preimplantation genetic diagnosis, sex selection and surrogacy.\(^\text{23}\)

When the NHMRC Guidelines were first issued in 1996, the more controversial aspects of ART practice (such as sex selection, PGD and surrogacy) were not addressed by the Guidelines, as they were considered to be beyond the remit of the Australian Health Ethics Committee (AHEC), the major committee of the NHMRC responsible for developing the Guidelines. However, the NHMRC issued a call to all States and Territories to adopt a uniform and comprehensive framework of legislation so that the social and ethical issues concerning the more controversial aspects of ART were addressed. The most recent edition of the Guidelines has responded to many of these issues due to the lack of legislative action within many Australian States and Territories. Victoria has regulated the field of ARTs comprehensively and is one of the few jurisdictions to have addressed the social and ethical issues in detail.

### The Regulation of Assisted Reproductive Technologies in Victoria

The Assisted Reproductive Treatment Act 2008 (Vic) has repealed the provisions of the former Infertility Treatment Act 1995 (Vic). Fundamentally, the change in the Victorian legislation is representative of the change in the underlying philosophy of the regulatory approach to ART services in Victoria. Thus, one Member of Parliament noted that the new statutory framework represents “a change in focus from treatment of

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\(^{15}\) Assisted Reproductive Treatment Act 2008 (Vic); Reproductive Technology Act 1991 (WA); Assisted Reproductive Treatment Act 1988 (SA); Assisted Reproductive Technology Act 2007 (NSW).


\(^{17}\) Fertility Society of Australia, Reproductive Technology Accreditation Committee, n 12.

\(^{18}\) Chalmers, n 10 at 418.

\(^{19}\) NHMRC Guidelines, n 14 at [6], [7] and [8].

\(^{20}\) NHMRC Guidelines, n 14 at [9].

\(^{21}\) NHMRC Guidelines, n 14 at [9].

\(^{22}\) NHMRC Guidelines, n 14 at [10].

\(^{23}\) NHMRC Guidelines, n 14 at [11]-[13].


\(^{26}\) Some have argued that the Victorian framework is, in fact, too prescriptive and that this results in an inability to keep up with the technological and social developments in this field of practice. See Petersen K, “The Regulation of Assisted Reproductive Technology: A Comparative Study of Permissive and Prescriptive Laws and Policies” (2002) 9 JLM 483.
infertility to a broader purpose of regulating assisted human fertilisation procedures".28 This is immediately obvious from the change in the title of the Act.29

Some of the former legislative provisions are changed significantly by the new Act. A new statutory body replaces the Infertility Treatment Authority (ITA) and the creation of a separate review panel has been implemented to consider applications by prospective participants who do not meet the statutory eligibility criteria.30 The legislation widens the restrictive eligibility criteria previously in force in Victoria (discussed below). It also seeks to further entrench the rights of donor-conceived children to access information about their genetic origins, and implements detailed provisions relating to the practice of surrogacy.31

Under the former 1995 legislation, the ITA was created as an independent statutory body responsible for regulating the provision of ART services in Victoria.32 To replace the ITA, the 2008 legislation establishes the Victorian Assisted Reproductive Treatment Authority (VARTA).33 Some of the duties and responsibilities previously undertaken by the ITA34 have not transferred to the new body.35 However, the VARTA is responsible for:

- administration of the system of registration for ART providers;
- undertaking public education about treatment procedures and the best interests of children born as a result of treatment procedures;
- consulting with the community about matters relevant to the legislation;
- monitoring the programs and activities in relation to the Act, programs and activities relating to the causes and prevention of infertility, and programs and activities relating to treatment outside Victoria;
- keeping the body’s functions, operation and composition under review;
- promoting research into the causes and prevention of infertility;
- approving the import and export of gametes and embryos; and
- other functions required by the Act or any other Act.36

The legislative scheme (and its administration) is informed by the five guiding principles contained within the legislation:

- the welfare and interests of persons born or to be born as a result of treatment procedures are to be paramount;
- at no time should the use of treatment procedures be for the purposes of exploiting the reproductive capabilities of men and women, or children born as a result of treatment procedures;
- children born as a result of the use of donated gametes have a right to information about their genetic origins;
- the health and wellbeing of persons undergoing treatment procedures must be protected at all times; and

28 Victoria, Legislative Assembly, Parliamentary Debates (10 September 2008) p 3442 (Rob Hulls). Another Member of Parliament noted that the “Bill abandons the long-held principle of Victorian legislation that reproductive treatment is to help infertile couples to have children and replaces it with the concept that any person who is unable or unwilling to have children by natural means can have children produced for them”: Victoria, Legislative Assembly, Parliamentary Debates (7 October 2008) p 3759 (Robert William Clark).
29 Thus, as one Member acknowledged when the Bill was passing through the Legislative Assembly, “[t]he change is explicit even in the name of the Bill”: Victoria, Legislative Assembly, Parliamentary Debates (7 October 2008) p 3783 (David Morris).
30 See eg Assisted Reproductive Treatment Act 2008 (Vic), Pts 4 and 6.
31 Infertility Treatment Act 1995 (Vic), s 121. The ITA proclaimed that since its formation in 1996 it had sought to ensure that those seeking treatment receive appropriate information and counselling; that it assisted in the smooth provision of health care by treatment institutions; that it gathered and stored information relevant to the proper regulation and broad oversight of the provision of reproductive assistance and released such where appropriate; and that it promoted a community understanding of the complex issues involved in fertility treatments and reported to Parliament under the terms of the Act: Infertility Treatment Authority, Annual Report (2006) p 8.
32 Assisted Reproductive Treatment Act 2008 (Vic), s 99.
33 This includes the requirement to compile and provide access to records relating to treatment procedures, including access to records of donors of gametes and children born as a result of treatment procedures by those seeking identifying information. The ITA also had the responsibility of issuing licences for treatment services and research. This involved issuing a licence to a treatment centre so that research could be carried out at a centre, and approving medical professionals and scientists who were involved in the delivery of such services. The ITA was also responsible for ensuring that licence conditions were met in accordance with the legislation. See Infertility Treatment Act 1995 (Vic), Pt 9.
34 For example, the responsibility for the central register of donors/donor-conceived children will rest with the Registrar of Births, Deaths and Marriages. See Assisted Reproductive Treatment Act 2008 (Vic), Pt 6.
35 Assisted Reproductive Treatment Act 2008 (Vic), s 100.
• persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status or religion.

Although the first guiding principle remains the same under the new legislative scheme, the remaining principles have been modified significantly. The third principle reflects the emphasis that the new legislation places on the right of donor-conceived children to access information about their genetic origins. This is a particularly welcome addition to the principles, given the growing recognition of this right generally. Similarly, another welcome addition is the prohibition on discrimination against those seeking treatment. As discussed below, under the former statutory framework, there were significant inconsistencies in the way that the eligibility criteria were applied to those seeking treatments in Victoria.

The Assisted Reproductive Treatment Act 2008 (Vic) also abandons the previous licensing system which was impliedly described as onerous by some commentators, and instead adopts a system of registration which enables individual medical practitioners and fertility clinics to apply to the VARTA for registration as an ART provider. This system of registration works alongside the national accreditation requirements set out by the FSA (discussed above). The 2008 legislation may, in time, facilitate a more positive response from ART providers in Victoria as it decreases the burden to comply with the complicated multi-layered system that previously existed.

The 2008 legislation also creates the Patient Review Panel, a new entity established to consider and review decisions relating to the provision of ART services. The Patient Review Panel is responsible for approving access to some ART procedures, such as those involving surrogacy arrangements or techniques resulting in posthumous conception. The Panel is also responsible for reviewing individual cases where prospective participants have a presumption against treatment imposed upon them on the basis of their previous criminal convictions, where participants have been refused access by ART providers, or where participants do not meet the statutory eligibility criteria. The significance of the Patient Review Panel is considered below.

Regulating access to assisted reproductive technologies in Victoria

Throughout Australia, limitations are placed on the accessibility of ART services. The availability of services will be dependent upon a number of factors, including:

• the personal circumstances of those seeking treatments;
• the financial costs of such treatments;
• the geographical proximity of treatment services; and
• the statutory or other legal limits (if any) imposed on those seeking access to treatments.

While the factors in this list may be significant in the debate surrounding access to ART services generally, it is the last-mentioned aspect which is considered in the context of the Victorian legal regime.

Access was originally limited to married or heterosexual de facto couples in Victoria, but this was challenged on the basis that it was inconsistent with a provision of the Sex Discrimination Act 1984 (Cth) which

37 The guiding principles under s 5(1) of the Infertility Treatment Act 1995 (Vic) required the application of the legislation to be informed by (a) the welfare and interests of any person born or to be born as a result of a treatment procedure are paramount; (b) human life should be preserved and protected; (c) the interests of the family should be considered; and (d) infertile couples should be assisted in fulfilling their desire to have children. The principles are listed in order of importance: Infertility Treatment Act 1995 (Vic), s 5(2).

38 The Hon Dr Denis Vincent Napthine commented in relation to the addition of the principle, stating that “It is an important addition and reflects a real need, which is very important to children born as a result of donated gametes. It is important for their psychological health, for their access to genetic information and for their fundamental understanding of who they are”: Victoria, Legislative Assembly, Parliamentary Debates (9 October 2009) p 4017 (Denis Vincent Napthine). Furthermore, James Merlino MP argued that children “are not commodities. Children are not extensions of the rights and desires of adults; children exist in their own right. A child has the right to the truth – the truth to fundamental questions such as, “Where did I come from? Who are my biological mother and father ... As an absolute minimum children who are born as the result of donor conception programs must be afforded the identical right and access to identifying information that we all agree is the right of adopted and surrogate children.” Victoria, Legislative Assembly, Parliamentary Debates (7 October 2008) p 3770 (James Merlino, Minister for Sport, Recreation and Youth Affairs).

39 This is also similarly acknowledged by Thorpe et al, n 4.

40 For example, Baker described the ITA as generally unhelpful and intrusive: Baker HWG, “Problems with the Regulation of Assisted Reproductive Technology: A Clinician’s Perspective” (2002) 9 JLM 457 at 462.

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

42 The Patient Review Panel consists of five members: Assisted Reproductive Treatment Act 2008 (Vic), s 83. Under s 85 of the legislation, its functions include: “(a) to consider applications for surrogacy arrangements; and (b) to consider whether there is a barrier to treatment if a presumption against treatment applies; and (c) to consider applications for posthumous use of gametes and embryos; and (d) to consider applications for treatment in circumstances in which a registered ART provider or doctor is concerned about the risk of abuse or neglect of a child that may be born as a result of treatment; and (e) to consider applications for treatment in circumstances in which the applicant does not meet the criteria for treatment; and (f) to consider applications for extended storage periods of gametes and embryos or removal of embryos from storage; and (g) any other functions given to the Panel by the Act or by the Minister.”

43 See Thorpe et al, n 4 at 837-841.
prohibits discrimination on the grounds of marital status. Following the successful legal challenge to the marriage requirement, it has now been completely removed by the 2008 Act.

Although marital status is not of relevance for determining eligibility for ART services, there are still some requirements that must be met by participants before a woman (and where relevant, her partner) will be granted access to such services. The former legislation required participants to be infertile or at risk of passing on a genetic condition when conceiving naturally. Due to the fact that infertility had traditionally been interpreted as meaning medical infertility, this requirement had proven an obstacle to single and lesbian women seeking to access ART treatments. However, being single or having a female partner no longer constitutes infertility. The ITA had sought guidance on the interpretation of the term “unlikely to become pregnant” (contained within the former legislation). The ITA concluded that a woman must be medically infertile to gain access to treatment and therefore advised licensed clinics that women (including those who were not married or in a de facto relationship) could only be treated after a medical assessment confirming clinical infertility.

The review of the Victorian legislation conducted by the VLRC noted that the eligibility criteria under the 1995 Act had been applied inconsistently to married women, women in heterosexual de facto relationships and women without legally recognised partners. It was for this reason that the report recommended a wider approach to the issue of eligibility in Victoria. The 2008 Act has widened the eligibility criteria by permitting access in cases where a doctor is satisfied, on reasonable grounds, that:

- the woman is unlikely to become pregnant other than by a treatment procedure; or
- the woman is unlikely to be able to carry a pregnancy or give birth to a child without a treatment procedure; or
- the woman is at risk of transmitting a genetic abnormality or genetic disease as a result of a pregnancy conceived other than by a treatment procedure, including a genetic abnormality or genetic disease for which the woman’s partner is the carrier.

The wording of the new legislation is arguably broad enough to encompass the provision of services to single and lesbian women, even if those individuals are not medically infertile, as those women are “unlikely to become pregnant other than by a treatment procedure”. Furthermore, in cases where prospective participants do not meet the statutory eligibility criteria, the Patient Review Panel is able to make a decision as to whether a woman is able to access treatment procedures. In such circumstances, the Panel is required to make a decision in accordance with the guiding principles and whether the general or specific treatment is consistent with the best interests of a child born as a result of the procedure. In certain circumstances, a presumption against treatment will also apply to participants if certain criminal convictions are discovered after a criminal records check. In such cases, the Patient Review Panel is similarly able to review whether those seeking treatments should be provided with ART services. It is interesting to note the position in the United Kingdom where the Human Fertilisation and Embryology Authority (HFEA) has moved towards

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44 In McBain v Victoria (2000) 99 FCR 116, the statutory marriage requirement was challenged on the grounds that a doctor could not comply with both the Commonwealth legislation and the State legislation when approached by a single woman seeking access to fertility treatment. The Federal Court of Australia held that the Victorian legislation is discriminatory and that the marriage requirement is inconsistent with the Commonwealth legislation under s 109 of the Constitution.

45 The new legislation is based on many of the recommendations made by the Victorian Law Reform Commission and the Final Report concluded "that the marital status requirement is not only inconsistent with the principle of non-discrimination, but it also bears no relationship to the health and wellbeing of children, which must be the paramount concern of the law governing ART": Victorian Law Reform Commission, n 3, p 67.

46 Legal opinion of Gavan Griffith QC previously obtained from the ITA website. Contradicting advice was also given to the ITA by Peter Hanks QC who advised that Griffith’s interpretation reinforced the discriminatory nature of the legislation which was ruled unlawful in McBain – as women in a married or de facto relationship do not have to be clinically infertile to gain access to treatment procedures whereas a single woman does have to be clinically infertile to meet the access requirements. In response, Griffith confirmed his original interpretation of the term: Victorian Law Reform Commission, Assisted Reproduction & Adoption: Should the Current Eligibility Criteria in Victoria be Changed? Consultation Paper (2003) pp 26-27.

47 VLRC, n 3, p 67.

48 The VLRC, n 3, p 68, recommended that a “woman be eligible for treatment if she is unlikely to become pregnant and that her inability to become pregnant (or to carry a pregnancy or give birth to a child, or likelihood of transmitting a genetic abnormality or disease) be assessed on the basis of the circumstances in which she finds herself (whether single, married, in a same-sex relationship, psychologically averse to having sexual intercourse with a man, or otherwise)”.

49 Assisted Reproductive Treatment Act 2008 (Vic), s 10(2).

50 Assisted Reproductive Treatment Act 2008 (Vic), s 10(1)(b)(ii).

51 Assisted Reproductive Treatment Act 2008 (Vic), s 15(3).

52 Those seeking treatments are also required to undergo a criminal records check and where the woman or her partner (where relevant) have been convicted of particular sexual offences, or where there is a conviction in relation to a violent offence (or where a child protection check reveals that a child has been removed from the custody of the woman and/or her partner), a presumption against treatment will be imposed: Assisted Reproductive Treatment Act 2008 (Vic), s 14.

53 Assisted Reproductive Treatment Act 2008 (Vic), s 15(1)(a).
imposing a presumption in favour of treatment which is rebutted where there is evidence to suggest significant harm or neglect to the child who will be born.\textsuperscript{54} As a result, prospective participants in the United Kingdom are no longer subjected to routine background checks. In Victoria, however, there has been a shift in the opposite direction under the new legislative scheme: the new provisions impose compulsory background checks upon those seeking treatment and in some circumstances a presumption against accessing treatment will be imposed.\textsuperscript{55} In such circumstances the participants would have to make an application to the Patient Review Panel in order to gain access to services.\textsuperscript{57} The scope of the Patient Review Panel’s decision-making in this context is outlined further below.

The statutory eligibility criteria concerning access to ART services also impact significantly on the issue of accessibility more widely. When restrictions are imposed on the basis of medical need (eg medical infertility or avoiding transmission of genetic disease), such as those in Victoria, the result is that ART services are restricted in a narrow sense. For example, the imposition of narrow eligibility criteria restricts the availability of IVF for preimplantation tissue-typing; this technology is only available if the couple are at risk of passing on a genetic condition when conceiving naturally (or in cases where they are clinically infertile).\textsuperscript{59} To fall under the statutory eligibility criteria, it is necessary that the family’s primary intention is to use PGD techniques to detect a genetic condition in the embryo. If tissue-typing is undertaken, it is ancillary to this main purpose.

An example that falls outside the scope of the narrow eligibility criteria is a couple seeking access to IVF for preimplantation tissue-typing, who are not at risk of passing on a genetic condition when conceiving naturally. Such a couple has no “medical need” (based on their reproductive capacity) to access services. In this context, the couple may have an existing child who is suffering from a condition that is not genetically inherited but has onset after birth. The desire to access IVF services is not based upon the need to prevent transmission of a genetic condition but is instead based on the wish to select an embryo for implantation that is of a matching tissue-type to the existing sick child. The medical need is for the benefit of treating the affected child. In this context, the couple would not be eligible for treatment in a jurisdiction (or an individual clinic) where narrow eligibility criteria are imposed. Fundamentally, such a family is prima facie ineligible for treatment under the Victorian legislation.

In cases where prospective participants do not meet the statutory eligibility criteria, the Patient Review Panel is able to make a decision as to whether a woman is able to access treatment procedures.\textsuperscript{58} Thus, where a family does not meet the criteria contained within the reformed legislative scheme, they are able to apply to the Patient Review Panel to gain access to IVF for preimplantation tissue-typing.\textsuperscript{59} The Panel is required to make a decision in accordance with the guiding principles and to consider whether the general or specific treatment is consistent with the best interests of a child who may be born as a result of the procedure.\textsuperscript{60} For those families who do not fall within the scope of the statutory eligibility criteria, the option to apply to the Patient Review Panel is a welcome addition to the legislative scheme. However, as discussed below, in some cases this requirement may result in the need for families failing within this category to apply to multiple committees before being granted access to the technology. This hurdle creates an unnecessary inconsistency between the two categories of families who may seek access to such services in Victoria.

**The role of the Patient Review Panel and the Victorian Civil and Administrative Tribunal under the legislation**

It is evident that the Patient Review Panel and the Victorian Civil and Administrative Tribunal (VCAT) (in cases of review) have been entrusted with significant discretionary powers under the scope of the Victorian legislation. Thus, the Panel and VCAT are able to grant access to treatment in circumstances where participants would ordinarily be prevented from accessing services. Given the short timeframe which has passed since the legislation came into force, there is only limited authority to assist with interpreting the legislative provisions relevant to this specific aspect of the legislation. However, there are two VCAT decisions of particular relevance to the scope of these powers.

In the decision of \textit{ABY, ABZ v Patient Review Panel (Health & Privacy)} [2011] VCAT 1382 VCAT considered an application made by a couple who had sought IVF services from a registered ART provider. The female applicant, ABZ, was prevented from accessing IVF due to the fact that a ‘presumption against


\textsuperscript{55} \textit{Assisted Reproductive Treatment Act 2008} (Vic), ss 11, 14.

\textsuperscript{56} \textit{Assisted Reproductive Treatment Act 2008} (Vic), s 15. For further discussion see Thorpe et al, n 4.

\textsuperscript{57} It is submitted that this latter criterion is only likely to apply to a very small number of families seeking access to tissue-typing techniques, as the first (affected) child would have been conceived prior to the need for IVF. It is, however, possible to envisage a situation where a family has suffered diminished capacity to reproduce naturally following the birth of the affected child and in such circumstances they would fall within the statutory criteria.

\textsuperscript{58} \textit{Assisted Reproductive Treatment Act 2008} (Vic), s 10(1)(b)(i).

\textsuperscript{59} \textit{Assisted Reproductive Treatment Act 2008} (Vic), ss 10(1)(b), 15(1)(b).

\textsuperscript{60} \textit{Assisted Reproductive Treatment Act 2008} (Vic), s 15(3).
treatment’ was imposed on the basis of her partner’s prior criminal convictions. ABY’s criminal record check had revealed that he was convicted of a sexual offence falling within cl 1, Sch 1 of the Sentencing Act 1991 (Vic). On this basis, ABY and ABZ made an application to the Patient Review Panel. As outlined above, the Panel is able to exercise its discretion to authorise the provision of treatment even in circumstances where a ‘presumption against treatment’ exists. The Panel refused to exercise its discretion in the applicants’ favour. However, VCAT subsequently set aside the decision of the Patient Review Panel and ruled that there was no barrier to ABZ undergoing the treatment sought. VCAT made it clear that its functions when reviewing a decision of the Patient Review Panel are not appellate. They are instead focused on making the decision from ‘the shoes of the original decision maker ... on the basis of the material before it’ (at [31]). VCAT concluded that the applicants in this case should not be prohibited from accessing treatment services.

Ultimately, VCAT’s ruling to set aside the decision of the Patient Review Panel was based on the fact that ABY’s prior criminal convictions were not necessarily contrary to the welfare or interests of any child who may be born following the provision of treatment services. VCAT observed that the majority of the Patient Review Panel had arrived at their decision on the basis that approval should not be granted for someone who is a registered sex offender (at [39]). It stated that the Victorian legislation confers a discretionary power upon the Patient Review Panel to consider applications such as this on a case-by-case basis and that the adoption of a rule which imposes a blanket prohibition on access to treatment for all registered sex offenders was ‘clearly wrong’ (at [39]). Thus, VCAT’s decision makes it clear that the discretionary power conferred upon the Patient Review Panel must be exercised on a case-specific basis and that the decision-making process must be guided by reference to the matters set out in s 15(3) of the Assisted Reproductive Treatment Act 2008 (Vic). It was further emphasised that the overarching principle in this context is based on how the circumstances in each case impact on the welfare of the any child who may be born.

It is interesting to note that VCAT’s decision in ABY, ABZ made reference to a number of further factors which are relevant to applying the welfare principle in the context of the 2008 Act. It was stated that the principle does not require the Patient Review Panel or VCAT to conduct a general inquiry into participants’ parental capabilities. Instead, it requires an assessment of how the risks arising from previous criminal convictions would impact on a child who may be born following the provision of IVF services if access to treatment is granted (at [50]). VCAT distinguished the application of the ‘welfare principle’ in this context from the interpretation adopted in other legislative contexts involving children, such as cases concerning child protection and adoption. It also noted (at [51]) that ‘it is impossible to predict what will be in the best interests of a child who has yet to be conceived as each person is unique’. Furthermore, it stated (at [55]) that there is no ‘comparator’ to be drawn in the case of a child who is yet to be born as the decision to deny access to treatment would deny the potential child in question her or his ‘very existence’. It was acknowledged (at [55]) that a comparison between existence and non-existence is something that the courts have been unwilling to address. VCAT also refused to address the issue of how ABZ and ABY’s interests in having a child should be considered in the balance with the potential child’s interests. The interpretation of the welfare principle in this way could have a significant impact in cases where the parents are seeking access to IVF and preimplantation tissue-typing. This is because, ultimately, the child’s welfare cannot be assessed and therefore adversely

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61 Assisted Reproductive Treatment Act 2008 (Vic), s 14(1).
62 Assisted Reproductive Treatment Act 2008 (Vic), s 15(1).
63 This decision was made subject to the condition that ABY attended 12 counselling sessions to address the implications of his previous convictions. Section 91(3) of the Assisted Reproductive Treatment Act 2008 (Vic) provides that the Patient Review Panel, and VCAT on review, may impose conditions on a decision which are considered to be ‘necessary and reasonable in the circumstances’. On this basis, VCAT set out detailed reasons as to why the condition was ‘necessary and reasonable’ in the circumstances.
64 VCAT stated that s 15(3) imposes an obligation for the Patient Review Panel to have regard to the matters listed within that section and that the term ‘have regard’ to has been ‘constantly interpreted to mean that the decision-maker must take into account the matters to which regard is to be had [eg those factors listed within the Act] and each must be treated as a matter of significance in the decision making process’ (at [44]). Section 15(3) states: ‘In deciding the application for review, the Patient Review Panel must have regard to – (a) the guiding principles referred to in section 5; and (b) whether carrying out a treatment procedure, whether generally or of a specified kind, on the person – (i) is for a therapeutic goal; and (ii) is consistent with the best interests of a child who would be born as a result of the treatment procedure.’
65 VCAT noted (at [45]) that the use of the word ‘paramount’ in the context of the welfare principle means that it is interpreted to be an ‘overriding’ principle.
66 VCAT stated (at [53]-[54]) that the important difference between the welfare principle in the context of ART and the way it is applied in other contexts is that ‘in the other contexts the best interests of the child are evaluated by reference to a comparator. In family law it is in the context of a decision between parents (usually) as to who should have custody; in adoption cases it is between the couple before the court and others wishing to adopt; in cases involving the removal of a child from parental care it is between the status quo and care by the state. There is no appropriate comparator in the [context of ART].’
67 It should be noted that the courts have been unwilling to address this issue in the context of wrongful life claims. The decision in this instance was of a very different nature as it concerned the interests of a potential future person who would hopefully be born in a healthy state. It did not concern an assessment of whether an existing child, born with a disability due to alleged negligence, had been harmed for the purposes of establishing damages under the tort of negligence and thus, the only comparison that can be made in such circumstances is what would have happened if the harm had been avoided in some way.
affected, until that child is permitted to come into being. Thus, the reliance on welfare objections to deny access to treatment in this context may deny a potential saviour sibling her or his ‘very existence’.

In the decision of JS and LS v Patient Review Panel (Health and Privacy) [2011] VCAT 856 VCAT was faced with an application from a couple seeking to utilise ARTs for the purpose of social sex selection. Section 28 of the Assisted Reproductive Treatment Act 2008 (Vic) prohibits the use of ARTs for ‘producing or attempting to produce a child of a particular sex’ unless such practices are utilised for preventing the transmission of a genetic abnormality or disease, or where the Patient Review Panel has otherwise approved the use of such technologies for this purpose.68 JS and LS had lost a child of one sex and wanted to conceive another child of the same sex. The applicants had children of the opposite sex to the child who had died, but they did not want to conceive any further children of the same sex as their existing children. The applicants expressed their wish to complete their family by having a child of the desired sex and relied upon expert evidence to demonstrate how the loss of the child had impacted negatively on their emotional and psychological wellbeing. The couple sought to argue that by exercising discretion within the relevant provisions of the statutory framework, the Patient Review Panel (and subsequently VCAT) would allow the couple to ‘move on’ and this course of action would assist in stabilising the couple’s emotional and psychological wellbeing. VCAT refused to exercise its discretion within the scope of s 28 of the Act. The primary reason for refusing to do so was again based on the interpretation of the welfare principle. VCAT observed that all of the supporting statements and expert evidence submitted in relation to the couple’s case had focused on the implications of having or not having a child of the same sex to the child who had previously died. It further observed that the evidence in the case had neglected to address the fact that the welfare and interests of any child who may be born following the provision of treatment services is the paramount consideration. Thus, the medical and supporting evidence was ‘concerned entirely with the interests of the parents’ (at [75]).

Interestingly, and of most significance to the focus of this article, the VCAT decision concerning JS and LS referred to circumstances where IVF is utilised for the purpose of creating a tissue-matched child in order to draw a comparison between the two uses of ART. VCAT observed that there is some support (albeit, ‘qualified’ for the use of ART in the latter context (at [30]). It observed that the creation of a saviour sibling is ‘limited’ by the conditions imposed under the NHMRC Guidelines (as outlined below). However, it went on to comment that there ‘is a clear difference between protecting a child to be born from inheriting a serious genetic disorder, and bringing a life into being to provide tissue to save or prolong the life of a person who needs tissue from a compatible donor’ (at [33]). It did not elaborate fully on the ‘clear difference’ in this regard, but did observe that the ethical issues in the saviour sibling context require a weighing of the interests of the person who would receive the tissue and the interests of the saviour child. The distinction between ‘protecting a child to be born from inheriting a serious genetic condition’ and selecting embryos on the basis of tissue-type, which was highlighted by VCAT, has been criticised heavily by other commentators with the observation that the PGD process does not provide a ‘benefit’.69 This is because the post-PGD embryo is in the same condition that it was prior to the biopsy process being undertaken and it is therefore difficult to argue that the particular child who is born has been ‘benefited’. Thus, the use of PGD in this context merely increases the probability of an unaffected embryo being implanted to achieve a pregnancy.70

More concerning, however, is the lack of clear reasoning that was offered by VCAT as to why the saviour sibling issue is a relevant comparator for a case concerning sex selection for non-medical reasons. Social sex selection is prima facie prohibited by the Victorian legislation with the exception that the prohibition can be circumvented by the Patient Review Panel (or VCAT). In contrast, the provisions concerning the creation of saviour siblings are set out in the NHMRC Guidelines, which impose a number of factors that must be ascertained by an ethics committee prior to a family being granted access to IVF for this purpose. Fundamentally, this latter practice is not directly prohibited by the Assisted Reproductive Treatment Act 2008 (Vic); it is merely regulated by the national ethical guidelines. This is a significant distinction that is not articulated clearly enough within VCAT’s decision in JS and LS.

Furthermore, it is worth highlighting the inconsistency in the reasoning adopted by VCAT in the decision of JS and LS. The reasons put forward by VCAT were ultimately based on the fact that creating a child of one particular sex for non-medical reasons was not in accordance with the interests and welfare of the child to be born (or at least, that the parents did not take account of those interests). However, its reference to the use of IVF for the creation of a saviour sibling, which was deemed to be ‘supported’ to some extent, also fails to accord with this approach. Thus, relying on the assertion that JS and LS were concerned solely with their own motives is not significantly different from a case where the parents of an existing sick child rely on the desire to help cure their own sick child. In both cases, the reasons for having the child are not solely related to the welfare of the child who will be born or the desire to have a child for that child’s own worth. In both cases, to some extent the motives are instead related to the motives of someone other than the child who will be born (eg the parents’ desire for having a child of a particular sex, or the parents’ desire to help an existing child of their family and the existing sick child’s need for treatment). VCAT’s distinction between the two different

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68 The practice is also prohibited at a national level under the NHMRC Guidelines, n 14 at [11].
uses of IVF for the selection of embryos must therefore be underpinned by some other undefined normative distinction, which deems the use of IVF as acceptable in one case but not another.

Regulating preimplantation genetic diagnosis and preimplantation tissue-typing in Victoria

The regulatory position concerning preimplantation tissue-typing has also been changed quite significantly following the reform process. Under the former statutory framework, the ITA oversaw the regulation of PGD techniques. Victoria’s approach to PGD regulation was one of the most comprehensive and prescriptive of all the Australian States and Territories. A three-tier system of regulation existed, requiring clinics to gain permission prior to undertaking PGD for certain purposes, including the detection and selection of embryos on the basis of tissue-type. It was initially expected that the VARTA would assume a similar responsibility for overseeing the regulation of PGD, as the new statutory body had updated the ITA’s guidance concerning PGD and pre-implantation tissue-typing. However, the statutory body has confirmed that it will not play a role in the future regulation of PGD techniques. Thus, regulation is a matter to be determined by individual clinics. This significant change seems to accord with the general spirit of the new statutory framework, which has attempted to adopt a “light touch” compared to the former framework. This change in policy leaves the regulatory position in Victoria concerning PGD similar to the position in New South Wales.

The implication of this change in policy is that the regulation of PGD and preimplantation tissue-typing will no longer be determined by the Victorian regulatory body, but will instead be subject to the usual regulatory provisions impacting on fertility clinics (including the NHMRC Guidelines). It is no longer necessary to gain case-by-case approval from the statutory body, due to the fact that the policies developed by the former ITA and updated by the VARTA concerning PGD and preimplantation tissue-typing are no longer in force. In some respects, this change is a move in the right direction, given that the former tissue-typing policy explicitly excluded access to the technology in cases where the statutory eligibility criteria were not met. However, complete removal of the policy also raises a number of concerns, some of which are outlined below.

As established above, all ART clinics in Australia are required to adhere to national guidelines relevant to ART practices. Therefore, PGD practices in Victoria will now be influenced solely by the NHMRC Guidelines as there is no longer a specific State policy. According to the NHMRC Guidelines, ART providers must carefully evaluate any use of PGD and in the context of preimplantation tissue-typing, the technology should only be provided where:

- the intended recipient of tissue is a sibling, and in such instance, the clinic must seek advice from a clinical ethics committee (or where relevant, a State or Territory regulatory agency); and
- the relevant committee or agency must ascertain that:
  - preimplantation tissue-typing does not adversely affect the welfare and interests of the child who may be born;
  - the medical condition of the sibling must be life-threatening;
  - there are no other means available for treating the condition; and
  - the wish of the parents is to have another child as an addition to their family and not merely as a source of tissue.

In addition to these factors, there are a number of general requirements stipulated under the national guidelines relating to the provision of information and counselling which must also be complied with. However, in relation to information-giving, the NHMRC Guidelines are specific to the genetic implications of

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71 See Petersen, n 26.
72 The three-tier system permitted the use of preimplantation genetic diagnosis under three categories: (i) cases for which no permission or notification is required to undertake preimplantation genetic diagnosis – this only applied to established uses as outlined in the preimplantation genetic diagnosis policy; (ii) cases that are not established did not require permission to be obtained, but the use of preimplantation genetic diagnosis was reportable to the ITA; and (iii) in cases where the use of the technology is novel, approval had to be obtained from the ITA (and clinics were also required to notify the Authority of such uses); Infertility Treatment Authority, Genetic Testing and the Requirements of the Infertility Treatment Act 1995: Policy in Relation to the Use of Pre-implantation Genetic Diagnosis (PGD) (2008) pp 5-6.
74 Victorian Assisted Reproductive Treatment Authority, Conditions for Use of Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis (PGD) (2010).
75 This information was provided by Tracey Petrillo, Senior Policy and Education Officer, Victorian Assisted Reproductive Treatment Authority: email communication (February 2011).
77 Confirmed by Tracey Petrillo, Senior Policy and Education Officer, Victorian Assisted Reproductive Treatment Authority: email communication (February 2011).
78 NHMRC Guidelines, n 14, pp 55-56.
79 NHMRC Guidelines, n 14, pp 55-56.
PGD and fail to address the implications of using the technology for the purpose of creating a tissue-matched child.\textsuperscript{80} In the latter context, the level of information that should be provided to participants by ART clinics is left unclear. Similarly, the counselling process is also inadequately addressed under the NHMRC Guidelines as there is little detail provided in relation to the level of counselling that should be provided to families utilising tissue-typing techniques. These factors were addressed in greater detail under the State-specific policy that was created by the ITA (as updated by the VARTA).\textsuperscript{81} It is unfortunate that these factors will be left in a state of uncertainty following the removal of the policy. It should be noted, however, that counselling for IVF procedures in Victoria is compulsory under the statutory scheme and this would hopefully enable many of the specific issues associated with preimplantation tissue-typing to be addressed.

Although there is no longer a requirement for clinics to seek case-by-case approval from the VARTA for the provision of tissue-typing techniques in Victoria, there is a requirement under the NHMRC Guidelines to refer the request to an institutional ethics committee. This requirement is underpinned by the need to consider the welfare of any potential child who may be born. However, as outlined above, a family that is not eligible for treatment under the statutory scheme in Victoria would need to apply to the Patient Review Panel to be granted access to treatment. The Patient Review Panel (or, where relevant, VCAT) is required to make an assessment in each case on the basis of the circumstances of the case before it. At both stages of this process, the Patient Review Panel and the ethics committee are required to consider, among other things, the welfare of any child who will be born following the provision of treatment services. There appears to be no consideration given to the fact that some families seeking to create a saviour sibling, who fall outside of the statutory eligibility criteria, will be subjected to two levels of scrutiny when seeking access to the technology. The legislature had the option to include this specific exception within the statutory eligibility criteria when drafting the legislation, but failed to do so.

Furthermore, as outlined above, a welfare assessment may be particularly difficult to make in the context of a case concerning preimplantation tissue-typing. In this specific context, the literature has outlined a range of potential risks that a child may be subjected to if he or she is created as a saviour sibling.\textsuperscript{82} However, such risks are merely speculative at the pre-conception stage. The difficulty is that the NHMRC Guidelines lack specificity as to how a child born in this way may have her or his welfare adversely affected. For this reason, there is no clear basis upon which an ethics committee (or other relevant body) is justified in preventing a clinic from providing IVF and PGD services for this specific purpose. The previous State-level guidelines elaborated on at least some of the requirements that are relevant to assessing the welfare of the child. For example, it was necessary to establish:

- that specific consideration be given to the first guiding principle of the legislation (that the interests of the person to be born are of paramount concern); and
- that the resulting child born as a result of the procedure should only provide cord blood or bone marrow and that the harvesting of “hard” or non-regenerative organs is not acceptable.\textsuperscript{83}

In addition to these factors, the ethics committee of the institution where the procedure would be carried out was also required to consider a number of further issues, including:

- the motivation and level of understanding of the parents in seeking to have an additional child;
- the issues that may arise where the birth of a child does not resolve the genetic condition for the existing sibling; and
- the status of the child within the family and the relationships, which grow, with the growth of all children within the family.\textsuperscript{84}

Given that the State-level guidance had been in force for some time before it was revoked, it is possible that in the future, ethics committees of ART clinics in Victoria may make reference to these factors. In the absence of such considerations, given the lack of detail in the national guidelines, there is the potential that different ethics committees will adopt different reasoning to justify why some families should be prevented from accessing the technology.

For the specific issue of preimplantation tissue-typing, the NHMRC Guidelines are arguably inadequate in addressing the full range of factors that are relevant to the welfare assessment. Despite this conclusion, however, the adequacy of the guidelines should be considered in context. The original NHMRC Guidelines released in 1996 did not address a number of the more controversial aspects of ARTs (including PGD) as these issues were considered to be beyond the remit of the Australian Health Ethics Committee (AHEC). These issues were left to each State and Territory to decide upon and it was the failure of the majority of Australian jurisdictions to address the more controversial issues which led the AHEC to issue a more

\textsuperscript{80} This can be compared to the position in the United Kingdom, where the implications of using preimplantation genetic diagnosis for tissue-typing are addressed in considerable detail: Human Fertilisation and Embryology Authority, \textit{Code of Practice} (8th ed, 2009) at [10].

\textsuperscript{81} VARTA, n 74.


\textsuperscript{83} VARTA, n 74, pp 2-3.

\textsuperscript{84} VARTA, n 74, pp 2-3.
comprehensive set of guidelines in 2004 (which were again updated in 2007 to incorporate changes in Commonwealth legislation relating to human embryo research and cloning). Therefore, the inadequacy of the current guidelines is not necessarily a reflection of the way that the AHEC developed policy on this matter. The national guidelines were aimed at providing a minimum standard of ethical practice in the context of ARTs. It was intended that each State and Territory provide further detail to supplement the guidelines. It is therefore interesting to note that Victoria has reversed its approach concerning this issue, as it was the only Australian jurisdiction that did, in fact, address it beyond the scope of the NHMRC Guidelines.

CONCLUSION

The changes to the Victorian regulatory framework concerning ART are some of the most significant since State legislation on the issue was first enacted. The statutory scheme has moved towards a light touch. This is a growing trend within the Australian statutory jurisdictions, with a number of States adopting a registration-based regulatory approach (compared to the former licence-based approach). One explanation for this shift in direction could be the recognition that the previous, multi-layered approach to regulation was complicated and burdensome. Thus, as outlined above, there is a need to comply with a number of different sets of national guidelines as well as the statutory system in place in Victoria.

A more radical change in policy is that concerning PGD and preimplantation tissue-typing. The change in policy concerning PGD has not resulted directly from the changes to the legislative scheme, but has occurred as a result of the VARTA’s decision to hand over the regulatory issues associated with the technology to the profession. This is not necessarily a radical step when considered in the context of other State approaches, many of which have failed to regulate PGD in any sense. However, this is a significant shift in policy when considered in the context of the history of ART and PGD regulation in Victoria.

It was established that the MHHMC Guidelines with respect to PGD and tissue-typing techniques will continue to apply in Victoria following the abolition of the State-specific policies. Although the changes to the statutory eligibility criteria open up the possibility that those families who do not fall within the criteria may be able to gain access to preimplantation tissue-typing, there is still a requirement that such families seek approval from the Patient Review Panel prior to being considered for IVF treatment. This means that those families who do not meet the statutory eligibility criteria (eg families who have a sick child with an acquired condition) will have to gain permission from the Patient Review Panel prior to having their case considered by an institutional ethics committee. Both the Patient Review Panel and the ethics committee are obliged to consider the respective applications in accordance with the guiding principles of the legislation (among the other considerations mentioned), and place the welfare of the child to be born as paramount. As highlighted by the recent decisions of the Victorian Civil and Administrative Tribunal, welfare assessments in this specific context may prove particularly difficult to make.

The effect of the change in Victorian regulatory policy concerning preimplantation tissue-typing is that it amounts to a double assessment of the decision of some families to access IVF for this purpose. Essentially, at both stages of the assessment, the Patient Review Panel and the institutional ethics committee are required to consider the same matters: the family circumstances and how these impact on the welfare and interests of any child who may be born following the procedure. This double assessment is an unjustified hurdle for some families, given that other families who are at risk of transmitting a genetic condition via natural conception are not subject to the same requirements. Arguably, both families have the same motivation and intention in using the technology. For this reason, there is a need for Victoria to reconsider its approach in relation to this specific issue, so that all families who seek to rely on IVF and preimplantation tissue-typing for such compelling reasons are able to do so without having to jump through unjustifiable hurdles.

Szoke, Neame and Johnson, n 25.

This position has also been adopted in New South Wales (see Smith, n 76) and South Australia.