

Donating **Eggs**

for Research

**Safeguarding
Donors**



A report on the HFEA consultation

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Chair's Foreword

The HFEA consultation 'Eggs for research: safeguarding donors' addressed the question of whether women should be allowed to donate their eggs to research projects and, if so, how to ensure that their interests are best protected. From September to December 2006 information and views were gathered to inform an Authority policy on the use of donated eggs in HFEA licensed research. This consultation was an opportunity for the public to comment on where they think the balance lies between protecting people from the risks of egg donation for research and the right to choose whether to donate. Views were also gathered on how donated eggs should be used.

The questions of payment and the medical risk of donation were considered previously as part of the HFEA's sperm, egg and embryo donation (SEED) review and so were not considered as part of this consultation.

This report presents a summary of the information we gathered including an outline of the main themes of the responses we received to each question posed in the consultation document. Two strong themes that emerged from these responses were: autonomy (the woman's right to choose whether to donate) and ensuring medical risks of donation are minimised.

After analysing the information gathered, the Authority decided that egg donation for research is appropriate and developed principles to ensure that research donors are protected. These principles will apply to all egg donors, whether their donation is to be used for research or for other purposes.

Guidance for centres concerning donation for research will be developed and added to that already in the Code of Practice to ensure robust safeguards for those involved. This guidance will be added in the first update of the 7th Edition of the Code of Practice in Autumn 2007.



Shirley Harrison
Chair, HFEA



1. Introduction

1.1 The purpose of this review was to gather information and views to inform an Authority policy on the use of donated eggs in HFEA-licensed research.

1.2 As part of this review we have carried out various pieces of work including:

- A public consultation;
- Hosting a meeting of researchers and experts in the field;
- Opinion gathering by attending a public meeting discussing the issue of egg donation to research;
- A literature review on donor motivations;
- Desk based research on the medical, legal and international issues relevant to egg donation for research.

This report presents a summary of some of the information gathered to support the Authority's decision making on this issue. The key decisions taken by the Authority following the review can be found at the end of the document.

2. Background

2.1 This topic was first considered in February 2006. Subsequently, the Authority decided that more information was required and that a public consultation should be undertaken. This was announced in May, and the consultation ran from September until December 2006. The consultation document can be viewed on the HFEA website.¹

2.2 During the consultation period, a research Licence Committee was required to consider an application from a research group who wanted to recruit egg donors for research projects both through egg sharing arrangements and as non-patient donors. This application was approved.

2.3 Following the Authority decision, a policy statement was produced and is available on the HFEA website. New Guidance will be introduced into the 7th Edition of the Code of Practice including measures to safeguard donors in addition to those that are already in place.

¹ <http://www.hfea.gov.uk/en/1417.html>

“New Guidance will be introduced into the 7th Edition of the Code of Practice including measures to safeguard donors in addition to those that are already in place.”

3. Summary of the consultation responses

3.1 The consultation addressed the question of whether or not members of the public and interested parties, thought that it was appropriate for women to donate eggs for use in HFEA-licensed research. The consultation provided some background to the issues and then presented questions in two sections. The first section of the questions related to whether or not respondents agreed with egg donation in general. The second section related to measures that could be introduced to protect the donor should donation to research be permitted. The responses that we received were varied and there was no clear consensus. Some responses related to the views of many people and therefore it is not appropriate to present the consultation responses numerically. The purpose of the consultation was to understand the range of views rather than to carry out a poll.

3.2 The consultation responses will be briefly summarised in this report. A more detailed description of the responses including examples of the reasons given to support answers can be found in Annex A.

Should women be able to donate eggs to research?

3.3 This question was divided into two parts, firstly considering this question for non-patients and secondly for women participating in an egg-sharing arrangement.

3.4 For non-patient donation, a slight majority of respondents felt that women should be allowed to donate. The reasons given to support this answer were largely based around autonomy (the right of individuals to make free decisions). The reasons given by most of those who disagree with donation for research related to the medical risks of donation.

3.5 For the second part of this question, where egg sharing for research was considered, slightly more respondents said that women *should not* be able to donate eggs to research. This shift in opinion was due to the fact that many respondents disagree with egg sharing in general because of concerns around the possible incentive of reduced treatment costs.

“For non-patient donation, a slight majority of respondents felt that women should be allowed to donate.”

Do you consider the medical risks of donation too great to allow non-patients to choose to donate to research?

3.6 This question was specifically asked to address the risk-to-benefit ratio associated with donation to research. This question largely related to non-patient donation because egg-sharers would be undergoing treatment anyway and would therefore have accepted the risks for their own treatment. The majority of people that answered this question thought that the risks were not too high, again stating that it is up to the individual woman to decide for herself. For those people that felt that the risks were too high this was most often because of the unknown long-term health risks associated with the drugs and treatment.

Do you consider the ethical risks too great to allow women to donate to research?

3.7 For non-patient donation, most respondents did not feel that the ethical concerns were too great to allow egg donation to research. Many respondents referred to the autonomy argument to explain this point of view. When asked about egg sharing more people considered there to be ethical concerns, particularly the risk of coercion because of the incentive of reduced treatment cost.

Do you consider egg donation to research to be significantly different to egg donation for treatment?

3.8 A small majority of people did consider there to be differences between donation to treatment and donation to research. The reason most often given for this was the relative benefits that each result in. For treatment it was generally felt that the benefits are more immediate and tangible whereas for donation to research the benefits are currently theoretical and may not necessarily be received within the lifetime of the donor.

Do you consider the issues associated with non-patient donation to be different to those associated with egg-sharing for research?

3.9 The majority of people who responded to the questionnaire did think that there was a difference between donating to research as a non-patient and donating through an egg sharing arrangement. The main reason for this related to the motivation of the donor. It was felt by some respondents that people who donate through an egg-sharing arrangement are more likely to be doing so only because they will receive reduced treatment costs, while those people who donate as non-patients are more likely to be doing so only to benefit research.

Measures to safeguard donors

3.10 The measures that were suggested in questions 6 and 7 are ones that were already in place in some form (for research that may result in stem cell lines being derived) to ensure informed consent and prevent potential conflicts of interest. Most respondents agreed that the measures proposed in questions 6 and 7 should be in place.

3.11 The measures suggested in questions 8 and 9 are ones that could be introduced in order to ensure informed consent and prevent conflicts of interest respectively. The views expressed in response to question 8 were more varied than for questions 6 and 7. One measure that was well-received was a cooling-off period, whereby the donor can withdraw her consent before any treatment takes place. A measure that the majority of respondents did not agree with was that which required relatives of people who suffer from a condition that could potentially be cured by treatments resulting from stem cell research to have additional counselling before donation.

3.12 The measure which the fewest amount of respondents agreed with was where formal consent to donation should be taken by someone not directly involved in the research project.

“some of the researchers felt that it was too soon to be carrying out somatic cell nuclear transfer (SCNT) research with human materials.”

3.13 Question 10 asks whether respondents felt that additional whistle-blowing measures should be put in place. The majority of respondents did not feel that this would be necessary.

3.14 The final question offered respondents an opportunity to comment on whether they felt that the suggested measures would adequately protect donors, and if not, what additional measures they thought would be necessary. The majority felt that if the measures that they had agreed to were introduced women wishing to donate would be adequately protected.

3.15 Some respondents felt that even with all the measures to which they had agreed in place, donors would not be adequately protected. Additional suggested measures were follow-up health checks for donors to improve understanding of the long-term effects of stimulation.

3.16 A proportion of respondents felt that no measures would be adequate to protect donors. This was often because they disagreed with women being able to donate eggs to research in general.

Letters and views

3.17 In addition to the formal responses to the consultation, we received a number of letters and emails from people sharing their views on the issue of egg donation to research without specifically addressing the questions in the consultation document. The majority of the ‘views’ we received disagreed with egg donation for research. The main reason for this was because it resulted in embryo research which many of the respondents objected to.

4. HFEA expert meeting with researchers

4.1 In order to inform the discussion from a scientific point of view, we hosted a meeting of scientists involved in stem cell and embryo research. The purpose of the meeting was to address some of the questions relating to the eggs for research project. When the consultation was launched, it was clear from reports in the media that there were divided opinions on the issue of human eggs being used in somatic cell nuclear transfer research. We wanted to address this, and other related issues.

4.2 The meeting was attended by 16 researchers including two from outside the UK. The questions addressed at the meeting were:

- What is the current situation in basic embryo research?
- What is the future of basic embryo research, how will another source of eggs impact on this research?
- How efficient are we at producing human embryonic stem cell lines?
- How efficient are we at directed differentiation of embryonic stem cell lines?
- What are the alternatives to individualised stem cells for therapy?

4.3 Notes of the meeting are attached in Annex B. To summarise, some of the researchers felt that it was too soon to be carrying out somatic cell nuclear transfer (SCNT) research with human materials as there was still a great deal that could be learnt using animal studies. Those that held this opinion fell into two groups. The first group felt that the field could benefit from further research using only animal materials (not using human eggs or nuclear material). The other group felt that it was too soon to use human eggs for this research but it was appropriate to use human nuclear material with animal eggs, creating ‘hybrids’ (interspecies cell nuclear transfer embryos). There were also those who felt that stem cell research would benefit from work using human eggs.

4.4 Although there was no consensus about the research priorities at this point, the purpose of this review was to consider the use of donated eggs in research in general in order to develop an Authority policy. Any decisions relating to specific applications would be considered on its own merits by a Licence Committee taking into account the Authority policy.

5. Medical risks of egg donation to research

5.1 Egg donation involves medical procedures. The medical procedures that are undertaken for egg donation are the same as those that women undertake when they undergo IVF. As with other medical treatments, there are risks associated with egg collection and IVF. It has also been proposed that there may be long-term risks associated with taking the fertility drugs. The most significant risk associated with IVF treatment is that of ovarian hyperstimulation syndrome (OHSS).

5.2 The risk of OHSS and donation was considered recently as part of the Sperm, Egg and Embryo Donation (SEED) review. As part of this consideration we commissioned a report from an expert on OHSS, Professor Adam Balen, in February 2005. This report is available on our website (www.hfea.gov.uk) and it concluded that:

'There is insufficient evidence to suggest that women should not undergo altruistic 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.'

5.3 As part of this review, research published since the Balen report was also considered. We are not aware of any new evidence that would suggest that this position has changed and Professor Balen also felt that there was no new information to add.

5.4 Professor Balen also responded to the consultation stating that he did not consider the medical risks of egg donation to be too great to allow non-patients to choose to donate eggs to research.

6. Information relevant to Authority decision

6.1 In addition to the views gathered in response to the public consultation and the meeting of experts, the Authority also considered other information in order to inform their decision. A summary of this information can be found on the website.² This included:

- A literature review on donor motivation.
- Details of a public meeting held in Edinburgh discussing egg donation to research.
- Details of the Helsinki Agreement and research trials.
- Infertility Network UK (IN UK) survey on egg sharing (brief summary of the relevant information relating to research).
- Views of international organisations on the acceptance of stem cell lines derived from eggs procured through egg sharing arrangements.
- Preliminary views of some research funding bodies on egg sharing for research.
- Summary of legal issues.

² www.hfea.gov.uk/en/14117.html

“The most significant risk associated with IVF treatment is that of ovarian hyperstimulation syndrome (OHSS).”

7. Conclusions

7.1 At their meeting in February 2007, the Authority discussed the responses to the consultation and the other information relating to the review that was presented to them. A summary of the decisions can be found below.

Key decisions made by the Authority

- 1.** Egg donation, either as non-patient donation or through egg-sharing arrangements, to HFEA-licensed research should be permitted, if considered to be appropriate by a Licence Committee.
 - 2.** Where it is possible to donate through egg-sharing arrangements to either research or treatment, there should be parity in the benefit-in-kind offered so that it is not advantageous to donate to either one or the other.
 - 3.** The following principles should be in place (not all of these measures will require changes to the Guidance as they are already in place) to ensure that donors are protected. These measures should, where appropriate apply to all research donors.
 - a.** Donors should be approached about the possibility of donation by someone not involved in the research project.
 - b.** Patients should be provided with detailed information relating to the research project including the likely outcomes and how any donation will impact on the work.
 - c.** Potential donors should have the option to discuss the project with a researcher.
 - d.** Before consent is given, potential donors should be given information on the personal and financial benefits that the researchers may receive as an indirect result of the donation.
 - e.** For egg sharing, the eggs should be divided into those for research and those for treatment by an embryologist not involved in the research project.
 - f.** For egg sharing, prior to collection there should be an arrangement in place detailing how the eggs are to be divided between the donor and the research project.
 - g.** For egg sharers, the centre should ensure that the research will not affect the outcome of treatment and that donation would not impact on their treatment.
 - h.** There should be some principle of separation between making the decision to donate and taking consent/starting treatment.
 - i.** Where the donor is in a dependent relationship with the person taking consent, or with someone involved in the research project, extra caution should be taken when obtaining consent.
 - j.** Formal consent to donation should be taken by someone not directly involved in the research project.
 - k.** The medical treatment should be overseen by someone not involved in the research project.
 - 4.** The selection and screening criteria for research donors should be considered further as current donor guidance is aimed at donation for treatment. This work should be carried out with research groups and professional bodies.
- 7.2** These principles will be developed into Guidance during Spring 2007 and will be incorporated into the first revision of the 7th Edition of the Code of Practice which is likely to be in Autumn 2007.

“At their meeting in February 2007, the Authority discussed the responses to the consultation and the other information relating to the review that was presented to them.”

Summary of the consultation responses

Question 1a Do you think that women should be able to donate eggs to research as **non-patient donors**?

The majority of people who answered this question were in favour of women being able to donate eggs to research. Where reasons were given, most people supported their answer with the autonomy argument, suggesting that it was for the woman considering donation to decide.

The next most common reason given, referred to the medical risk associated with the stimulation for the donors particularly because the donors would be undertaking medical procedures that were not necessary for their own treatment.

A proportion of the respondents objected to donation to research because of moral objections to embryo research. Others disagreed because they objected to the use of human eggs for specific research. For example, many people commented that cell nuclear replacement is inefficient and that the treatments that could result from this research are only theoretical.

Other reasons were that the long-term risks of ovarian stimulation are not adequately understood or that there are alternate sources of material for research e.g. spare embryos or failed to fertilise eggs.

Specific responses to question 1a

“Harvesting eggs from women for research is a violation of the Helsinki Declaration, which was introduced to protect people involved in medical research. We call for a global moratorium on egg harvesting for cloning research purposes, at least until we understand its human costs more fully.”

Hands off our Ovaries

“There are medical and scientific requirements for egg donors and provided fully informed appropriate consent is obtained, competent adults should be free to participate in either aspects of this work.”

Member RCOG

“Whilst many women are prepared to undergo the unpleasant and risky procedure of IVF in order to overcome infertility, a major benefit to themselves, in basic research, the benefits are very speculative, and since it is inevitable that some women will suffer OHSS, the risk/benefit ratio is much too high.”

Human Genetics Alert

Question 1b Do you think that women should be able to donate eggs to research as **egg sharers**?

In contrast to the first part of this question where the majority of respondents were in favour of (non-patient) women being able to donate to research, when asked about egg sharers, the majority changes and slightly more respondents disagree. However, this was not a significant majority.

When the reasons given are analysed it is clear that this shift is likely to be due to many of the respondents disagreeing with egg sharing in general primarily because of concerns around coercion (financial incentive to donate).

Other reasons given were disagreeing with the research or the medical risk of donation regardless of the fact that women would be undergoing this treatment anyway. Several of the responses refer to the unknown long-term risks of the treatment.

The main reason given for those who supported egg donation for research was around autonomy. Other respondents pointed out that the woman is not undertaking any additional risk as she intended to have treatment anyway.

Other people commented on the necessity of egg sharing. Although not necessarily supporting it, some respondents acknowledged the need for it to enable more people to be able to access fertility treatment. However it was also noted that participation in an egg sharing arrangement could impact negatively on a patient's treatment as they may ultimately require more cycles.

Specific responses question 1b

“The BMA's Medical Ethics Committee discussed this issue on two occasions and reached the conclusion that it did not have any ethical objections to egg sharing for research.”

British Medical Association

“.. the only form of 'free-choice' (free from coercion, exploitation, inducement or pressure) can be one in which woman can be certain to have not been swayed in their decision by other factors. Any 'arrangement' by its very definition would involve some form of 'deal' and so the eggs would become a commodity and these other factors, e.g. money, desire for a child, would be on the table and exploitation inevitable.”

Individual

Question 2 Do you consider the medical risks of donation too great to allow non-patients to choose to donate to research?

The majority of people who responded to this question did not think that the medical risks of donation were too great to allow non-patients to donate to research. Of those that gave reasons for this, the most frequently given was that it is up to the woman donating to decide whether she is prepared to accept the risks and consent accordingly.

For those that did think the risks were too high it was largely because of concerns that the long-term risks are not sufficiently well understood. On the other hand, some people who responded to this question suggested that there are not actually any medical risks associated with donation.

For some respondents who felt that the medical risks would be too high it was because the donor would be undergoing treatment that they don't require which would be without any direct benefit to them. Finally, there was a small percentage who argued that because egg donation for treatment is accepted, it would be inconsistent to not allow women to donate for research.

Specific responses to question 2

"While research on somatic cell nuclear transfer would benefit from higher quality eggs than are presently available, with current knowledge it is unlikely that the medical risks to the non-patient donor would be outweighed by the research benefits. This is not a reason to make such donation illegal; rather each case should be considered on its merits by the local research ethics committee and the research funder (and possibly others)."

Colin Blakemore, MRC

"With appropriate counselling the risks are minimal – it should be mandatory to use only low doses of gonadotropins if ovarian stimulation is required."

Adam Balen

"The risk to benefit ratio in this case is too loaded towards harm when individual treatment benefits do not apply. Although the chance of death is very small, less serious harm is likely and we do not fully know the longer term effects of ovarian hyperstimulation."

**Joint response, Innogen,
University of Edinburgh**

Question 3. Do you consider the ethical concerns so significant that people should not be able to donate to research?

For non-patients

The majority of respondents felt that the ethical concerns were not so significant that it should prevent women from

being able to donate. The primary reason given to support this was because it should be the right of the woman to decide whether or not to donate.

A proportion of respondents did not agree with embryo research. A similar amount of respondents had concerns associated with the medical risks for the donors. There were also some respondents that commented specifically on the long-term risks of medical treatment suggesting that too little is known about how donation may affect women in the future or alternative sources of eggs that could be used for this research.

Specific responses to questions 3a and b

"Bearing in mind the risks involved, it is seriously questionable whether any woman should be asked to undergo ovarian stimulation to procure eggs as a medical procedure at all: the risks demand that it should not be undertaken unless it is in the woman's best interests, which it would never be."

Lawyers Christian Fellowship

"Provided that both proper measures are in place to assuage ethical concerns; and that women are properly informed of the risks, benefits and procedures involved, women should be allowed to donate if they so choose."

Genetic Interest Group

"If the risks were so great to be "too great" why do we allow non-patients to donate for treatment? Obviously it is vital that information and counselling are provided and that donors are aware of the implications of their donation. But it should be their choice."

Infertility Network UK

"All research projects should (with procedures currently in place) be scrutinised by various bodies to ensure it makes best use of precious material such as human eggs, has feasible objectives and is carried out with the greatest integrity."

Royal College of Nursing – Fertility Nurses

"In relation to egg sharing, we do not believe that offering a reduction in treatment costs to women who choose to donate their eggs, whether for treatment or for research, amounts to an inducement to donate or presents ethical difficulties. In our experience, the reduction in costs is not the determining factor when women decide to donate and again make the point that this is already allowed in the case of egg donation for treatment purposes"

North-East England Stem Cell Institute

Question 3b Do you consider the ethical concerns too great to allow egg sharers to donate to research?

A small majority of people who responded to this question did not think that the ethical concerns were too significant to prevent people from donating to research. There are

more people that think there are ethical concerns associated with egg sharing for research than non-patient donation for research. Again, this is because many respondents disagree in principle with egg sharing because of concerns around coercion and financial inducement. Other reasons given for disagreeing with egg sharing for research is because the risk-to-benefit ratio is too high or that respondents disagreed with the research in general.

For those that did not think there were specific ethical concerns associated with egg sharing for research two main reasons were given. The first was that the woman should be able to decide for herself. The second reason is that as the woman is willing to undergo stimulation to get pregnant, she has already accepted the risks and by donating eggs to research she is not undertaking any additional risk.

Some respondents commented that egg sharing can have an impact on the patient's treatment, perhaps resulting in them requiring additional cycles. Others felt that egg sharing for research has less ethical implications than egg sharing for treatment because there is no chance that a child will be born as a result of the donation.

Question 4 Do you consider egg donation to research to be significantly different to egg donation for treatment?

The majority of people who responded to this question did think that there are significant differences in donating to research and treatment primarily because there are more immediate and tangible benefits from donating to treatment. Respondents felt that the research for which donated eggs may be used only offered treatments which *may* be available a long time in the future.

Another reason given was that there is a difference because donating to research will not result in the birth of a child and therefore there are less associated emotional and/or long-term implications. Some considered donation to treatment preferable to donation to research because they object to embryo research.

The fact that donation to research will result in the 'advancement of science' was also given as a reason for the difference between donation to research and treatment. A similar proportion reasoned that the motivation of the donors was likely to be an important difference between those wishing to donate to research and to those who might wish to donate to treatment.

The reasons given by respondents who thought that there was no difference between donation for treatment and research, was because the only thing that mattered was the woman's right to choose.

Specific responses to question 4

"Providing eggs for fertility purposes has an immediate and direct benefit, while there are no direct benefits to anyone in the research context."

Pro-Choice Alliance for Responsible Research

"The central difference between donation for research and donation for the treatment of others is that the latter is intended to result in the birth of a child which may have emotional and social significance for the donor and her family, whether or not she has children herself or intends to. Donation for research will not result in the existence of a child, but may raise critical ethical and moral issues about the status of the embryo and its destruction."

Project Group on Assisted Reproduction (PROGAR)

"Other members took the view that the principle is the same: eggs are being provided either without compensation, which may compromise treatment, or with compensation, which is arguably coercive. This applies regardless of the intended use or fate of the eggs."

British Fertility Society

Section B The following measures are already in place. Do you agree that they should be introduced to apply to egg sharing and non-patient egg donation for research?

These questions relate to how to protect donors if donation to research were to take place and measures that are already in place but largely only for research resulting in embryonic stem cells. We asked these questions to understand whether people felt that similar measures should apply to all research donations. We received fewer responses to these questions because a proportion of people who disagree with egg donation for research declined to answer these questions.

Question 6 relates to measures to ensure informed consent. The significant majority of respondents agreed with all the measures put forward in section 6. The measure that the fewest people agreed with related to potential financial and personal benefits that the researcher might receive as a result of the donation. The measure that the greatest number of people agreed with is that patients are expected to be provided with detailed information relating to the research project.

At the end of each section respondents were given an opportunity to comment or give reasons for their answers. Some of the reasons given for disagreeing with the measures have been picked out for further information.

One person who disagreed with all the measures in section B gave the following reason for doing so. "As this consultation is about whether egg donation should be allowed I have answered 'disagree' to these questions - I don't believe they should be asked in this consultation because they should not be considered until the general principle of egg donation has been accepted."

One person disagreed with the first measure relating to who should approach potential donors in the first place. Their reasons for saying so was: "Research subjects should not be approached until we can tell them this is safe."

One respondent gave the following reason for disagreeing with the measure 'Donors should have the option to talk to researchers about the work that they are carrying out': *"It is likely that researchers of the greatest integrity would be, understandably and naturally, biased towards promoting the most positive aspects of donation."*

A reason given for disagreeing with 'Potential donors should be given information on the personal and financial benefits that the researchers may receive as an indirect result of the donation' was that it is not possible to determine accurately what the outcomes or benefits of the research may be, it is simply 'conjecture'.

One organisation (Our Bodies Ourselves) gave the following general comment *"I believe that there should be a moratorium on egg donation for research purposes, but if policies were to go forward that allowed for such egg donation, then the answer would be "yes" to all of the above."*

Question 7 presents measures to prevent conflicts of interest. In general, a significant majority of respondents who answered this section agreed with the measures put forward. The measure that many respondents supported was ensuring that for egg-sharing, the centre should not have any policy or make any decisions that would impact adversely on the patient's chance of becoming pregnant.

Where people disagreed with any of the suggested measures they were given an opportunity to comment. The following reasons were given for disagreeing with the measures proposed in question 7.

"Similar policies to egg sharing for treatment should be in place to protect the egg donor going through treatment to ensure as much as possible that the patients chance of a pregnancy is not compromised. For instance, random allocation of oocytes and a pre-determined threshold for the number of eggs recovered for acceptance into the egg share arrangement."

Association of Clinical Embryologists

"It should always be the case that the eggs considered most likely to give rise to a healthy embryo should be the ones used for treatment."

MRC

"Clinical embryologists should work 'blind' until embryos are selected for embryo transfer and cryopreservation, then should find out if patients consented for research."

Human Embryonic Stem Cell Coordinators (HESCCO)

Section C The following additional safeguards could be introduced for research. Do you agree with the following measures?

Section C details possible measures that could be introduced in addition to those already in place.

Question 8

Question 8 details potential measures designed to ensure informed consent. One proposed measure that a significant majority agreed to was that of a 'cooling-off period'. In this section, respondents agreed to most of the measures to some extent.

One measure that the majority of people disagreed with was that relatives of people who suffer from a condition that could potentially be cured as a result of research following egg donation should be subject to additional restrictions. This would suggest that respondents did not feel that this group of women are likely to have been coerced or persuaded into donating. Reasons given to disagree with this were that it might be a beneficial or healing experience for family members to donate eggs to research that may help cure a condition from which a family member is suffering.

The BMA's medical ethics committee disagreed with all the proposals suggested in question 8 but specifically for the cooling-off period. The reason given for this was *"[...] that individuals' needs should be considered individually. So, women considering donation should be given as much time as they need to assess the information and decide whether to proceed – this will vary between individuals."*

Many respondents who answered this question disagreed with the proposed measure that before consent is given, independent assessors should evaluate potential donors to ensure that they have not been coerced. The British Fertility Society (BFS) were one of those who disagreed with the second proposal because *"This might be desirable in an ideal world but would be unworkable. It would be expensive to employ independent assessors, and patients would be deterred from consenting by the additional time and invasive nature of the assessment."*

One respondent who disagreed with the measure that potential donors would be expected to see independent counsellors to ensure that they have fully understood the implications of donation, gave the following reason for doing so: *"Independent counsellors should be available, as in all licensed clinics, but donors who consent should not be forced to see independent counsellors."*

There was less support for the measure ensuring informed consent by requiring potential donors to take a test. Reasons given for not agreeing with this potential measure were that it seems like unnecessary nannying or that women would resent having to pass an exam before they were allowed to donate.

One measure suggested that women should not be able to donate to research projects with which they were involved. Although there was some agreement with this proposal it was not universally welcomed. Of those that disagreed, the following reasons were given. *"Those working in the research or research institution are likely to have a greater understanding of what is involved once the eggs are donated and, of course, it's a matter of freedom of choice and will."*

Question 9

Question 9 suggests possible measures that could be introduced to prevent conflicts of interest. In general, most respondents agreed with all of the measures. The measure that most people disagreed with was where consent should be taken by someone not directly involved in the research project.

One respondent who disagreed with the measure that formal consent should be taken by someone not directly involved in the research project, did so for reasons of logistics, suggesting that it would be impractical and costly to have a separate member of staff to take consent.

Specific responses to question 9

“One of the concerns that has been raised is the risk that clinics might be tempted to give higher doses of drugs to donors in order to maximise the number of eggs available for donation [...]. It is important that there are safeguards to remove any suspicion that this might or could happen; separating the clinical care of the donor from the donation of the eggs and from the research provides this reassurance.”

British Medical Association

“The extent of the safeguards proposed simply underscores the basic ethical uncertainties inherent in these proposals.”

Individual

“If the senior consultant in a unit is involved in research, he or she would here be denied the right to oversee the care of some of the patients in the unit. We do not believe this is workable, enforceable or desirable from the point of view of either patients or staff.”

North-East England Stem Cell Institute

Question 10

The majority of respondents did not feel that it was necessary to introduce an additional whistle blowing procedure in addition to what the HFEA already has in place. Those people who thought it might be necessary suggested that it should include not just people working at licensed clinics but to also include staff at, for example, the research institution.

Specific responses to question 10

“As a general principle, I support the facilitation of ‘whistleblowing’ as a means of ethical peer review where they may not be any alternative and this may be the only way of a case being brought to light for examination.”

Individual

“All staff working in assisted conception units are aware of the HFEA through its regular inspections. Staff are reassured by a visible regulatory body assessing the unit’s work and appreciate they can contact the HFEA as an independent body which is separate from the NHS and their local Trust.”

Advisory committee on ethics for the assisted conception unit

“The HFEA should also deal with whistle-blowers from the research team (or those in the same establishment), but this should be on the basis that the HFEA would share the information with the research funder as soon as an allegation has been substantiated.”

Medical Research Council

Section D

Question 11

The majority of people who responded to the consultation felt that if the measures that they had agreed to were introduced, women wishing to donate would be adequately protected. Additional suggested measures were medical follow-up of women after donation. Additionally, some people considered that there should be a limit on the number of times that people should be able to donate, or be encouraged to hear the views of people who disagree with embryo research.

Specific responses to question 11

“We believe that there are no additional safeguards that would ever ensure the safety of donors. As described above under question 2, the medical risks associated with egg donation need full and thorough research. There are no safeguards that would ever take away the ethical concerns associated with egg donation (see our answer to question 3 above). For the sake of the poorest and most vulnerable in our society, for the sake of women and human life in the womb, egg donation is something that should be resisted.”

The Lawyers Christian Fellowship

“I think the risks are too great so that no safeguards would be sufficient”

Individual

“The project details and patient notes should be thoroughly audited at inspection. There should be an agreed patient pathway for the management of complication of stimulation and egg collection e.g. OHSS and all cases audited.”

HESCCO member

Views from the consultation

We received responses from 11 organisations and 15 individuals (although one of the individual responses represented the views of 18 people). The views in this section were from people that did not complete the questionnaire provided in the consultation. Of the views that we received there was one organisation and one individual who felt that women should be able to donate eggs to research projects. The majority of responses were from people who disagreed with the use of donated eggs for research projects.

Notes from the embryo research expert meeting 30th November 2006

1. Present

Researchers

Peter Braude	Daniel Brison
Henry Leese	Stephen Minger
Harry Moore	Alison Murdoch
Lorraine Young	Bruce Campbell
Jose Cibelli	Luca Gianaroli
Richard Gardner	Maureen Wood
Maybeth Jamieson (Authority)	Chris Barratt (Authority)
David Barlow	

Authority members

Neva Haites (Chair)
Lord Richard Harries
Emily Jackson

Observer

Andy Earnshaw (DH)

Executive

Katy Berry	Hannah Darby
Thomas Girling	Charles Lister
Chris O'Toole	Sarah Payton
Tim Whitaker	

2. Notes from the meeting

Professor Neva Haites introduced the meeting stating that the purpose of the meeting was for the HFEA to improve its understanding of what is happening now in research and what may happen in the future. The topics for discussion would be broadly related to the current consultation that the HFEA is carrying out considering the use of donated eggs in research. It was noted that this meeting would not be minuted but notes would be made of the meeting. No comments would be directly attributable to any individual.

2.1 Basic embryo research

Very little is known about early human development. Some people were of the view that more basic research is required and to continue solely on human embryo research would be 'unthinkable'. However, it is not always necessary to assume that animal research will tell us what we need to know about humans as the mouse has turned out to be very different to humans with respect to some areas of research. For example testing an oocyte for cryopreservation techniques would require human oocytes (because of fundamental differences in animals and human embryo membranes) but for deriving stem cell lines, we should still use animal models.

2.2 How efficient are we at producing stem cells?

A stem cell line is produced in about 5-10% of embryos donated to research for this purpose. If the embryos reach the blastocyst stage, there is a higher chance that a human embryonic stem cell (hESC) line will be established, usually about 25%. The quality of the embryo or the ICM is not necessarily an indicator of the likelihood of a stem cell line being derived.

2.3 How efficient are we at directed differentiation?

The development of therapies from differentiated embryonic stem cells is a long way off. Although the timing would depend very much on what cell type was being derived, the soonest we would be likely to see any results would be 10 years. To date no one has been able to define repeatable differentiation protocols.

It was also noted that every stem cell line is unique and research often states that hESCs behave in a certain way. It would be more accurate to say that at a specific time a specific stem cell line behaves in a given way. One member of the group commented that stem cell therapies are going to come. Even if it takes 20 years, that is no reason not to carry out the preliminary research at this point. It was noted that research on human embryonic stem cells is still very new and is likely to be equally valuable for study purposes not just for therapies.

2.4 What are the alternatives to individualised stem cells for therapy?

It was noted that although there are alternatives we should be careful to avoid the debate that has been seen in the USA relating to embryonic stem cell research. There was some agreement with this amongst the group.

Although somatic cell nuclear transfer is one therapeutic option there are likely to be other options. In reality, the technique used will depend on the condition in question. One of the most successful areas of regenerative medicine is deriving them from patients e.g. cornea or skin.

Umbilical cord blood

Although umbilical cord blood has been proposed as an alternative source of stem cells it has so far not proved possible to reprogram them effectively.

***In vitro* matured eggs**

Another source is eggs that are grown or matured in the lab (*in vitro* matured oocytes or *in vitro* growth) but it was commented that there were problems with the calcium signalling of eggs developed by IVM (*in vitro* maturation) and access to immature eggs for this use would still require a medical procedure. *In vitro* growth of oocytes is the development of eggs in the lab from an earlier stage to IVM. It takes several months to 'grow' an egg in this way and the regular use of this technology is still about 10 years away.

Failed to fertilise eggs

The use of failed to fertilise eggs in this research is possible and has been a major source of material for embryo research to date. It was commented that these eggs have a limited ability to reprogram nuclear DNA (as is required in somatic cell nuclear transfer) but it is still possible to use these eggs and learn things from them.

Animal eggs

Another alternative that was discussed was the use of animal eggs for practising techniques rather than human eggs. It would not be possible to use the stem cell lines produced using animal eggs therapeutically but it might be a valid alternative in the short-term.

One researcher commented that creating hybrid embryos would result in a confusion of information and that it would not tell us what we need to know. It was felt by this person that all the questions could be answered using animal models, without the need to use human material at this stage. Another commented that efficiency of cloning was so low and that it is still not clear how it works. It was felt that there was still so much work to be done in animals before it was attempted in humans.

Another researcher commented that although there could be complications in using animal eggs and human nuclear material it would still be possible to obtain high quality data and it would still be possible to learn a great deal. As a personal view, this researcher felt that it was premature to use donated eggs from women for this research. There was agreement on this from many attendees at the meeting.

In response to this, one researcher commented that it was the right time to carry out this research on humans, initially on small numbers of eggs as it has been proved to work in animals. By designing experiments properly it is possible to learn things even from negative results (when an embryo is not produced).

3. Meeting close

Professor Haites thanked attendees for coming to the meeting and for their useful comments.



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