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Ethics, legal, social, counselling

What about the women? Ethical and policy aspects of egg supply for cloning research

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Abstract

As more and more countries open their doors to human cloning and embryonic stem cell research, scientists will be confronted with one fundamental problem: where will all the eggs come from? The mass harvesting of eggs raises serious issues about women's health, status and well-being. This paper critically examines proposals for ova supply such as altruistic donation, surplus IVF eggs and commercial sale. It questions the meaningfulness of informed consent and the risk–benefit ratio in a climate where powerful economic and social forces increasingly view the risks to women as the necessary trade-off for scientific advance.

Keywords: *cloning, egg donation, egg extraction, ovarian hyperstimulation syndrome, women's health*

Introduction

Cloning and stem cell research have been at the forefront of public debate worldwide. In November 2006 Missouri voters narrowly approved amendments to the state's constitution, which allow cloning for research purposes (sometimes referred to as 'therapeutic cloning'). Nationally, a number of US state governors and congressional aspirants have campaigned on their support for, or opposition to, embryonic stem cell research (Kintisch, 2006). In December 2006 the Australian parliament voted to allow research cloning under licence. But what about the women? Although cloning is unfeasible without a continuous supply of women's ova, the ethical and policy implications of egg harvesting have been treated largely as a side issue, the hope of therapies versus the moral status of the embryo dominating the debate.

The recent exception is in the UK where research efforts have been seriously hampered by an egg shortage. The Human Fertilisation and Embryology Authority (HFEA) last year initiated public consultation about egg supply for research. While acknowledging the health impacts on women, the HFEA has now agreed to allow altruistic donation of ova by non-patients for research.

Since women and their bodies are central to cloning, I contend that advocates of this research bear the onus of demonstrating that sufficient ova can be sourced without harm to women. I argue that they have failed to discharge this onus. I begin this paper with a brief overview of the health risks associated with egg extraction, already documented in an earlier edition of this journal (Beeson and Lippman, 2006). In a context of powerful social and economic forces with a vested interest in women's decisions about their eggs, I question the meaningfulness of informed consent.

There are also serious ethical and social policy implications for the status and treatment of women raised by supply proposals such as altruistic donation, surplus IVF eggs and commercial payment, not to mention practical limitations. In sum, egg extraction carries definite health, social and ethical risks, but offers no benefits to the supplier herself.

Short-term health risks

Beeson and Lippman (2006) have recently outlined the health risks associated with the ovulation induction process. Either 0.3–

5% or up to 10% of women who undergo the process experience ovarian hyperstimulation syndrome (OHSS) (Magnus, 2005; and studies cited therein). More serious symptoms of OHSS can require hospitalization and include unintended pregnancy, renal failure, intrauterine polyps, ovarian cysts, thromboembolism, adult respiratory distress and haemorrhage from ovarian rupture and infertility (Magnus, 2005; Beeson and Lippman, 2006; Demirol *et al*., 2007). OHSS can necessitate one or both of the ovaries being removed (Steinbock, 2004).

The American Society of Reproductive Medicine Practice Committee (2003) has said that the occurrence of these more severe symptoms is 'by no means rare'.

Some scientists have pointed out that because egg suppliers for research do not become pregnant, they are not at risk of the more severe form of secondary-onset OHSS, which can affect IVF patients who achieve pregnancy (Balen, 2005). However, the risks of primary OHSS should not be underestimated. It caused a 22-year-old Stanford graduate, Calla Papademas, to suffer a massive stroke and brain damage after she had commenced egg extraction for a $15,000 fee (Hamilton, 2000). Jacqueline Rushton died in 2003 after complications arising from IVF. She was not pregnant (BBC, 2005a).

In 2005 Temilola Akinbolagbe, 33, developed pelvic vein thrombosis, which led to cardiac arrest and death just two days after commencing treatment for IVF (BBC, 2005b). The most recent death was unrelated to OHSS or pregnancy and occurred after a complication during egg retrieval, causing internal bleeding and renal failure (Boseley, 2006).

There are other serious risks for all egg suppliers even in the absence of pregnancy. A recent study reports on 34 cases of arterial thrombosis following fertility treatment, including three myocardial infarctions: 19 of the women were pregnant, but 15 were not and in 'a few cases, thrombotic phenomena were seen even in the absence of overt OHSS' (Girolami *et al*., 2007).

Recent reports suggest that ovulation induction drugs can also lower the chance of achieving pregnancy, risking chromosomal damage to more than half the eggs in a woman's ovaries (Marsh, 2006).

The risks of OHSS can be minimized by the application of inclusion criteria to women considering egg extraction. However, there is an essential tension between the needs of researchers and the interests of some at-risk women who should be protected by inclusion criteria. Women under 30 years of age are at particular risk of developing OHSS (Balen, 2005). Yet cloning researchers require young eggs. As Balen has reported to the HFEA: 'Women undergoing oocyte donation should be less than 35 years of age and may be even younger …' (2005). If women's health were the overriding concern, young women would be advised against inclusion in egg supply programmes.

The health risks of OHSS can also be reduced by other strategies should women develop overstimulated ovaries, such as lowering the dosage of human chorionic gonadotrophin, or withholding it altogether (Balen, 2005). Nevertheless, it is clear that, despite efforts to minimise risks to women, a not insignificant number of women will suffer damage to their health as a result of the egg extraction process.

Long-term health risks

'One of the most striking facts about IVF is just how little is known with certainty about the long-term health outcomes for the women who undergo the procedure.' This was the conclusion of the most recent assessment of the medical risks of egg extraction by the US Institute of Medicine and the National Research Council (*Committee on Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research,* 2007). The report also notes that there are no registries that track the health of women who undergo ovarian stimulation and that most studies of IVF have been anecdotal or have focused on relatively small groups of women.

Beeson and Lippman's review of the long-term health studies revealed conflicting conclusions. 'Nevertheless, many clinical reports associate infertility treatment with ovarian cancer, and two major studies suggest a link between ovarian cancer and ovarian stimulation' (2006). The 2007 report concluded that fertility drugs might cause an increased risk of uterine cancer (Committee, 2007). The same report pointed to one study showing that, with increased passage of time since exposure to clomiphene, there was an increase in the incidence of ovarian, breast and endometrial cancers. Dr Ness commented to the Committee: 'This is of particular concern … because it raises the possibility that many studies have missed the increased cancer risk because they haven't followed their subjects for enough years' (Committee, 2007).

While the links between ovarian stimulation and cancer are not clear, what is clear is the inadequacy of existing data. Further research, including longitudinal studies, is urgently required.

Informed consent?

Too often these risks are dismissed in the name of informed consent, the duty to disclose and warn patients or research participants of risks to their health and well-being. The argument is that if women are informed about the risks of egg extraction for research, it should be their choice as to whether they assume those risks and provide their eggs.

However, it is not entirely accurate to speak of 'informed consent' when there is a lack of independent assessment about the long-term health risks of egg harvesting. As Ahuja *et al*. (1999) remark, '[the] present uncertainty and the paucity of meaningful statistics dilutes "informed consent"'. As noted above, however, some research links egg harvesting to hormonal cancers. Scientific investigation of these long-term risks is required before women can meaningfully consent to egg extraction for research.

Secondly, the practice of egg extraction in assisted reproduction has raised practical concerns about the level of informed consent experienced by women.

The recent report by the HFEA (2006a) into the UK's fertility sector identified the greatest need for improvement as the provision of information to patients (men as well as women undergoing egg extraction), with 47% of clinics failing to meet the standards expected in this area. Access to counselling services to allow discussion of patient's options was also

inadequate. These are two of the areas of most concern to patients who complained to the HFEA. In the 12-month period of review, the HFEA noted eight breaches of the law and 11 violations of the Code of Practice regarding consent.

A number of Australian studies about assisted reproduction report on the lack of accurate information on the risks (Klein, 1989; Ewing, 1992; National Health and Medical Research Council (NHMRC), 1998). A NHMRC clinic survey found that not all clinics disclosed key adverse outcomes and tended to downplay the risks (1998). Bell concludes that whether 'women are adequately informed of the health risks is highly debatable' (2006).

Thirdly, consent does not occur within a vacuum, but always within a context. Women's decisions to provide ova should be considered against the background of powerful social and economic forces that have vested interests in women's decisions about their eggs: the biotechnology industry, scientists, research advocates and patients themselves who may well exercise influence – albeit well meaning – in the hope of treatments.

As Beeson and Lippman have noted, some physicians who extract eggs are also involved in cloning research. 'Seeking consent from women in these circumstances is problematic when clinicians have an interest in obtaining their eggs' (Beeson and Lippman, 2006). This is not to assert that women are incapable of exercising choice in this context. But it does require us to question the value, worth and power of a woman's decision to provide ova.

Risk–benefit calculus: serious risks, whose benefits?

Cloning advocates have argued that since women are permitted to undertake the risks of egg extraction for assisted reproduction, they should be free to assume the same risks for cloning. The risks of egg harvesting for research are the same as the risks of harvesting for assisted reproduction and like any medical procedure, the risks must be weighed against the benefits. However, Beeson and Lippman point to an important difference: a woman who undergoes ovarian stimulation for assisted reproduction treatment has a 10–40% chance of producing a baby for herself. But the risk–benefit calculus is very different for a woman who assumes the same risks for research cloning: she is part of a research project that has uncertain benefits and may never benefit directly from the risks, she has assumed (2006).

What model of consent fits these women? Magnus and Cho (2005) argue that if we consider them clinical patients then the doctor–patient relationship would seem to suggest 'counsel against undergoing such a procedure for no benefit' to themselves.

Alternatively, should these women be viewed as research subjects? 'After all, research often requires individuals to expose themselves to risk for the benefit of others …' (Magnus and Cho, 2005). However, unlike in other research, the risks to egg donors do not lie in the research itself, but in the extraction of the materials necessary for the research (Magnus and Cho, 2005). Sperm donors for research are not exposed to similar risks.

Supporters of research cloning envisage altruistic donation of ova by non-patients, reflected in the recent HFEA decision in the UK. Thus a better model to describe egg donation by women is altruistic organ donation by living donors to strangers (for example a kidney or liver lobe) (Magnus and Cho, 2005). Neither women egg donors nor living organ donors are patients and any benefits of the donation will be to strangers, not to themselves. Magnus and Cho point out that in these circumstances 'taking the best interests of the donor into account, it is hard to justify organ donation'. The same can be said about women egg donors.

In Australia the NHMRC also recognizes the special ethical issues raised by organ donations in these circumstances: 'There must be a very low risk of immediate or long-term harm to the donor's physical or mental health … there must be a very high chance that there will be a good outcome for the recipient' (NHMRC, 2006).

If this model is applied to women egg donors, it is difficult to justify the donation of ova for research. The risks to women's short-term and long-term health are significant. It cannot be said that there is 'a very high chance' of a good outcome for any potential recipient of a therapy derived from the use of women's ova. The benefits of this new research are, at best, speculative. Thus the serious risks of research cloning to women cannot be justified.

Cloning advocates argue that egg suppliers are in a similar position to volunteers in clinical trials who are permitted to take on serious short-term and long-term risks in an effort to advance science. However, such trials only proceed when there are clear benefits for the indicated patient population. Donna Dickenson (2006) has questioned the comparison of egg suppliers with research volunteers. The latter have the advantage of 'an entire apparatus of randomized clinical trials and meta-analyses in evidence-based medicine'. This includes the standard practice of animal trials before proceeding to human trials. Yet, so far, there has been no proof of concept of the efficacy or safety of cloning in any animal model. During the recent Australian debate, even some supporters of embryonic stem cell research questioned the urgency to approve human cloning. As scientist Silviu Itescu commented: 'I don't see why we don't wait until we have the results of animal trials with embryonic stem cells for specific therapeutic applications before we have this debate' (Davies, 2006).

Thus I argue that the analogy between egg extraction and clinical trials is misleading and disguises the fact that women suppliers are being asked to assume definite health risks with no demonstrated clinical benefits.

This is underscored by the Declaration of Helsinki which states: 'Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others … Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed'.

Egg extraction for research offends these principles. There are significant short-term risks and burdens on women and these are

well documented. At the same time there has been no 'careful assessment' of the long-term health risks of egg extraction. In comparison there are no foreseeable benefits to the subject herself and the benefits to future generations are far from certain. Yet public debate on research cloning is dominated by talk of therapies, cures and biotech 'boom', with scant scrutiny of the impact on women. This disparity belies the Declaration's statement that 'considerations related to the well-being of the human subject should take precedence over the interests of science and society'.

Where will all the eggs come from?

Cloning has been described as 'a wildly inefficient process, often requiring hundreds of eggs to [merely attempt to] produce a single viable clone' (Dennis, 2006). In South Korea, the now discredited Dr Hwang used 2061 eggs taken from 169 women and failed to produce a single cloned embryo (Steinbrook, 2006).

The sheer number of eggs required for research cloning is a major obstacle and 'a shortage of them could hold back the entire field' (Dennis, 2006). As the UK experience demonstrates, the 'main limiting factor in the research is the availability of human eggs to practise on' (Check, 2006). Where will all the eggs come from? I argue that a number of proposed egg sources have practical limitations that undermine their viability. Moreover, some ova sources raise serious concerns about the exploitation of women in the name of scientific advance.

Altruistic donation

Some argue that supplies of ova will come from altruistic non-patient donors, as is now permitted in the UK. This is despite research which shows that very few women are willing to donate eggs and that altruism is not linked to willingness to donate (although this research relates to donation for infertility, not for research) (Purewal and van den Akker, 2006). Australian stem cell scientist Alan Trounson has said that 'most eggs are likely to come from women who have family members with a disease and want to donate their eggs to advance research on that disease' (Dennis, 2006). But is there a danger that 'altruistic' donation and its attendant health risks might become a duty for women whose ova could save a loved one?

Already there are indications of such an ethic. Ethicist Julian Savulescu argues that we have an ethical and economic imperative to pursue cloning and stem cell research because of the potential benefits. Since women have so many ova, very few of which will actually produce offspring, scientists should use the 'spare' ova for research (Savulsecu, 2005). Will it become the 'ethical imperative' of women to donate ova?

There is evidence of social and cultural expectations of feminine self-sacrifice that impact on women. In her groundbreaking work on psychological development, Carol Gilligan (1982) observed that: '… while society might affirm publicly the woman's right to choose for herself, the exercise of such choice brings her privately into conflict with the conventions of femininity, particularly the moral equation of goodness with self-sacrifice … it is … in their care and concern for others that women have both judged themselves and been judged'.

Another theorist has characterized the stereotype of the 'good woman' thus: 'She is loyal and loving, compliant and altruistic … good women can be distinguished by their abandonment of their own interests and their overriding concern for the interests of family members' (Naffine, 1990).

Gilligan is not without her critics. However, even some of those who question her empirical rigour admit that the stereotype of female self-sacrifice resonates strongly: 'It is clear that women have a greater *reputation* for altruism and empathy than do men, and that women accept its validity. Whether the reputation is deserved is a more complicated question' (Greeno and Maccoby, 1993).

Seeking 'altruistic' donation from the female relatives of the sick and suffering plays to this powerful stereotype of female altruism. The risk is that in the minds of some women this would create an expectation that they sacrifice their own interests and assume the health risks of ova extraction.

Left-over frozen IVF eggs

Another suggested source of ova is the frozen ova that are surplus to IVF and assisted treatment requirements. However, there are more significant problems with this proposal. Leftover IVF eggs are usually aged and have failed to fertilize following fertility treatment. When used for cloning, these eggs typically fail to reprogramme, 'probably for the same reasons they failed to fertilize', according to Alison Murdoch (Dennis, 2006).

This is confirmed by a recent study (Hall *et al.*, 2007) that compared the developmental competence of fresh ovulation-induced ova with surplus, failed-to-fertilize human ova as host cells for nuclear transfer. The study found that surplus ova are 'a poor source of [ova] for human [cloning]'. Most of the surplus ova could not support cleavage and further development and there were chromosomal aberrations and aberrant spindle structures. The authors concluded that: 'progression of human [cloning] is therefore dependent on alternate sources [of ova] … The ethical implications in harvesting fresh [ova] from fertile women will therefore be a critical factor for the development of human [cloning] and the generation of patient-specific stem cell lines'.

Similar conclusions were reached in a separate study (Lavoir *et al.*, 2005). The need for recently collected eggs is also acknowledged by the HFEA (2006b).

In summary, research cloning requires freshly harvested ova. Surplus IVF ova are not a viable source.

Fresh eggs from IVF patients

Because women undergoing egg extraction for IVF assume the same health risks as those who provide ova for cloning, it has been proposed that these women donate some fresh ova for research purposes. However, experience demonstrates that only a minority of IVF patients are willing to do this.

In the UK, the HFEA has granted permission for researchers to ask women to donate some of their IVF eggs for research if the women had 12 or more eggs retrieved. However, this

strategy failed to yield sufficient eggs for their research needs. The researchers commented: 'only a minority were willing to donate fresh oocytes reflecting the psychological importance of the oocytes … this practice demonstrated that the numbers recruited by this strategy are small and will continue to be a major rate-limiting factor in the progress of the research' (Choudhary *et al*., 2006).

The researchers have called upon commercial payment for ova in order for cloning research 'to achieve its full potential' (Choudhary *et al*., 2006). In the UK, commercial incentives are now being used, detailed below (Wallace, 2006).

The proposal is also contrary to developments in fertility technology that are moving towards natural cycle/minimal stimulation IVF where fewer ova are retrieved than with standard IVF. In these less harmful procedures, low doses of hormones are administered for only a few days causing few side effects. Retrieval of the egg or eggs is comparatively quick and easy and can be performed without analgesia. The natural cycle procedure carries a zero risk of OHSS and, per cycle, demands less time, money and physical and emotional stress than standard IVF (Pelinck *et al*., 2002). A recent study confirms that the minimal stimulation technique virtually eliminates the risk of OHSS and is suitable for all types of patients (Pelinck *et al*., 2006).

Thus, the proposal to harvest extra eggs from IVF patients puts the needs of researchers ahead of women patients since recent research suggests ovarian hyper-stimulation is no longer medically indicated or necessary. 'The primary concern should be what is in the woman's best interests. That is to have the most minimally invasive treatment with the minimum use of drugs and the minimum harvesting of eggs' (Quintavalle, 2006).

Stimulating IVF patients to produce extra eggs for research might benefit researchers but it is against the best interests of the women patients when less intrusive techniques are now available.

Animals

Some cloning advocates have proposed the use of animal ova in order to alleviate the demands on women. However, the lack of scientific agreement on the efficacy of hybrid and chimera research is well known. There are doubts that mixing mitochondria and nuclei from different species will work (Dennis, 2006). Researcher Doug Wallace of the University of California, Irvine has commented that: '[f]rom our experience, combining the mitochondrial DNA from even a species as closely related as chimpanzees result in incompatibilities' (Dennis, 2006).

Moreover, even if animal eggs are used in the early research stages, women's ova will be required in huge numbers if cells are ever to be transplanted to patients. Cells derived from animal eggs cannot be transplanted into a human because of the mixing of interspecies DNA and the risk of infection with animal viruses. Even if cloning eventually develops into a highly efficient technique where only one ovum is required for each therapy, it is extremely unlikely that sufficient numbers of ova could ever be obtained to make this a reality.

Hundreds of thousands of ova would be required to treat just some of the conditions identified by scientists: in Australia alone 1 million adults suffer from diabetes (Department of Health and Ageing, 2006a); 200,000 suffer from Alzheimer's disease (Department of Health and Ageing, 2006b); and 10,000 from spinal cord injuries (Spinal Cord Injuries Australia, 2006).

Advocates who promote the potential of embryonic cell transplants to treat these conditions must explain how these treatments can ever be achieved when plainly there will never be enough human ova.

Commercial payment

With cloning research only in its infancy, there are already indications that this research might not be practicable without the commercial sale of ova. In the UK extensive publicity campaigns have failed to recruit sperm and egg donors without commercial payment (McLaughlin *et al*., 1998). As noted above, very few IVF patients will donate fresh ova.

In the UK, the HFEA has allowed commercial incentives for egg donation, dubbed 'egg sharing'. The North East England Stem Cell Institute now offers women IVF at a reduced cost in return for their surplus eggs for research (*Nature,* 2006). This is payment in kind for ova and the money saved would be worth the equivalent of several thousand pounds.

The exchange of eggs for fertility services occurs in a relationship of asymmetrical power between patient and the doctor/ IVF clinic who control access to their services. Patients with limited financial means will have restricted or nil access to fertility services unless they donate their eggs for research. Notwithstanding some arguments for the advantages of egg sharing (Rimington *et al*., 2003), a qualitative survey of egg sharing confirms the exploitation inherent to this practice.

The survey showed that such donors are desperate to have a baby and are motivated by financial necessity because of the expense of the procedure. Some donors reported reluctance to give the eggs but believed that they had little choice given their financial limitations (Rapport, 2003). When women are offered commercial incentives they are left vulnerable to pressure to provide eggs.

UK researchers have been at the forefront of demands for commercial payment for ova, over and beyond incentives such as egg sharing and payment of expenses: '[m]ost oocyte donation for treatment involves payment. In the USA this is routine practice … If [cloning] research is to achieve its full potential we must explore these other options …' (Choudhary *et al*., 2006).

A comparative analysis of countries that do and do not allow commercial compensation suggests that commercial payment does increase supply, although the magnitude of the effect is unclear (Baum, 2001), and as long as biotechnology companies are profit-making ventures, commercial payment for the raw material necessary for their business may be the logical corollary: 'there is a tension between the altruism individuals are supposed to exhibit by donating their tissue for research and the current patent system, which encourages companies to stake lucrative property claims in that research' (Knowles, 1999).

However, does commercial payment relegate egg suppliers to marketable matter for research, rather than unique human beings? Even in the absence of payment, some women who have experienced egg donation describe feeling like a commodity. In one qualitative study (Kalfoglou and Gittelsohn, 2000), women used metaphors such as farm animals, produce and meat to describe the experience. Chris thought that: 'I just got the feeling … you were second class … I wondered did they treat everybody that way, or is it 'cause I'm a donor? … I'm just the produce stand … like the cow at the market …'. Melanie likened the experience to prostitution: 'I definitely wasn't in charge there. It was a little like what I would think prostitution would be like … you've rented your body out … You would be prepped and there would be none of the small talk that usually goes on to put the patient at ease; and it's kind of like "Spread your legs, there we go" … It was like you were some kind of prized heifer or something'. Treating women's ova as sources of profit risks the further objectification of women.

In the USA, one of the few countries to permit commercial trade in gametes for assisted reproduction treatment, payment for ova has increased sharply in recent years because supply cannot keep up with demand. The shortage of ova supply would intensify with research cloning, increasing the market value of ova. Research indicates that, as payment escalates, money becomes the dominant motivation, not altruism (Lindheim *et al.*, 2001).

There is already evidence that the commercial trade in ova leads to the exploitation of women, particularly the economically disadvantaged. Underprivileged East European women have been physically damaged, in some cases rendered infertile, after selling their ova to London fertility clinics (Abrams, 2006). It must be asked whether the high levels of payment that could be expected with research cloning would amount to an enticement that would undermine the voluntariness of the procedure (Lindheim *et al.*, 2001). In Australia, this was the key reason for the expert committee, which recommended in favour of research cloning, to advise against commercial payment: 'the healthiest eggs would be those from young women … the potential exists for coercion of young women to donate eggs (such as through social disadvantage, family or workplace pressures)' (Australian Government, 2005).

Conclusion

Research cloning involves serious health risks to women ova suppliers including OHSS and attendant risks of renal failure, infertility, and even death. There are a host of other suspected complications, including reproductive cancers in later life. Yet there are no benefits to the woman supplier.

Advocates of research cloning have failed to demonstrate that sufficient ova can be sourced without harm to women. Despite prohibition of commercial sale of ova in most countries, the UK experience suggests that when research cloning is permitted commercial incentives are required to augment egg supplies. Some scientists have called for the commercial sale of ova. However, documented cases of exploitation demonstrate that trade in ova induces disadvantaged women to assume the serious health risks of ova extraction for money. It is meaningless to speak of 'choice' and 'informed consent' in such a context.

Ethical standards require that women are safeguarded from exploitation and harm in the application of science. Cloning scientists seek to promote the health of the sick and disabled, but women bear disproportionate burdens and risks in this research.

Declaration

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