Chisholm Health Ethics Bulletin

Vol 16 No 4 WINTER 2011

Australia's Cloning and Embryo Research Laws

This article explores the report of the 2010 independent review committee into Australia's cloning and embryo research laws. Its author, the Director of the Centre, was one of the five members of this committee.

Australia is currently undertaking a scheduled review of its cloning and embryo research laws.

Many people who respect life were concerned about this review. The original 2002 Australian laws legalised destructive research on human embryos left over from IVF. After a review in 2005, a revision of these laws in 2006 also legalised the creation of human embryos for research and destruction through SCNT (somatic cell nuclear transfer) or so-called 'therapeutic cloning.' With that history, many feared that the current review would legalise even worse abuses.

This did not happen.

The process has begun with a report[1] by an independent review committee appointed by the Australian government. Along with former Federal Court judge Peter Heerey QC, scientist and 2006 Australian of the Year Prof Ian Frazer, legal scholar Prof Loane Skene, and midwife educator Dr Faye Thompson, I was a member of that committee. We were a diverse committee whose knowledge and opinions about embryonic stem cell (ESC) research varied considerably.

Over the first half of this year, the committee received a total of 264 written submissions. We also heard from fourteen groups of expert witnesses, again with a variety of opinions about ESC research.[2]

Proponents of ESC Research

In their submissions, proponents of ESC research called for payments for women who 'donate' eggs for research, permission for research involving animal-human hybrids ('cybrids'), and permission to create embryos using DNA from more than two persons as a possible way to prevent the transmission of mitochondrial disease.[3]

One submission, for example, reported on a study of attitudes towards egg donation in Australia. It found that "young healthy" women were generally "unwilling to donate" eggs for ESC research and "also were concerned about the effects of egg extraction on their fertility." They "would only consider donation of eggs to stem cell research once their own family had been completed." This submission supported "compensation for oöcyte donation… in return for the significant amount of labour involved."[4]

Research involving animal-human hybrids can take several forms, but the most common is SCNT using eggs from cows and human nuclear material. When this was first attempted, the aim was to use these hybrid embryos as a source of ESCs. In 2009, however, a report from the Advanced Cell Technology laboratory in Worchester, Massachusetts demonstrated that in such widely separated species this was simply not possible.[5] Since then, scientists have revised their rationale for attempting this research. They say it is now "to understand more about early human development."[6] Even this modest aim is unlikely, however, because the pattern of reprogramming in these hybrid embryos is so different from normal human development. Thus, for example, when animal-human hybrids were considered by the Australian Senate in 2006, Senator Andrew Bartlett noted scientific advice that "using more than one species could make the interpretations of some experiments more difficult." He added that this line of research was "not essential," "not significant," and "potentially problematic."[7] He then moved a successful amendment not to allow research using animal-human hybrids within Australia. In 2011, in their submission to the review, the Australian Stem Cell Centre (ASCC) stated that "with little scientific progress… at this stage the ASCC does not believe there is sufficient merit to call for a change to the legislation."[8]

The review committee did not support payments for egg 'donation' nor requests to permit animal-human hybrids nor any of these other proposed changes. If the Australian government follows our recommendations, all these things will remain illegal in Australia.

During the review, Prof Bob Williamson from the Australian Academy of Science campaigned in the media particularly for permission to create embryos containing DNA from three people.[9] After taking into consideration

IN THIS ISSUE

Australia's Cloning and Embryo Research Laws Pg 1

Induced Pluripotent Stem Cells Pg 4

Gamete Donation Pg 7

evidence and advice from Australian researchers, however, the review committee concluded that "these techniques are not sufficiently advanced to be permitted under the current legislation."[10] In the report, I added my own conclusion that, given both the scientific difficulties and the risk to any child created in this way, "this proposed therapy could not be used for human beings not just in the short term but for the foreseeable future."[11] Once our report was made public, Prof Williamson expressed his disappointment in the media about this decision.[12]

Opponents of ESC Research

While the report of the review committee disappointed many proponents of ESC research, it also disappointed many of its opponents. In their submissions, the opponents of ESC research called for removal of the permission in Australian law to create human embryos for research using immature eggs or 'precursor cells' from aborted human foetuses, as well as a ban on ESC research using embryos left over from IVF, and a ban on SCNT. Of the 264 submissions received, 188 (71%) stated that they opposed the use of human embryos in research, and 112 (42%) stated that their opposition to human cloning.

As regards the use of precursor cells from aborted foetuses, the report acknowledges that many people "experience the 'yuck factor'" when they consider this issue. It notes, however, that any embryos created from these immature eggs will only ever be used in research, and therefore that "there is no prospect of a child becoming aware that he or she is derived from a deceased fetus." Australian law permits women to donate their own eggs for medical research. It also permits parents to donate tissue from a deceased foetus. In such a legislative framework, even opponents of ESC research must acknowledge that "it is difficult to see how an exception could reasonably be made" to forbid the donation and use of precursor cells from aborted foetuses.[13]

… "the decision whether or not to recommend the banning of human SCNT was the 'most contentious' and difficult decision that the committee had to make." …

SCNT or 'Therapeutic' Cloning

In their calls for a ban on SCNT, the opponents of ESC research above all noted the discovery and ongoing development of induced pluripotent stem (iPS) cells. These stem cells are derived from somatic cells from the body such as skin cells. They hold promise to allow the development of replacement cells, tissues and organs from the cells of an individual's own body, theoretically eliminating the risk of rejection by the individual's immune system. Further, because the use of iPS cells does not involve the destruction of human embryos, the most serious ethical concern raised by SCNT is eliminated. Thus, for all these reasons, the opponents of ESC research argued that with the discovery of iPS cells, the need for SCNT in regenerative medicine no longer exists.

Often by a majority rather than a unanimous decision, the review committee rejected these calls too. However, it noted that the decision whether or not to recommend the banning of human SCNT was the "most contentious"[14] and difficult decision that the committee had to make. If SCNT is to be useful in the treatment of degenerative diseases, embryonic stem cells must be derived from human SCNT embryos. To date, however, this has not happened anywhere in the world. Thus, the committee also noted the "lack of progress in SCNT research."[15]

Each proposal for embryo research in Australia must be approved or 'licensed' by Australia's Licensing Committee. To issue such a licence, the Licensing Committee must be convinced that this particular research is likely to produce a significant advance in knowledge. The lack of progress in SCNT research, the review committee noted, reduces the likelihood of a significant advance in knowledge through this type of research. The review committee therefore advised that there must now be greater promise of a significant advance in knowledge before a licence for human SCNT research could be issued in Australia.

I did not support even this restricted endorsement of human SCNT. In my minority view, I noted that SCNT "involves the most profound of ethical concerns" because it is "the creation of human life which will be used in research and then destroyed." By contrast, I argued that the proposed benefits of SCNT are "mostly theoretical" and little more than "the possibility of what 'might' be learnt." When these theoretical benefits trumped the most serious of ethical concerns, I wondered whether the ethical concerns about embryo research "are ultimately being given anything more than lip-service."[16]

There were four more minority views about recommendations in the report – one from Dr Faye Thompson also about SCNT, and three more from me.[17] I also opposed the recommendation to continue ESC research using left-over embryos as I do not think that the evisceration of these embryos is a respectful way of disposing of them.

Other Recommendations

Australia's National Health and Medical Research Council (NHMRC) was concerned that researchers might stockpile embryos left over from IVF for possible ESC research. The review committee made two recommendations to prevent this. The first was that licences should impose restrictions on the number of embryos which can be stored for research. The second was that embryos for research should be stored for a maximum of five years, and that they should be respectfully disposed of even before that time if it is clear that they are unlikely to be used in research.[18]

All up, the review committee made a total of 33 recommendations. Many of those not discussed here were either to correct ambiguities in Australia's existing laws or to improve the licensing process. For example, embryo

research in Australia must first be approved by a Human Research Ethics Committee (HREC) before it can be considered by Australia's Licensing Committee. Thus, the committee recommended a system of credentialing for HRECs so that only credentialed HRECs with appropriate expertise are able to consider and approve embryo research.[19]

Artificial Gametes

Five recommendations pertained to artificial or *in vitro* derived (IVD) gametes. In contrast to natural eggs and sperm, these are artificial eggs or sperm made from stem cells or even from a somatic cell from the body such as a skin cell. Already, baby mice have been created using natural mouse eggs and artificial mouse sperm.[20] While functional human IVD gametes have not yet been manufactured, their development should be anticipated.

As the report notes, when one partner or both is not producing natural gametes, human IVD gametes could be used to enable a heterosexual couple to have a child. If opposite-sex IVD gametes (an egg from a male or a sperm from a woman) could be produced, they could also be used to enable a same-sex couple to have a child which is biologically theirs.

IVD gametes might also enable one person to have a child without another parent through fertilisation of his or her natural gamete with an opposite-sex gamete also derived from the same person.[21] As this process may lead to different combinations of dominant and recessive genes, this child would not exactly be a clone.

… "Could the community ever accept the use of artificial gametes in human reproduction? … Would it ever be fair to create a child who would be subject to these risks?" ...

IVD gametes have not yet been considered in Australian law. The report from the review committee recommends that research using IVD gametes should be permitted in Australia under licence from the Licensing Committee, but that the use of IVD gametes in reproduction should be forbidden at this time.[22]

More than that, the report calls for community debate about IVD gametes. Could the community ever accept the use of IVD gametes in human reproduction? There are at least three issues here:

The first is whether or not the use of IVD gametes is inconsistent with human dignity, particularly the human dignity of any children produced in this way. The report notes that Article 11 of the United Nations' *Universal Declaration on the Human Genome and Human Rights* insists that "practices which are contrary to human dignity, such as reproductive cloning of human beings, should never be permitted." It then invites "states and competent international organisations" to "cooperate in identifying such practices and in taking, at national and international levels, the measures necessary to forbid them."[23] I have only spoken to small groups of people about this issue, but many of these have reacted to the possibility of artificial gametes being used in human reproduction with something akin to horror. Their moral intuition is that the use of IVD gametes in human reproduction would indeed be incompatible with human dignity.

A second issue concerns the rights of the child. The report quotes ethicist Margaret Somerville who recognises a right "to be conceived with a natural biological heritage" – that is, "a right to be conceived from a natural sperm from one identified, living, adult man and a natural ovum from one, identified, living, adult woman."[24] Debates about the assisted reproductive technologies almost certainly focus too much on the wishes and desires of adults - and too little on the rights, best interests and well-being of any children conceived. This focus has led, for example, to the use of anonymous gamete donation in human reproduction – even though recent reports indicate that this has often caused serious problems for many of the children conceived in this way.[25] I believe, therefore, that as we consider the possible use of IVD gametes in human reproduction, we must focus very seriously on the rights, best interests and well-being of children. If we do not, in a few decades there will be at least some emerging adults conceived in this way who will cry out to their parents, "I've always felt like I'm some sort of Frankenstein's Monster. How could you have done this to me?"

The third concern here is safety. In both animal and human cloning – and indeed in just about every other area in which we have tried to copy natural processes – our artificial copies have always contained more errors and defects. Could we ever be confident enough of artificial gametes to risk using them in human reproduction? Would it ever be fair to create a child who would be subject to these risks?

If human IVD gametes are developed, my prediction is that this will bring about the next major conflict in the stem cell wars. This conflict will be between those whose focus is almost exclusively on the wishes and desires of adults, and those who are at least equally concerned about the rights, best interests and well-being of children. Or, to put this another way, it will be between those who believe that ethical concerns impose almost no limits on doing what is technically possible, and those who believe that ethical concerns about the rights, best interests and well-being of any children conceived impose very serious limits on what should be permitted in human reproduction.

After a Foreword, Table of Contents and Executive Summary, the two main sections of our report are a comprehensive review of developments in stem cell research since 2005, and a detailed discussion of our 33 recommendations. The report is 96 pages in length, and available on-line at https://legislationreview.nhmrc.gov.au/

Australian legislation on cloning and embryo research is found in two laws, the *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002*.[26]

Our report was tabled in both Houses of Federal Parliament on 7 July 2011. The Australian government must now decide what to do with its 33 recommendations. Of these, the recommendation not to remove the current permission for SCNT or so-called 'therapeutic' cloning remains the most controversial. Recommending another review in five years, the report considers that "it may be that by the time of the next review it has become accepted that SCNT is no longer appropriate."[27] My hope is that Parliament will not wait five years. My hope is that Parliament will recognise now the serious ethical concerns raised by the creation of human life for research and then destruction. My hope is that Parliament will remove the current permission for so-called 'therapeutic' cloning not in five years but now.

ENDNOTES

[1] *Report of the Independent Review of the* Prohibition of Human Cloning for Reproduction Act 2002 *and* Research Involving Human Embryos Act 2002, 2010 Legislation Review, https://legislationreview.nhmrc.gov.au/
[2] Ibid., 14, 96.
[3] As noted, for example, in Andrew Elefanty, "Striking the balance in laws for stem cell research," The Conversation, http://theconversation.edu.au/striking-the-balance-in-laws-for-stem-cell-research-309
[4] Catherine Waldby, *Submission 107*, 2010 Legislative Review, https://legislationreview.nhmrc.gov.au/sites/default/files/submissions/waldby%20submission%20legislative%20review.doc; cf Loane Skene, "Donating eggs for research is tough – so why not pay for it?" *The Age* (Melbourne), 13 July 2009.
[5] Y. Chung et al, "Reprogramming of human somatic cells using human and animal oocytes," *Cloning and Stem Cells* 11 (2009): 13-23. The report notes that the pattern of reprogramming in these hybrid embryos is very different from the normal process, and significantly that the majority of the critical genes associated with pluripotency are either down-regulated or silenced. For more on this, see Peter McCullagh, *Submission 281*, 2010 Legislative Review, https://legislationreview.nhmrc.gov.au/submission/submission-281
[6] Prof Robin Lovell-Badge, quoted in Daniel Martin and Simon Caldwell, "150 human animal hybrids grown in UK labs: Embryos have been produced secretively for the past three years," Daily Mail Online, http://www.dailymail.co.uk/sciencetech/article-2017818/Embryos-involving-genes-animals-mixed-humans-produced-secretively-past-years.html
[7] Senator Andrew Bartlett in *Hansard – Commonwealth of Australia: Senate*, 7 November 2006, 118.
[8] Australian Stem Cell Centre, *Submission 231*, 7, 2010 Legislative Review, https://legislationreview.nhmrc.gov.au/submission/submission-173
[9] For one example, see Simon Lauder, "Scientists want stem cells from three donors" (18 April 2011), ABC, http://www.abc.net.au/am/content/2011/s3194136.htm
[10] *Report*, 61. [11] Ibid., 61.
[12] Simon Lauder, "Stem cell researchers disappointed by ruling" (8 July 2011), ABC, http://www.abc.net.au/am/content/2011/s3264174.htm
[13] *Report*, 63-64.
[14] Ibid.,14. [15] Ibid., 53. [16] Ibid., 54.
[17] Ibid., 54; 44, 61 and 66.
[18] Ibid., 69-70. [19] Ibid., 62-63.
[20] Chunli Zhao et al, "Establishment of customised mouse stem cell lines by sequential nuclear transfer," *Cell Research* 17 (2007): 80-87; K. Hayashi et al, "Reconstitution of the mouse germ cell specification pathway in culture by pluripotent stem cells," *Cell* 146 (2011): 1-14. For a discussion of these developments, see Cristina Luiggi, "Lab-Grown Sperm," *The Scientist*, http://the-scientist.com/2011/08/04/lab-grown-sperm/
[21] *Report*, 65. [22] Ibid., 66. [23] Ibid., 65.
[24] Margaret Somerville, "Children's Human Rights to Natural Biological Origins and Family Structure," *International Journal of Jurisprudence of the Family* 1, no. 1 (2011): 35-53 at 37, 38; reprinted in *Bioethics Research Notes* 23, no. 1 (March 2011): 1-11 at 2; cf http://www.law2.byu.edu/organizations/marriage_family/past_conferences/may2010/drafts/CHILDREN%20RIGHTS.pdf
[25] For example, see Elizabeth Marquardt, Norval D. Glenn, and Karen Clark, *My Daddy's Name is Donor*, Center for Marriage and Families, http://www.familyscholars.org/assets/Donor_FINAL.pdf
[26] These laws can be accessed from https://legislationreview.nhmrc.gov.au/current-legislation
[27] *Report*, 78.

All on-line resources accessed 22 August 2011

Kevin McGovern ✠

Induced Pluripotent Stem Cells

Many people think that the Catholic Church is morally opposed to all research and therapeutic use of stem cells. This is far from the truth. The Church is rightly morally opposed to all destructive use of human embryos to obtain pluripotent embryonic stem cells, but it is not opposed to pluripotent stem cells ethically derived from adult cells.

From Human Embryonic Stem Cells to Induced Pluripotent Stem Cells

Human embryonic stem (ES) cells are sought by researchers for scientific and therapeutic purposes. They are derived from the inner cell mass (ICM) of a six to seven day old blastocyst. Once they divide, they renew themselves and also give rise to more specialised cells. They are *pluripotent* because after transplantation, their cell progeny can become virtually any cell type of the body or repair damaged human cells or tissue. Using ES cells, however, is unethical because they are obtained from destroyed human embryos. An ethical alternative is urgently needed.

Towards the end of 2006, Dr. Shinya Yamanaka and Dr Kazutoshi Takahashi were developing adult stem cell

technology when they found a method to convert differentiated adult mouse cells into pluripotent stem cells.[1] Their aim was to find and study the genes which acted as master regulators of genes by turning them on and off in skin cells or other tissues to modify cellular behaviour. They narrowed the field down to 24 promising genes chosen, believe it or not, by an educated guess.[2] They examined these 24 genes by inserting them into enucleated mouse oocytes. They found that only four of these factors were essential for the formation of pluripotent cells. They then introduced these four factors (Oct3/4, Sox2, c-Myc, and Klf4) into adult mouse fibroblast cells under specific culture conditions. This resulted in the formation of induced pluripotent stem cells (iPSCs) whose properties resembled those of ES cells, though without being identical. After these cells were injected under the skin of mice, they formed unorganised groups of cells called teratomas which consist of all three germ layers. This confirmed that these cells were indeed pluripotent. These cells also passed another test for pluripotency by contributing to the formation of the ongoing developing embryos when they were injected into mouse blastocysts.[3]

In the following year Dr. Takahashi and his colleagues reported their findings as follows:

> Human iPS cells were similar to human embryonic stem (ES) cells in morphology, proliferation, surface antigens, gene expression, epigenetic status of pluripotent cell-specific genes, and telomerase activity. Furthermore, these cells could differentiate into cell types of the three germ layers in vitro and in teratomas. These findings demonstrate that iPS cells can be generated from adult human fibroblasts.[4]

They also reported:

> Successful reprogramming of differentiated human somatic cells into a pluripotent state would allow creation of patient- and disease-specific stem cells… we demonstrate the generation of iPS cells from adult human dermal fibroblasts with the same four factors: Oct3/4, Sox2, Klf4, and c-Myc. Human iPS cells were similar to human embryonic stem (ES) cells in morphology, proliferation, surface antigens, gene expression, epigenetic status of pluripotent cell-specific genes, and telomerase activity.[5]

The Potential of iPSCs for Therapies and Research

What is scientifically and ethically significant is that this new procedure bypasses the use of eggs and the creation of embryos. If trials with human cells verify that this method does indeed give rise to pluripotent stem cells, an ethical way would be on the horizon for medical research and therapies without the need of human eggs, the creation and destruction of embryos, and even somatic cell nuclear transfer (cloning). This is exciting news for scientists and ethicists alike, not to mention law makers who are morally opposed to the destruction of human embryos as a source for ES cells for research. However, more research is needed to be carried out on the safety of these pluripotent stem cells before therapies become available.[6]

Renowned scholars Dr. Holm Zaehres and Dr. Hans R. Schöler recognised the importance of Yamanaka's work: "This is a significant turning point in nuclear reprogramming research with broad implications for generating patient-specific pluripotent stem cells for research and therapeutic applications."[7]

Gojo and his colleagues compared induced pluripotent stem cells, directly reprogrammed cardiomyocytes (heart muscles), and somatic stem cells as a cell source for future cell-based therapy.[8] They also supported the application of iPSCs in artificial organs. They believe that tissue engineering in regenerative medicine should give rise to a new era of medical treatment for organ failure.

… With induced pluripotent stem cells "an ethical way would be on the horizon for medical research and therapies without the need for human eggs, the creation and destruction of human embryos, and even somatic cell nuclear transfer (cloning)." …

Dyson and Barker hold that cell transplantation has improved to the point of being a potentially reparative therapy for Parkinson's disease. The following are likely good and varied sources for these cells: developing ventral mesencephalon, several autologous somatic cell types, embryonic stem cells and induced pluripotent stem cells. Indeed, iPSCs are seen as a likely suitable long-term source of transplantable dopaminergic neurons.[9]

Wallia and his associates point out that supporters of iPSC therapy need to show to their critics that iPSCs can be proven to be safe for clinical practice.[10] They cover in detail the pluripotency factors responsible for iPSC generation as well as the signalling pathways and epigenetic modifications involved in the reprogramming process. They also discuss the molecular compounds which have been shown to replace one or more genetic factors or to improve overall efficiency and kinetics of iPSC induction. Mention is also made of some problems that hinder iPSC research aimed at bringing iPSC therapy and other potential applications closer to success in practice.

Fujiwara reports that the appearance of beating colonies of cardiac cells from human iPSC was increased approximately 4.3 times by addition of cyclosporine-A [CSA] at mesoderm stage about 13 days after fertilisation.[11] CSA-expanded human iPSC-derived cardiomyocytes showed various cardiac marker expressions. Elucidation of mechanisms and exploration of efficient methods for their differentiation to functional cardiomyocytes are essential for developing cardiac cell models and regenerative therapies in the future. They say that they combined these technologies and extended them to mouse and human iPSCs. The results provide a

technological basis to obtain functional cardiomyocytes from iPSCs.

Yamanaka's great scientific breakthrough in 2006 showed that "it was possible to reprogramme somatic cells back to the pluripotency stage by modifying a few key transcription factors." These iPSCs "exhibit the morphology of embryonic stem cells" and resemble them in many ways, including "maintaining their developmental potential to differentiate into derivatives of all three primary germ layers." Up to now, the only available sources for stem cell therapy are bone marrow and umbilical cord derived stem cells.[12]

The Future: iPSCs[13]

"Stem cells are able to proliferate and differentiate into various cell types, create mixtures of cells representing tissues created under *in vitro* conditions. Disease-specific… iPSCs are now available and are used to study pathogenesis of inherited and [other] disorders.… In addition, patient-specific iPSCs generated from humans with specific diseases maintain some of the programming characteristic of that disease. This implies that patient-specific iPSCs or iPSCs obtained from a wide variety of people encompass the broad spectrum of metabolic abilities, drug susceptibilities, resistance or susceptibility to disease and are very useful for the testing of new biological agents or drugs in order to find the most effective therapeutic agent for the treatment of iPSC-derived-patient's disease."

"Several laboratories have already derived iPSCs from patients suffering from Huntington's and Parkinson's disease, juvenile diabetes, muscular dystrophy [and] Down syndrome … thus recapitulating the cell abnormalities in a plastic dish as they appear in patients. When the cultured iPSCs obtained from patients with familial dysautonomia and LEOPARD syndrome [an autosomal dominant inherited disorder characterised by freckle-like spots on the trunk] were exposed to experimental drugs for these diseases, the 'symptoms' were partially alleviated in culture. This principle may result in the development of new drugs and should be applied to many other diseases for which currently there are not any efficient therapies."[14]

"Innovative technologies of reprogramming and derivation of iPSCs address concerns [such as]…. immune rejection, risk for malignant transformation and medical ethics…. Derived from the patient's own somatic cells, IPSCs eliminate the potential for immune rejection and represent an ethically acceptable alternative to the use of human embryos for ESCs derivation. Key advantage of iPSCs compared to ASCs [adult stem cells] is the possibility of repairing disease-causing mutations by homologous recombination. … Promising experiments in mice suggest that the treatment of genetic disorders sickle cell anaemia and haemophilia A with iPSCs is feasible. … In principle, this approach could be applied to any disease in humans for which the underlying mutation is known and that can be treated by cell transplantation."[15]

"However, despite successes in animal models, iPSCs are not yet ready for transplanting into humans. Most iPSCs have been generated with integrating vectors, which may not get silenced efficiently …[and] which pose potential impediments for the use of human iPSCs in cell therapy. In addition, iPSCs-derived haematopoietic progenitor cells have been shown to undergo premature senescence and iPSCs therapy can lead to tumour formation. For instance, an increased propensity of iPSC-derived neural cells to form tumours after transplantation into the brains of immune-compromised mice has been noted. It will thus be critical to further improve the transgene-free approaches for derivation of new patient-specific iPSC lines."

"Researchers must evaluate different types of original cells and induction methods to determine the best combination for generating the safest iPSCs. At minimum, researchers need to focus on the safety of iPSC therapy in the light of the potential for cancer formation. Therefore, removal of the c-Myc transgene from reprogramming cocktail and the use of synthetic mRNA to reprogram human fibroblasts to pluripotency are new approaches for generating safe iPSCs."[16]

iPSCs "have dramatically emerged as a potential novel approach to understand and treat devastating and otherwise incurable diseases…. Relatively little is known about iPSCs molecular and functional equivalence to hESCs, which could affect their potential therapeutic utility. Addressing this question will require a careful analysis of the genetic and epigenetic integrity of human iPSCs. Further studies are necessary to develop optimized growth and differentiation protocols and reliable safety assays to evaluate the potential of stem cells and their derived specialized cells for the broader application in regenerative medicine and drug development."[17]

Conclusion

While iPSCs hold great promise, they are yet to be trialled as a therapy for degenerative diseases in human beings. R. K. Fung and I. H. Kerridge have reflected on the ethical issues raised by the possible first-in-human use of iPSCs. These ethical concerns include issues related to informed consent, patient recruitment, harm minimization, and the unavoidable uncertainty and risks involved in human treatments for the first time. Especially given "the seriousness of the potential risks, the unreliability of available animal models, the vulnerability of the target patient group, and the high stakes of such an intensely public area of science," these are significant concerns.[18] But while there are many technical and ethical concerns yet to be addressed, even now we can conclude that induced pluripotent stem cells hold great promise for an effective and ethical means of treating degenerative disease.

ENDNOTES

[1] K. Takahashi and S. Yamanaka, "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors," *Cell* 126, no. 4 (2006): 663-676.

[2] Mariam Gohsn and Norman Ford SDB, "Stem Cell Technology Update," *Chisholm Health Ethics Bulletin* 12 no. 1

(Spring 2006), 10-12 at 12.
[3] Takahashi and Yamanaka.
[4] K. Takahashi et al., "Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors," *Cell* 131, no. 5 (30 Nov 2007): 861-72.
[5] Ibid.
[6] Norman Ford, "Ethical alternatives to research that destroys embryos," *Eureka Street* 27 February 2007.
[7] H. Zaehres and H. R. Schöler, Comment in *Cell* 131, no. 5 (30 Nov 2007): 834-5.
[8] S. Gojo, M. Toyoda and A. Umezawa, "Tissue engineering and cell-based therapy toward integrated strategy with artificial organs," *Journal of Artificial Organs* 10 June 2011 [Epub ahead of print].
[9] S. C. Dyson and R. A. Barker, "Cell based therapies for Parkinson's disease," *Experimental Review of Neurotherapy* 11, no. 6 (June 2011): 831-44.
[10] B. Wallia, N. Satija, R. P. Tripathi and G. U. Gangenahalli, "Induced Pluripotent Stem Cells: Fundamentals of the Reprogramming Process and its Ramifications on Regenerative Medicine," *Stem Cell Review* 14 June 2011[Epub ahead of print].
[11] M. Fujiwara et al, "Induction and enhancement of cardiac cell differentiation from mouse and human induced pluripotent stem cells with cyclosporine-A," *PLoS One* 6, no.2 (22 Feb 2011): e16734.
[12] Vladislav Volarevic et al., "Human stem cell research and regenerative medicine – present and future," *British Medical Bulletin* 1-14 at 4 [Advance Access published 13 June 2011].
[13] Practically all the remainder of this section is either slightly modified or directly taken from the article of Volarevic et al mentioned in endnote 12 above.
[14] Ibid., 9-10.
[15] Ibid., 10-11.
[16] Ibid., 11.
[17] Ibid., 11-12.
[18] R. K. Fung and I. H. Kerridge, "Uncertain translation, uncertain benefit and uncertain risk: ethical challenges facing first-in-human trials of induced pluripotent stem (iPS) cells," *Bioethics* 4 July 2011: 1467-85. [Epub ahead of print].

All on-line resources accessed 22 August 2011

Norman Ford SDB ✠

Norman M Ford SDB STL PhD lectures in Bioethics and Healthcare Ethics at Catholic Theological College, East Melbourne.

Gamete Donation

Children born through gamete donation can be genetically linked to one or neither parent. This article examines the practice of gamete donation, seeking to establish if there is cause for concern.

The Catholic Church holds that "the origin of human life has its authentic context in marriage and in the family, where it is generated through an act which expresses the reciprocal love between a man and a woman." There are at least three truths contained within this teaching. Firstly, the Church recognises that the proper place for procreation is within the marriage of one man and one woman.[1] Secondly, the Church affirms that this procreation should only come about through sexual intercourse, which at once expresses the spouses' love and creates new life. And thirdly, the Church holds that this creation of new life should involve the union of the husband's sperm with his wife's egg. The Catholic Church therefore teaches that "fertilization of a married woman with the sperm of a donor different from her husband and fertilization with the husband's sperm of an ovum not coming from his wife are morally illicit."[2]

Within the wider society, however, gamete donation has become an increasingly common practice within assisted reproductive technology (ART). Female gametes (oocytes) or male gametes (sperm) can be donated to a couple who are unable to produce their own gamete(s). A legal challenge in Victoria in 2000 opened the door to single women, and gay and lesbian couples being able to become parents through ART.[3] People born as a result of donor gametes are usually referred to as donor conceived. This article will review both the increase of this practice and some of the difficulties which this has caused. In the opinion of its author, these difficulties confirm that we should listen to the wisdom of the Church's opposition to gamete donation.

Number of Births through Donated Gametes

The first recorded case of the utilisation of donor sperm and subsequent successful pregnancy occurred in 1884.[4] In Australia, sperm banks were established in the early 1970s. In 1972, in the first report to the Australian Obstetrical and Gynaecological Research Society, six pregnancies were documented from 120 donor sperm inseminations.[5] The first successful pregnancy in Australia from oocyte donation was in 1984.[6] In the two calendar years, 1992-3, there were 288 pregnancies from donor sperm which resulted in 221 live births.[7] Further, in 1992-3 there were 673 treatment cycles with donor oocytes which resulted in 119 pregnancies and 88 live births.[8] Additionally, there were 11 clinical pregnancies from donor embryos with six resulting in live births.[9] In 2002, there were 1,052 donor oocytes/embryo transfer cycles utilising 1,733 donated oocytes/embryos with 294 clinical pregnancies resulting in 209 live births, and there were 340 live births from 3,419 donor insemination cycles. The average age of a woman undergoing ART with donated oocytes or embryos in 2002 was 39.4 yrs compared with women undergoing other ART practices which was 35.3 yrs.[10] In 2008, 2,390 donor insemination cycles were reported, resulting in 347 clinical pregnancies and 266 live births.[11] There were 1,760 oocyte donation cycles resulting in 447 clinical pregnancies with 327 live deliveries and (allowing for multiple births) 374 live births. Also in 2008, 239 embryos were donated, with 46 resulting in a clinical pregnancy, with 30 live deliveries (35 live births). The

average age of women who sought donor oocytes or embryos was 41 years.[12]

As can be seen from the above figures, the number of births from the donation of oocytes and embryos is steadily increasing, while the number of births from donor sperm is not experiencing the same growth. This has been due to the increase in the success of the technique of intracytoplasmic sperm injection (ICSI). Kay and Barratt report ICSI has been the basis of the significant drop in donor insemination practices. The urge of parents to be genetically related to their children has led them to undergo the more invasive and costly procedure of ICSI.[13]

It is worth noting here that the number of children available for adoption in Australia has fallen significantly since the 1970s, with the number adopted stabilising during the 1990s to approximately 400-600 children adopted per year. In 2009-10, 412 children were adopted compared to 8,542 in 1972. Ninety-two percent or nine out of ten adoptions in 2009-10 were open adoptions. (Open adoption is when all parties are open to freely discussing the adoption within their families, and are happy to allow contact to occur between the relinquishing family and the adopting family.) The other eight percent requested anonymity with no exchange of information.[14]

Australian Senate Committee Report 2011

In February 2011, a Senate report was released on *Donor Conception Practices in Australia*.[15] With the concerns of the offspring as the major issue in this report, 32 recommendations were put forward to protect the children born through these practices. Most practices involved in donor conception are done within a formal clinical setting; however it is not unusual for gay sperm donors to donate to lesbian couples through an informal arrangement. Thus, the number of children born through donor conception practices is a conservative estimate, as the children born through informal arrangements are not necessarily officially recorded. The Senate report suggests that at a rate of approximately 600 children per year since the 1970s there could at least 20,000 donor conceived children in Australia. However, some would assess that the number is closer to 60,000.[16]

The Senate report explored such issues as the past requirement for anonymous donation and the consequences of this practice, the issues of paying donors of gametes as encouragement to donate (there is a shortage of both sperm and oocytes in Australia at present), the need for counselling and its importance for all involved - the donor, the recipient(s), and the child - in relation to disclosure and acceptance of their origins. The report acknowledged that academic literature shows that the social environment in which a child is raised shapes their development but their genetic heritage is intrinsic to their identity. The report also recognised the inconsistencies between the states and territories concerning the number of donations, the number of recipients of gametes, the counselling requirements, and legislation that allows access to donor identification. It was noted, in Australia there was no controlling organisation who administered ART practices in Australia, and under the Australian Constitution the Commonwealth is unable to pass donor legislation.[17]

Donor Conception Practices

Early donor conception practices were not regulated in Australia, often arranged privately between clinic, donors and recipient parents. The usual prerequisite to participate in such a program required anonymity for both donor and the recipient, further encouraging parents not to disclose to their children their origins. Victoria, South Australia, Western Australia and New South Wales all have legislation that specifically addresses donor conception. Although not legally binding, the 2007 *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practices and Research* published by the National Health and Medical Research Council (NHMRC) are applied in all states and territories including those that do not have their own regulations. As noted earlier, with no Commonwealth regulations considerable differences exist between Australian states and territories with regard to the information recorded and the availability of this information to donor conceived children and their families.[18]

… "it is in the child's best interests to grow and develop in the security and love of their biological family." …

The NHMRC guidelines request the following data to be recorded by the fertility clinic: name including any previous names, date of birth, most recent address, family medical history including genetic testing (if available), physical characteristics and the number of children conceived through a particular gamete donor. This data must be collected, recorded and stored. The NHMRC guidelines state that donor conceived persons are "entitled to know their genetic parents."[19] This requirement reflects the United Nations Convention on the Rights of the Child where Article 7.1 states that children have the right to a name, and to know and be cared for by their parents, and Article 8.1 acknowledges the right of children to know and preserve their identity, including their nationality, name and family relations.[20]

In the transmission of life within the Catholic Tradition, we seek to uphold the procreative and unitive themes of marriage. This maintains the genetic dimension within the gestational and birthing process of creating a family as we profess a belief that it is in the child's best interests to grow and develop in the security and love of their biological family.[21] As seen by the children of gamete donation in the American report *My Daddy's Name is Donor* the importance of their biological, genetic link is strong.[22] This has also been seen by a preference for ICSI over donor insemination practices in ART. Furthermore, changes in the practices of adoption, and Australia's

apology to the Stolen Generation and the Lost Innocents also seek to acknowledge the significance of a child's genetic inheritance.[23] All of these situations were initially created as we thought they were in the best interests of the children involved.

Margaret Somerville comments that "donor conceived people are challenged to prove 'scientifically' the harm done to them." She continues that it is unfair to expect the "impossible", as how do you gauge harm? Further, Somerville proposes that we listen to donor conceived people and recognise how they feel, acknowledging that the harms may not become evident until early adulthood when there is a natural drive to understand their origins as part of their formation of a "mature self-identity." Nurturing their own children can also enhance the dislocation that donor conceived people experience.[24] Chan et al detailed a study on children born through donor insemination programs to both heterosexual and lesbian mothers.[25] The children were found to be developing normally and "well adjusted," irrespective of their family situation. The study concluded that the best predictor of the children's welfare was the quality of the parental relationships. However, this study did not address the issue of the lack of identity that some children may encounter. Nordqvist states in her study that "matters of kinship" have not been part of the paradigm in sociological studies on the family.[26] Nordqvist notes that in the clinical situation of donor conception in a heterosexual couple the donor is "matched" with physical characteristics of the birth mother or the non-biological father.[27] This is to fit into society's ideal of the nuclear family where children resemble their parents. Lesbian couples also seek to fulfil this ideal, by seeking a donor that has physical characteristics that would allow the child to be considered the genetic offspring of the couple; this is despite the fact that their relationship does not represent the conventional model of a family. Nordqvist suggests this accepted practice is to "conceal a foundational and inevitable condition…….: non-genetic family relationships and donor conception."[28]

… "those that were donor conceived fared much worse than their peers who were raised by their biological parents" …

The American report *My Daddy's Name is Donor* which compared 485 adults conceived through donor sperm, 562 adults adopted as infants and 563 adults raised by their biological parents, established that those who were donor conceived fared much worse than their peers who were raised by their biological parents when depression, delinquency and substance abuse in the cohorts were evaluated. There were fifteen major findings with 65% stating "my sperm donor is half of who I am" and 45% troubled by their birth circumstances, in particular when money was involved in their conception.[29] They hurt more, felt more confused and alienated from their family and often looked at people whom they may resemble speculating on a possible relatedness and felt a dread of falling in love with a half-sibling.[30] Although parents would have turned to an alternative means of making a family later in their marriages, 44% of donor conceived children experienced at least one family transition before the age of 16 compared to 22% of the adopted children and 35% of the biological children.[31] Curiosity about biological fathers was most prevalent in families headed by a single mother with 71% of children expressing an interest compared to 65% of children born to heterosexual couples and 46% of children born to lesbian mothers.[32] With approximately two-thirds of the donor conceived adults supporting the right to access at least non-identifying information about their biological father, the move of some Australian states to ban anonymous donation is a positive one.[33]

Limits need to be placed on the number of families a donor can potentially donate to, for a number of reasons. Children need to be able to form meaningful relationships with their donor conceived siblings. This is not easily done (as the Senate Committee was informed) if large numbers of children are conceived by the same donor.[34] Further, the fear of forming an intimate relationship with an unknown sibling becomes a life-long fear, which bridges the generations. Not only do these donor conceived children live in fear of consanguinity, but they live in fear of consanguinity for their children as well. As one mother who conceived a child through sperm donation declared when she could not locate any of her child's half-siblings, he "will simply have to have genetic testing with any girl he seriously considers having sex with."[35]

Today the opportunity exists to buy an oocyte from one country, retrieve sperm from another, create an embryo and gestate it in another. Is this in the best interests of the parent(s) or the child? Joanna Rose is a donor conceived person who won a High Court case in Britain to ban anonymous sperm donation and is the founder of Tangled Webs. Joanna felt the separation of her parents when she was about ten years old was due to the strain on her parents' marriage caused by the lack of a biological link between her father and both herself and her brother (who may have a different donor father).

> "For Joanna, one painful irony is that despite her striking success at the national level she still does not who her own biological father is. She was given a tip that he might be a certain doctor. But after writing to him twice, seeking information on her medical history and ethnic background, and hoping for any sense of closure he might be able to give, all she has received from him are 'legal threats and disregard.' If he is her father she feels doubly abandoned by him, the first time when he walked away from a child he conceived when he gave away his sperm, and the second time when he rejected her when she was grown. She still would like to know whatever she can about

her biological father, whoever he may be. 'Anything is better,' she says 'than the paternal oblivion I am left with now.'"[36]

One of the aims of Tangled Webs is to present "an alternative voice to ARTs through greater recognition for the complex, lifelong issues that affect the person created through donor conception."[37] This voice is not often heard. As a society we are sympathetic to infertile couples, both medically and socially. Society is also sensitive towards the ticking biological clocks of single women. However, the report *My Daddy's Name is Donor* found that those who are donor conceived and have reservations are less likely to publicly articulate their view.[38]

… "'Anything is better,' Joanna says 'than the paternal oblivion I am left with now.'" ...

Many issues faced by adopted people and donor conceived people can be similar as seen by the following comments where each is seeking knowledge.

"I wanted to meet up for some information-type purposes – to see what I looked like, missing pieces, that kind of thing. Curiosity and like completing the picture." (adopted woman, 2000)[39]

"I found out my biological father was a vial of frozen sperm labelled 'C11' when I was 21. Finding out so late was a huge shock. With my childhood already behind me, the neural connections identifying my dad as my dad were cemented. Emotionally I could never think of him as anything other than my dad (and I still don't), yet suddenly I was told we were genetic strangers. My identity had been splintered and the social and biological aspects of parenthood carved up. In the place where I inherited half my genes, all I could see was a vial of semen in cold storage. I mourned the human face behind that vial, somebody I had never and would never meet. A little bit like a mother might mourn the baby she could never have, I suppose." (donor conceived woman aged 21, 2005)[40]

"I need to find the mystery man because this information is infinitely personal to me. It is linked to my personality and medical health and will explain the questions in my head and mend the hole in my heart…." (Donor Conception Support Group, 1999)[41]

"I think it is preposterous that anyone would expect me not to wonder about and want to know who this man is. …. This does NOT mean that I desire a personal relationship with the donor or his family members…..I do not imagine or wish for a 'replacement father.' … My curiosity is mainly genealogical in nature: a 'family tree' project, if you will." (Melody, donor-conceived adult, told by her godmother at 33).[42]

Victorian Legislation – a case study

The Victorian *Infertility (Medical Procedures) Act 1984* implemented on 1 July 1988 was the impetus for the establishment of the Central Register which was administered by the Chief General Manager of the Health Commission. This Register was established to record information for those involved in donor conception. They could release identifying information to a donor regarding their donor-conceived offspring or advise a donor-conceived person of their donor. However, this identifying information could only be released with written permission. Prior to the introduction of this *Act* it was the individual clinic policy that controlled what non-identifying information could be released as donor anonymity was assured. The Victorian *Infertility Treatment Act 1995* was implemented on 1 January 1988 with its prevailing interest being that of the donor conceived person. The Infertility Treatment Authority (ITA) was established under Section 82 of this *Act.* This Act also launched the Donor Treatment Procedure Information Register known as the Voluntary Register. This register collects information provided on a voluntary basis by gamete donors, donor conceived persons and their relatives and descendants. In 1998, the Voluntary Register and the Central Register were administered by the ITA. An adult donor conceived person can access identifying information from the ITA if a donor gave approval for use of their gametes after 1 January 1998. On the other hand, the parents of either gamete donors or donor conceived persons require the person's written permission to access identifying information.

… "I found out my biological father was a vial of frozen sperm labelled 'C11'" ...

In 2001, this *Act* was further updated to allow people who were involved in procedures prior to 1 July 1988 to provide personal information to the Voluntary Register.

The implementation of the Victorian *Assisted Reproductive Treatment Act 2008* in 2010, required that clinics and independent doctors who provide donor gamete treatment must disclose to the Registrar of the Victorian Central Register, details of the child who is born consequent to the provision of donor gametes, the birth mother, and details of the gamete donor. The Registrar of Births, Deaths and Marriages in Victoria assumed responsibility for the Central Register and the Voluntary Register under this *Act*. One of the major changes of the 2008 *Act* was to allow children under 18 with parental consent to access identifying information regarding their gamete donor. These advances through the 2008 *Act* help to alleviate some of the anonymity and to allow donor conceived people access to what is their biological inheritance.[43]

ITA Victoria released a booklet *Telling It Your Way* in 2007.[44] This book seeks to be a guide for parents of donor conceived children on how and when families may decide to inform their children of their genetic heritage. The publication of this book was timely. In 2006 the first cohort of children born under the 1984 Victorian legislation (implemented on 1 July 1988) turned 18. This legislation meant that if parents had not disclosed to their children the origins of their conception then it may happen through another source or a letter from the ITA. Victoria is one of a small group of legislative jurisdictions globally who allow donor identifying information to be released when a child reaches 18 years of age. The book provides some profound advice to parents of donor conceived children - "children will be influenced by their parents' attitudes; it's important that parents have come to terms with having donor-assisted conception. At the same time, they need to accept that their children might see the matter differently."[45]

… "A moral compass that is child-centred rather than based on the desires and rights of parents could enlighten ART practices." ...

Conclusion

The creation of a child through gamete donation revolves around the rights of the would-be parents. There is a market which indulges the reproductive desires and privacy of the parents. However, in this rush to fulfil the desires and rights of the parents, and to utilise the technologies available, are the rights of children who are born as a result of the technologies also considered? In ART clinics, the attention is focussed on the parents, who are the consumer of the product, the fertility treatments that will provide them with a pregnancy. While a pregnancy is a desirous and understandable outcome for the parents, this review has provided an insight into the children who are born as a result of these interventions. A moral compass that is child-centred rather than based on the desires and rights of the parents, could enlighten ART practices.[46] While the number of children conceived through sperm donation has levelled, the number of children born through oocyte and embryo donation has been steadily increasing. The differences in these practices are due to the advancement of technology not due to advances that are for the betterment of the children conceived and born.

While we were busy protecting the rights and identity of gamete donors during the early stages of ART practices, often stating that if the anonymity was taken away the number of donors would decrease, adoptees were being given legislation to allow them to trace their genetic heritage. Can we learn from the mistakes of yesteryear? The report *My Daddy's Name is Donor* states that donor conception is not just like adoption. Adoption finds parents for children who need parents due to the child being unable to grow up within their natural biological structure. Donor conception is about deliberately denying children any chance of growing up with both their biological parents. The similarity between adoption (a now uncommon practice) and donor conception (a practice that is rising on examination of oocyte and embryo donation) are the common struggles over identity and this is what should ask us to proceed with prudence.

ENDNOTES

[1] Congregation for the Doctrine of the Faith, *Dignitas Personae (Instruction on Certain Bioethical Questions)*, #6, Holy See, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html

[2] Congregation for the Doctrine of the Faith, *Donum Vitae (Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation)*, II.A.2, Holy See, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html

[3] When Artificial Reproduction Technologies (ARTs) were first utilised, clinics were only permitted to provide assistance to heterosexual couples who were in a genuine domestic situation. In Victoria this changed with *John McBain vs State of Victoria & Others*, Federal Court of Australia, http://www.austlii.edu.au/au/cases/cth/federal_ct/2000/1009.html

[4] Sonia Fader, "Sperm Banking History, An excerpt from 'Sperm Banking: A Reproductive Resource,'" California Cyrobank Reproductive Tissue Services, http://www.cryobank.com/Learning-Center/Sperm-Banking-101/Sperm-Banking-History/

[5] Collin Matthews, "The establishment of a human semen bank and early results with artificial donor insemination," *Aust NZ J Obstetrics and Gynaecology* 13 (1973): 40; Frank Quinn and Cherish Borosh, "Oocyte donation in assisted conception," *O&G Magazine* 9, no.4 (2007): 12-13 at 12.

[6] Quinn and Borosh, 12.

[7] Paul Lancaster, Esther Shafir, and Jishan Huang, *Assisted Conception Australia and New Zealand 1992 and 1993*, 42, Australian Institute of Health and Welfare National Perinatal Statistics Unit Sydney, http://www.npsu.unsw.edu.au/PRERUWeb.nsf/resources/ART_1991-97/$file/ac1.pdf

[8] Lancaster, 28, 34, 42.

[9] Ibid., 42.

[10] Joanne Bryant, Elizabeth A Sullivan, and Jishan H Dean, *Assisted reproductive technology in Australia and New Zealand 2002*, 36, 10, 44, 18, 40, Australian Institute of Health and Welfare National Perinatal Statistics Unit, http://www.preru.unsw.edu.au/PRERUWeb.nsf/resources/ART_2000-02/$file/ART8+report+30_9_04.pdf

[11] Yueping Alex Wang, Georgina M Chambers, and Elizabeth A Sullivan, *Assisted reproductive technology in Australia and New Zealand 2008*, 32, Australian Government, Australian Institute of Health and Welfare www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=6442458980

[12] Wang, 4, viii. Not all statistics are included in each year's report, thus there is a variation in the presentation of data from the Australian Institute of Health and Welfare.

[13] In intracytoplasmic sperm injection, a single sperm is injected into an oocyte, increasing the chances of conception compared with traditional IVF techniques. Vanessa J. Kay and Christopher L. R. Barratt, "The use of donor insemination" in *The Subfertility Handbook: A Clinician's Guide,* ed. Gab Kovacs (New York: Cambridge University Press, 2nd edition 2011), 148-157 at 148.

[14] Australian Institute of Health and Welfare, *Adoptions Australia 2009-10*, 12, Australian Government, Australian Institute of Health and Welfare, http://www.aihw.gov.au/

publication-detail/?id=6442472452&tab=2
[15] Legal and Constitutional Affairs References Committee, *Donor conception practices in Australia*, Commonwealth of Australia, http://www.aph.gov.au/Senate/committee/legcon_ctte/donor_conception/report/report.pdf
[16] Ibid., 1, 3.
[17] Ibid., 58, 63, 65-6, 80-1, 91-2. [18] Ibid., 5-7, 12.
[19] National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practices and Research June 2007,* 25, National Health and Medical Research Council,http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e78.pdf
[20] Legal and Constitutional Affairs References Committee, 10, Office of the United Nations High Commissioner for Human Rights, *Convention on the Rights of the Child,* United Nations, 1989, Office of the United Nations High Commissioner for Human Rights, http://www2.ohchr.org/english/law/crc.htm
[21] Although this is the preferred option for a child to flourish, a child who cannot be assured of this right may need to be placed in an alternative situation where they can flourish.
[22] Elizabeth Marquardt, Norval D. Glenn, and Karen Clarke, *My Daddy's Name is Donor* (New York: Institute for American Values, 2010).
[23] Kevin McGovern, "Adoption is better than Abortion," *Chisholm Health Ethics Bulletin* 16, no 1 (2010): 4-9 at 5-6.
[24] Margaret Somerville, "Donor conception and children's right: 'First, do no harm,'" *Canadian Medical Association Journal* 183, no. 2, (2011): 280.
[25] Raymond W. Chan, Barbara Raboy, and Charlotte J. Patterson, "Psychosocial Adjustment among Children Conceived via Donor Insemination by Lesbian and Heterosexual Mothers," *Child Development* 69, no. 2, (1998): 443-457.
[26] Petra Nordqvist, "Put of Sight, Out of Mind: Family Resemblances in Lesbian Donor Conception," *Sociology* 44 (2011): 1128-1144.
[27] Ibid., 1129. [28] Ibid., 1141.
[29] Marquardt, Glenn and Clarke, 7. Gamete donation in the United States attracts significant financial incentives compared to Australia where only out of pocket expenses are covered.
[30] Ibid., 5-6. [31] Ibid., 9.
[32] Ibid., 10-11. [33] Ibid., 11-12.
[34] Legal and Constitutional Affairs References Committee, 101-2. The committee suggest that a maximum should be set at four families. However the lack of Commonwealth legislation allows donors to donate in one jurisdiction and then move to another to provide further donations.
[35] Marquardt, Glenn and Clarke 35.
[36] Ibid., 27-8. [37] Ibid., 27-8. [38] Ibid., 67.
[39] Marilyn Crawshaw, "Lessons from a recent adoption study to identify some of the service needs of, and issues for, donor offspring wanting to know about their donors," *Department of Social Policy and Social Work,* University of York, Heslington, York, YO10 5DD, UK, 8.
[40] Lauren and Barbara, "Talking To Young Adults About Their Conception," Victorian Assisted Reproductive Treatment Authority http://www.varta.org.au/www/257/1003057/displayarticle/1003786.html
[41] Crawshaw, 8.
[42] Maggie Kirkman, Doreen Rosenthal, and Louise Johnson, *Telling It Your Way: A guide for Parents of Donor-Conceived Adolescents* (Victoria: Infertility Treatment Authority, 2007), 53.
[43] State Government of Victoria, Victorian Registry of Births, Death and Marriages – Births – Births FAQs, https://online.justice.vic.gov.au/CA256902000FE154/Lookup/BDMContentSite-PDFs/$file/ART-Q&As.pdf; Births, Deaths and Marriages, Victoria, Background: Donor treatment registers, State Government of Victoria Department of Justice, http://online.justice.vic.gov.au/CA256902000FE154/Lookup/BDMContentSite-PDFs/$file/Background-DonorTreatmentRegisters.pdf
[44] Kirkman, Rosenthal and Johnson. [45] Ibid., 25.
[46] Raymond Devettere, *Practical Decision Making in Health Care Ethics* 3rd edition (Washington: Georgetown University Press, 2010), 258.

All on-line resources accessed 22 August 2011

Kerri Anne Brussen ✠

Caroline Chisholm Centre for Health Ethics

Suite 47, 141 Grey Street, East Melbourne Vic 3002

Tel (03) 9928 6681 Fax (03) 9928 6682 Email: ccche@stvmph.org.au

www.chisholm.healthethics.com.au

Subscription fees: Single $30.00 + GST; Overseas [single] AUD $40.00

Director/Editor: *Rev. Kevin McGovern Dip Ap Sc (Optom) (QIT), STL (Weston Jesuit School of Theology)*

Research Officers: *Mrs. Kerri Anne Brussen BApp Sci (RMIT), Grad Dip Health Ed (La Trobe)*

Administrative Assistant/Layout/Sub-editor: *Josette Varga*