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Human Tissue Providers for Stem Cell Research

Freedom, Fairness and Financial Recompense

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In the attempt to ascertain whether stem cell science can fulfil its potential of creating treatments and cures for serious conditions, a variety of contributors have important roles to play. Scientists must use their own expertise and insight to explore how current knowledge about our bodies and their constituent parts can be used therapeutically. Increasingly, in the future, reassurances about the safety of resulting therapies will not be able to be given without the contribution of research subjects on whom such treatments can be trialled. Lawyers, ethicists and others will contribute to discussions about and the implementation of regulation to ensure that scientists' activities lie within appropriate bounds. However, in the stem cell research arena, none of this will be possible or necessary without reasonable access to human tissue samples. The freedom of scientists to explore the veracity of their hypotheses, to add to the body of scientific knowledge and to attempt to achieve therapeutic advances will be thwarted in its earliest stages if systems are not in place to facilitate access to such tissues. In this way, freedom on the part of scientists is intrinsically bound up with the freedom of tissue providers to make their tissues available.

Tissue providers will take into account numerous considerations in making the decision to contribute to the research endeavour in this way. In this chapter it will be argued that, where they decide to play this vital role, they should be provided with fair recompense for doing so. In making this argument, a specific category of tissue provider will be focussed on, i.e. women who make their ova available for stem cell research. Human ova can be used in stem cell research to create embryos through somatic cell nuclear transfer (SCNT, also known as therapeutic cloning). The techniques for this have not yet been perfected and many eggs will be required to be used if there is to be any hope of achieving scientific advances.¹ The argument that payment for the provision of ova to research would impair their ability to participate voluntarily by acting as an undue inducement will be considered. It will be concluded that they should

have the freedom within appropriately regulated boundaries to play their part in stem cell research. Payment would allow them to contribute on a fair basis, and would not impair their ability to do so of their own free will.²

Recompense for ova in SC research

In the United Kingdom, the Human Fertilisation and Embryology Act 1990 (as amended) (the 1990 Act) governs the licensed use³ and storage⁴ of live gametes (eggs and sperm).⁵ The Human Fertilisation and Embryology Authority (HFEA) is the regulator which oversees the lawful implementation of the 1990 Act. As part of this role it has explored the implications of and responded positively to scientists' indications that the success of some stem cell research depends on the ready availability of human ova.

In July 2005 it was reported that the stem cell scientist Ian Wilmut was considering asking women to provide ova for research purposes⁶ while in September 2006 the HFEA revealed that scientists had made direct representations to it that SCNT research would benefit from a greater supply of ova and possibly also more recently collected ova than those available as a surplus from IVF treatment.⁷ Between September and December 2006 the HFEA therefore undertook a public consultation on whether women in the United Kingdom should be permitted to provide eggs for research as non-patients, i.e. without this being linked to their own fertility treatment.⁸ As a result it made a number of decisions, now incorporated into its Code of Practice,⁹ permitting the provision of ova to SC research, whether connected to a woman's own treatment or not.¹⁰ Ova provision, either through egg-sharing arrangements (in which some of a woman's eggs will be used in her own IVF treatment while the remainder will be made available for the treatment of others or for research) or as a non-patient, to HFEA-licensed research (i.e. research involving the creation and/or use of embryos) will be permitted, if considered to be appropriate by a Licence Committee. In doing so, the law has taken an important step towards facilitating women's freedom to make an important contribution to the scientific endeavour.

This author has argued that excised human tissue provided for use in stem cell research is a form of property for which appropriate recompense should be provided¹¹ and that ova providers in particular should receive fair recompense for their role.¹² Such recompense should be awarded on the basis of a tariff system which reflects the physical burdens which providers of certain types of tissues must undergo in the attempt to extract the relevant tissue.¹³ The method of payment recommended is one based on a similar form of tariff system used as a starting point in personal injury compensation cases. The level of recompense provided would take into account the 'time, inconvenience, physical burden

and risk' posed to the provider by the extraction of their tissue,¹⁴ resulting in an award of £2,500 to ova providers.

Currently, all ova providers for research are entitled to capped reimbursement of any reasonable expenses they incur which directly relate to carrying out this role.¹⁵ This reimbursement puts the woman back in the financial position she was in before the provision of her ova¹⁶ and so cannot be classed as recompense for this provision. In addition, ova sharers may be entitled to a significant reduction of their own treatment fee where they choose to make some of their ova available for other purposes.¹⁷

The impairment of voluntariness – Undue inducement

The argument that women should be paid a reasonable amount for providing ova to stem cell research might give rise to concerns that the offer of recompense places women in a position of vulnerability by impairing their ability to make a voluntary choice about whether to expose themselves to the inherent risks. However, these concerns serve to highlight the dangers of an inadequate regulatory system, rather than being compelling arguments against recompense *per se*. A regulatory regime can include protections against such dangers so that they become irrelevant to the issue of whether or not payment is provided. To explore the validity of this argument, the concern that payment represents an undue inducement to provide tissue will be explored. The undue inducement argument posits that in making financial recompense available in return for ova provision, women will be induced to expose themselves to situations which they otherwise would avoid¹⁸ raising the spectre of them choosing to provide ova in response to financial need, and to concealing information about their state of health.¹⁹

A simple inducement is 'the offer of a good meant to change our behaviour',²⁰ such as payment for products or services. This is generally regarded as acceptable; it would arguably be exploitative not to provide appropriate reward in such circumstances. In contrast, undue inducements involve two main elements: unacceptable risk and the removal of the ability to make a voluntary choice.

Women providing ova are exposed to a number of risks in doing so. To make their ova available, their reproductive cycles must be suppressed and then stimulated through medication.²¹ Short-term risks include discomfort, mood swings, infections, bleeding and the risk of developing Ovarian Hyperstimulation Syndrome (OHSS)²² but there is little information about the long-term risks of the drugs used to achieve these effects.²³ OHSS occurs in between 1–10 per cent of cases.²⁴ In its most serious form (occurring in approximately 1 per cent of cases of OHSS²⁵) this condition has a mortality rate in the United Kingdom estimated at 1:30,000 cycles of IVE.²⁶ Minor additional surgical and anaesthetic risks are also inherent in the process of ova retrieval in which a needle is passed through the vaginal wall into the ovary.²⁷

Thus, while the risks the process poses are rare, the most extreme form of complications is significant. Balen states that, 'there is insufficient evidence to suggest that women should not undergo altruistic oocyte donation because of the risk of OHSS. Indeed because of the self-limiting nature of the condition in women who do not conceive, those undergoing oocyte donation appear to be at lower risk than women receiving IVF treatment for themselves'.²⁸ Given that women are permitted to run such risks as part of their own treatment, and that the risks are arguably lower where the ova will be provided for research in the absence of their provider's own treatment, these risks can be deemed acceptable as long as the woman receives sufficient information about them to enable a voluntary choice.²⁹ It is for ova providers to decide, within an appropriately regulated arena, whether or not to expose themselves to risks in light of their wish to contribute to the aims of stem cell research³⁰ and that where they choose to do so appropriate recompense should be provided.

This leads us to the second element of undue inducement. The voluntariness of a consent to risk exposure can be impaired where individuals are incentivized by the offer of something desirable to expose themselves to excessive risks which in other circumstances they would not run, thus making their decisions less autonomous.³¹ Payment to someone to assume reasonable risks does not necessarily raise ethical concerns, being comparable to the situation of workers in hazardous industries.³² It is unreasonable to prevent an individual from taking such risks which they may see as being their only option to take action to improve their circumstances, for example by increasing their chances of conceiving a child through IVF.

Evidence exists that the provision of financial benefit is a significant motivating factor in the decision to donate ova generally.³³ Studies show that in the United Kingdom, Canada and Finland, where direct payment for ova is restricted, the number of women donating ova for reproductive purposes is less than half the rate of that in the United States where payment is permitted.³⁴ In one survey of women who had donated ova in the United States, 18.8 per cent of respondents had purely financial motivations.³⁵ However, altruism and the desire to help others was also a significant factor, with 32.2 per cent of respondents expressing exclusively altruistic motivations and 41.2 per cent expressing a combination of financial and altruistic motivations.³⁶ While this questionnaire related to women who had donated ova for reproductive purposes, in the United Kingdom, significant expressions of willingness to donate ova for research purposes have also been expressed by randomly selected survey respondents who were not receiving treatment for infertility.³⁷ The motivation for such willingness was said to be altruistic³⁸ but this was within a system where financial motivations would not be a factor as no such benefits are provided for non-patients.

In relation to egg sharers, although the reduction in IVF fees is not a direct payment, it has been reported to the HFEA that 'the vast majority of egg sharers are motivated by financial reasons'³⁹ although it is not clear from the limited

statistics available on numbers of egg sharers whether the fee reduction has led to more women choosing to take this option.⁴⁰ Nevertheless, this observation appears to correlate with the experience in Belgium where, since a policy decision was taken to provide six free cycles of IVF, the number of ova sharers has fallen by around 70 per cent.⁴¹ It can therefore be concluded that the UK policy of providing a reduction in IVF fees to ova sharers is a significant financial benefit, perceived as such by its recipients, which is not made available to non-patient ova providers and it is highly likely that this factor will be taken into account by ova providers in their decision-making process. On the basis of evidence from systems where payment is made for ova, it is not unreasonable to conjecture that were appropriate recompense available in the United Kingdom, this would provide an incentivising factor to provide ova to research in combination with the altruistic grounds expressed for this willingness.

An argument could be made however that such payments would represent an incentive to the poorest in our society. The fact that offering payment in return for contributing to scientific endeavour may lead to 'preferential enrolment of the poor'⁴² applies in many commercial practices, not just those relating to human tissue.⁴³ Emanuel is of the view that this element is really an issue of justice, stating, 'when one is tempted to charge "undue inducement" because of too many poor people enrolling and the possibility of exploitation, the response should be to increase the inducement',⁴⁴ while Wilkinson queries whether there is a general duty on society to improve conditions for the poor so that they do not have to enter into such arrangements.⁴⁵ Guidelines provided by the International Society for Stem Cell Research suggest that payments to non-patient ova providers are acceptable as long as they do not constitute undue inducement to make such provision.⁴⁶ One criticism of this approach is that 'to avoid undue inducement, as required by the ISSCR Guidelines, one would have to insist that women from poorer nations be paid considerably less for their eggs than women from wealthier nations (or insist that all women be paid the same low amount, an unlikely scenario and an ethically troublesome one)'.⁴⁷ To follow the potential consequences of this approach, this may lead researchers to seek out those women to whom, under the guidelines, lower payments should be made in order to avoid undue inducement, thus encouraging their exploitation.⁴⁸ This leads to a vicious cycle in which:

[T]o avoid unduly inducing women from poorer nations to undergo superovulation and egg retrieval, one would have to keep payments small; but in doing so, one creates the problem of these women being exploited. Yet by increasing payments to try to eliminate the exploitation, one reintroduces the problem of undue inducement.⁴⁹

A consideration of mechanisms to improve the overall level of wealth within society is beyond the scope of this chapter. Suffice to say that if levels of risk to which tissue providers are exposed are judged by the regulator, after

appropriate consideration, not to be excessive, it should not matter whether the tissue provider is wealthy or poor – both are entitled to the same levels of information, the same protection from exposure to unreasonable risk and the same opportunity to obtain financial recompense for their contribution. This financial recompense should fairly reflect the impact on their body which such provision has and, while having potential to act as an inducement, is not so large as to impair the voluntariness of their decision. The tariff system proposed recommends payment of relatively modest sums to ova providers, which would be unlikely to be such a strong incentive that it would cloud judgement about risk taking.⁵⁰

In the clinical research setting, studies have led to the conclusion that although higher payment for participation in clinical trials also incentivized participation in this context, there was no evidence that this blinded subjects to the potential risks.⁵¹ If the suggested tariff scheme was established, the amounts paid to tissue providers would not be so disproportionate to the risks posed that it was impossible for a potential donor to refuse to participate. Women who are provided with accurate information about the risks will therefore be able to make an autonomous decision⁵² about whether to provide ova for research. Providing reasonable payment to women who make their ova available for others' purposes is part of ensuring that they are treated fairly.⁵³ Given that little is known about the long-term risks of ova stimulation and extraction however, where this is permitted for research purposes, the regulator should impose a burden on the researchers to collate information about the nature and extent of the risks that are realised so that over time an accurate assessment of all risks can be used in assessing the risk: benefit ratio.

Conclusion

Ova providers make a raw material available to science which is vital to the success of this type of research and without which, advances in stem cell therapies are unlikely to be made. In addition, the contribution they make is an intrinsic part of the facilitation of scientific freedom in this arena. This is not adequately acknowledged under the current regulatory regime in the United Kingdom. A carefully judged tariff system of recompense, while being one factor which women would take into account in their decision, would not put them in the position of being unable to refuse to participate in the face of undue inducement. Rather, the provision of relatively modest sums, appropriately justified within a scheme monitored by the regulatory agency, would mean that women would have the freedom to choose whether or not to contribute to scientific research in this way and would be able to be reassured that they were being treated fairly in doing so.