Published in final edited form as:

Hum Fertil (Camb). 2006 June ; 9(2): 67–71. doi:10.1080/14647270500422075.

Studying potential donors' views on embryonic stem cell therapies and preimplantation genetic diagnosis

ERICA HAIMES and JACQUELYNE LUCE

Policy, Ethics and Life Sciences (PEALS) Research Institute, Bioscience Centre, International Centre for Life, Newcastle upon Tyne, UK

Abstract

Embryo experimentation raises many ethical questions, but is established as acceptable practice in the UK under the Human Fertilisation and Embryology Act 1990. The development of preimplantation genetic diagnosis (PGD) and embryonic stem (ES) cell research is dependent on couples undergoing in vitro fertilization (IVF) donating for research embryos that are unused in, or unsuitable for, treatment. Rarely is the role of these donors acknowledged, let alone studied. One concern is whether couples feel an obligation to donate embryos because of their gratitude for the IVF treatment they have received. This article, based on an ongoing study investigating the similarities and differences between the views and values of those IVF couples who agree to donate embryos for research and those who refuse to donate embryos, explores the broader issues around embryonic research. Discussions such as this, embedded in a background of empirical research, will assist practitioners and policymakers in assessing the social and ethical contexts of this very important aspect of current and future scientific developments.

Keywords

Embryo research; donors' views; IVF

Introduction

This article explores the wider social and ethical issues around embryo experimentation. It is based on an ongoing Wellcome Trust-funded study on the views of in vitro fertilization (IVF) patients who have been asked to provide embryos (that are unused, or unsuitable, for treatment and that are commonly designated as 'spare') for embryonic stem (ES) cell research, and for research to assess the effects of preimplantation genetic diagnosis (PGD) on embryo development. These issues need to be considered from the potential donors' perspective if we are to gain a fully rounded understanding of the social and ethical implications of research on embryos. This is particularly important in light of recent debates regarding the applications and implications of PGD, the use of embryonic stem cells for research and the development of therapies.

The aim of this ongoing study is to provide practical feedback to clinical scientists, practitioners and policymakers involved with genetic and reproductive medicine. It will provide much-needed data on the ethical and social acceptability of embryo experimentation to potential donors. It will also contribute new knowledge to bioethical debates on embryo

research. This article briefly summarizes the well-established debates around embryo experimentation and raises new questions about how these debates might be perceived by the potential embryo donors. By taking an approach that foregrounds the potential donors' views and values, we identify fresh insights to these debates.

Social and ethical aspects of embryology

As tissue sources, embryos present the same sort of opportunities for controversy as do donor cadavers and fetuses: they reside at the margins of human life, and their relationship to the human community and human status is ambiguous and contestable.

Waldby & Squier, 2003

Embryo experimentation raises many questions, including the ethics of conducting research on potential human beings, the definitions of the start of human life and the possible destruction of that life. However, it has been established as an acceptable practice in the UK by the Human Fertilization and Embryology (HFE) Act 1990. Justifications which have been made for embryo research include:

- 'the argument from suffering' (because of its potential to treat disease);
- 'the argument from twinning' (i.e. that early embryos are not human individuals because of the potential of blastocyst cells to develop into two human beings);
- 'the argument from capacities' (i.e. that embryos lack the ability to think, act and communicate so cannot therefore be accorded full status as human beings); and
- 'the argument from potentiality' (i.e. that the embryo is not a human being, even though it has the potential to become one under specific circumstances).

Even so, most regulatory bodies agree that respect for early human embryos is appropriate and that research requires careful regulation. Since the HFE Act 1990, the grounds for research on human embryos (up to 14 days old) have been: advancing fertility treatment, improving knowledge about congenital disease and miscarriages, improving contraceptive techniques and developing methods for detecting the presence of gene or chromosome abnormalities before implantation of the embryo (House of Lords, 2002; Song, 2002).

PGD received least public attention when the Act was passed, but has since generated additional ethical and social concerns. These include:

- whether it devalues individuals with impairments, given its aim to eliminate those impairments before embryo replacement;
- its potential to be used for sex selection;
- the fear that it might lead to a demand for testing embryos for common disorders;
- whether embryos that are carriers, rather than directly affected by a condition, and embryos affected by a late onset disorder, should also be excluded from transfer; and
- whether parents should be allowed to choose to have an affected embryo replaced.

Nonetheless, PGD is regarded by its proponents as having much to offer families who are confronted with the possibility of a child affected by genetic disorders such as cystic fibrosis or Huntington's disease. It is argued that PGD reduces the need for prenatal diagnosis and subsequent abortions (Beyleveld, 2000; Anstey, 2002). However, more research is needed to improve PGD techniques and assess the effects of blastomere removal; this, in turn, is

dependent on embryos being donated by couples from IVF programmes. Rarely is the role of these donors acknowledged, let alone studied.

In 2001, the Human Fertilisation and Embryology Act defining the acceptable purposes of embryo research was amended, and the UK became the first country in the world to allow ES cell research. Many other jurisdictions have not followed this move because ES cell research raises all of the ethical concerns around embryology cited above (Heinemann & Honnefelder, 2002; Romeo-Casabona, 2002). In addition, there is contention surrounding whether adult stem cells could be used instead of embryonic stem cells. There is also a concern that cell nuclear replacement, used to create embryos, raises the possibility of reproductive cloning. However, ES cell research is seen as a very promising area for future therapy, since embryonic stem cells are 'totipotent' (they are thought to be capable of developing into all of the two hundred different cell types) and potentially 'immortal' (they have the capacity to replicate themselves indefinitely). It is anticipated that cell lines could be established to provide patients with diseases which result from the degeneration of certain cell types (e.g. Alzheimer's, Parkinson's, heart and liver disease) the chance to replace these cells with new ones. ES cell research could also lead to a better understanding of the genetic basis of disease (Vogel, 2001; Holm, 2002).

In the UK, research gained impetus with the Medical Research Council's announcement in September 2002 that a stem cell bank was to be established, and its subsequent opening in May 2004. A major difficulty in ES cell research is the lack of understanding of how stem cells differentiate into particular cell types, demonstrating the need for further research, which is reliant on the donation of embryos by IVF patients. Again, only rarely have discussions about the ethics of ES cell research involved consideration of the embryo donors' perspective. Exceptions include the Nuffield Council (2001), Harris (2002) and Parry (2003), who suggest that it is important to know whether embryo donors understand the purpose and nature of the research they are contributing to and whether there is indirect pressure on IVF patients to donate, given their possible gratitude to clinical staff. An additional consideration is whether donors appreciate the potential for their cell lines to be 'immortalized' and whether this concerns them. Generally, therefore, there is a lack of data on the views and values of the couples who are asked to donate embryos for PGD and ES cell research. It is this gap which our ongoing study aims to fill. It is important to know whether those asked to donate embryos for research assign a similar relevance to the arguments of scientists and ethicists or whether they appeal to other arguments, in explaining why they do, or do not, donate their embryos. Some initial indications of factors influencing the donation of fresh (as opposed to frozen) embryos are available from a recent study by Choudhary et al. (2004). This study, based on information collected from patient records at one clinic, shows that:

- i. fifty-four per cent of couples undergoing IVF/ICSI treatment consented to donate their surplus embryos for research;
- ii. the number of ovarian follicles at pre-hCG scan and the number of embryos obtained were significantly higher in couples consenting to research;
- iii. couples with previously failed fertilization were less likely to consent to embryo research;
- iv. the funding source of treatment (NHS or private) did not appear to influence the decision to donate; and
- v. couples of ethnic minority origin were less willing to consent to research.

However, this study is limited in its ability to explain why couples choose, or decline, to donate their spare embryos; that is, why and how the factors identified above are associated

with their decision, and whether other factors might be raised as being significant by the couples themselves. Also, given the ethical concerns already identified, the 54% donation response rate raises questions. Is it that donors: (a) are well disposed towards this clinic and are not fully aware of the implications of donating embryos; (b) do not share the concerns of others; (c) perceive the benefits of donation to outweigh any concerns; or (d) feel their concerns have been fully addressed and their anxieties allayed? Equally, why do some couples decline to donate? Do they make a conscious decision not to donate because they have concerns similar to those already cited or because of other, as yet unknown, concerns? Non-donors might be better informed about the implications; it has been suggested that those who are most informed about bioscience have the most polarised views (Crook, 2000).

Broadly, we need to know the repertoire of perceptions, concerns, views and understandings that couples, who have been asked to donate their embryos for research, consider, as part of the process of deciding whether or not to donate. To address this, the following more detailed areas of inquiry need to be covered:

- i. What are the personal and family biographies of donors and non-donors, and do these differ significantly between the two groups?
- ii. What knowledge, attitudes, values and concerns do couples have about and towards PGD, ES cell research and embryo research in general? Do they distinguish between these different uses?
- iii. What do couples think they are being asked to consent to? What are their understandings of the short- and long-term potential use of the embryos? How do they view the notion of 'spare' embryos? Do they want to impose any limits on embryo research? If so, what and why?
- iv. How do couples view their potential donation? Who do they think would benefit or suffer from the donation? Have these views altered at all in light of their treatment experiences (such as the outcome of being pregnant or not)?
- v. What are couples' views of the consenting procedures?
- vi. Are there differences between the views of couples who have used IVF technology to try to conceive and those who have not, on the moral status of the embryo and on embryo research? What personal, social and ethical factors shape these positions?
- vii. How are the views and values of couples expressed, adapted, challenged, revised and confirmed when they enter into dialogue with others who hold broadly similar or sharply contrasting views?

These questions, and the resulting responses, allow a broader set of questions to be considered. For example, it will be useful to know how decisions regarding embryo donation in the context of PGD and ES cell research compare to decisions about tissue donation in other contexts. As Haimes and Whong-Barr (2003) and Hoeyer (2003) demonstrate in their respective research on donations to biobanks, the concept of informed consent is embedded in contexts, in lived histories and meanings associated with treatment, organs, blood, cells, tissue and research. Signing a consent form, on the basis of information provided and offered, is not necessarily an indication that the person consenting is informed, nor does it provide an indication of why the individual has consented to participation in research. Rather, providing, reading, signing and returning the consent form are acts in a series of communicative engagements which assume meaning according to the broader contexts in which they occur. Such comparisons, therefore, will shed much-needed light not just on the concept of 'donation', but also on the much debated concept of 'informed consent', and might further our understanding of the broader issues surrounding the donation of cells, tissues and organs.

Another important consideration is the extent to which the conflicting views of those couples who do and do not donate should be incorporated into the ethical, legal and social debates surrounding embryology. Should they play a central role in policymaking, as the key source of the ethically contentious material, even if they decline to provide that material? Does their pivotal role give them a privileged position in these debates, or should this role mean that they should simply be one voice among many?

A third related question is what role can empirical data play in shaping ethical guidance and policymaking in embryology (Haimes, 2002)? One argument might be that the normative claims of formal ethics take precedence over the interesting, but logically flawed, views of non-ethicists. An alternative argument is that such views constitute a challenge to formal logic and should be taken seriously, if only because they inform and shape the actions of practitioners and non-professionals as they go about their everyday tasks, including, of course, requesting and giving or refusing consent to research.

Clearly these questions and debates are themselves related to wider discussions about the roles of commodification and consumerism in healthcare more generally (and indeed in any sphere of professional activity). These debates indicate, by their very existence, that the very practice of embryo experimentation is subject to a number of competing discourses (at the very least scientific, clinical, legal, ethical, professional and 'lay'), each keen to shape the moral framework of practice. These discourses have proliferated as understandings of the complexities of embryo experimentation, and its wider impact, have increased. A question that clinicians reading this article might like to ask themselves is what weight do they, and what weight should they, give to the views of their patients when conducting their everyday practice, developing practice guidelines and implementing informed consent procedures? The responses might well be varied, but the point of asking the question is to stimulate further thought around these issues at a time when 'lay' discourses are having an increasing impact on professional practice.

These broader questions indicate that whilst embryo experimentation is a very important issue in its own right, it can both contribute to, and learn from, debates in related fields.

Summary

In summary, we argue that the extent to which donation and non-donation are aligned to the arguments presented earlier by ethicists, or to more widely held concerns, and the extent to which nondonation is a distinct stance from donation, are matters for empirical investigation. It is important to know how much donors understand about what they are actually agreeing to. Equally, evidence of good consenting practices by clinical research teams needs to be identified so that these can be applied more widely. In brief, it is important for policymakers, researchers and practitioners to know whether the practical gains of embryo donation are achieved at social and ethical costs. If they are, what are those costs? Finally, is such a cost-benefit analysis the only, or most suitable, model for judging these practices? Central to these discussions are the views, values and experiences of the potential donors themselves.

Acknowledgments

The authors wish to thank the Wellcome Trust for their support of this research and Dr Michael Barr, Dr Meena Choudhary, Dr Jan Deckers, Susan Dowdle and Professor Alison Murdoch for their contributions to this study. They would also like to thank the referees for their useful comments.

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