Freedom to choose?

Embryo selection, reproductive decision-making and the role of the state

By Isabel Karpin and Belinda Bennett

Genetic technologies are making it possible to test for genetic traits at an earlier and earlier stage and are having an increasing impact on reproductive decision-making.[1] The technology of preimplantation genetic diagnosis (PGD) is one such example.

Involving the biopsy of an eight-cell embryo, PGD has been hailed as a means of making reproductive decisions without having to face the heart-wrenching decision to abort an affected foetus. However, controversy around the kinds of traits for which testing can be done, and who has access to the technology, has led to questions about the way in which the technology is developing. Women who are allowed to access *in vitro* fertilisation (IVF) services can currently also access PGD in limited circumstances.

The provision of PGD services in Australia is governed by the regulatory framework for assisted reproductive technology (ART). Regulation of ART varies across the states, with specific legislation only in Victoria, South Australia and Western Australia.[2] Recent ART legislation in NSW does not specifically regulate PGD, but will require ART-providers to be registered.[3]

Some national uniformity in the requirements relating to ART-providers is set down through s11 of the *Research Involving Human Embryos Act* 2002 (Cth), which makes it an offence to use an embryo produced through a combination of human sperm and egg (that is, not an excess embryo as defined in the Act) other than for a purpose relating to ART treatment of a woman carried out by an accredited ART centre.

An accredited ART centre is defined in s8 of the Act as a person or body accredited to carry out ART by either the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia or, where prescribed by regulations, other bodies. To date, no other bodies have been prescribed.

To be accredited by the RTAC, ART-providers must comply with the National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004 as revised in 2007) (the Guidelines). These Guidelines, which have been developed by the Australian Health Ethics Committee of the NHMRC, set down limits and restrictions to the provision of PGD.

This article discusses the three main areas of regulatory concern in the provision of PGD services: sex selection; selection to avoid a serious genetic condition; and 'saviour' siblings.

SEX SELECTION

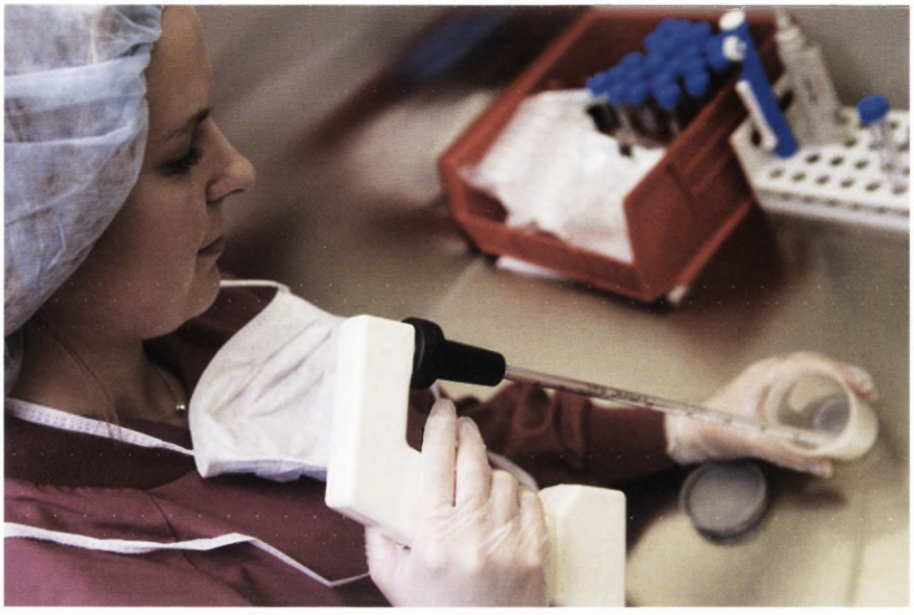
The NHMRC's Guidelines prohibit sex selection for so-called 'non-medical' purposes. Selective reduction of embryos based on sex is allowed under the Guidelines only to reduce the risk of transmission of a serious genetic condition. Up until the introduction of the Guidelines, it was possible for a woman seeking PGD to use it to select an embryo on the basis of sex for non-medical reasons. Sydney IVF, for instance, notes on its website that it offered sex selection for 'family balancing' up until 2005, when the Australian Health Ethics Committee first introduced the Guidelines.[4] Section 11 of the Guidelines provides that:

> 'Sex selection is an ethically controversial issue. The Australian Health Ethics Committee believes that admission to life should not be conditional upon a child being a particular sex. Therefore, pending further community discussion, sex selection (by whatever means) must not be undertaken except to reduce the risk of transmission of a serious genetic condition.'

The NHMRC's Guidelines allow selective reduction of embryos only to reduce the risk of transmitting serious genetic conditions.

This restriction is further reiterated in s12 of the Guidelines, which specifically regulates the provision of PGD. Section 12.2 repeats the view stated in s11 that, pending further community discussion, PGD must not be used for 'selection of the sex of an embryo except to reduce the risk of transmission of a serious genetic condition'.

Similar provisions exist in Victoria and Western Australia, where there is specific legislation. In Victoria, the *Infertility* >>



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Treatment Act 1995 expressly prohibits sex selection unless 'it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or a disease to the child'.[5] In Western Australia, the *Human Reproductive Technology Act* 1991 allows for diagnostic procedures to be carried out on embryos where the procedures have been specifically approved by the Western Australian Reproductive Technology Council.[6] The Reproductive Technology Council has prohibited the use of an embryo diagnostic procedure for sex selection alone, and requires that where diagnostic testing for other purposes is undertaken, information about the sex of the embryo should not be given 'unless this is relevant to the genetic abnormality or disease'.[7] This is particularly interesting because there is no such restriction on the provision of advice regarding sex in the context of prenatal testing of foetuses where a woman is already pregnant. There is thus a clear tension in the kind of reproductive choice afforded to women in the prenatal as opposed to the preimplantation context. Surveyed community attitudes in Australia reveal a preference for women's reproductive freedom in the context of abortion.[8] Given this support for reproductive freedom, it is not clear why restrictions have been imposed on the provision of information about the embryo's sex when decisions are being made at the preimplantation stage.

It might be argued that reproductive decisions – such as a decision to use PGD to sex-select whether for medical or non-medical purposes – should be in the hands of the woman, and not be subject to legislative intervention. Julian Savulescu argues, for instance, that procreative freedom is paramount in countries such as Australia 'where there will not be a systematic bias in favour of one sex across the whole community'.[9] Surveys undertaken in the UK to determine attitudes to sex-selection support the claim that systematic bias is unlikely. A recent survey indicated no clear gender preference, suggesting that were sex-selection allowed, it would not be a discriminatory practice. In that study, the strongest preference (68 per cent) was for an equal number of boys and girls in a family.[10] A further 73 per cent indicated no preference for the sex of the first-born child. These results suggest that legislative intervention in this area may be unwarranted and unjustified.

On the other hand, there is ambivalence when it comes to constraining choice in the context of a potential medical condition associated with sex. While testing is supposed to be conducted only where the condition is linked to sex and is serious, approval has been sought for conditions whose connection with sex is as yet unproven. For instance, in the list of Approved Genetic Testing (July 2008) released by the Infertility Treatment Authority of Victoria, Schedule D gives examples of the kind of testing for which notification and case-by-case approval will be required. Listed as one of those examples is:

> 'Conditions where there is a higher incidence in one sex, but there is inconclusive genetic evidence about the transmission of that condition (excluding Autism Spectrum Disorders).'

SERIOUS GENETIC CONDITIONS

What constitutes sufficient medical reason for selection is further complicated in the context of testing more broadly; that is, where the issue of sex is irrelevant. The NHMRC's Guidelines note that 'PGD is currently used to detect serious genetic conditions, to improve ART outcomes and, in rare circumstances, to select an embryo with compatible tissue for a sibling.'[11] It has been largely left to clinics and individual state legislatures to determine the outer limits of what constitutes a serious genetic condition. This is despite the continuing controversy about the appropriateness of testing for conditions that are late onset, such as breast cancer, or for genes that will not manifest in the child, such as those that indicate carrier status.

The BRCA1 gene is a particularly interesting example, because it is not fully penetrant. This means that even if you have the gene there is a small chance that you may never develop the related cancer, and prophylactic treatment options mean that it is possible to prevent it. Taking these factors into account, women are often faced with risk calculations that are almost impossible to weigh up. Abby Lippman argues, for instance, that 'women only come to "need" prenatal diagnosis after the test for some disorder has been developed'.[12]

> '[P]osing a "need" for testing to reduce the probability that a woman will give birth to a child with some detectable characteristics rests on assumptions about the value of information, about which characteristics are or are not of value and about which risks should or should not be taken.'[13]

> The conception of a child destined to be a tissue donor for a sick sibling is controversial.

Similarly, Nikolas Rose argues that 'genetic styles of thought not only give life strategies a genetic coloration but also create new ethical responsibilities'.[14]

Consider, for example, the following scenario. You are advised that you have an 80 per cent chance of developing breast cancer and that your safest option is to have a prophylactic mastectomy. You have the mastectomy. You are 35 years old, and you and your partner now want to have children. The doctor who identified your predisposition to hereditary cancer advises you that there is a chance you could pass the gene on to your child. While it is true that the child may never develop breast cancer, you are troubled by the thought that if it is a daughter, like you, she may one day have to face the decision to have a prophylactic mastectomy. You decide that this is not a reason not to have a child, particularly as the disease is a late-onset disease and treatments may well have improved in another 35 years. After you have made this decision, you are told that PGD can select out embryos that have the gene.[15] Nevertheless, you opt not to undergo an onerous cycle of IVF followed by PGD and, instead, plan to have an abortion if your foetus is female, on the grounds that only a very small incidence of breast cancer is found in men. Your friend, faced with the same decision, opts to have PGD, while a third friend decides not to have PGD or prenatal testing and to risk having a child with the gene.

The question for regulators is what role they should play, if any, in the reproductive decision-making of such women and their families.

SAVIOUR SIBLINGS

The final area where there is some controversy surrounding the provision of genetic testing services involves the selection of so-called 'saviour' siblings. This issue arises where a family has a sick child who requires a transplant of umbilical cord blood or bone marrow from a tissue-matched individual, and where no such match can be found. In such circumstances, the family may try to have another child who can provide a tissue-match for the existing child. PGD makes this process easier by allowing couples to actively select embryos prior to implantation that provide a tissue-match with an existing child and can therefore be a matched donor for their sick sibling. >>

There is a clear tension in the kind of reproductive choice afforded to women in the prenatal as opposed to the preimplantation context.

The conception of a child destined to be a tissue donor for a sick sibling is controversial.[16] The NHMRC's Guidelines provide that 'Except in the case of siblings, PGD must not be used to select a child to be born with compatible tissue for use by another person.'[17] If requested to create a tissue-compatible child, clinics must seek advice from a clinical ethics committee or the relevant state/territory regulatory agency.[18] The Guidelines provide that 'the ethics committee or relevant agency should ascertain that:

- the use of PGD will not adversely affect the welfare and interests of the child who may be born;
- the medical condition of the sibling to be treated is life-threatening;
- other means to manage the medical condition are not available; and
- the parents wish to have another child as an addition to their family and not merely as a source of tissue.'[19]

The Guidelines include a test that assesses parental motivation, and yet no such motivation is required to have a baby without assistance. If a person chooses to have a child by natural methods, not because they wish to add to their family, but because they hope to provide an organ donor for themselves or another family member, there are no ethics committees or regulatory agencies that can intervene to limit their capacity to do so.

THE ROLE OF THE STATE

The role of the state in regulating reproductive decision-making is central to the issue of the rules regulating the selection of embryos using PGD. As is clear from the above discussion, PGD is subject to varying degrees of regulatory oversight and limitations on its use, depending on its purpose. The restrictions on choice in the context of ART and, in particular, in relation to PGD, are arguably at odds with the relative freedom accorded to other aspects of reproductive decision-making in Australia. Some commentators have argued, however, for greater regulatory oversight for PGD, while others have maintained that reproductive autonomy is paramount and women, not the state, should determine whether or not a particular embryo is appropriate for implantation.[20]

While the debate is not easily resolved, it is clear that if the state is going to have a role in regulating reproductive decision-making, it needs to be grounded in and responsive to the context in which the technology is operating. Systemic discrimination against people of one sex for instance, may warrant state intervention to protect against that discriminatory impact. However, in the absence of such discrimination, it is hard to justify state intervention. Furthermore, it is clear that the NHMRC Guidelines are calling for more community involvement in decisions about which uses of PGD are acceptable and which are not. Perhaps the next step is a comprehensive engagement with the community on these issues. ■

Notes: **1** I Karpin and B Bennett, 'Genetic Technologies and the Regulation of Reproductive Decision-Making in Australia' (2006) 14 *Journal of Law and Medicine* 127 and B Bennett, *Health Law's Kaleidoscope: Health Law Rights in a Global Age*, Ashgate Publishing, 2008, chapter 4. **2** *Infertility Treatment Act* 1995 (Vic); *Reproductive Technology (Clinical Practices) Act* 1988 (SA); *Human Reproductive Technology Act* 1991 (WA). **3** *Assisted Reproductive Technology Act* 2007 (NSW). At the time of writing the Act had not commenced. **4** http://www.sydneyivf.com/PGDIVFforgeneticdisorders/SexselectionwithPGD/tabid/130/Default.aspx. **5** *Infertility Treatment Act* 1995 (Vic), s50(2). **6** *Human Reproductive Technology Act* 1991 (WA), s7(1)(b). **7** RTC Policy, *Approval for Diagnostic Testing of Embryos* (March 2008) s2.2.4 para 26 at p8, http://www.rtc.org.au/clinics/docs/Approval_for_Diagnostic_Testing_of_Embryos_Advice_to_Clinics.pdf. **8** See the Australian Survey of Social Attitudes 2003 dataset Australian National University ACSPRI Centre for Social Research showing that 81.2% of people support a woman's right to choose an abortion, (cited in the Australian Reproductive Health Alliance, Fact Sheet Nov 2004) at http://www.arha.org.au/factSheets/socialattitudestowardsabortionnew.pdf; see also LCannold, *What No Baby?* Freemantle Arts Centre Press, 2005. **9** J Savulescu, 'Sex Selection: the Case for', *MJA* 1999; 171: 373. **10** E Dahl, K-D Hinsch, M Beutel, B Brosig (2003) 'Preconception Sex Selection for Non-medical Reasons: A Representative Survey from the United Kingdom', *Hum Reprod* 18: 2238. **11** NHMRC, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice or Research* (2004 as revised in 2007) at 12.1. See discussion of saviour siblings, below. **12** A Lippman, 'Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities', *American Journal of Law and Medicine*, Vol. XVII, Nos 1 and 2, 1991, at p27. **13** *Ibid.* **14** N Rose, *The Politics of Life Itself*, Princeton University Press, 2007, p108. **15** See Sydney IVF website, List of Inherited Disorders for which it is currently possible to have PGD http://www.sydneyivf.com/PGDIVFforgeneticdisorders/PGDforinheriteddisease/tabid/368/Default.aspx. **16** See B Bennett, 'Symbiotic Relationships: Saviour Siblings, Family Rights and Biomedicine' (2005) 19 *Australian Journal of Family Law*, 195. **17** NHMRC, Guidelines, above n11 at 12.3. **18** NHMRC, Guidelines, above n11 at 12.3. **19** NHMRC, Guidelines, above n11 at 12.3.1. **20** I Karpin 'Choosing Disability: Preimplantation Genetic Diagnosis and Negative Enhancement' (2007) 15 *Journal of Law and Medicine*, 89.

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