Legislative responses to recommendations of the Lockhart Review – submission to the Senate Inquiry

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I write in response to your invitation to provide a written submission addressing issues relevant to the forthcoming inquiry regarding the recommendations of the Lockhart Review and the Exposure Draft of a *Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill* (2006).
I wish to first express my support for scientific research that would improve the treatment outcomes or prevention of infertility, or improve the health of the population generally. However at the same time I wish to raise an issue I perceive to be important and that has not received sufficient attention.

These issues concern the ethical sourcing of human genetic material – ie. human oocytes (eggs) and embryos that will be used in stem cell research and SCNT. It is my view that we should not proceed further by expanding regulatory policy to include SCNT research until we have fully considered the implications to the community in sourcing material for this work. Specifically we need to consider where the genetic material required for progress will be sourced and under what conditions we are comfortable with it being obtained. We cannot and indeed should not assume human ova will be readily available and if they are not, we must consider what measures we are prepared to adopt to obtain them – including but not exclusively, financial measures.
In raising this issue I am concerned to specifically (a) protect the interests and protection of infertile women patients who are potential donors of genetic material such as oocytes (eggs) or embryos, and (b) advance the fair management of gamete donation alongside scientific progress.

Background

In the drafting of the current legislative framework that allows and regulates research involving embryos there has been due attention paid to societal interests and the consequences of destroying human embryos. Further, in the Draft Explanatory Memorandum to the Bill Senator Stott-Despoyer has laid out the consequences to science itself of restricting research so that it cannot progress in a competitive global context. Clearly scientific progress is a matter of national interest. The commercialised research context is a province of ethics because stem cell research is not just a matter of community need for effective cures or treatments of debilitating diseases. Stem cell research is also concerned with national reputations and scientific prestige – in other words economies of knowledge and credibility (Franklin 2006). Moreover stem cell research is concerned with commercial development, venture capital and lucrative profits.
But stem cell research relies on the donation of genetic material from women, exclusively (for the moment) infertile women patients of IVF programs and their partner if they have one. I urge the committee to carefully consider the consequences to these women of the proposed amendments.

The amendments extend the use of genetic material in research from excess embryos to human oocytes without due regard to the source of the material that will be sought, the impact of this shift in source to women and in particular to infertile women, and the fair management of oocyte and embryo donation in the context of commercialised scientific research.

The doctrine of informed consent has gained salience in medical and research procedures. The existing *Research involving human embryos* Act (2002) and Licensing Committee guidelines rely heavily on the processes of informed consent to protect embryo donors in the context of competitive and profitable scientific research. However, infertile women undergoing IVF procedures should be considered vulnerable in the sense that due to their patient status and the stressful circumstances within which the donation of eggs is requested they are susceptible to feelings of obligation, duty and may be easily persuaded to agree to donation (Hoffmaster 2006). Infertile women endure much stress from repeated invasive procedures and the self-regulation necessary for success, and are subject to the authority of medical practitioners upon whom they rely for a positive outcome from their treatment.

The source of genetic material

There is an over-reliance on infertile women in the supply of gametes such as embryos and eggs for research. At present 100% of the embryos used in research are donated by infertile patients who have determined that they wish to have no further treatment. Patients derive no benefit from their donation other than their perception that their considerable effort in creating embryos and the potential of embryos is not wasted (de Lacey, unpublished data). In my recent study of patients' decisions for excess embryos several participants were interested in supporting stem cell research but the majority were more supportive of research that they perceived would benefit infertile couples through the improvement of treatment procedures and outcomes. Some participants in my study were suspicious and wary of donating embryos to stem cell research because they were concerned about the possibility of cloning or found the idea of embryo destruction in general morally abhorrent. However others were interested specifically in donating embryos to stem cell research, some for community benefit with regard to specific diseases or disabilities and some for their own personal health benefit.

Fresh embryos

Frozen embryos will continue to be sought for infertility research but increasingly fresh embryos are being sought. These embryos have been judged to be too poor in quality to freeze or transfer. Yet technically it is not yet possible to categorise embryos in this way with certainty. Clinical experience attests to the fact that when no good quality embryos are available and poor quality embryos are transferred, pregnancies sometimes occur.

Practices of grading IVF embryos enhance the vulnerability of patients. For instance in a paper reporting findings of focus group data participants were reported to be confused about the concept of 'viable' or 'quality' embryos (Parry 2006). In a Swedish study where embryos were judged unsuitable for transfer or freezing 90% of patients donated them during treatment to stem cell research. Interestingly 10% of these embryos went on to form Blastocysts thus raising a question as to the accuracy of the grading criteria (Bjuretsen and Hovatta 2003). In a study in the UK where researchers recruited fresh embryos deemed unsuitable for transfer or freezing, 94% of patient couples gave their consent on the day of egg retrieval. On the day of egg retrieval it cannot be known conclusively how many embryos there will be for their own treatment and what quality they will be. The remaining 6% of patients donated on the day of embryo transfer. This behaviour could

be interpreted as extremely generous or altruistic, or alternatively it could be a symptom of deference to medical authority.
In my own study the decisions of participants varied in their qualitative freedom. Decisions for frozen embryos were most often influenced to varying degrees by frozen embryo storage fees imposed by clinics or by embryos storage time limits imposed by regulatory bodies.

Human Ova

If amendments are made to allow Somatic Cell Nuclear Transfer (SCNT), therapeutic cloning, human oocytes will be preferred. A source of eggs for stem cell research in the UK has been surplus eggs donated from IVF patients. An advantage of this source is argued to be that the donor women are already undergoing the medical procedures necessary for the collection of eggs. This perceived advantage makes infertile women having IVF treatment vulnerable to recruitment strategies.
Research has so far relied on the donation of embryos that are excess or surplus to a patient's treatment. But there is no such thing as a 'surplus' egg. Every egg collected represents a potential embryo and a potential pregnancy for an infertile woman. Donating eggs to research during treatment is likely to reduce the woman donor's chance of success thereby increasing her risk of ongoing childlessness, her use of ART and elevating the costs involved, and thereby risking harm to her. In the absence of any monetary incentive it is yet to be seen just how many women will come forward and subject themselves to these procedures in the interests of science. There is the possibility that women in the community may offer to donate eggs but given the degree of risk, discomfort and inconvenience involved in egg donation it is a far more likely scenario that infertile women will be targeted for egg donation and indeed in the UK this is already the case (Draper 2006). In the recent case of the Dr Woo Suk Hwang scandal in Korea, eggs were donated by female members of his research team (Snyder and Loring 2006) suggesting that perhaps only women scientists or staff within laboratories appreciate the importance of donating eggs for scientific research. Alternatively it suggests that coercion and deference to authority extends beyond the province of therapeutic relationships.

Fair management of embryo or egg donation

The draft legislation aims to prohibit practices in which infertile egg donors may be induced to donate (see: 15 Offence - commercial trading in human eggs, human sperm or human embryos, p5). This rightly precludes the possibility of compensated egg-sharing [1]. The draft legislation also prohibits payment other than expenses to women in the community who may be recruited to donate eggs for research yet implies that reasonable expenses such as those incurred in connection with the donation of eggs can be met.

We ought to be concerned about money, payment and its potential for corruption and coercion, and payment for donation of eggs could be perceived to be an inducement. In the case of embryos a payment is rather too close to the notion of buying children. However inducements are widely recognised as coming in many forms other than money (Grady 2001). For example, it has recently been argued that so-called informed decisions in medical care and participation in research can sometimes involve simple deference to medical authority rather than self-determination (Corrigan 2003; Kukla 2005). Currently infertile women donate embryos without re-imbursement but their

[1] In the UK a practice known as 'compensated egg-sharing' has been adopted. Egg share arrangements traditionally allowed one patient to share eggs with another woman in exchange for receiving treatment at a reduced cost. The practice is contentious and just tolerated by the Human Fertilisation and Embryology Authority (HFEA) who have not yet acted to prohibit it. Compensated egg sharing is also currently being considered for the donation of eggs to research.

contribution is rarely acknowledged. In previous debate and media coverage they are almost invisible in discussions about scientific progress and indeed IVF funding was the subject of Government review in 2005. In this context mandatory *non*-payment is perceived to be exploitative (Dickenson 2001; Bovenberg 2005; de Lacey 2006). Compensation for effort, or systems of benefit-sharing (Le Bris and Luther 2004) could be considered as a form of valuing donation (de Castro 2005).

While donors are precluded from compensation or reciprocal benefit, scientists are encouraged in their acquisition of patents and other lucrative commercial gains in the process of their research. This is unjust when aside from the out of pocket expenses incurred in treatment for infertile patients there are many non-monetary expenses incurred for both embryo and egg donors – such as loss of work in sick leave, paid care for existing children and so forth.

Summary

We should not proceed to allowing SCNT until an ethical sourcing of human eggs or fresh embryos has been thoroughly considered, debated and ethical guidelines developed. In this process community donors should be considered the primary source of donated genetic material. Further, in the interests of social justice, the issue of benefit-sharing in relation to scientific profit should be seriously considered.

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