

HFEA Consultation

Donating Eggs for Research: Safeguarding Donors

A Response from the Evangelical Alliance

The Evangelical Alliance, founded in 1846, and born out of the fight for civil liberties, is the umbrella body that brings together a majority of Britain's 1.3 million Evangelicals. In 2005 40% of the church going public was Evangelical¹. Furthermore, 2005 statistics showed that 26% of Anglicans, 87% of Baptists, 79% of Independents, 32% of Methodists, 93% of Pentecostals, 26% of URC members, and 69% of other churches identified themselves as Evangelicals². The Alliance exists to promote unity and truth amongst these churches, individuals and evangelical organisations, and to represent their concerns to the wider Church, State and society. Amongst the many member organisations of the Evangelical Alliance are well known historic names such as the Salvation Army, CARE, the Shaftesbury Society, the Bible Society, Tearfund, etc.

We have decided to respond separately to this consultation rather than merely answer the narrow questions specified in the consultation document which we regret to note largely sidestep what we consider to be the key issues.

It is acknowledged that there are strident voices in favour of individual liberty and the right of people to have control of their own bodies and make decisions in relation to them. Nevertheless, it is crucial that in the interest of the common good, society recognises that community interests and ethical concerns for the wellbeing of the human race, not least in areas of health and welfare, require overriding protection. This, of course, involves controversial debate relating to various rights e.g., the rights of women, the rights of unborn children, the rights of scientific research, the rights of future generations to benefit from advancements in healthcare.

It is within this challenging context that the Evangelical Alliance wishes to raise crucial issues that are entirely relevant to the major question of egg donation which the HFEA is charged with deciding.

Before we respond in greater detail, we wish to emphasise two fundamental points that we believe the HFEA needs to take account of. In this regard, we acknowledge the expert input to our thinking provided by consultants working with CARE which has largely informed our response.

Firstly, as the HFEA recognises, the regulation of bioethics and embryonic stem cell research is not just a UK matter but an international one. We therefore urge that the regulatory guidance of international declarations and conventions must be heeded in the UK. The proposals in this consultation appear to be at odds with current international guidelines. These international guidelines include:

¹ *Pulling out of the Nose Dive: A Contemporary Picture of Churchgoing: What the 2005 English Church Census Reveals*, Brierley, P. (Christian Research: London, 2006), 56.

² *UK Christian Handbook: Religious Trends 6, 2006/2007*, Brierley, P. (ed) (Christian Research: London, 2006), 5.14.

1. the Charter of Fundamental Rights of the European Union: Article 3
2. the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004
3. the UNESCO Universal Declaration on Bioethics and Human Rights, Article 3
4. the Declaration of Helsinki

Our second major concern relates to the overriding priority to protect the welfare of women. We believe that the HFEA's priority should unambiguously focus on protecting women and the children born as a result of IVF treatment rather than the provision of eggs for scientific research. In this context, we must express concern that women are not being provided with the necessary facts and information to reach important decisions. For example, the medical risks for women and the long term risks involved with egg sharing and egg donation are completely understated within the consultation document.

A woman's decision concerning egg donation is severely compromised by what appears to be an unethical inducement concerning an offer to reduce IVF fees as a trade-off for egg donation. This will inevitably have a disproportionate impact on those sectors of society who are at an economic disadvantage or who are psychologically or emotionally vulnerable.

The Question of Financial Inducement

Current EU regulations permit the voluntary donation of human tissues and cells for research and treatment purposes. The voluntary donation of gametes is included in such regulations and is thus permitted.

However, offering compensation or financial benefits creates an incentive for economically vulnerable women to take known and unknown health risks for money. This is why EU agreements also make it clear that member countries should not consider this kind of inducement: "... the human body and its parts must not, as such, give rise to financial gain or comparable advantage."³

Yet the proposal in the HFEA consultation to reduce IVF fees for those who 'share' their eggs is a direct financial incentive and deliberate inducement for women to 'donate' some of their eggs. In effect, it is a 'benefit in kind' or 'financial gain', in the same way as direct monetary 'payments' would be. The Evangelical Alliance believes that offering to reduce IVF fees by way of incentive falls into the category of direct financial gain, and thus should not be permitted ethically.

We are in agreement with Dr Michael Wilks, the chairman of the British Medical Association ethics committee, who has stated:

...the BMA cannot back this practice because we feel it places unacceptable pressures on women who cannot afford IVF treatment to donate their eggs. Given the restricted provision of IVF treatment on the NHS, the offer of free or reduced price treatment, worth thousands of pounds, is a very large inducement which could affect the validity of the woman's consent.⁴

³ Explanatory Report of Additional Protocol on transplantation of organs and tissues of human origin, for Art 21.

⁴ "Free fertility treatment for egg donors wins backing", *Daily Telegraph*, 07/10/2005.

The Medical Risks for Women

A woman undergoing IVF stimulation today to conceive a child has, we assume, accepted that there are some health risks to her body from the drugs, but accepts the risks in terms of the potential benefit to conceive a child. However, the risk versus benefit calculation for a healthy woman providing her eggs, or extra 'spare' eggs, for stem cell research is not the same.

Ensuring the welfare and complete protection of women should be accorded the greatest priority, over the interests of scientific research. A woman must be provided with enough unbiased information to make the best decision for herself, including full information on the short- and long-term risks of egg extraction. The HFEA paper fails to provide adequate information on the short-term medical risks for women and it plays down the long-term risks of egg extraction. This does not serve or safeguard the interests of women.

There is a distinct lack of data in this area. The procedures and drugs used to extract eggs have not been adequately studied.⁵ The lack of investigation and analysis of drugs used for egg extraction means that women contemplating any form of egg donation are not being provided with the information necessary for making a fully informed decision.

There are significant short-term medical risks. The HFEA consultation paper states that between 1-10% of treatment cycles may result in mild and treatable ovarian hyperstimulation syndrome (OHSS) which can cause symptoms such as swelling, and in some cases blood clots and even death. However, the American Society of Reproductive Medicine says that mild forms of OHSS actually occur in 10–20% of cycles, significantly more than the HFEA claims.⁶ This figure means that between 1 in 5 to 1 in 10 of all treatment cycles could result in OHSS.

There are possible long-term medical risks. It is possible that some deaths and longer-term side effects of OHSS have not been linked officially to the egg extraction procedures that preceded them. Many clinical reports have associated infertility treatment with ovarian cancer, and two major studies have suggested a link between ovarian cancer and ovarian stimulation.⁷

Recently the Head of Reproductive Medicine at St George's Hospital in London publicly called for more research into the long-term consequences of egg stimulating drugs, warning of their effect on a woman's reproductive organs in later life and, again, of cancer risks. She also called for more research into the long-term problems associated with IVF drugs.⁸

Failure to both inform and keep long-term data does not safeguard the interests of women. Women cannot make fully informed decisions if they are not given all information on the long term problems associated with IVF drugs, including cancer, and are not told that long-term data has neither been collected nor recorded.

These medical concerns are relevant for both voluntary egg donation that is not part of IVF treatment, and for egg 'sharing' during IVF. If a woman does not become pregnant after say fertilisation of four eggs and 'sharing' two she is likely to repeat the whole procedure and increase

⁵ Parisian S., former Chief Medical Officer of the US Food and Drug Administration, open letter, Feb. 2005. <http://handsoffourovaries.com/pdfs/appendixb.doc>

⁶ "Egg harvesting for stem cell research: medical risks and ethical problems", RBM Online, Beeson, D., & Lippman, A., 14/8/06.

⁷ Parisian S. Open Letter, February 2005. Also "Uterine Cancer after Use of Clomiphene Citrate to Induce Ovulation", *American Journal of Epidemiology*, April 1, 2005.

⁸ "Why leading fertility expert thinks women are being put at risk", *Independent*, 8/10/06.

the potential long-term health risk to her body because she failed to freeze her 'spare' eggs. Most women do not choose voluntarily to 'give' eggs away, as evidenced by the proposed incentive of cut-price IVF treatment.

Some Other Concerns with Egg Donation for Research

Information on use of the eggs needs to be comprehensible and clear. Women need to be informed that their eggs will be used for cloning or embryonic stem cell research - to create cloned embryos that will then be destroyed when they reach 14 days old. This use of eggs is likely to be of concern for many women because: 'there is probably a majority of people (for whom) the deliberate discarding of human embryos is morally troubling'.⁹ Indeed, it is important to understand that for most Christians and faith groups the creation and then killing of human embryos is morally unacceptable. The methods and aims of researchers should not be disguised by technical language.

Many potential donors, as well as the broader public, wrongly believe that therapies are likely to result from embryo research in the near future so they believe that providing eggs is a way to help others around them. In fact therapies from embryonic stem cells research are still far off, have yet to be seen and may never result. Embryo cloning has also been described as 'a wildly inefficient process, requiring hundreds of eggs from perhaps thousands of women to merely attempt to produce a single viable clone'¹⁰ In contrast, alternative methods of ethical adult research are already available and successfully treating diseases (see www.cloning.org.uk).

Conclusion

The Evangelical Alliance believes that the HFEA must publicly demonstrate that its priority is to safeguard the interests of women together with their rights and welfare. The interests of scientists and researchers must be subordinate. It is not appropriate or ethically acceptable for women to be offered financial inducements to donate their eggs in furtherance of promises from the research world of future 'cures'. Reasons for this include the fact that as a result women undergoing IVF treatment, or indeed women who are not undergoing IVF treatment will be induced to take acknowledged and unknown health risks for research which many believe to be ethically questionable. We conclude and warn that inducing healthy women to risk damage to their own health by donating 'spare' eggs for the hypothetical treatment of others cannot be justified on medical, ethical or social grounds.

Consequently, we recommend that the HFEA donates considerably more time to investigating the welfare of potential egg providers, to commissioning serious research and data collection on the long term consequences and impact of egg harvesting on women and their children, and to involve Parliament directly before placing women at risk from such ethically controversial and unnecessary research.

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⁹ Sheila McLean, "New approach could ease the stem-cell fears", *The Scotsman*, 25/08/06.

¹⁰ "Mining the secrets of the egg", Dennis, C. 2006, 652-655. *Nature* 439.