Authority Paper

Committee:	Authority
Meeting Date:	9 December 2009
Agenda Item:	6
Paper Number:	528
Paper Title:	Sperm Egg and Embryo Donation Policies
Author:	Danielle Hamm (Policy)
For information or decision?	Decision
Resource Implications:	Dependent on Authority recommendations. Resources may include staff and consultation budget.
Implementation	Detailed work plan to be brought to March 2010 Authority meeting. Policy work to commence in business year 2010/11.
Communication	A targeted selection of UK licensed centres, patient and donor groups and internal colleagues have been consulted during this evaluation.
Organisational Risk	Medium
Recommendation to the Committee:	Members are asked to provide recommendations on future policy, operational and evaluation work around policies pertaining to sperm egg and embryo donation.
Annexes	Annex 1 - Systems of expenses and compensation within the European Union Annex 2 – Legally prohibited degrees of relationships

Section A: Overview

1 Overview

1.1 The following paper:

- Outlines the Authority's commitments regarding donor codes.
- Outlines the findings of the SEED evaluation.
- Outlines the main issues engaged in intra-family donation.
- Aims to enable the Authority to prioritise donation policy review work for the 2010/11 business year.

1.2 Various different work strands around sperm, egg and embryo donation have been initiated over the past year:

- Authority commitment to review policy and practice surrounding the release of donor codes (Section B)
- Executive evaluation of sperm, egg and embryo donation (SEED) review policies (Section C)
- ELAC consideration of intra-family donation (Section D)

1.3 Section E invites the Authority to consider which aspects of donation policy work the Authority wishes to prioritise in the 2010/11 business year.

Section B: Disclosure of Donor Codes

2 Background

2.1 This Section outlines the Authority's decision and commitments regarding the disclosure of donor codes and asks the Authority to agree proposals for future work on this issue.

2.2 Between October 2004 and January 2009, the HFEA provided donor codes to parents of donor-conceived children, on request, if the code did not contain donor-identifying information.

2.3 Donor codes are used as an auditing tool within clinics, to track and monitor donor usage internally. Permitting the disclosure of donor codes enables parents, or their children, to make contact with children in different families who were born after treatment with the same donor's gametes. Parents do this through comparing donor codes with other parents of donor-conceived children.

2.4 In January 2009, the Authority took the decision to cease the disclosure of donor codes to parents of donor conceived people, on the basis of several actual or potential risks, including:

- Potential for erroneous matching between siblings (result of the fact donor codes are not 'built for purpose' and codes may be duplicated between clinics)
- Disclosure could enable donors to seek out their donor-conceived offspring
- Risks that donors could be inadvertently identified

2.5 In view of the risks identified, the Authority decided to stop issuing donor codes on an interim basis.

2.6 The Authority committed to further policy work to:

- Analyse the risks attached to the disclosure of donor codes and ways of reducing such risks
- Review its decision on whether donor codes should be released, as a matter of principle, having regard to the competing considerations identified and the intention of parliament

2.7 Following the January 2009 Authority decision, the HFEA has allocated a unique identifier to all existing and new donors. This unique identifier could potentially overcome the risk of erroneous matching between siblings if the HFEA provides it to parents instead of the clinic donor code. The HFEA unique identifier has not been introduced in clinics, which continue to allocate donor codes for internal auditing purposes; the risk of erroneous matching has not therefore been eliminated at clinic level.

Proposed policy work

2.8 Due to the large workload generated by implementing the revised HFE Act, the Executive has not yet undertaken further policy work on donor codes. The following work is recommended by the Executive:

- Assess the legality and desirability of releasing donor codes, in light of Section 31ZE of the HFE Act, which permits the HFEA to disclose identifying information to donor-conceived people of 18 years or over about any donor-conceived siblings who have also consented to the release of their identifying information.
- Assess the risks entailed in the release of donor codes and possible ways of mitigating these risks.
- Hold a consultation event, to include all interested parties, to discuss policy options.

Recommendation

The Authority is asked to:

- Discuss and agree proposed policy work outlined in 2.7

Section C: SEED Evaluation

3 Summary

3.1 In 2005, the HFEA undertook a major review of its policies relating to sperm, egg and embryo donation in the UK. In the wake of the removal of donor anonymity, the review aimed to ensure that HFEA policies relating to donation enabled an adequate, effective and safe service for those requiring donor treatment, whilst protecting the interests of donors, recipients and the donor conceived.

3.2 The original SEED review committed the Authority to monitoring and evaluating the impact of SEED policies; the Executive undertook this evaluation during autumn 2009. This section documents the results of the evaluation and asks the Authority to prioritise future policy and evaluation work in light of the findings in this report.

3.3 The original SEED review was led by an Authority working group and encompassed a survey of clinics, a review of contemporary scientific evidence and a public consultation. On the basis of this review, the following polices were agreed and implemented by the Authority:

Screening of sperm, egg and embryo donors
Professional guidance should be relied on for the medical and laboratory screening of gametes and embryos.

Selection of donors
There should be no prescriptive guidance from the HFEA on the selection of donors for treatment for a particular recipient.

Limiting the number of families conceived per donor
Gametes from an individual donor should not be used to create more than 10 families in the UK. Donors can, however, limit the use of their gametes to fewer than 10 families.

Out-of-pocket expenses for sperm, egg and embryo donors
Donors may be reimbursed for all demonstrable out-of-pocket expenses incurred within the UK in connection with gamete or embryo donation.

Additional compensation for gamete donors
Donors may be compensated for loss of earnings up to a daily maximum commensurate with jury service, but with an overall limit of £250 for each course of sperm or egg donation.

Benefits in kind
Benefits in kind should be limited to discounted treatment services.
Eggs collected from an egg sharer in a single cycle should not be shared amongst more than two other recipients.

Procurement of gametes from abroad

Procurement of gametes from abroad should fulfil the same quality standards as would apply in the UK.

4 Reasons for this evaluation

4.1 The SEED report committed the HFEA to monitoring and evaluation of SEED policies. This evaluation aims to fulfil this commitment.

4.2 In addition, the HFEA is aware of anecdotal evidence, both internally and from parts of the sector, that some aspects of the SEED policies may not be working as well as they could be.

5 Method and aims of the evaluation

5.1 The evaluation focussed on three main strands of evidence gathering:

- Compliance: inspection and incident reports; interviews with inspectors
- Clinic experience: interviews with clinicians, nurses and counsellors who work in donor treatment centres; meetings with the Senior Infertility Nurses Group and the Licensed Centres Panel
- Patient and donor stakeholder input: interviews with parents of donor-conceived children; meetings with:
    - Association of Fertility Patient Organisations (including representation from the Donor Conception Network)
    - National Gamete Donation Trust
    - British Infertility Counselling Association
    - Project Group on Assisted Reproduction

5.2 The evaluation considered SEED policies in light of the original SEED objectives, which can be summarised as follows.

Adequate – policies should not pose unjustifiable barriers to the recruitment of donors and therefore the provision of an adequate number of donor gametes to meet demand for treatment.

Effective – policies should facilitate the effective use of the donor gametes and embryos which are available for use in treatment.

Safe – both donors and recipients should be not be treated in ways which pose unjustifiable risks to their health or safety.

Protection of interests – concerns the ethical dimensions of donor treatment. Including protecting donors from undue pressure or coercion to donate; promoting patient welfare; the effect of donation policies on people born as a result of donor conception.

5.3 It is important to note that the evaluation was a desk-based piece of work, undertaken in a relatively short time frame, which aimed to build a sufficient picture to enable Authority members to identify problematic areas of policy for full review. The evaluation has not involved public consultation and it is important to note that the results represent a relatively small sample of views. Wider and more formal consultation would have to follow for those strands, if any, of policy the Authority identifies for review.

5.4 As outlined in Section E, on the basis of the SEED evaluation, polices have been divided into three categories:

- no major operational issues identified - no further work recommended
- operational issue or a need for further evaluation work identified – operational/evaluation work recommended
- major issues identified – full policy review recommended

6 Selection of donors

Current policy: There should be no prescriptive guidance from the HFEA on the selection of donors for treatment for a particular recipient

6.1 Prior to the SEED review, the HFEA issued prescriptive guidance to clinics expecting them to match the physical characteristics of the donor with those of the infertile partner or, if a women receiving treatment with donated sperm has no partner, with those of the woman herself.

6.2 Following the SEED review, the decision was taken to cease issuing prescriptive guidance on the selection of donors for use in treatment. The decision was taken in light of feedback from the sector that the requirement to match donors and recipients was impractical, given the shortage of donors, and had a negative impact on the availability of donor treatment. In addition, the SEED review found little evidence on the effectiveness of donor-recipient matching, in relation to the welfare of resulting children.

Evaluation results: policy issues

6.3 There seems to be general satisfaction with the policy regarding selection of donors; it is appropriate to allow couples to match according to physical characteristics, but that this should not be prescriptive guidance to clinics.

6.4 Interviewees with experience in adoption argued that recipients should never be matched with donors from a different ethnic origin, because it has a negative impact on the welfare of the child. The analogy with adoption, however, must be treated cautiously as there are important differences between adoption and donor conception which will mean different things for the welfare of the child.

Evaluation: Operational issues

6.5 Some interviewees commented that a consequence of an increasing culture of openness around donation and telling donor-conceived people about their origins means that physically matching donors and recipients is becoming less important.

6.6 The majority of interviewees reported that, in practice, recipients have little choice between donors and therefore physical matching is not a realistic option for most, despite the fact patients often feel it is important. This is heightened with ethnic minority recipients, due to a shortage of donors.

6.7 Some concern was raised that over-emphasis from patients on physical matching could indicate that they were not intending to be open with their child or that they had not come to terms with using donor gametes. It was noted that such issues are properly addressed in counselling and the new legal requirement to inform patients of the importance of being open with their child provides an opening to address such issues.

6.8 Before offering treatment, clinics have a legal obligation to consider the implications for any children born as a result of donation, in the short and long term. Treatment should not take place if any child born as a result of donor treatment is likely to experience serious physical, psychological or medial harm. Concerns regarding welfare of future children with regard to selection of donors should be picked up by this assessment.

Summary and recommendations

6.9 There was a general satisfaction with the current policy and guidance regarding selection of donors.

Recommendation

The Authority is asked to:

- Consider the executive recommendation that no policy or operational review is required.

7 Importing gametes from abroad

Current policy: Procurement of gametes from abroad should fulfil the same quality standards as would apply in the UK and the HFEA would expect to authorities imports only where these standards can be met.

7.1 In recognition of the likely effect changes in UK policy and law surrounding donation would have on people both travelling abroad for treatment and importing gametes from abroad, the SEED review examined the HFEA's policy regarding importing gametes from abroad.

7.2 The Authority agreed that the imported donor gametes should meet the same quality and safety standards as apply in the UK. In addition, it agreed that applications for imports should be reviewed on a case-by-case basis through Special Directions.

7.3 The Authority kept the policy under review and, following the implementation of the European Tissues and Cells Directive (EUTD), the Authority reviewed the licensing procedure for the import of gametes and embryos and moved to issuing General Directions (Direction 0006 *Import and export of gametes and embryos*) for the majority of imports.

Evaluation results – policy issues

7.4 There was general satisfaction amongst interviewees that the policy relies on the correct principle – ie, that imported gametes should fulfil the same quality standards as apply in the UK in order to safeguard the interests of recipients and the donor conceived.

Evaluation results – operational issues

7.5 The most common concern expressed by clinics regarding HFEA policy on procurement from abroad was it is difficult to prove that imported gametes meet the same standards as in the UK, particularly with respect to payment of donors; the importing clinic relies on the assurance of the overseas clinic that donors have not been paid. Within the EU this is not a huge concern, given that it is only possible to import from EU countries which have implemented the EUTD. Outside the EU, especially concerning imports from America, where payment of donors is commonplace, importing centres must take the guarantee of the supplying centre.

7.6 Clinics in the UK which frequently import sperm tend to have established relationships with one or two overseas clinics which they trust. One interviewee reported how they only use sources which they know are familiar with UK practice; it was acknowledged that such relationships are time consuming and expensive to establish. This was corroborated by other centres who had decided not to import on the basis of cost and administrative burden. It was noted that it would be useful to have a central list of approved centres, which clinics can confidently import from.

7.7 Centres noted that importing from abroad has become administratively easier since the EUTD and the introduction of General Directions. Despite this, it is sometimes easier to import from outside of Europe, because of the requirements of the EUTD.

Summary and Recommendations

7.8 The principle of the policy regarding imports is widely endorsed by the sector. Centres were also clear that imports have become administratively easier since the introduction of General Directions.

7.9 There was doubt as to the extent importing centres can guarantee gametes and embryos meet UK standards; this can be mitigated through importing from within the EU and/or building up relationships with overseas clinics.

Recommendation

The Authority is asked to:

- Consider the executive recommendation that no policy or operational review is required.

8 Screening of sperm, egg and embryo donors

Current policy: Professional guidelines should be relied on for the medical and laboratory screening of gametes and embryos

8.1 The SEED review identified a need for the development of joined-up professional guidelines on medical and laboratory screening. In response, the relevant professional bodies worked together to produce consolidated guidelines on screening of sperm, egg and embryo donors which was published in 2008.[1]

8.2 HFEA guidance (Code of Practice, 11.15) expects clinics to screen donors of gametes and embryos in accordance with current professional guidance. In addition, specific screening requirements and methods are required by European law under the European Union Tissues and Cells Directive 2004/23/EC (EUTD).[2] These requirements have been transposed directly into licence conditions.

Evaluation results: Policy issues

8.3 There was general agreement with the policy to rely on professional guidelines with regard to medical and laboratory screening; it was felt that this is properly the role of the profession, rather than the HFEA.

Evaluation results: Operational issues

8.4 Most interviewees, including donors and patient representatives, expressed concern regarding screening recommendations on cytomegalovirus (CMV).

8.5 Professional guidelines expect centres to recruit CMV-negative donors in preference to CMV-positive donors. Where this is not practical (for example where there are not sufficient numbers of CMV negative donors), CMV-positive donors may be recruited, but they should, when used, be matched to CMV-positive recipients. The guidelines state, however, that the decision to treat with a seropositive (without active infection) donor should be a matter of clinical judgement.

8.6 A common view amongst clinical interviewees was that the clinical case for CMV matching has not been made and a requirement to CMV match poses an unnecessary barrier to donation, especially in the case of known donation.

8.7 The professional guidelines do, however, allow for clinical discretion regarding CMV matching. Some clinics seem to have interpreted the guidelines to mean that they must always match CMV status in donors and recipients whilst other clinics exercise their

[1] UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008), Human Fertility, December 2008, 11(4), 201-210

[2] These requirements are outlined in Commission Directive 2006/17/EC

clinical discretion and waive this requirement in some cases, on the basis of informed consent from recipients. This indicates some confusion regarding the status of the professional guidelines.

8.8 The confusion around the professional guidelines on CMV screening is added to by the HFEA licence condition requiring clinics to screen all donors for CMV (T52e). This requirement is not accompanied with instructions on how CMV matching should take place. The existence of T52e in the Code of Practice appears to be an oversight. In April 2007, the then Regulation Committee recommended that T52e was included in the screening licence conditions, *pending* a review of the professional guidance. When professional guidance on CMV was subsequently published, T52e was not removed.

8.9 An additional concern amongst clinics is the fact that HFEA guidance recommends that the upper age limit for sperm donors should be 45 years; by contrast the professional guidance recommends 40 years or younger. The National Gamete Donation Trust has made representations to the HFEA arguing that guidance regarding donor age limits should also be deferred to the profession. A report from the BFS in 2008 (Working Party on Sperm Donation Services in the UK), however, recommended that we keep our upper age limit for sperm donors at 45 years. This report was released before the joint professional guidelines on screening were published, which recommend an upper sperm donor age limit of 40.

8.10 A general concern was raised by inspectors that sector knowledge of the professional guidelines on screening is poor. Though not widespread, lack of screening for sexually transmitted diseases has been picked up in inspection reports. In addition, mixing of tested and untested sperm in 'quarantine' storage has also been picked up on inspection.

8.11 It was noted that NHS centres often find meeting screening requirements easier than private centres. This is primarily because NHS centres tend to have good relationships with sexual health clinics and pathology labs. Some interviewees commented that screening requirements are also confusing for patients and donors; it was suggested that patient and donor information leaflets should be produced on screening.

Summary and recommendations

8.12 Whilst there is general agreement that the HFEA should defer to the professional screening guidelines, there can be poor awareness of those guidelines.

8.13 There is particular concern that the professional requirements regarding CMV are confusing and the HFEA licence condition requirement to screen for CMV adds to this confusion.

8.14 The different recommendations from the profession and the HFEA with regard to the upper age limits of sperm donors can be a cause of confusion. There is some demand to bring the HFEA age limit in line with professional guidance.

Recommendations

The Authority is asked to:

Consider the executive recommendations to:

- Provide clarification to clinics by summarising the professional guidance in Code of Practice.
- Bring HFEA guidelines with regard to upper age limits of sperm donors in line with professional guidelines.
- Delete licence condition T52e and defer to professional guidelines on CMV screening.

*If agreed, bullets 1-3 could be incorporated into the next update of the Code of Practice.

9 Limiting the number of families conceived per donor

Current policy: Gametes from an individual donor should not be used to create more than 10 families in the UK. Donors can, however, limit the use of their gametes to fewer than 10 families.

9.1 Prior to the SEED review, an individual donor's gametes could only be used to produce 10 live births, unless the donor specified a lower limit, although this number could be exceeded if a couple wished to create genetically related siblings to an existing child. In effect, therefore, a 10 family limit existed prior to the SEED review.

9.2 Following the SEED review, guidance to clinics was simplified and a 10-family limit was implemented in the UK, although donors retain the discretion to specify a lower limit. In addition, it provided for the creation of siblings and half siblings for existing children in non-traditional families (step families, same-sex families) where a genetic link between siblings might be thought to be beneficial.

9.3 The limit of families conceived per donor is not laid down in primary legislation. It was originally recommended in the Warnock Report (1984); which further recommended that the number should be kept under review by the licensing body.

9.4 The HFEA has implemented the 10-family limit via guidance contained in the Code of Practice. Guidance expects clinics to have documented procedures to ensure the limit is not breached. If sperm is being provided to secondary centres (ie, a receiving centre) it is the primary centre's (ie, the dispensing centre) responsibility to ensure the limit is not breached and to liaise with the secondary centre to ensure this.

Evaluation results: policy issues

9.5 The majority of interviewees had concerns regarding the evidence base underlying the 10 family limit and thought that an evidence-based review of the limit should be undertaken.

9.6 The SEED policy decision to maintain the limit of 10 families was based on consultation feedback regarding the perceived social and psychological interests of the donor conceived (and their parents) in maintaining a smaller number of genetic siblings. The SEED review found no evidence that consanguinity was a significant risk associated with slightly increasing the 10 family limit, given the relatively small numbers involved in donation and the large and mobile populations typically served by UK clinics.

9.7 Research on donor limits focuses on two main issues; mathematical population modelling looking at the risk of consanguinity and qualitative research on the psychological effects of donors and the donor conceived. Numerous studies have taken place on the risk of consanguinity following donation and various different models have been proposed for calculating risks of consanguinity. What appears clear from this research is that risks of consanguinity need to be calculated on a local level.

9.8 There has been no systematic research into the psychological affects of multiple siblings/offspring on donors and the donor conceived. In the absence of such research, it has been argued that the donor limit should reflect the number of individuals with whom a donor can have meaningful interactions.[3]

9.9 The 10-family limit was considered by the British Fertility Society Working Party on Sperm Donation Services in the UK in 2008.[4] The Working Party concluded that, whilst the genetic hazard of increasing the limit was low, there was concern that the welfare of the donor conceived may be prejudiced through an increased number of genetic siblings.

9.10 The Working Party recommended that:

- The number of families created through a single donor should be re-evaluated and a flexible approach, taking into account the particular views of patients and donors, should be encouraged.
- Social science research should be initiated on the outcomes for donors, the existing children of donors and donor-conceived children.

9.11 The prominent view of interviewees involved in donor treatment services was that supply for donor treatment currently far outstrips demand and that raising the 10-family limit would increase the availability of donor treatment in the UK. It is clear that the main driver to increase the limit is the shortage of donor gametes in the UK. In addition, many people involved in donation felt that donors would be amenable to an increased family limit and argued that donors should retain their current discretion to set a lower limit.

9.12 Conversely, a significant minority of interviewees involved in treatment services, felt that the 10-family limit is appropriate. It was argued that increasing the limit would inevitably increase the risk, or perceived risk, of consanguineous relationships. Despite the low statistical risk of consanguinity, the perceived risks amongst parents can cause

[3] Schieb, Beyond consanguinity risk: developing donor birth limits that consider psychosocial risk factors, Fertility and Sterility, Vol. 91, No. 5 p12, May 2009
[4] (2008) Working Party on Sperm Donation Services in the UK; Human Fertility, 11:3, 147-158

considerable concern. It was also highlighted, however, that with increased openness regarding donor conception, the risks regarding consanguinity are reduced.

9.13 Concern was also expressed by some clinical staff, counsellors and patients regarding the social and psychological impact on both donors and the donor conceived of having multiple offspring/siblings. The relatively new statutory provisions for tracing donors and siblings will make this experience more tangible for donors and the donor conceived.

9.14 Many interviewees called for research on the attitudes of donors, donor-conceived people and recipients, regarding the number of families donors should be entitled to donate to.

9.15 Even those against increasing the limit, or in favour of moving towards an even lower limit, recognised that there is a balance to be struck between concerns about the impact on the donor conceived and access to donor treatment. Parents of donor-conceived children acknowledged that they would probably have felt very differently regarding this balance before they had successful treatment.

9.16 Proponents of increasing the 10-family limit argue that the psychological and social concerns could be mitigated through allowing donors to retain the discretion to set a lower limit. In addition, recipients could also be allowed, where possible, to choose a donor who has set a lower limit.

9.17 Different countries have chosen to implement different donor limits. The below provides an overview of family limits in other jurisdictions.

Country	**Donor Limit**
Sweden	Six children
Switzerland	Eight children
New Zealand	Ten children
Netherlands	25 children
France	Five children
Austria	Three families
Finland	Five families
New South Wales, and Western Australia	Five families
Victoria, Australia	Ten families
Norway	Six or seven families and 12-14 children

Evaluation results: Operational issues

9.18 A number of operational issues were identified by the evaluation. These issues are a result of having an enforceable donor family limit at all, rather than specific to the limit of ten families.

9.19 Monitoring the 10-family limit when sperm is being provided to secondary centres relies on good communication and reporting controls between primary and secondary centres. Poor communication between primary and secondary centres can:

- lead to anxiety about breaching the 10 family limit and therefore pose a disincentive to provide donor sperm to other centres;
- lead to tight restrictions on the use of donor gametes;
- cause primary centres to under-use a donor through fear of inadvertently breaching the 10 family limit.

9.20 Some centres get around poor reporting by secondary centres by selling a 'pregnancy slot' rather than ampoules of sperm. Primary centres may also place conditions on the use of donor sperm, in order to make it easier for them to monitor the family limit. For example, donor sperm may be provided with the condition that it can only be used for donor insemination (DI), rather than IVF. This is because the outcome of a DI cycle is likely to be known sooner than an IVF cycle (it cannot result in frozen embryos which could be used at a later date).

9.21 Placing strict conditions on the use of donor sperm can have a negative impact on patient care. For example, it may transpire that a patient, who has been identified as suitable for DI treatment, is better suited to IVF with donor sperm. Restrictions on the use of donor sperm may, however, prevent such treatment. In addition, such restrictions potentially lead to an increased shortage of donor sperm for use in IVF and therefore might incentivise couples to import donated sperm from abroad.

9.22 Some interviewees argued that the HFEA has a role in ensuring the 10-family limit is not breached and this could be achieved by sending an alert to the primary centres once 9 pregnancies had been achieved. The efficacy of such a system, however, would rely on centres promptly reporting the use and outcome of donor treatment to the HFEA.

9.23 The strongest reported concern from both HFEA inspectors and clinics was monitoring of the 10-family limit when imported sperm has been used in treatment. The concern is that more than one UK centre could import the same donor sperm from a non-UK clinic.

9.24 Despite such concerns, analysis of HFEA Register data indicates that there have been no breaches in the ten family limit since SEED was implemented in 2006. Although it is possible that ongoing cleaning of HFEA data may highlight a small number of previously unidentified breaches of the limit, HFEA data provides a reassuring message of widespread compliance with the ten family limit.

Summary and Recommendations

Policy issues

9.25 There is a clear demand from both clinicians and patient groups for an evidence based review of the 10-family limit. This demand is primarily based on the premise that increasing the 10-family limit is likely to increase the availability of donor treatment in the

UK. There is, however, significant concern that increasing the family limit will have a negative impact on the donor conceived (and their parents).

9.26 There is a paucity of evidence regarding the social and psychological impact of increasing the family limit, which appears to be of greater concern than increased risks of consanguinity.

Recommendations

The Authority is asked to:

Consider the executive recommendation to undertake review of family limit, to include:

- Impact assessment of increasing limit
- Analysis of risks of consanguinity entailed in increasing the limit
- Commission social research and/or focussed consultation with the donor conceived and their families, regarding the social and psychological impact of increasing the donor family limit

10 Reimbursement of expenses and loss of earnings

Current policy: Donors may be reimbursed for all demonstrable out-of-pocket expenses incurred within the UK in connection with gamete or embryo donation.

Donors may be compensated for loss of earnings up to a daily maximum commensurate with jury service, but with an overall limit of £250 for each course of sperm or egg donation.

10.1 Prior to the SEED review, donors were permitted to receive a £15 flat fee in respect of each donation they made, as well as reimbursement of expenses.

10.2 The Authority took the decision, following the SEED review, that donation should be 'expense neutral' for donors. Consequently, donors are only reimbursed for actual expenses, upon proof of expenditure. In addition, donors can be compensated for loss of earnings, based on compensation offered to those involved in jury service, with an absolute limit of £250 for each course of sperm donation or each cycle of egg donation.

10.3 The Authority concluded in 2005 that compensation for inconvenience was undesirable because of the risk that it may encourage some people to donate without thinking sufficiently about the consequences.

10.4 These policies are laid out in Directions (Gamete and Embryo Donation 0001), which have statutory force under Section 12 (1) (e) of the Human Fertilisation and Embryology Act 1990 (as amended). .

10.5 The Directions also stipulate that centres must not accept donors who are known to have received, or are reasonably suspected of receiving, benefits in excess of the reasonable expenses and loss of earnings permitted by the HFEA. This is to discourage individuals

from making private arrangements to exchange gametes for money when using a licensed centre.

Legal framework

10.6 Article 12 of the European Tissues and Cells Directive 2004/23/EC (EUTD) provides that:

> 1. Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells. 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 may be granted.
>
> 2. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage.
>
> Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis.

10.7 The UK has an obligation to comply with the requirements of the Directive which limit compensation to "*making good expenses and inconveniences related to the donation".* The Directive does leave it to member states to define the conditions under which such compensation may be granted. Following the SEED review, the HFEA decided to compensate donors for expenses (including loss of earnings), but not for inconveniences related to donation, as outlined above.

10.8 Some member states have chosen to compensate for inconveniences relating to donation, such as time disruption and discomfort experienced. A table detailing different systems of expenses and compensations within Europe is attached in Annex 1.

Evaluation results: Policy issues

10.9 The vast majority of clinic staff interviewed felt that the current system of reimbursement and compensation for loss of earnings does not adequately reflect the time given and dedication shown by the donor and the inconvenience they experience.

10.10 Interviewees argued that, whilst donation should not become an open market, there was scope for greater flexibility in compensating donors as a gesture of good will and appreciation. Strictly interpreted, current HFEA guidance does not even allow for any gestures of good will towards donors of monetary worth, including buying donors a bunch of flowers.

10.11 Many commented that compensation does not necessarily have to be a significant amount of money; indeed, it should not be enough to incentivise people to donate for

purely monetary reasons. Most interviewees felt that donors who wished to donate for financial gain would be identified during the screening and counselling process.

10.12 Some interviewees felt that egg donors should be compensated more than sperm donors because of the higher risk and increased discomfort they are exposed to during donation. Others held the opposite view and believed that sperm donors should be compensated more, because sperm donation is considerably more time-consuming than egg donation. Many felt that both types of donation should be compensated equally to reflect the relative risks and time loss egg and sperm donors experience.

10.13 People who advocated increased financial compensation for donors, also believed that a more flexible system which acknowledged the time, good will and inconvenience of donors would increase donor numbers. Many commented that that the general shortage of donors in the UK was driving people overseas, with patients receiving treatment in a potentially unregulated environment. Moreover, donor-conceived peoples' interests are arguably damaged through being conceived outside the UK, as they will not necessarily have access to information about their donor or siblings. It was argued that there is a duty to increase the availability of donors in the UK.

10.14 Counsellors and parents tended to warn against permitting additional compensation for donors, arguing that connotations of payment for donation would have a detrimental effect on the donor conceived. It was noted that there is a fine line between compensation and payment, and that telling donor-conceived people that their donor had been paid might make them feel that they were in fact bought. In addition, it was noted that donors often refuse any sort of financial reimbursement and do not wish to have their donation associated with money. Some felt that it may detract from the gift nature of donation or might affect the type of donor who chose to donate.

10.15 Many respondents, including advocates of increased compensation to donors, expressed concerns regarding unintended consequences of increasing compensation to donors. In private treatment centres the cost of increased compensation is likely to be borne by patients; in NHS centres it will be borne by the NHS. Both individuals and the NHS have difficultly meeting the cost of donor treatment under the current system. Many interviewees warned that increasing compensation to donors may effectively price the NHS out of the market and could mean that treatment becomes unaffordable to many, further increasing the existing inequalities of access to fertility treatment.

Evaluation results: Operational issues

10.16 A number of operational issues were identified with the current system of reimbursing donor expenses and compensating for loss of earnings.

10.17 The first of these issues concerns the time and cost involved in reimbursing for expenses. The majority of centres commented that the requirement to only reimburse demonstrable expenses is administratively time consuming to implement. It was argued that it would be considerably easier administratively, and more cost-effective, for donors to be reimbursed a fixed amount. Other detailed issues, such as how travel should be

reimbursed where travel cards have been used, were raised. Despite this common view, some centres did not feel that it was administratively burdensome; some commented that it was an improvement from flat fees. From a compliance perspective, it was noted that a flat fee would of course be easier to inspect against.

10.18 Various newspaper articles and advertisements hinting at the inappropriate payment of sperm donors, and the recruitment of donors who have no intention of being contactable by anyone born as a result of their donation, came to the HFEA's attention in November 2008. Although the HFEA had no reason to believe that such practice was widespread, the Chief Executive took the opportunity to write to all centres in the UK which offered gamete and embryo donation to reiterate HFEA guidance regarding expenses.

10.19 Inspectors report that they have seen evidence that HFEA guidance is not always being followed and flat-fee payments to donors are still being issued in some cases. There is concern that HFEA guidance is misinterpreted by some by clinics in an attempt to offer greater financial incentives to donors. The NGDT advised that there is confusion across the sector as to the status of HFEA guidance which leads to some donors not being paid their real expenses, and some being paid compensation *and* expenses to a maximum of £250.

10.20 Concerns around compliance with reimbursement for loss of earnings were raised by both clinics and inspectors. For example, issues around how far clinics should go to satisfy whether donors are employed or not. In addition, what does loss of earnings actually mean – is it, for example, only when people are missing wages rather than taking holiday or using time in lieu? In addition, many clinics commented that the policy does not recognise the value of the time of unwaged people, such as students.

10.21 HFEA guidance states that there is a £250 maximum compensation for loss of earnings '*per course of donation'*; although this is not defined . The logical reading of the phrase is from the first donor visit, to the time gametes are released from quarantine (sperm and embryo donation).

10.22 Such a definition, however, cannot touch on realistically recompensing sperm donors for their loss of earnings. Sperm donors can donate every week for several months before the 10 family limit is met. Each visit is likely to take a couple of hours, including travel, which means that donors are likely to end up being compensated for less than the minimum wage. As a result of this impracticality, centres define *course of donation* for themselves; as a result, a course of donation can mean different things in different centres – for example 10 donations, or three months of time.

10.23 Some clinics, however, felt that £250 is an appropriate maximum limit for loss of earnings. Reimbursing actual salaries would not only be administratively difficult, it may also become unaffordable to clinics. Some NHS clinics already cannot afford to pay donors the current maximum limits for loss of earnings, or even reimburse expenses.

10.24 Another key operational issue identified by both clinics and inspectors is the significant drop-out rate of sperm donors following the mandatory 180 day quarantine period. Many donors do not return to the clinic for their six month check and, as a result, their stored donor sperm cannot be used in treatment. In response, some clinics withhold some expenses until the six-month check. This is undesirable, however, as it means that donors may be out of pocket for legitimate expenses.

Summary and recommendations

Operational issues

10.25 Reimbursement of documented expenses poses an administrative burden on clinics. In addition, some clinics may have continued to offer set payments to donors.

10.26 The lack of flexibility in the HFEA's current policies may be posing a barrier to donation, and thus might lead some people to travel abroad for treatment.

Policy issues

10.27 There is strong support from people who work in donation services to review financial compensation arrangement for donors. Balanced against this, the parent and counselling voice represented in the evidence gathered for this evaluation tended to warn against increasing compensation for donors. In addition, any increased compensation to donors will inevitably be transferred to patients or the NHS and make donor treatment less affordable and equitable than it already is.

Recommendations:

The Authority is asked to:

Consider the executive recommendation to undertake a review of reimbursement and compensation for donors, to include:

- Further research into reimbursement schemes in other jurisdictions and motivations of donors
- Consultation into public attitudes surrounding compensation for donors
- Targeted consultation with recipients, donor-conceived people, parents and donors
- Review operation of payment of reimbursement and compensation to donors, with a view to increasing ease of compliance

11 Benefits in kind (Egg Sharing)

Current policy: Benefits in kind should be limited to discounted treatment services. Eggs collected from an egg sharer in a single cycle should not be shared amongst more than two other recipients.

11.1 The SEED review examined the practice of permitting 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) while undergoing fertility treatment or sterilisation. Prior to the SEED review, the benefits that egg providers received were limited to discounted fertility treatment or sterilisation.

11.2 Following the SEED review, donors are permitted to provide gametes in exchange for reduced cost treatment cycles only. In addition, the practice of 'egg giving' is prohibited. By contrast to 'egg sharing', where eggs retrieved per treatment cycle are shared between the provider and recipient, in 'egg giving' arrangements the egg provider undertakes two treatment cycles, one for her own treatment and one for donation. These policy changes were based on a concern that a potential financial incentive in the form of free or reduced treatment or sterilization should not cause a woman to undergo more stimulated treatment cycles than are necessary for her to achieve her own reproductive ends.

11.3 In order to reduce the risk of OHSS and possible emotional complications for women who take part in egg-sharing arrangements, the number of recipients in any one treatment cycle is limited to two.

11.4 The policy is implemented via Directions (Gamete and Embryo Donation 0001), which have statutory force under Section 12 (1) (e) of the Human Fertilisation and Embryology Act 1990 (as amended). Directions stipulate that there are no restrictions on the value of other benefits which may be given to the donor, but the only benefits which may be offered are treatment services. In addition, these services should be provided to the donor in the course of the donation cycle unless there is a medical reason why they cannot be provided at that time.

Evaluation results: policy issues

11.5 The vast majority of interviewees felt that a policy whereby donors can receive reduced or free treatment in return for donating some of their eggs is inconsistent with the rest of the HFEA's policy on reimbursement and compensation. Despite this apparent anomaly in policy, most interviewees who worked in clinics felt that egg sharing works well in practice and should continue to be available.

11.6 In addition, it was commonly argued that this anomaly in policy should be addressed through increasing financial compensation to donors, rather than prohibiting egg sharing. One interviewee suggested that a set financial compensation should be paid to donors and that egg sharers should receive a reduction in the cost of their treatment which corresponds to that amount. For example, if egg donors are compensated by £500, egg sharers should receive a £500 reduction in treatment costs.

11.7 A minority of clinic staff and PROGAR, argued that offering benefits in kind in exchange for reduced treatment provides a financial incentive for people to donate. It was argued that such a policy is coercive to the extent it causes people to donate when they would otherwise not choose to do so. Concerns about the egg sharer's emotional well-being,

having made the decision to donate under such circumstances, were also prominent; for example, the impact on the donor if the recipient gets pregnant, but the donor doesn't.

11.8 The concern that egg sharers are motivated by financial reasons seems to be supported by evidence from Belgium. Since July 2003 Belgium has provided six free cycles of IVF. In this time, the number of egg-sharing donors has dropped by around 70%.[5]

11.9 Others, including the parents interviewed, felt that egg sharing is different from offering financial incentives to donate. Firstly, women who egg share are wishing to undergo treatment anyway, so they are not being induced to undertake physical risks they would otherwise not undertake. Secondly, rather than a financial benefit, gamete sharers are being offered the benefit of accessing reproductive treatment, and thus having the chance of conceiving, when they would otherwise not be able to do so. As a result, some interviewees felt that donating in exchange for reduced treatment was qualitatively different from donating in exchange for financial benefit.

Evaluation results: Operational issues

11.10 Many clinics report having a considered and careful approach to egg sharing which aims to protect the donor's interests. For example, some clinics will only allow egg sharing on the second treatment cycle, to ensure the donor can produce enough eggs to share without detriment to her treatment.

11.11 Some clinics require counselling in advance of donating to ensure that egg providers have considered the implications; including the possibility that the recipient may fall pregnant, but the donor might remain unsuccessful. In practice, however, few interviewees had experienced this scenario and believed that ensuring good success rates for donors and recipients is partly a result of appropriate selection criteria.

11.12 Most clinic staff reported that, in their experience, egg sharers have altruistic motives and want to help others in the same position as themselves. It was also anecdotally reported that most egg providers achieve a pregnancy and report a positive treatment experience.

11.13 Some interviewees reported that they were initially sceptical about egg-sharing as a policy, but these doubts have been dispelled through their positive experiences running egg sharing programmes. Others, however, reported that the vast majority of egg sharers are motivated by financial reasons. Those who had such concerns, advised that if egg sharing continues as a practice of donation, counselling should be mandatory.

11.14 The Senior Infertility Nurses Group gave a strong message that egg sharing works well in practice and, given the shortage of donor eggs more generally, should not be altered as a policy or operationally.

[5] Pennings et al, Cross-border reproductive care in Belgium, Human reproduction, Vol. 0, No. 00, pp 1-11, 2009

11.15 One interviewee argued that, through prohibiting egg giving, a sizable number of women who wish to donate their eggs in return for treatment services are prevented from doing so, because they cannot produce enough eggs in one cycle.

Summary and recommendations

Policy issues

11.16 The vast majority of interviewees argued that the policy surrounding benefits in kind for donating gametes is incongruent with the wider HFEA policy on payment and reimbursement of expenses.

11.17 Whilst some interviewees argued that the response to this should be increased compensation to donors generally, others argued that the practice of egg sharing should be abolished.

Recommendation

The Authority is asked to:

- Consider the executive recommendation that a review of benefits in kind be included in a wider review of reimbursement and compensation for donors (see Section 7.28).

12 Other emerging themes

12.1 During feedback on the specific policies implemented following the SEED review, some interviewees provided views on other matters pertaining to donation. The two main additional themes raised by interviewees were cross border fertility care and donor's limits to the use of their gametes or embryos.

Cross border fertility treatment

12.2 Some interviewees felt that the current shortage of donor gametes and embryos in the UK motivates some people to go abroad for treatment. There was some concern about the lack of regulatory oversight outside the UK. Many argued that there is a need to increase the availability of donor treatment in the UK to prevent people going abroad.

12.3 An additional concern was that the interests of donor-conceived people are compromised through being conceived outside the UK, as they will not necessarily have access to information about their donor or siblings.

12.4 There has been concern raised that UK centres are sometimes involved in shared care arrangements with overseas clinics, in which the UK clinic provides, for example, ovarian stimulation and then sends the patient abroad, sometimes for treatment which would be illegal in the UK. The legal and ethical implications, and in particular the potential liability of the UK centre, of such arrangements are of clear concern to the HFEA.

Donors specifying limits on their donation

12.5 Data from the SEED evaluation to date suggests that it is relatively common for donors to restrict the use of their donor gametes or embryos to specific family types or religions, for example, to married heterosexual couples, or people of a particular faith.

12.6 Interviewees had differing opinions on the ethics of restricting donations in such a way. Some felt that donors have a right to specify family types as it is essentially their gift. In addition, with the removal of anonymity, they may end up playing a role in the life of any offspring. Conversely, some felt that allowing donors to restrict their donation to specific family types tacitly endorses discrimination.

12.7 It is of note that donors are not allowed to restrict their donation in any other type of tissue or organ donation.

Recommendation:

The Authority is asked to:

Consider the executive recommendation that:

- Cross border fertility care be discussed at the ELAC open meeting in February 2009
- The legal and ethical implications of cross border care to be considered by ELAC in the 20010/11 business year.

- ELAC consider limits on donations in 2009/10

Section D: Intra-family gamete and embryo donation

13 Introduction

13.1 The Ethics and Law Advisory Committee (ELAC) considered issues relating to intergenerational donation, and intra-family donation more widely, in July and October 2009. ELAC has referred the issue to the Authority for decision.

13.2 This section of the paper summarises the main issues considered by ELAC and asks the Authority to decide whether future policy and consultation work in this area is desirable.

13.3 Intergenerational donation was referred to ELAC in July 2009 in anticipation of new statutory storage regulations[6], which came into force on 1 October 2009. These regulations widen access to storage of gametes and embryos to those wishing to store for the use of others, and extend the statutory storage period. As a consequence, it is now possible for a parent to store gametes for the future use of his or her child.

14 Intra-family donation within the UK

Prevalence

14.1 There is a lack of data on the prevalence of intra-family donation in the UK. The HFEA analyses the number of newly registering donors on a yearly basis; it does not record whether donors are known or even related to the recipient.

14.2 Discussions with clinic staff and inspectors indicate that intra-family donation is not uncommon in the UK, although some forms are likely to be more prevalent than others. For example, sister to sister donation seems to be relatively commonplace and donation from a younger generation to an older generation seems to occur more frequently than from older to younger generation. There has also been a case reported in the British media of father to son sperm donation.

Motivation

14.3 The majority of studies on the motivations of known donors report that such donors are primarily motivated by their personal relationship with the recipient and their views relating to benefits of having a family.[7] The donation relationship is not a sexual relationship nor a parenting relationship. In fact it represents an explicit choice in many circumstances to avoid a sexual relationship – for example in the case of single women and lesbian couples – and to avoid a parenting relationship with any subsequent child.

14.4 From the recipient's perspective, motivations include the preservation of genetic inheritance within the family and a reduction in cost and waiting times compared to using

[6] The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

[7] S. Purewal and O.B.A. van den Akker .*Systematic review of oocyte donation: investigating attitudes, motivations and experiences.* Human Reproduction Update Advance Access published online on May 14, 2009

an unknown donor.[8] Given the shortage of donor gametes and embryos within the UK, donation from a family member may present the most realistic option to some infertile couples.

15 Law and guidance

Legal background

15.1 Both sex (and therefore natural conception) and marriage between close relatives are prohibited in the UK by primary legislation[9]; a list of legally prohibited marriages and civil partnerships between close relatives is contained in Appendix 2.

15.2 The Human Fertilisation and Embryology (HFE) Act 1990 (as amended), prevents people within 'prohibited degrees of relationships' from joint parenting. The prohibited degrees of relationships are those where one party is the other's parent, grandparent, sister, brother, aunt or uncle. This mirrors wider legal prohibitions on sex and marriage between close relatives.

15.3 The HFE Act, however, does not prohibit close relatives from donating to each other. Some types of donation arrangements may be more or less acceptable than others. As the regulator, the question we need to address is: what represents cause for concern amongst certain types of donation relationships and what, if any, safeguards, should be implemented?

HFEA current guidance

15.4 Current HFEA guidance on donation is general to all types of donation, ie, donation involving known and unknown donors.

Consent

15.5 Clinics are legally required to obtain informed consent from people who wish to donate gametes or embryos for the treatment of others and people undergoing treatment with donated gametes and embryos.

15.6 Clinics are required to provide both donors and recipients with enough information to enable them to understand the nature, purpose and implications of the treatment or donation. Both parties must also be provided with a suitable opportunity to receive counselling about the implications of the treatment or donation. Donors also have the right to vary or withdraw their consent at any point.

[8] The Ethics Committee, American Society for Reproductive Medicine, Birmingham, Alabama. *Family members as gamete donors and surrogates*. Fertility and Sterility. Vol 80, No. 5, November 2003.
[9] The Sexual Offenses Act 2003 prohibits sex between close relatives; marriage between close relatives is prohibited by the Marriage (Prohibited Degrees of Relationship) Act 1986; civil partnership between close relatives is prohibited by the Civil Partnership Act 2004.

Counselling

15.7 Clinics are legally required to provide both donors and recipients with a suitable opportunity to receive proper counselling about the implications of the proposed treatment or donation.

Welfare of the Child

15.8 Before offering treatment (including treatment with donor gametes), clinics are required to consider the implications for any children born as a result of the donation, in the short and long term. Treatment should not take place if the recipient, or any child born as a result of treatment using the donor's gametes, is likely to experience serious physical, psychological or medical harm.

15.9 In addition, clinics are legally required to give recipients information about the importance of telling donor-conceived children, at any early age, of their donor-conceived origins. Clinics are instructed to encourage recipients to be open with their children and to provide counselling on how information could be shared with resultant children.

16 Ethical considerations

Welfare of the child – genetic concern

16.1 Brother to sister donation or father to daughter donation, each resulting in the creation of an embryo between close genetic relatives, are legally permitted in the UK; no cases, however, are known to the Authority.

16.2 A donation relationship which involves the creation of an embryo between close genetic relatives raises concerns regarding possible increased risks of genetic abnormalities for any resultant child. In addition, such an arrangement would seem to run contrary to the spirit behind the legal prohibition of sex and marriage between close relatives. The sexual offences legislation in the UK, for example, is "founded equally on fears of genetic abnormalities in children born of close blood union and on the public distaste for sexual relationships between such close relatives."[10]

16.3 It is very unlikely that donation which would lead to the creation of an embryo between close genetic relatives would satisfy the welfare of the child assessment that clinics are legally obliged to undertake.

16.4 ELAC recommends to the Authority that the mixing of gametes of close genetic relatives should be prohibited through a licence condition.

Welfare of the child – social concern

16.5 The existence of assisted reproduction techniques creates the possibility of unusual genetic and social relationships. A case, for example, of daughter to mother donation creates the situation whereby the genetic mother of the child will be its social sibling and

[10] Ms Harriet Harman (Solicitor General, Law Officers' Department), Sexual Offences Bill [Lords], Public Committees, 16 September 2003.

the social mother will be its genetic grandmother. This scenario creates a potentially confusing situation for the child.

16.6 Although intra-family donation creates potentially confusing and unusual relationships, such relationships are not, however, unique to children born as a result of assisted reproduction using intergenerational donor gametes. It is not unusual, for example, for children to be raised by their genetic grandparents or aunts and uncles and for families to manage the additional complexities of this type of relationship.

16.7 ELAC is concerned about the potential implications for the welfare of the child born as a result of intra-family donation; notably the impact of unusual social and genetic relationships. The Committee noted, however, that there had been little study or analysis of the effects of intra-family donation on the donor-conceived child.

16.8 ELAC also noted that to deny people the opportunity to donate gametes to family members could have a detrimental effect on the family and the treatment options available to people requiring donor treatment.

Consent – pressures on consent

16.9 Despite the fact that donors must be over the age of 18, there may be pressures which influence the quality of consent to donation. There may, for example, be undue influence placed on the donor as a result of financial dependency on the recipient. Even if financial dependency is not an issue, there may be other factors, such as controlling relationships between relatives and wider family pressures. There may well be a strong sense of duty, or sense of obligation, felt by the donor, which is not likely to be an influence on unknown donors. Some commentators have argued that risks associated with coercion and manipulation in such relationships cannot be eliminated and therefore such donation should not be permitted.[11]

16.10 On the other hand, the donor is, by definition, legally considered to have the capacity to consent to donation; to curtail an adult's ability to become a donor in the absence of evidence of harm to the donor or future child is likely to be unduly restrictive to their personal autonomy. In addition to concerns surrounding individual autonomy, there are issues surrounding family autonomy. It may be difficult to evaluate and judge personal family decisions which take into account motivations and values such as loyalty, altruism and the wish to continue the genetic line.

16.11 ELAC expressed concern regarding the potential pressure on family members to donate; however the Committee noted that the personal motivations of donors are likely to be complex and difficult to assess.

16.12 It is of note that safeguards on consent in the case of living organ donation are far more stringent than gamete donation. In the case of live organ donation, an independent

[11] Sureau C, Shenfield F. *Oocyte donation by a daughter*. Human Reproduction 1995; 10:1334.

assessor will interview the donor and recipient separately and report back to the Human Tissue Authority who will make the final decision. The independent assessor ensures that donors:

- Understand the medical risks and wider implications of the donation
- Have sufficient capacity to consent
- That the consent it not obtained by duress or coercion
- That there is no evidence of an offer of reward
- That the donor understands that they are able to withdraw their consent at any time.

16.13 It should be noted that these safeguards apply to all living donations, not just those between family members. In addition, there are notable differences between gamete and organ donation, most notably the clinical risks are much more considerable in the latter.

16.14 By comparison, all decisions regarding a gamete donor's suitability to donate are undertaken by the recruiting clinic only, in accordance with HFEA guidance.

Telling the child – support and counselling needs

16.15 The issue of known donation generally, and intra-family family donation specifically, adds another dimension to the issue of telling donor-conceived children about their origins. Parents would need to consider both how they tell their child they are donor-conceived, how they introduce the donor to the child and how they manage that relationship throughout life. Given this, there seems to be a need for both the recipient and the donor to consider the boundaries of the subsequent relationship with the child. Unforeseen feelings may also arise once the child is born and during the course of the child's life.

16.16 It is of note that a recent literature review of egg donation found that known donors are less likely to believe the child should be informed of their genetic origins than unknown donors.[12] However, the majority of donors recognised that disclosure was the parents' decision. Donors' attitudes may impact on how open the family is about the donation with subsequent children, and may be indicative of additional counselling and support needs with intra-family donation.

16.17 ELAC discussed the importance of counselling on the implications of intra-family donation. Members noted that all clinics must offer counselling to donors and recipients; however people are not required to undergo counselling.

[12] S. Purewal and O.B.A. van den Akker .*Systematic review of oocyte donation: investigating attitudes, motivations and experiences.* Human Reproduction Update Advance Access published online on May 14, 2009

17 ELAC's recommendations to Authority

17.1 After consideration of the above issues, ELAC recommends to the Authority that the mixing of gametes of close genetic relatives be prohibited through a licence condition.

17.2 The Authority may also wish to consider whether Code of Practice guidance relating to intrafamily donation should be introduced. If so, the additional guidance could address, for example:

- specific information requirements and consent requirements on the impact of intrafamily donation
- the importance of telling children about their genetic origins, when a known donor has been used
- whether all cases of intrafamily donation be considered by a clinical ethics committee
- whether counselling both donors and recipients on the implications of donation should be mandatory

17.3 The Authority may wish to consider whether there are sufficient concerns to warrant public consultation on this issue.

Section E: Recommendation to the Authority

18 Recommendation and next steps

18.1 A summary of the recommendations contained in this paper is provided in the table below. Once the Authority has made a decision about future policy work around donation, the Executive will draw up a detailed work plan for Authority consideration in March 2010.

	Leave	Review operationally	Review policy
Donor codes		Assess risks, legality and principles entailed in supplying donor codes to parents of donor conceived people.	
Selection of Donors	No policy or operational review required.		
Procurement from abroad	Authority considers facilitating information exchange in sector regarding overseas gamete supplying centres.		
Refer to professional guidance on screening		Provide greater clarity on professional and HFEA guidance requirements.	
10 Family Limit			Undertake review of 10 family limit.
Reimbursement of expenses **Compensation for loss of earnings** **Benefits in kind**			Undertake a review: - reimbursement - compensation - benefits in kind
Limitations on use of donor gametes		ELAC to consider limits on donations, within context of wider Equalities and Donation framework	
Cross border fertility		Discuss at ELAC open meeting in February 2009, with a view to prioritising work on this topic.	
Intra-family donation			Undertake a review of policy and guidance surrounding intra-family donation.

Annex 1
Systems of expenses and compensation within the European Union

Data taken from *'Report on the Regulation of Reproductive Cell Donation in the European Union'* (2006)

This is the most up-to-date report detailing payment for donation within Europe; it may not reflect practice in 2009. The EU has announced an intention to update the report in 2009/10.

Country	Systems of compensation
Czech Republic	▪ Regulated by binding guidelines. ▪ Sperm donors receive reimbursement between 300-600 Czech Crowns (£10-20) which covers wage losses only. ▪ Egg donors receive between 8,000 – 15,000 (£275-£515) Egg donors receive compensation for both wage and time disruption and discomfort during the medical procedure is taken into account
Denmark	▪ Sperm donors receive 50-150EUR (£44-134) for the examination and use of their time. ▪ Egg donation is prohibited by law
Estonia	▪ Compensation is small and only covers travel/accommodation relating to the process of donation
Greece	▪ No donor compensation
Spain	▪ Egg donors are compensated up to 1000 Euros (£890)
Finland	▪ Ovary and sperm donors in practice receive a reimbursement to cover their expenses
France	▪ Donors receive no compensation besides the reimbursement of travel expenses.
Hungary	▪ Remuneration for donating reproductive cells shall not be requested or provided. ▪ Donation-related necessary and certified costs of a donor, including loss of income, shall be reimbursed
Italy	▪ Only permits reproductive cell donation within homologous male-female couples who are over the age of 18 and either married or living together
Slovenia	▪ Giving and receiving remuneration or any other benefits as compensation for donated reproductive cells is not permitted. ▪ A male or female donor of is entitled to the reimbursement of costs associated with his/her arrival to, stay in and return from a bio-medically-assisted reproduction as well as with the examinations and reproductive cell collecting.

Annex 2

The below table was taken from the Citizen's Advice Bureau's website on 7 October 2009, 18.24.

The Civil Partnership Act 2004 extends the same prohibitions which apply to marriage between family members, to civil partnerships between family members.

Men cannot marry:-	**Women cannot marry:-**
Grandmother	Grandfather
Mother	Father
mother's sister	father's brother
mother's half sister	father's half brother
father's sister	mother's brother
father's half-sister	mother's half-brother
adoptive mother	adoptive father
Sister	Brother
half-sister	half-brother
Daughter	Son
adoptive daughter	adopted son
sister's daughter	sister's son
half-sister's daughter	half-sister's son
brother's daughter	brother's son
half-brother's daughter	half-brother's son
Granddaughter	Grandson