Egg donation: A case of body shopping

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All out of the (female) body: aspects of human reproduction

The demand for women's eggs whether for assisted reproduction or for stem cell research is increasing at an accelerated pace and is leading to transnational oocyte trafficking. In the last decade, a new branch of mainly private fertility centres has emerged that specialize in providing oocytes for patients coming for other countries. This so called reproductive tourism is triggered by several factors. Clinics are often located at tourist sites or near airports with cheap flights, and they offer in the Internet special services for clients from abroad.

Egg-cell tourism

"Egg-cell tourism" demand comes from countries where egg donation is prohibited, like Germany, Italy or Austria, as well as from countries where there is an "egg shortage" due to recent requirements for open non-anonymous germ cell donation, as is the case in the UK. This demand is attended in countries like Spain, the Czech Republic, Russia, Cyprus and Crete, where these restrictions do not exist and egg cells are offered at a low price. Many centres in Germany or Austria direct their patients to Spanish clinics when egg cell donation is required (Heng 2006). In 2005, donors recruited in Romania by the Global Art Clinic received a compensation of 100 to 250 US dollars. The resulting embryos were sent back to Britain to be implanted. At least two Romanian women suffered severe ovarian hyperstimulation syndrome and did not receive any medial care by the Clinic, which forms part of a US-israeli company. In Spain 20 to 25 year old students, who have no regular salary and count only on their pocket money are regularly recruited; and also immigrant women, from Eastern countries, who offer interesting "caryotypes" for the clients of the centres. "Good donors", i.e., women who respond adequately to the hormone stimulation programme and produce large quantity of ova, are invited to undergo 3 and even 4 cycles per year. In Spain, a cycle of egg donation, including the fee for the donor and all the drugs, costs round 5000€. According to one British patient: 'It's actually cheaper for me to use a donor egg in Spain than it is to use my own eggs at home. The last time I tried at home the bill was well over £5,000 and I didn't even get past embryo transfer stage.' (France 2006) Bigger clinics in Barcelona and Valencia charge more but the total cost, including flights and accommodation, is rarely higher than the bill from a private clinic in Britain. Some even offer deals - a lump sum for three cycles.

These are trips often booked in secrecy. If any of these women do get pregnant, many of their relatives and friends will never know that their trip to Spain was anything

more than a last-minute dash for some November sun. This is a word-of-mouth phenomenon which might never have happened even five years ago. In a bizarre way, completely unrelated modern-day breakthroughs like the spread of the internet, the launch of cheap flights, the opening up of the European Union have all played a role. To a generation brought up on foreign holidays, with careers which take them all over the world, the idea of going abroad for treatment holds little fear. As one woman said: 'I've trekked across South Africa in the back of a truck. I can do Spain, for God's sake.' (France 2006)

Some consider this movement merely as a normal process of Europeanization and legitimate consumer choice. Others view it as disrespect for national legislation and as private undermining of rules which were democratically passed in the public good. Shall we regard these developments as consumers “voting with their feet”? Or does the clandestine nature of many of these transactions and the gaps in living standards and conditions between individuals in the respective countries raise concerns regarding inequality and injustice? And what about potential of cross-border trade to lead to the erosion of normative standards, and to the exploitation of vulnerable segment of the population? (Schneider 2007)

Eggs for research

The advent of embryonic stem cell research has strongly expanded the already pacing demand for female egg cells. In Somatic Cell Nuclear Transfer (SCNT), the nucleus of an egg is removed and replaced by a somatic cell drawn from an adult person. The resulting blastocyst´s cells have the potential to differentiate into various types of tissue. Researchers hope to develop the techniques that will let stem cells develop sufficiently to be used for repair or regeneration of the patient providing the somatic cell. However, this is but a promise, cloning to produce an embryonic stem cell line has so far not been successfully achieved in humans. South Korea was for some years regarded as heaven for human cloning research. Dr. Hwang Woo Suk at Seoul National University was actually considered to be the first to have achieved therapeutic human cloning. But Hwangs claim to be the firs one to create a cloned stem cell line was but a fraud. Official inquiries revealed that Hwang´s team failed to produce even one single cloned embryo cell line, despites he used 2.236 eggs coming from 122 women, 71 of whom had been paid for their donation. It also turned out that several female subordinates in Hwang´s laboratory were pressured to donate their own eggs for research.

In the aftermath of the Hwang scandal, pressure for producing harmonised standards on egg procurement is growing, particularly given the international background of most stem cell research teams. Some specific guidance for research-oriented human egg procurement is now being produced at the demand of researchers, who would like to rely on a regular, common framework (EuroStemcell 2007, ISSCR 2007). But disagreements on the ethics of egg cell donation and long-lasting controversies on payment are preventing interested countries from reaching any binding international norm on this matter.

Most states have not yet provided specific legal norms to regulate such donation, but lack of regulation does not prevent some of them from tolerating oocyte donation for research; these states along with countries that have developed permissive regulatory regimes (such as Australia, Iran, Israel, India, Singapore, China, India, Japan, South

Korea and South Africa) are dictating where ‘‘therapeutic’ cloning’ research is actually taking place (Walters 2007, 2004).

Within the European Union, diverse regulatory frameworks coexist. The principle of subsidiarity applies for all the fields of science and technology, assuming respect of fundamental ethical principles. The ruling Research Framework Programme (FP7) does not fund the derivation of new stem cell lines from donated pre-implantation human embryos or embryonic cells, or via nuclear reprogramming (which does not mean that it is prohibited to obtain new cell lines using these methods within the Union). Countries within the EU currently allowing egg donation for somatic cell nuclear transfer --which remains, as said, expressly excluded from EU funding -- are the UK, Sweden, Belgium and, more recently, Spain (EGE 2007).

The United Kingdom is one of only a handful of countries in Europe which explicitly permit egg donation for stem cell research. A highly publicised ‘open’ consultation, intended to clarify the regulatory regime, unfortunately failed to settle any of the epistemological, political or ethical questions posed by egg disposition. Left untreated, these issues have now degenerated into a polarised and divisive situation which may even undermine the passage of the long-awaited revised Human Fertilisation and Embryology bill (Alkorta & Dickenson, 2008).

Spain, with the greatest number of donated egg cycles for IVF in Europe, has recently joined the ‘therapeutic’ cloning club (Act 14/2007), offering an experienced egg-collecting network of clinics to researchers. In Spanish practice, donors—better termed sellers-- are paid up to 1,200 Euros, and fertility clinics are starting to fear that, given the confidentiality implications of donating gametes for reproduction, women would rather donate for research than for IVF.

In Sweden the government has placed considerable emphasis on encouraging investment and collaboration in the area of stem cell research, and the feeling that Sweden has to ‘think big’ in order to maintain its place in the global competition around regenerative medicine means that national researchers are being encouraged to look further abroad than Europe for partners and collaborations (UK Stem Cell Initiative 2007). Due to the shortage of eggs in Sweden, there is an increasing focus on finding research partners in such countries as China, India, Israel, Singapore and South Korea, which also allow ‘‘therapeutic’ cloning’.

Despite profound disagreement and tension among countries on the legitimacy of stem cell derivation methods, relevant inner EU institutions are interested in fostering a European regenerative medicine market, and for that the Union needs to encourage research on stem cells. Several legal *instrumenta* have already been enacted that favour that purpose. The provisions of a European Directive ‘on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells’ (better known as the ‘Tissue Directive’) apply, amongst others, to cellular stem-cell derived materials intended for human application. Following the opinion of the European Parliament on 25 April 2007, the European Council of Ministers approved the Regulation on advanced therapies, in first-reading on 31 May 2007, and on 30 October 2007 the Advanced Therapy Regulation was formally adopted by the EU Council. The declared aim of the ‘Advanced Therapies Regulation’ is to harmonise guidelines that will create a centralised process for approving new tissue and cell engineering therapies.

However, neither of the afore mentioned statutes provide guidance on oocyte donation for research purposes. The provisions of the Tissue Directive only apply to reproductive-oriented donation, not to donation for research purposes, although the Directive might influence policy regarding compensation for egg donation. It

recommends that member states ‘endeavour’ to ensure that donations are voluntary and unpaid, but it does not make that a stringent requirement.

At the non-legislative level, oocyte procurement for research has been addressed on least two occasions by European authorities. The European Group on Ethics in Science and Technologies (EGE), which advises the European Commission and whose opinions are relevant in determining scientific policy, recommended in 2007 that, among others, the following considerations must apply to hESC research funded by the EU: no pressure may be put on the donor at any stage, the donor’s health should not be put at risk by excessive ovarian stimulation; information must be given that consent could be withdrawn up to the stage of the creation of the stem cells; infertility treatment and research must be appropriately separated; researchers must present all the data referred to donors in an anonymous way; and no financial incentive can be offered to donate embryos or egg cells at any stage, in line with art. 12 of Directive 2004/23. However, some members of the EGE -as the UK, for instance- hold the view that the reduction of IVF costs for egg donors is acceptable.

In the USA egg procurement for stem cell research has also been controversial. Proponents of SCNT differ in their views on the legal status of the donor and compensation for the donation. Following the US Code of Federal Regulations (CFR), stem cell research is not considered under clinical trials regulation; nor does it technically imply ‘research on human subjects’, as we saw in the instance of Gerard Shatten’s Institutional Review Board. When donated germ cells are anonymised, regulations no longer recognise donors as research subjects, and federal definition of human subjects research (45 CFR 46) exempt research from full Institutional Review Boards (IRB) procedures if samples cannot be traced back to their donors. Therefore specific guidance for IRB review of procurement of eggs for stem cell research has, until now, been minimal. (Magnus and Cho 2005). Only California Bill 1260, following the recommendations of the California Institute of Regenerative Medicine (CIRM), defines women who provide ova for research as research subjects. It also provides that all such research should have IRB approval and additional oversight by a special human embryonic stem cell research ethics oversight committee.

Regarding compensation to donors, the use of financial incentives to obtain oocyted has been a contentious issue. Many regulations, including the Tissue Directive allow compensation for inconveniences and just expenses. Obviously, there are many possible interpretations about what constitutes „just expenses“ – does it only include e.g. travel costs, or also reimbursement of lost wages and for instance costs for child care? And what can compensation for „inconveniences“ encompass: compensation for pain and suffering, or even for other immaterial damages? As we can easily imagine, the more „compensation“ is considered as fair, the more it equates the sale and purchase of ova. The more broadly expenses and inconveniences are interpreted, the more there is space for indirect commercialization.

The USA maintains the inconsistency of allowing payment for reproductive purposes, but not for the same eggs used in stem cell research. (Spar 2007) In April 2005 a committee of the US National Academies for Science recommended in its ‘Guidelines for Human Embryonic Stem Cell Research’ that no payments should be provided for donation of eggs, sperm or embryos for research. Following those directives, states that explicitly permitted SCNT, such as Massachusetts, limited payment for egg donation for research to reimbursement costs. In California, Senate Bill 1260 also placed a limit on payment for oocytes: only direct expenses and lost wages may be compensated. The 1260 Bill also mandates that costs for women suffering from adverse reactions will be covered. The Director of the California Institute for Stem Cell

Research, Dr Alan Trounson, has publicly expressed his frustration at not being able to pay women for their eggs because of this statute. He is not the only restive researcher: Dr Kevin Eggan, a Harvard stem cell scientist, has complained vehemently about the failure of his efforts to recruit altruistic donors (Bioedge 2008). We can expect such pressures from disgruntled researchers to continue, and to result in regulatory backsliding. For example, the guidelines issued by the International Society for Stem Cell Research recommend that decisions about paying women for their eggs should be left to local oversight committees (ISSCR 2007): a recipe for competitive de-regulation, no doubt.

This brief legal survey has revealed a variety of regulatory regimes, some of which confront the ethical issues concerning exploitation and risk far more openly and effectively than others. Even the most inconsistent regulatory regimes, however, might be thought better than no regulatory regime at all. In the great majority of countries, oocyte donation for research purposes lacks any governance framework whatsoever, at either national or international level. Those few states which allow or are intending to allow egg donation for 'therapeutic' cloning find themselves erecting an entirely new structure of norms with no binding international framework, even lacking consensus on the moral and legal nature of egg procurement itself. Taking into account actual and prospective regulations, egg donors for research have been characterised in at least four different ways: as subjects of research, participants in clinical trials, organ donors, or mere tissue or 'raw material' providers (Magnus and Cho 2005). With such fundamental epistemological disagreement on the status of egg donors and egg donation, it is hardly surprising that governance is unsatisfactory. Paces for exploitation of vulnerable collectives of women are laid.

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