

SEED Report

A report on the Human Fertilisation & Embryology Authority's review of sperm, egg and embryo donation in the United Kingdom

Chair's Foreword

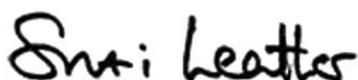
When I launched the Sperm, Egg and Embryo Donation consultation in November 2004, I said that the field of donor-assisted conception would experience profound changes and face significant challenges in the next couple of years. As we publish our conclusions, less than one year later, some of these changes have already been implemented, some of the challenges already met. But many more still lie ahead.

Few aspects of the HFEA's work can be more difficult than to review the set of policies surrounding donor-assisted conception. The hours the Authority has spent deliberating these issues over the last few months is both a measure of how difficult they are to exhaust and how important they are to resolve. This brief report cannot do justice to the volume and variety of evidence we have considered in the course of this review or to the range and richness of the arguments with which we have had to grapple. I am especially grateful to all those who contributed to our research and responded to our consultation – through your submissions you have enriched our understanding of the perspectives of treatment providers, donors, donor-conceived people and their families.

Parliament's decision to remove donor anonymity was greeted with enthusiasm by those advocates of openness – donors, recipients and donor-conceived people among them – who have long argued that donor-assisted conception is about much more than the anonymous, clinical transfer of genetic material. Some were more cynical, expressing concerns that the decision would make donor recruitment more difficult. Although we are now only just beginning to see the initial effects of the decision, those clinics who have met this challenge with energy and optimism seem to have found an answer to the cynics. But despite promising early signs it is not yet possible to say that the anticipated 'culture change' has been fully accomplished. The SEED review has given us the chance to take account of how the removal of donor anonymity is to be embedded in the regulatory measures already in place and to make any necessary adjustments to take this significant change into account.

But donor assisted conception services face an even greater challenge than finding a new generation of identifiable donors: new legislation from Europe. The EU Tissues and Cells Directive will impose new standards of quality and safety with which UK clinics will be obliged to comply. This does not mean that the UK clinics have been sub-standard in the past; on the contrary, many already meet or exceed the standards that the Directive will impose. But adaptations will inevitably be necessary to adjust to new ways of managing the quality of the service clinics deliver. The SEED Review has also given us an opportunity to begin thinking, in good time, about some of the main revisions that will be required when the Directive comes into force.

When you read this report you will see that the measures it contains, which will be implemented in UK clinics in the course of the next few months, hardly amount to a revolution in fertility regulation. But donor-assisted conception is nevertheless entering a new era. I believe that our conclusions represent a necessary reorganisation of the system of regulatory measures relating to donor-assisted conception, their re-calibration against new standards coming from Europe and their re-alignment with the evolving attitudes and values of our society. In some cases this has allowed us to lighten the impact of regulation on those seeking and providing treatment. In all cases in which measures remain in place our maxim has been to ensure that the requirements we impose are necessary to protect the interests of all those involved in, or affected by, donor-assisted conception treatment, and proportionate to that end. I believe that our conclusions will provide a consistent and enduring framework for the provision of treatment in the UK and a paradigm for good practice everywhere.



Suzi Leather, Chair

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Summary

The aim of the Sperm, Egg and Embryo Donation (SEED) review was to identify measures to secure a safe and effective service for those requiring treatment with donor sperm, eggs and embryos, whilst protecting the interests of donors, recipients and those who may be born as a result. The review was set against the background of new UK regulations to allow information about donors to be disclosed to those born as a result of their donation and the EU Tissues and Cells Directive. The review focussed on those aspects of donor-assisted conception which fall within the scope of HFEA policy and regulation. These are:

- medical and laboratory screening of gamete and embryo donors
- the selection of donors
- the number of families that may be created using gametes from each donor
- payment of expenses and other compensation (including benefits in kind) to donors
- cross-border transport of gametes and embryos and matters affecting those travelling abroad for treatment

Our conclusions are:

- i. the HFEA should move towards a reliance on professional guidance on the medical and laboratory screening of sperm, egg and embryo donors once revised guidance becomes available (para.1.6).
- ii. there should be no prescriptive guidance from the HFEA on the selection of donors for treatment of a particular recipient but the HFEA should produce guidance on issues to be taken into account (para.2.7)
- iii. although donors should continue to be able to set their own limits on the use of their gametes which must never be exceeded, gametes from an individual donor should not be used to produce children for more than 10 families in the UK (para. 3.9)
- iv. donors may be reimbursed all demonstrable out-of-pocket expenses incurred within the UK in connection with gamete or embryo donation (para. 4.5)
- v. in addition to reimbursement of out-of-pocket expenses, donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum commensurate with jury service but with an overall limit of £250 (or the equivalent in local currency) for each 'course' of sperm donation or each cycle of egg donation (para.5.11)
- vi. the egg sharing guidance should indicate that eggs collected from an egg provider in a single cycle should not be shared among more than two other recipients (para.6.9)
- vii. gamete donors may receive benefits in kind in return for supplying gametes for the treatment of others but that these benefits should be limited to discounted treatment services (para.6.14)
- viii. procurement of gametes from abroad should fulfil the same quality standards as apply in the UK and the HFEA would expect to authorise imports only where these standards can be met (para.7.4)

0 Introduction

- 0.1** People may require treatment with donated sperm, eggs or embryos for a variety of reasons. The most common of these is that they are affected by infertility or subfertility which means that they are unable to produce adequate numbers of healthy gametes (the general term for male and female reproductive cells – sperm and eggs). Other reasons include where a couple is at risk of passing on an inherited genetic condition if they conceive naturally, where a woman is unable to carry a pregnancy herself and a surrogate is required or where a woman who wants to conceive does not have a male partner to provide sperm.

Treatments for infertility

- 0.2** Where a man is unable to produce enough healthy sperm his partner can be inseminated with sperm provided by a donor to help the couple to have a child. Where a woman is unable to produce healthy eggs, eggs from another woman (egg donor) can be fertilised in the laboratory using the woman's partner's sperm (or sperm from a donor) and the resulting embryos transferred to her so that she can carry the pregnancy herself. Occasionally there will be reasons why the donation of embryos (using both eggs and sperm from third parties) will be appropriate.

The role of the HFEA

- 0.3** All treatment using donated sperm, eggs or embryos in the United Kingdom is regulated by the Human Fertilisation & Embryology Authority (HFEA). This means that treatment cannot be provided by any clinic, whether NHS or private, without a licence from the HFEA. The HFEA inspects all licensed clinics regularly to ensure that the treatments they provide meet standards laid down in the HFEA's Code of Practice. These standards relate to issues such as the screening of donors to ensure that no diseases are passed on to the mother or to any resulting child, payments that can be made to donors, and the number of children that may be born to different women using the same donor.
- 0.4** The HFEA also collects and stores information about donors and about treatments that have been provided. However its functions do not include the routine collection of information about the demand for or availability of treatment, or regulation of the cost of treatment services.

Why review sperm, egg and embryo donation now?

- 0.5** Evidence emerging over recent years has shown that some people seeking treatment with donated sperm, eggs and embryos have been finding it difficult to obtain treatment using appropriate donors. However this evidence had not been collected systematically and a comprehensive picture of the demand for donor-assisted conception services has not been available.
- 0.6** In July 2004, after two years of consultation and public debate, Parliament amended the law to allow people born as a result of donor-assisted conception to have access to information about the donors used when they reach the age of 18. For donors who donate after 1st April 2005, and any previous donors who wish to re-register, this information will include identifying information such as the donor's name and address. Whilst this is thought to be in the best interests of donor-conceived people, some believe that this change is likely also to have a significant effect on donation and donor-assisted conception. The change in the law has been accompanied by a public awareness campaign to tell people more about gamete donation and highlight the need for suitable donors to come forward. However, it is probably too early to tell what the true and lasting effects of this will be.

- 0.7** Another major legal development comes from the European Union (EU). The EU Tissues and Cells Directive, which will soon come into force in the UK, requires all clinics in the European Union which process tissues and cells for human use – including gametes and embryos – to meet common standards of quality and safety set by the EU. Most UK clinics already meet or exceed the majority of these standards, but some changes of practice to take account of the EU requirements are still necessary.
- 0.8** All these developments make the current review particularly timely. The review has allowed us to take a comprehensive look at the set of interdependent policies that affect gamete and embryo donation as a whole. The findings of the review have helped us to identify changes to our policies and guidance to support donation and treatment in this changing context. We hope that they will also assist the Department of Health to develop plans to support the change to identifiable donors and feed into the longer-term review of the legislation surrounding assisted conception that is currently underway.

What did the SEED review cover?

- 0.9** There were three main elements to the review:
- In Spring 2004, we conducted a survey of clinics to develop a detailed understanding of the current demand for and provision of treatment using donated gametes or embryos, and to identify relevant trends. Sixty-two out of the 99 clinics then licensed to store gametes and/or provide donor-assisted conception treatment responded to this survey and the findings were published on the HFEA website.
 - At the same time we started a review of clinical and scientific evidence underlying current HFEA policies to see what developments had occurred since the existing policies were put in place. This led to two more pieces of work: we initiated written correspondence with authorities responsible for other kinds of tissue and blood donation and held a meeting with invited experts to discuss clinical and laboratory practice in screening donors. We also commissioned an expert report on the risk of ovarian hyperstimulation syndrome (OHSS) in egg donors which examined the latest evidence.
 - In Autumn 2004, we launched a three-month public consultation exercise. The Consultation document, *The Regulation of Donor-assisted Conception*, asked people to comment on the areas of possible revision that had been identified in the previous stages of the review and in earlier consultation with key stakeholders (organisations representing or comprising donors, parents of donor-conceived people, service providers, counsellors and others). The consultation document included a draft regulatory impact assessment (RIA) which set out how we thought the options suggested might affect the provision of treatment.
- 0.10** In the following pages we set out in each area of HFEA policy covered by the review:
- the reasons for reviewing the current policy
 - a summary of the main evidence we have collected and the submissions we received in response to our consultation and
 - our conclusions with proposals for changes to our existing policies.

1 Screening of sperm, egg and embryo donors

Issue and reason for review

- 1.1** When donated gametes or embryos are used it is important to minimise the risk of passing on any diseases or conditions that might adversely affect the woman who is treated with them or any resulting child. Sexually transmitted diseases (such as HIV) and a number of genetic conditions could all be passed on through sperm or eggs from an affected person or carrier. In order to avoid this, donors are routinely screened by a variety of methods, including taking family histories and laboratory analysis of blood samples.
- 1.2** Our initial research and information we received from practitioners revealed considerable differences in interpretation of the evidence base for current donor screening guidance. As well as the HFEA's own guidance, there are a number of sets of guidance in existence, such as those produced by the professional bodies, the British Andrology Society and British Fertility Society. Not all of these are in agreement on every aspect of screening practice. We therefore set out to identify an appropriate approach for creating clear, consistent and evidence-based guidance.

Evidence and submissions received

- 1.3** The conclusions of our initial research were reflected by our survey of clinics. The main issues on which views were divided were:
- laboratory screening for HIV and the need for extended quarantine periods for donated sperm
 - managing the risk of cytomegalovirus (CMV) infection (a common condition which is usually fairly harmless to adults but which can cause serious disability to a baby if the mother has it during pregnancy), and
 - what guidance should be given where donors might have been exposed to infection which can cause variant Creutzfeldt-Jakob Disease (vCJD).
- 1.4** At a stakeholder meeting we held in July 2004, there was strong support for the development of authoritative guidance by professional bodies and for the idea that the HFEA should refer to this guidance in regulating clinics. This was matched by enthusiasm from the professional bodies themselves at a meeting held at the HFEA in December 2004. A joint group involving the main professional bodies has since been established to produce authoritative, consolidated guidance on screening sperm, egg and embryo donors. This work is expected to conclude in the Summer of 2006.
- 1.5** We received mixed views on this issue in response to our consultation, and the preferences expressed did not seem to align consistently with the respondent's stated interest. Many were in favour of the use of standards set by professional bodies, as long as these standards remained strictly within these bodies' areas of expertise. However a similar number were concerned about disparities in existing professional guidance and many expressed scepticism about whether professional bodies were able to take all relevant interests into account. It seems clear to us that many of those who were sceptical about the use of professional standards mistakenly thought that this would mean that there would be no HFEA regulation in relation to these standards. This is not the case, as the consultation document attempted to make clear. Overall, it appears that what most respondents wanted were clear, unequivocal, expert guidelines based on the most up-to-date evidence, with compliance being monitored and, if necessary, enforced by the HFEA.

Our reasoning and conclusions

- 1.6 A reliance on professional guidance is consistent with the belief that standard setting is better accomplished by expert groups from within the professions themselves. The recently established joint committee of professional bodies promises to work transparently and collaboratively, adopting a process that should be responsive to emerging evidence and ensure consistency of approach and outcome. Standards set by such a body should command confidence among professionals and reduce unnecessary duplication since, in reality, the HFEA would be likely to draw on the same expertise as the professional bodies if it were to revise the existing guidance itself. At the same time, the HFEA could continue to monitor compliance with the guidance and, through its licensing system, retain the power to take action against clinics for failures of compliance which put the wellbeing of patients or offspring at risk.

Conclusion (i): the HFEA should move towards a reliance on professional guidance on the medical and laboratory screening of sperm, egg and embryo donors once revised guidance becomes available

2 Selection of donors

Issue and reason for review

- 2.1 The HFEA's *Code of Practice* currently gives guidance on selecting donors. Clinics are expected to try to match the physical characteristics of the donor with those of the infertile partner or, if a woman receiving treatment with donated sperm has no partner, with those of the woman herself. However, the limited choice of donors actually available makes close matching impractical. At the same time the HFEA's guidance has been criticised for being too prescriptive and doing little, in reality, to safeguard the welfare of the children produced.

Evidence and submissions received

- 2.2 It was clear from the survey of clinics and from comments from clinicians at our stakeholder meeting that any general requirement to match donors and recipients closely would drastically reduce the availability of treatment. There is no reliable evidence, however, about the value of donor-recipient matching in relation to the welfare of donor-conceived offspring. Nevertheless, concerns remained about using the gametes of a donor from a different ethnic group to the recipient and/or her partner (where she has one) and, to a lesser extent, about the potentially damaging effect of the strong expectations parents sometimes have that a child will bear a close physical resemblance to those whose genes he or she inherits.
- 2.3 Many who responded to the consultation, particularly recipients and those seeking treatment, argued that prospective parents, rather than clinics or regulators, are best placed to determine the best interests of their offspring. These arguments were counterbalanced, however, by those of the majority of donor-conceived people who responded (although small in number) and those of respondents with an ethical or religious interest, many of whom opposed the practice of donor-assisted conception in principle. Respondents in these groups expressed a preference for matching as a requirement to protect the interests of offspring from what they saw as the potentially conflicting and compromised interests of their parents.
- 2.4 The most common argument, was that whilst a match might be desirable and was what recipients generally wanted, it should not be made a requirement in view of the lack of clear evidence that having it as a requirement contributes significantly to the welfare of offspring. Most people who took this view, indeed most respondents, argued, whilst the interests of the resulting child were of the highest importance. The most proportionate way of protecting these was by providing advice and counselling for those seeking treatment rather than by limiting the choice of potential donors in order to achieve a close physical match.

Our reasoning and conclusions

- 2.5 There is little evidence available about the value or effectiveness of donor-recipient matching, particularly in relation to the welfare of resulting children. Evidence about the welfare of adopted children and those of undisclosed paternity, which some consultation respondents relied on, must be treated cautiously as the principal effects on their welfare are often due to other factors. In any case, within certain parameters, the donor's own appearance will give little information about what characteristics offspring might inherit. Added to this, the potential for discriminating against people with legitimate reasons for wanting to use gametes from a certain type of donor should be avoided if possible.

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- 2.6** We believe, the most appropriate approach is to offer those seeking treatment advice and counselling, is focussing on the implications of using gametes from a third-party donor and highlighting the value of openness about donor-assisted conception. It should also provide accurate information about the genetic inheritance of physical and other characteristics.
- 2.7** Where those providing treatment have genuine concerns that a patient's preference for a certain type of donor could have an adverse effect on the welfare of any resulting child this should be taken into account before a treatment decision is made. Where such concerns cannot be ruled out, it would be reasonable for clinics not to offer treatment using a donor of the kind requested.

Conclusion (ii): there should be no prescriptive guidance from the HFEA on the selection of donors for treatment of a particular recipient but the HFEA should produce guidance on issues to be taken into account

3 Limiting the number of families conceived per donor

Issue and reason for review

- 3.1** At present an individual donor may only be used to produce 10 live births – singletons, twins and triplets all counting as one ‘live birth’ – although this number may be exceeded in exceptional cases. An example of such an exceptional case is where a woman who has already had a child using gametes from a particular donor wishes to have another child who is genetically related to the first. It seems clear that when donors’ identities are revealed to people conceived as a result of their donation, the number of offspring – who are all genetic half-siblings of each other – could raise additional, important issues for them and their families.
- 3.2** We have found that the way the current limit is expressed can lead to confusion about the true scope of a donor’s consent. During the course of the review problems were identified – mainly in the early years of fertility regulation in the UK – with the way in which some clinics have tried to ensure that the limit is not exceeded. Accordingly we have been working with clinics and others to develop new guidance to ensure that this will not happen in future.

Evidence and submissions received

- 3.3** From the survey of clinics there was clear evidence that the number of donors with gametes available was not capable of fulfilling the demand for treatment in the UK. Despite this, only 1 in 10 clinics suggested raising the number of permitted births as a means of increasing the availability of treatment. The current number of permitted live birth events is unlikely to be of direct relevance to egg donors as few undertake more than one or two cycles of donation.
- 3.4** Whilst some people worry that the widespread use of gametes from a few donors could lead to consanguinity (genetically-related people having children together) our research found no evidence that this risk would be significant given the relatively small numbers involved and given the large and mobile populations typically served by UK clinics. Nor did respondents to the consultation produce any such evidence although some, with consanguinity in mind, proposed complicated approaches to controlling the use of each donor’s gametes, such as limiting the number of offspring according to the catchment area of the clinic and accounting for mobility of the population or, alternatively, ensuring that each donor’s gametes were widely distributed geographically. Others returned to the approach of appealing to a notion of how many genetic offspring it was ‘reasonable’ for one person (donor) to produce.
- 3.5** Given that only relatively small numbers of offspring per donor are contemplated, the principal concern seems to be the effect on donor-conceived people (and their parents) of knowing that there might be a large number of people who are genetically related to them. (As donors are free to set upper limits themselves, we can assume that their concerns can be addressed in this way.) These concerns were raised both by stakeholders at the meeting in July 2004, and by many respondents to the consultation.
- 3.6** Whatever limit is set it is clearly important for all those involved to have confidence that it will be observed. Those who attended our stakeholder meeting particularly agreed that a calculation based on the number of ‘families’ a donor would be used to create, rather than ‘live birth events’ was preferable because it would clarify the situation for both donors and recipients.

- 3.7 Among consultation respondents, many clinics and recipients (particularly recipients who had waited, or were waiting, a long time for treatment) argued for a higher limit to increase the availability of treatment. It was notable that the interests of some recipients appeared to be at odds with some of the views expressed by donor-conceived people. The difference of perspectives was reflected by the average value suggested by the different groups: medical and scientific respondents, gamete donors and recipients tended to favour a higher number (10 or more) whereas donor-conceived people and counsellors/ social workers and those with an ethical or religious interest favoured a lower limit (the average being in the range 4-5 families).

Our reasoning and conclusions

- 3.8 There is a strong case for moving to a calculation based on the number of families rather than 'live birth events' for two reasons. First, because it allows greater precision about the true scope of the donor's consent, replacing uncertainty about what the donor understood to be covered by the vague term 'exceptions'. Secondly, combined with a careful definition of the term 'family', it provides for the creation of siblings and half siblings for existing children in non-traditional families (step families, same-sex families, etc.) where a genetic link between siblings might be thought to be beneficial.
- 3.9 As there was little support for raising the number of families having children with gametes from a single donor, respondents who had concerns about consanguinity should be reassured. (Individual clinics that serve a small and immobile population should continue to take these concerns into account.) The real balance that needs to be struck is between making the best use of a donor's generosity and protecting the presumed interests of donor-conceived people which, it is widely believed, argues in the direction of fewer families per donor. Taking this into consideration, and as any maximum number is inevitably arbitrary, the case does not seem to have been made for a change to the existing maximum although there is a need for clinics to ensure that this maximum is not inadvertently exceeded.

Conclusion (iii): although donors should continue to be able to set their own limits on the use of their gametes which must never be exceeded, gametes from an individual donor should not be used to produce children for more than 10 families in the UK

4 Out-of-pocket expenses for sperm, egg and embryo donors

Issue and reason for review

- 4.1 Article 12(1) of the EU Tissues and Cells Directive provides that “*Donors may receive compensation which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation is paid.*”

The guidance given by the HFEA on reasonable expenses has not been reviewed since June 2000. A review is required to ensure that it is consistent with the Directive and takes account of the types of expenses currently incurred by donors.

Evidence and submissions received

- 4.2 It is clear from all the evidence collected that donors incur significant out-of-pocket expenses in order to donate. Such costs typically relate to travelling expenses, parking, childcare costs and, occasionally, overnight accommodation. Costs such as these are, with some minor variations (such as additional travelling expenses paid for a donor’s companion), permitted by UK authorities responsible for tissue, organ and, in some cases, blood donation. Some respondents to our consultation pointed out that those who donate left-over embryos from their own treatment should also be entitled to reimbursement of expenses as they have to attend their clinic again to alter their consent and to receive additional counselling.
- 4.3 Most of those who gave evidence agreed that donation should be ‘expense neutral’ for donors, meaning that donors should neither profit nor lose out financially as a result of donating. However, all the donor-conceived people who responded thought that even to reimburse expenses would risk obscuring the donor’s motivation. As we have noted there were some, particularly those with an ethical or religious interest, who consistently disapproved of gamete donation in principle.
- 4.4 This general principle of cost neutrality was frequently qualified, however, by concerns that donors coming from overseas might see the opportunity of a fully-reimbursed visit to the UK as an incentive to donate. Another concern was that high levels of expenses for some donors could be passed on to recipients.

Our reasoning and conclusions

- 4.5 There seems to be little reason to object to reimbursing a donor for money that they have already paid out where this payment is incurred in direct connection with their donation. As donors’ expenses vary considerably there should be no upper limit to expense payments to avoid disadvantaging donors who live a long way from a recruiting centre. However, there are persuasive reasons for restricting reimbursement to expenses incurred within the UK, such as that some might see a fully-funded visit to the UK to donate sperm, or even eggs, as a benefit in itself.
- 4.6 In all cases in which expenses are reimbursed, proof of expenditure should be required and we will give clinics additional guidance on how to judge which expenses are strictly ‘related to’ donation and which are merely coincidental.

Conclusion (iv): donors may be reimbursed all demonstrable out-of-pocket expenses incurred within the UK in connection with gamete or embryo donation

5 Additional compensation for gamete donors

Issue and reason for review

- 5.1 Discussion of compensation payments to gamete donors has been ongoing since the HFEA first commenced its powers in 1991. The HFEA has always advocated the principle of non-payment although, recognising the persistent difficulty in recruiting donors, it has not so far imposed this on clinics. Instead, donors have been permitted to receive £15 in respect of each donation, as well as reimbursement of expenses. However, the regulatory environment within which gamete and embryo donation takes place is changing. The EU Tissues and Cells Directive provides that donors may only receive compensation “*which is strictly limited to making good the expenses and inconveniences related to the donation*” (Art.12(1)).

A review of current UK provisions is therefore required to ensure compliance with the Directive.

Evidence and submissions received

- 5.2 In addition to out-of-pocket expenses our review investigated arguments relating to two further sorts of payment to donors:
- compensation for the ‘personal inconvenience’ of donation and
 - opportunity costs such as loss of earnings.
- 5.3 Despite the limitations of the Directive, some respondents to the consultation argued that donors should be free to sell their gametes on an unregulated market. Others said that compensation should be given in recognition of the disruption and physical inconvenience associated with gamete donation or even for the small health risk borne by egg donors.
- 5.4 Whilst some argued that donors were entitled to these payments, the assumption that the additional monetary compensation would have an effect on the number of donors was widely challenged in the evidence we collected. Many respondents to the consultation, notably donors, said that compensation was largely unimportant and may even deter truly altruistic donors. Many felt that greater advertising and public awareness of the need for donors would have a greater effect on the number coming forward. This is consistent with informal reports from certain clinics and with recent public opinion research. It is also supported by the findings of the National Gamete Donation Trust, which reports a significant increase in calls from prospective donors following the recent Department of Health’s sponsored campaign promoting public awareness of the need for gamete donation.
- 5.5 In the course of the review we sought additional evidence from authorities involved in blood, tissue and organ donation in the UK. This confirmed that payment for personal inconvenience (as distinct from expenses and loss of earnings) is not offered in return for blood, tissue or organ donation. There are a number of practical, as well as ethical, reasons for this, many of which may be applicable to gamete donation. Those reasons included the concern that additional payment might encourage donors to disregard risks to their health or to withhold important medical information, or that it might attract donors with whose motives, when disclosed, could be difficult for offspring to come to terms. Considerations like these moved some consultation respondents to say that donors should not be compensated at all, either because any compensation was indistinguishable from payment for gametes, or because, as donors, they felt that bearing these costs was part of the donation itself.

- 5.6 Most respondents felt that donors should not be 'out of pocket' as a result of donation and that there are costs, principally loss of earnings, for which donors are entitled to be compensated. This is consistent with current practice in tissue and organ donation. It was generally acknowledged, however, that the value of such 'hidden costs' might be difficult to establish for a number of reasons (such as donors being unwilling to disclose the reason for their absence to employers).
- 5.7 Among those supporting compensation for loss of earnings there were different opinions about whether there should be a maximum limit or even whether, for practical reasons, it would be desirable to offer a standardised level of compensation. At the stakeholder meeting, for example, a consensus emerged that a 'flat rate' for donors should be considered as long as this was thought to be consistent with the requirements of the Directive. Sums suggested were £15 per donation for sperm donors and £300-500 per cycle for non-patient egg donors.
- 5.8 Another argument put in favour of a standardised level of compensation was that highly variable costs could end up being passed on to recipients, resulting in a variation in charges for treatment with gametes from different donors. Others argued that if donors' variable costs were not always met and some maximum or standard rate were imposed, this might lead to some donors either losing out financially or declining to donate and to clinics focussing their recruitment efforts on 'cheaper' donors.

Our reasoning and conclusions

- 5.9 Donation is an important social act with significant consequences for all those involved. It is an important principle that a donor should be properly informed about these consequences and that their consent should be freely given. The donors who responded to our consultation do not, by and large, appear to be motivated by the possibility of financial gain. We have concerns that offering compensation for the physical inconvenience or risk of donation may encourage some people to donate without thinking sufficiently about the consequences of donation. As a result our conclusion is that compensation for the inconveniences related to donation is undesirable.
- 5.10 In the previous chapter, we discussed the principle that donation should be 'expense neutral' for donors. In our view, payment for loss of earnings is consistent with this principle and is also consistent with the EU Tissue and Cells Directive.
- 5.11 We looked at a number of options for reimbursing loss of earnings for donors. The setting of a single standardised payment, despite having the virtue of simplicity, was ruled out early on since any level set as a realistic reflection of the earnings lost by some could amount to an inappropriate incentive for others. However, the option of a variable rate led to fears that some donors may be perceived as being 'worth' substantially more than others and that a market in donors might develop. It was decided therefore to apply a reasonable maximum limit to reimbursement of loss of earnings on the basis that high earners could afford to forego some earnings whilst low earners should not be disadvantaged by having to take unpaid leave from work. We considered the advantages and disadvantages of various systems for determining a maximum value. These included the systems applied currently for tissue and organ donors, clinical trials and various other forms of donation. Our preferred system is based on the compensation offered to those involved in jury service (a maximum payment for loss of earnings of £55.19 per day) but with an additional, absolute limit of £250 for each course of sperm donation or each cycle of egg donation.

Conclusion (v): in addition to reimbursement of out-of-pocket expenses, donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum commensurate with jury service but with an overall limit of £250 (or the equivalent in local currency) for each 'course' of sperm donation or each cycle of egg donation

6 Benefits in kind

Issue and reason for review

- 6.1** The HFEA currently permits clinics to offer benefits in kind to a woman who donates a number of her eggs (an 'egg provider') to someone else (an 'egg recipient') whilst undergoing fertility treatment or sterilisation. The benefits that an egg provider may receive are strictly limited to a discount in the price of the fertility treatment or sterilisation. When the egg provider is undergoing fertility treatment this arrangement is known as 'egg sharing.'
- 6.2** Several developments in egg sharing make a review of the practice timely. These developments include:
- recent innovations such as 'egg giving' (which the Authority decided in 2003 was not to be regarded as a suitable practice)
 - the practice of distributing a donor's eggs to several recipients
 - the potential impact on egg sharing of policy changes affecting non-patient egg donation
 - the implementation of the new regulations on disclosure of information about donors and
 - the impact of the EU Tissues and Cells Directive.

Evidence and submissions received

- 6.3** Some, although only a few, respondents to the consultation argued against the practice of egg sharing itself. However, the majority of submissions and responses we received focussed on compensated egg sharing, and arguments related to the implications of the compensation that was offered rather than simply to allowing a woman undergoing treatment to give away some of her eggs. Arguments relating to compensated egg sharing tended to fall into three main groups:
- (i) it is equivalent to payment for gametes and should be prohibited
 - (ii) it is equivalent to payment but should be tolerated for other reasons (e.g. since it promotes a greater good by enabling people to receive treatment)
 - (iii) it is not equivalent to payment (i.e. because it cannot be exchanged for money or other goods or services) and far from being prohibited, it should be encouraged owing to the positive benefits it brings to all participants.
- 6.4** Many people argued that restrictions on compensated egg sharing could dramatically affect the availability of treatment in the UK for both egg providers and recipients. Whilst this was a persuasive reason for some to support compensated egg sharing others pointed to the fact that allowing this reason to prevail is inconsistent with our proposals relating to non-patient egg donation and with practice in other forms of donation, or because it could lead to undesirable consequences. These undesirable consequences fell into two classes depending on whether they affected those directly involved or affected others as a result of the principle underlying compensated egg sharing being generalised.
- 6.5** Adverse consequences for those involved might include:
- that it might place additional pressure on participants

- that the prospect of helping many people at once creates an incentive to overstimulate the egg provider
- that it might cause regret and unhappiness for the provider or recipient
- that any children conceived in an egg sharing arrangement might be affected by a poor perception of the circumstances of their conception.

6.6 Adverse consequences for others in relevantly similar contexts might be things like bone marrow donors demanding payment in exchange for a life-saving donation.

Our reasoning and conclusions

6.7 We found very little argument in favour of sterilisation being offered as a benefit because the benefit is of little practical value (it is widely available free of charge) and because the sterilisation procedure is conditional upon non-therapeutic ovarian hyperstimulation, which the woman being sterilised would not have to undergo if she were not also donating eggs at the same time. Therefore we do not think that sterilisation should be offered in exchange for donating eggs although we continue to believe that women undergoing sterilisation should be offered the opportunity of donating eggs to help others if they wish to do so.

6.8 A number of respondents to our consultation put the case for allowing an egg provider's own treatment to take place in a separate cycle to the one in which eggs are provided for donation. However, this was usually suggested in order to permit some flexibility if an initial cycle did not go according to plan rather than advocated as a separate, planned practice. Whilst we support a woman's choice to donate eggs when she is not herself undergoing treatment, where a woman wants fertility treatment in order to have her own children, the presence of a potential financial incentive in the form of free or discounted treatment makes us cautious about arrangements that require more stimulated treatment cycles than might be necessary for her to achieve her own reproductive ends. We therefore confirm the view that we reached in December 2003 that a so-called 'egg giving' arrangement, whereby a woman seeking IVF treatment agrees at the outset to go through one cycle of treatment in which all the eggs collected are donated followed by a further IVF cycle for her own treatment at reduced cost, should not be regarded as a suitable practice.

6.9 One of the most difficult areas of debate has been around 'egg sharing', whereby a woman agrees to give away some of the eggs collected during her own treatment cycle to one or more other women who cannot produce suitable eggs of their own. Whilst there are arguments against the practice of egg sharing as such, setting aside for the moment the question of compensation, none of these appears to be decisive, as long as egg sharing arrangements are carefully managed to protect the interests of participants. Unlike 'egg giving' discussed above, each stimulated treatment cycle undertaken by a woman who shares her eggs could result in the fulfilment of her own reproductive aims as well as co-incidentally helping others. Although we see the advantage in gaining the maximum benefit from an egg provider's generosity we are quite concerned about the practice of distributing the eggs from one provider amongst multiple recipients. Among other things, we believe that there is a potential for this to lead to an increase in the incidence of OHSS and emotional distress for women who take part in egg sharing arrangements. We therefore believe there is value in tightening the conditions under which egg sharing is practised to limit the number of women among whom eggs from one egg provider may be shared.

Conclusion (vi): the egg sharing guidance should indicate that eggs collected from an egg provider in a single cycle should not be shared among more than two other recipients

- 6.10** Many opponents of egg sharing clearly regard the value of the compensation offered to the egg provider as equivalent to a substantial payment amounting to a significant inducement to her to give up her eggs. One way of stating this argument is that the offer of discounted treatment encourages the egg provider to ignore the consequences and possible risks of donation and therefore invalidates her consent to the procedure. However, if an egg provider's judgement were really obscured by the promise of free treatment, one might expect to find evidence of people complaining about this afterwards, or at least that some egg providers later regret giving up their eggs.
- 6.11** Such evidence is scant, but even where it does exist this might not be a decisive objection, as long as the majority derive considerable benefit from the procedure (and as long as every effort has been made to ensure that their consent is properly informed and their choice is uncoerced). The argument that almost any adverse consequence is sufficient to prohibit a practice which brings great general benefit seems disproportionate. In any case, subsequent regret is not in itself evidence of vitiated consent (people often freely do things which they later wish they had not done) and may often have more to do with people's changing values than the impairment of their judgement or the constraint of their consent.
- 6.12** Among the arguments against compensation one of the most persuasive is that permitting compensation for egg sharing is inconsistent with – and would adversely affect – established approaches to blood, tissue and organ donation. The most powerful form of this argument is that permitting compensation for egg sharing could in practice lead to donors of other tissues and organs demanding or feeling entitled to similar compensation. For example, a bone marrow donor were to demand payment in exchange for life-saving donation this could amount, in effect, to putting a monetary value on human life, which many would find an intolerable consequence. However it does not seem to us either necessary or likely that compensated egg sharing will lead to a vibrant trade in other tissues, cells or organs. It has not, in fact, led to those consequences despite having been practised in the UK for over a decade.
- 6.13** It appears to us to be a significant distinction between donor-assisted conception treatment and forms of acute medical treatment using other donated tissues that fertility treatment is generally provided on a commercial basis in the UK, for example, it is something that those receiving it pay for in the first place. Thus a reduction in the charges made to an egg provider need not be seen as a payment for her eggs but a recognition that a part of her treatment involves an egg donation and, as such, should not be chargeable to her. That this enables a woman who could not otherwise afford or obtain treatment to be treated is seen by supporters of egg sharing as doubly beneficial: two people who want treatment are enabled to receive it whereas without this arrangement neither would do so.
- 6.14** Having debated these and many other arguments at length, it is our view that the opponents of compensated egg sharing have not succeeded in arguing that the alleged harms are proximate, likely or significant enough to amount to a sufficient or compelling reason to prohibit the practice. Having said this, we acknowledge that it will remain necessary to ensure that egg sharing, whether compensated or not, is managed in such a way as to minimise the acknowledged potential for adverse effects for those involved. We intend to keep egg sharing in general under review, in particular evidence of the emotional consequences for women participating in egg sharing arrangements, about which there is as yet little available.

Conclusion (vii): gamete donors may receive benefits in kind in return for supplying gametes for the treatment of others but these benefits should be limited to discounted treatment services

7 Procurement of gametes from abroad

Issue and reason for review

- 7.1 People are free to travel abroad to receive treatment and people who live abroad frequently come to the UK for similar reasons. Changes in UK policy relating to donor-assisted conception will inevitably have an effect on the numbers of people travelling between countries to receive fertility treatment or considering alternative treatment options outside the ambit of regulation (both in the UK and abroad). However it is not only people who may travel between countries: because of the relative scarcity of suitable donors in the UK we have noticed a recent increase in requests from clinics to import gametes (sperm) and embryos from abroad. This may be either from specific donors, for the treatment of specific patients, or in general, to meet general demand in certain geographical areas.

Evidence and submissions received

- 7.2 Many of those who responded to our consultation felt that the requirement for clinics to apply to the HFEA for prospective authorisation every time they wished to import gametes or embryos amounted to a disproportionate imposition of 'red tape', and that it had the potential to delay and increase the cost of treatment in exchange for little genuine benefit. These views were counterbalanced by the views of those who were suspicious about obtaining donated gametes from abroad, either because they believed that there was no guarantee that standards of procurement and processing in foreign clinics were sufficiently high or because using foreign donors presents peculiar welfare issues (for example, the additional difficulty for the donor-conceived person in contacting a donor and, should they do so, the potential lack of common cultural or linguistic background).
- 7.3 Another common concern related to the number of families who might be created using gametes from a single donor if their gametes were used in many countries. There was some cause for concern here, particularly where donated gametes are imported from countries outside the scope of the EU Directive, since one might expect commercial recruiters to want to maximise the revenue that they can obtain from each donor. Nevertheless it must be acknowledged that whilst the HFEA is able to place limits in relation to UK licensed treatment, it can apply no such control outside licensed clinics. The HFEA cannot, for example, control how many children the donor has naturally or independently of licensed treatment: they might donate 'unofficially' (perhaps through an internet introduction agency) or in another country as well as in the UK.

Our reasoning and conclusions

- 7.4 The provision of fertility treatment is increasingly taking on an international dimension, which the EU Directive implicitly acknowledges and to which it responds. Where an international consistency of approach exists there is an argument for reducing the burden of national regulation so that it only addresses those issues of national importance not covered by international measures. However whilst the Directive will cover procurement and processing of gametes and embryos, and their transportation into the EU and between EU countries, the difficulty of ensuring that acceptable standards of quality and safety are met at the point of origin still persists with gametes and embryos originating outside the EU.

- 7.5 Furthermore, there remain concerns which arise not from clinical and laboratory standards met by exporting clinics but from the ethical practices that are obtained in other countries or from the very fact that the clinics and donors are geographically remote, and operate and live in other cultures and jurisdictions. These kinds of concern are not addressed by international arrangements such as the Directive and dispelling them would necessitate a kind of consensus that goes beyond the common standards implicit in existing legal instruments. Nonetheless we do consider it desirable to investigate with other national regulators and foreign treatment providers whether any measures could be put in place to develop common positions or mutually acceptable terms of exchange, or at least to ensure that these matters may be kept under review.
- 7.6 In the absence of agreed measures of this kind, therefore, it seems to us prudent to retain the present arrangements requiring prospective scrutiny and authorisation of imports of gametes and embryos. As donor recruitment practices vary widely, both within the EU and throughout the wider world, we believe that the HFEA should retain the function of considering, in each case, whether the reason for the import is sufficient to justify setting aside any concerns that might exist (such as different consent procedures or donors not having been offered counselling prior to donation). Nonetheless we do not propose to introduce any new blanket constraints, such as making the import of a given donor's gametes conditional upon the number of families created using that donor outside the UK. While we recognise that there are legitimate concerns on this point, we think that matters such as this are better addressed through further international agreements of the kind mentioned above.
- 7.7 We will continue to expect all imported gametes and embryos to meet the same quality and safety standards that we expect from those originating in the UK. (Once the EU Directive comes into force we anticipate that it will be straightforward to satisfy this condition where gametes and embryos are to be imported from the EU.) In addition, we will expect importing centres to confirm that they have obtained reliable assurances that acceptable standards in other areas – including standards relating to consent, information provision and the treatment of donors – have been met by the clinics from which they are importing gametes or embryos, even if these standards are not exactly the same as those laid down for UK recruiters. We will take this information into account when considering whether to authorise each proposed import.

Conclusion (viii): procurement of gametes from abroad should fulfil the same quality standards as apply in the UK and the HFEA would expect to authorise imports only where these standards can be met

8 Other matters

- 8.1** A number of other matters which do not fall within the scope of HFEA policy were raised in the course of the review. Some of these were mentioned in the consultation document and we intend to share the findings of the review, including responses to the consultation (anonymised where appropriate) with other organisations to whom they will be relevant and with Government.
- 8.2** In particular, responses relating to the length of time sperm, eggs and embryos may be stored by clinics, and to unregulated treatments will be drawn to the attention of the Department of Health in the course of its review of the framework legislation. We also intend to raise issues relating to cross-border movements of reproductive material and those seeking treatment with the European Assisted Conception Consortium which was established in June 2005 with the involvement of regulators and practitioners from other European Countries and the European Society of Human Reproduction and Embryology (ESHRE).
- 8.3** We also received many helpful comments on the practice of donor recruitment which we intend to share with organisations involved in recruitment, including the National Gamete Donation Trust.

9 Implementation and evaluation of these measures

- 9.1** We are currently developing detailed standards and guidance to give effect to the changes to HFEA policy that will follow from the conclusions reached in this review and these will be brought into force as soon as they are complete. In some cases there will need to be transitional arrangements for those who may be in the process of donating or undergoing treatment, and as with all policy changes there will need to be time for centres and to amend and adapt their own information, approaches and procedures.
- 9.2** Some of the conclusions we have reached feed into other ongoing projects such as our review of the Welfare of the Child (conclusion ii) and our review of live birth limits (conclusion iii); where this is the case, the conclusions reached in the SEED Review will be implemented according to those policy review timetables. All the measures that we have described in this document will be consolidated in the seventh edition of the HFEA *Code of Practice* (due to be published in 2006).
- 9.3** Where we are implementing changes we will continue to monitor and evaluate their effect. In addition to the use of information from inspections and data collected on the HFEA register, we propose to commission a separate comparative evaluation of the changes we have proposed, particularly any impact on the number of donors coming forward to donate, one year after implementation and to make the findings of this research public as soon as they are available. The effect of these policies will be kept under review in the light of the findings of this research and on an ongoing basis by the HFEA.

Regulatory Impact Assessment

An assessment of the regulatory impact of policy proposals arising from the HFEA's sperm, egg and embryo donation (SEED) review.

Purpose and intended effect of measure

(i) The objective

The aim of this policy review is to identify measures to secure a safe and effective service for those requiring treatment with donor sperm, eggs and embryos, whilst protecting the interests of donors, recipients and those who may be born as a result. The review was set against new UK regulations to allow information about donors to be disclosed to those born as a result of their donation and the EU Tissues and Cells Directive. The review concerns the regulatory framework within which donor recruitment and donor-assisted conception take place and gives the policy proposals for the revision of existing HFEA Directions and *Code of Practice*.

(ii) The background

The Human Fertilisation and Embryology Authority (HFEA) was created by an Act of Parliament, the Human Fertilisation and Embryology Act 1990, to license and regulate the clinical practice of donor-assisted conception and the creation and use of human embryos outside the body in treatment and research. The Act and subsequent amending legislation contains provisions relating to the permitted use of gametes and embryos. Additionally the 1990 Act empowers the HFEA to apply further controls through licences (which may be subject to conditions) and Directions issued at the Authority's discretion. The Act also requires the HFEA to produce a *Code of Practice*, giving guidance on, *inter alia*, the meaning of the terms 'proper' and 'suitable' where these occur in the legislation.

Two recent legislative developments are particularly relevant: the Human Fertilisation and Embryology Authority (Disclosure of Information) Regulations 2004 (S.I. 2004 No. 1511) which removes statutory guarantees of anonymity from gamete and embryo donors registering from April 1, 2005, and Directive 2000/23 of the European Parliament and Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] O.J. L 102/48. The measures contained in these instruments will come into effect in the context of an acknowledged general shortage of donated gametes and embryos for the treatment of those requiring donor-assisted conception in the UK. This shortage was confirmed by a survey of licensed clinics conducted by the HFEA at an earlier stage in this review.

(iii) Risk assessment

The risks associated with each of the options contained in the consultation document will be discussed in relation to each measure, and are included in the summary table at the end of this document.

Benefits and costs

Benefits and costs associated with the measures identified in the consultation document are set out in the summary table at the end of this document.

Equity and fairness

It is not anticipated that any of the measures proposed will have an effect on the equity or fairness of regulation or treatment provision, however they are likely to reduce the present disparity between compensation for egg and sperm donors which has historically favoured sperm donors.

Consultation with small businesses

It is not anticipated that any of the measures proposed will have a disproportionate impact on small businesses.

Competition assessment

It is not anticipated that any of the measures proposed will affect competition between licensed centres in the private sector.

Enforcement and sanctions

Compliance with professional guidance could be inspected and enforced by the HFEA through its licensing system as long as this was referenced in the HFEA *Code of Practice*. Additionally, many common standards may be specified in the technical annexes of the EU Tissues and Cells Directive. These may be enforced through legislation (Regulations) and compliance would be monitored, and sanctions applied, by the relevant competent authority (the HFEA).

Monitoring and review

Compliance with professional guidance and with standards imposed by the EU Directive will continue to be monitored by the HFEA through inspection and information collection, as well as specific, targeted reviews. All HFEA policy is subject to periodic and ongoing review.

It is expected that professional guidance will be reviewed by the professional bodies in consultation with the HFEA and other stakeholder organisations. The HFEA will continue to monitor emerging evidence and knowledge and will bring it to the attention of the relevant professional bodies.

Other measures will be monitored by the HFEA through its existing inspection process and reviewed in the light of emerging evidence or, in any case, prior to publication of each edition of the Authority's *Code of Practice*.

Consultation

The proposals contained in this report were discussed with stakeholders, including representatives of the relevant professional bodies and groups representing donors and donor-conceived families, at a stakeholder meeting held by the HFEA in July and have been extensively communicated and discussed throughout the fertility sector. They have been discussed with officials in the Department of Health and their comments have been noted and incorporated as appropriate. They were also the subject of a three-month public consultation held between November 2004 and February 2005.

Costs and benefits: summary table

Policy Amendment	Costs	Benefits	Transfers	Risks	Net impact
<p>The HFEA should move towards a reliance on professional guidance on the medical and laboratory screening of sperm, egg and embryo donors when revised guidance becomes available.</p>	<p>Reduction in cost to HFEA Estimated Cost of a Policy Review would be:</p> <ul style="list-style-type: none"> • 3 public consultation meetings at different venues around the country approx cost: £7000 • Production of consultation document: £6500 • Patient information flyers: £500 • Report design and printing: £4500 • Estimated total cost: £18500 <p>The professional bodies already provide guidance so theoretically there will be no additional cost, however any costs are willingly being taken on by the professional bodies.</p>	<p>Clinics: One set of professional guidance to follow from a joint group of multi-disciplinary professionals will reduce confusion caused by varying advice.</p> <p>Donors: Increased confidence in the system knowing that they have been screened to the highest possible standards.</p> <p>Recipients: Increased confidence due to the knowledge that the guidance has been produced by those with the most expertise and direct experience.</p>	<p>None (as professional bodies already produce guidance)</p>	<p>Clinics: Professional bodies may not produce guidance in a timely manner or without taking into account all relevant factors, giving clinics out of date or unworkable advice.</p> <p>Donors: If the guidance is produced in a timely manner taking into account relevant factors there will be no increased risks to donors.</p> <p>Recipients: also will not be at risk if the guidance is properly produced.</p>	<p>Donors and recipients will have increased confidence in the screening procedure. Relying on professional guidance would reduce costs to HFEA.</p>
<p>There should be no prescriptive guidance from the HFEA on the selection of donors for treatment of a particular recipient but the HFEA should produce guidance on issues to be taken into account</p>	<p>HFEA to produce guidance on issues to be taken into account by recipients</p>	<p>Clinics: Less burdensome guidance will increase the autonomy of the clinics. Increased levels of treatment activity will increase revenue for the clinics</p> <p>Donors: Gametes more likely to be used</p> <p>Recipients: Less sense of choices being constrained by considerations that are not relevant to them.</p>	<p>Slightly increased discretion allowed to recipients/ clinics</p>	<p>Clinics: HFEA guidance on issues to be taken into account may not be observed</p> <p>Donors: Donations from donors with specific characteristics might be in greater demand</p> <p>Recipients: Greater freedom to choose donor characteristics for reasons which may not be compatible with the welfare of the child</p>	<p>Possible benefit to patients from more freedom of choice and increased levels of treatment activity</p>

Costs and benefits: summary table

Policy Amendment	Costs	Benefits	Transfers	Risks	Net impact
<p>Although donors should continue to be able to set their own limits on the use of their gametes which must never be exceeded, gametes from an individual donor should not be used to produce children for more than 10 families in the UK</p>	<p>Implications of new policy costs, informing counsellors and clinics and producing information leaflets for clinics and patients. The approximate cost of producing a patient information leaflet: £500.</p>	<p>Clinics: Benefits from clearer, easier to interpret guidelines</p> <p>Donor: The 'families-based' approach allows greater precision about the true scope of the donor's consent.</p> <p>Recipients: Provides for the creation of siblings and half siblings for existing children in non-traditional families</p>	<p>None</p>	<p>There is no evidence that the risks of consanguinity would reach significant levels due to the large, and changing populations served by clinics.</p>	<p>There is a possibility that this measure might result in a slight increase in revenue for the clinics as more recipients may, in some circumstances, be treated using gametes from each donor. Costs of recruiting a donor are high (£1500-£3000 per donor – clinics survey) the more frequently a donor can be used the lower the cost per treatment to the clinic</p>
<p>Donors may be reimbursed all demonstrable out-of-pocket expenses incurred within the UK in connection with gamete or embryo donation</p>	<p>Donors are currently paid receiptable, out-of-pocket, expenses; this will not change so no additional costs are incurred.</p>	<p>There will be no increased benefits to any parties as the policy has not changed.</p>	<p>None</p>	<p>There will be no increased risks to any parties as the policy has not changed.</p>	<p>Donors will continue to have confidence their costs will be reimbursed.</p>

Costs and benefits: summary table

Policy Amendment	Costs	Benefits	Transfers	Risks	Net impact
In addition to reimbursement of out-of-pocket expenses, donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum commensurate with jury service but with an overall limit of £250 (or the equivalent in local currency) for each 'course' of sperm donation or each cycle of egg donation	Donors may be compensated a daily maximum of £55.19, with an overall limit of £250 for each course of sperm donation or cycle of egg donation. Sperm donors were previously being paid gratuities amounting to approximately £300-400 for donations over an average of 19 sessions, whereas on average egg donors donate once and therefore receive £15 whilst still spending approximately the same cumulative amount of time at the clinic as sperm donors.	Donors: Can be confident that reasonable compensation is available for certified loss of earnings.	None	Clinics: It is not possible to determine the overall cost impact on clinics at this stage, but it will continue to be assessed as part of the monitoring stage. Donors: There is no good basis on which to infer that this will have an adverse effect on donation. It is likely that identifiable donors will be donating for altruistic reasons and there is a risk that poorer donors motivated by financial gain will cease donating.	The disparity between payments to egg donors and sperm donors will be greatly reduced. Donors will lose the gratuity payment consistently with the requirements of the EU Tissues and Cells Directive.
The egg sharing guidance should indicate that eggs collected from an egg provider in a single cycle should not be shared among more than two other recipients	Clinics may experience a decrease in revenue per donor if they would have used gametes from one donor to treat more than two recipients, assuming each recipient pays the same. Charges vary considerably from clinic to clinic and may also vary from cycle to cycle.	Donors: Limitation on sharing of eggs allows more eggs to be used in each donor's treatment giving a higher chance of creating a 'good' embryo and therefore a successful pregnancy. The risk of encouraging the over-stimulation of the donor is also reduced. Recipients: If more eggs are available per recipient, the chance of successful outcome will be increased for each recipient receiving treatment.	None	Clinics: Revenue will be lowered as the clinics will be treating fewer paying recipients. Recipients: There may be a slight decrease in the number of recipients treated due to the decrease in eggs available.	Limiting the number of recipients will decrease the incentive to over stimulate patients to produce a greater number of eggs. The possibility of selecting better quality embryos for treatment of each patient is increased.

Costs and benefits: summary table

Policy Amendment	Costs	Benefits	Transfers	Risks	Net impact
<p>Gamete donors may receive benefits in kind in return for supplying gametes for the treatment of others but these benefits should be limited to discounted treatment services</p>	<p>There is no change in the policy to allow gamete donors to receive benefits in kind in return for supplying gametes for the treatment of others, so there will be no additional costs involved.</p> <p>Sterilisation will no longer be available as a benefit but this is available free of charge through the NHS.</p>	<p>There will be no increased benefits to any parties as the policy has not changed.</p>	<p>None</p>	<p>There will be no increased risk to any parties as the policy has not changed.</p>	<p>Permitting benefits in kind may increase overall availability of treatment.</p>
<p>Procurement of gametes from abroad should fulfil the same quality standards as apply in the UK and the HFEA would expect to authorise imports only where these standards can be met</p>	<p>No change to present procedure so no anticipated additional costs.</p>	<p>No change to present procedure so no anticipated additional benefits.</p>		<p>No change to present procedure so no anticipated additional risk.</p>	<p>No change – the HFEA continues to authorise the import and export of gametes.</p>



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Trim No. 05/26766

Publication date: 7.10.05