## Paper

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<th>Donation review – early options</th>
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<td>Hannah Darby, Policy Manager</td>
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### Recommendation to the Committee:

The Committee is asked to recommend consultation options to the Authority on:

- Intra family donation
- Conditional donation

The Committee is asked to note the clinic survey results in relation to cross border care.

### Annexes

Annex 1 – Clinic survey results, donation review
1. **Introduction**

1.1. The HFEA is currently undergoing a programme of work to review aspects of its policies relating to sperm, egg and embryo donation (Donation review), as agreed by the Authority in March 2010.

1.2. The Donation review will address the following issues:
- Reimbursement, compensation and benefits in kind to donors
- Donor family limit
- Upper age limit for sperm donation
- Conditions placed by the donor on the use of donated gametes and embryos
- The release of donor codes to parents of donor conceived people
- Intra family sperm and egg donation

1.3. This paper presents the evidence gathered to date on:
- conditional donation
- intra family donation

1.4. The Ethics and Law Advisory Committee is asked to review the evidence and recommend consultation options on these two topics for consideration by the Authority in July 2010.

1.5. In addition, recent clinic survey findings around cross border reproductive care are documented in Section 5 of this paper. The Committee is asked to note the clinic survey findings and consider the relationship between people travelling abroad for treatment and gamete and embryo donation.

2. **Evidence gathering**

**Clinic survey**

2.1. An online, anonymous, survey was sent to all licensed centres in the UK. The survey explored the experience and attitudes around intra family donation and conditional donation, as well as other issues surrounding the broader Donation review. We received 31 responses from centres, 29 of which perform treatment using donor gametes or embryos (44% response rate from donor treatment centres). A full analysis of the clinic survey is attached in Annex 1.

**Expert workshop**

2.2. A workshop was held in June 2010, comprised of people who had some expertise around intra family donation, including clinic staff, social
scientists and patient representatives. The workshop explored the prevalence, motivations, ethical issues and current best practice around intra family donation.

**Literature search**

2.3. A further examination of the literature surrounding intra family donation and conditional donation has been conducted, including research into best practice in other jurisdictions.

**International regulators**

2.4. The Executive asked 32 regulators in other jurisdictions for information about their donation policies (the majority of whom are Competent Authorities to implement the requirements of the EU Tissues and Cells Directive: http://www.eurocet.org).

3. **Intra family donation**

**Background**

3.1. ELAC considered the issues engaged in intra family donation in both July and October 2009. A summary of the Committee’s considerations was presented to the Authority in December 2009. The Authority subsequently concluded that there were significant concerns engaged in intra family donation to examine the issue in more detail with a view to publically consulting on the ethical and policy issues pertaining to this type of donation.

3.2. Subsequently, the Executive has conducted a clinic survey and held an expert practitioner workshop to try and build a picture of the prevalence of donation between family members in the UK, the motivations of both donors and recipients, and current best practice.

3.3. The evidence gathered from both the survey and the workshop is examined below. On the basis of this evidence, and the previous considerations of both ELAC and the wider Authority, ELAC is asked to provide recommendations on public consultation options surrounding intra family donation.

**Prevalence**

3.4. The clinic survey and workshop have provided some insights into the prevalence of intra family donation within the UK. Respondents to the survey reported receiving requests for intra family donation from once a week to less than once a year. The majority of respondents received requests for this type of donation every one to six months and performed such donor treatment once every three to six months.

3.5. Centres were asked to document the types of intra family donation they had been involved in. The most common type of intra family donation reported was sister to sister donation; 23 out of 28 centres had received a request for this type of donation.
3.6. The second and third most common type of intra family donation seen by centres is brother to brother (13 responses) and father to son (8 responses). Other types of intra family donation requests seen in clinics include:

- Cousin to cousin - 7 responses
- Daughter to mother - 3 responses
- Niece to aunt - 3 responses
- Mother to daughter – 2 responses
- Step brother to step sister in law – 1 response
- Sister in law to sister in law – 2 responses

3.7. Feedback from the workshop tended to reinforce this broad picture of prevalence and types of donation seen by clinics. All centres represented at the workshop had performed several treatment cycles involving sister to sister donation. One centre had seen a case of a mother donating to her daughter, for future use, whose fertility was limited due to Turner Syndrome.

3.8. There was general agreement at the workshop that donation between generations is relatively unusual, but a handful of such cases had been seen – 2/3 cases had been seen at each of the clinics represented.

3.9. This picture is reflected within the Donor Conception Network, which reported a steady number of cases of donation within the family with a slight increase in sibling donation in recent years.

Motivations

3.10. The two most common reported motivations for donation between family members reported in the clinic survey were:

- wanting a genetic link with the offspring, and
- wanting to avoid very long waiting lists for an unknown donor.

3.11. This was reflected in the workshop discussion, although participants emphasised that people usually have more than one motivation for choosing intra family donation.

3.12. It was noted that related donors tend to have either proactively offered to help a family member or they have been directly appealed to by a family member. In the experience of workshop participants, the family members who volunteer are reported to be the least complex cases, in so far as donation is the choice of the donor, not something imposed on them. Participants reflected that sometimes recipients present to clinics with a known donor in a bid to reduce their waiting time for treatment, but have not fully thought through the implications of known donation, and subsequently change their mind.
3.13. It was also noted that different cultures expected different levels of duty towards their family members, and this can add to the difficulty of identifying whether donation is the true autonomous wish of the donor.

3.14. Ascertaining the motivations of donors and recipients is the main concern of professionals performing treatment with a known donor. Professionals represented at the workshop went to great length to ensure the donor’s consent is both free and informed, and that donors, recipients, and wider family networks have fully thought through the implications of intra family donation, before treatment commences.

Messages from the literature - motivations

3.15. There is little published literature on the motivations involved in intra family donation; however what there is tends to reinforce the findings of the clinic survey and workshop. A study conducted by the Centre for Reproductive Medicine of the Free University of Brussels found that 68.8% of donor recipients preferred known donation and that this choice was mainly motivated by reasons related to fears associated with anonymity, such as fear of the unknown origin of genetic material and the trust that couples had in ‘their’ donor. Almost one-third of the recipient couples, however, opted to use un-known egg donors; this was due to their desire to establish explicit boundaries between the two families involved.¹

Ethical issues

3.16. In December 2009, the Authority identified the following ethical issues of most concern with regard to intra family donation.

- Welfare of the child (genetic concern) – relating to the potential to create an embryo from gametes of close biological relatives.
- Welfare of the child (social concern) – relating to the potential for confusing genetic and social relationships resulting from donation between relatives.
- Pressures on consent - undue pressure may be placed on the donor as a result of financial dependency on the recipient, controlling relationships between relatives and wider family pressures.
- Telling the child, support and counselling needs – intra family donation adds another dimension to the issue of telling donor-conceived children about their origins. Parents would need to consider:
  o how they tell their child they are donor-conceived
  o how they introduce the donor to the child, and
  o how to manage that relationship throughout life.

¹ P. Baetens1,3, P. Devroey1, M. Camus1, A.C. Van Steirteghem1 and I. Ponjaert Kristoffersen ‘Counselling couples and donors for oocyte donation: the decision to use either known or anonymous oocytes.’
3.17. These concerns were echoed by the participants at the workshop and by respondents to the clinic survey. The key concern identified at the workshop was the risk that there may be undue pressure to donate and the subsequent importance of ensuring the donor’s consent is free and informed. Respondents to the clinic survey also highlighted the potential for coercion and pressure on the donor’s consent. Other issues highlighted by the clinic survey and the workshop were around the need to ensure both donors and recipients have considered, and are comfortable with, issues around telling the subsequent child about their origins, the ongoing relationships throughout any child’s life and the wider effects on the family, for example the impact on the donor’s own children.

Genetic concern

3.18. An issue which was discussed in some depth at the workshop was whether there should be any outright prohibitions on the mixing of gametes between closely related family members. The majority of participants at the workshop felt that donation which involves mixing gametes of close biological relatives should be prohibited, although no participants had reported dealing with a request for such donation. On consideration of this issue in October 2009, ELAC also recommended that the mixing of gametes of close genetic relatives should be prohibited.

3.19. If it is agreed that some donation relationships between close relatives should be prohibited, there is a further question of how we define such relationships. Two suggestions were proposed at the workshop. Some suggested that the HFEA examine the evidence of risk of congenital defects following reproduction between close relatives, and prohibit on the basis of this risk. Others felt that this evidence base would be hard to obtain and that prohibited donation relationships should be based on the prohibited degrees of relationships with regard to sex and marriage, outlined in the Sexual Offences legislation (see Annex 2). Such a prohibition would not prevent donation *per se* between people in these relationships, only where the intention is to mix gametes between people in one of the prohibited degrees of relationship.

3.20. The legally prohibited degrees of relationships prevent some non-biologically related family members from forming sexual relationships (for example men cannot marry their adoptive daughter or mother). As a result, banning mixing of gametes between people in otherwise prohibited degrees of relationships would prevent some types of donation relationship which do not involve the mixing of gametes between close genetic relatives, but which involve adoptive relationships, which are modelled on a biological relationship.

Models of good practice

3.21. 57% of respondents to the clinic survey undertake additional assessments in cases of intra family donation, as opposed to non-family donation.

3.22. Additional assessments which were reported include a requirement that the recipient and donor (and their partners) undergo implications
counselling. Some clinics require the donor and recipient to be counselled separately, some require joint counselling and some require both.

3.23. One centre stated that extra consideration needs to be given to the welfare of the child assessment, within the context of each different intra family donation.

3.24. The reasons given for these extra measures included:

- to ensure pressure of coercion and financial inducement is excluded
- to work out how the donor and recipient feel with respect to continuing involvement in any potential child’s life
- to ensure all parties understand the implications of being related
- to ensure social acceptance within the family
- the need to take into account the family dynamics for example, the effect on the donor’s own children
- general unease around intergenerational donation

3.25. These concerns were broadly reflected in the workshop discussions. Participants at the workshop emphasised the importance of implications counselling to address the issues outlined above. One centre explained that they counsel both donors and recipients separately and together, and in the wider family group, before donation between family members takes place. In addition, people are also informed of the option of pooled donation as an alternative to donating directly to a family member.

3.26. The group also noted the importance of ensuring people who wish to engage in these types of donation relationships are given adequate time to reflect on their decision and to take into account all relevant information and considerations. Participants also felt that having access to a clinical ethics committee is important in more complex cases, or where there is some concern about the donation relationship from clinic staff. Most commonly, cases of donation between generations are referred to ethics committees. It was noted, however, that not all clinics have access to such committees.

3.27. There is a limited body of literature on good practice surrounding intra family donation, however messages from this literature tend to reinforce the concerns and considerations of clinics performing intra family donation. Studies on the ethical and societal implications of known and intra family donation, for example, emphasise the importance of counselling for prospective participants, including recipients, donors, and partners of donors.

3.28. Marshall (1998) states that counsellors should address issues such as emotional risks, potential impact on family relationships, the donor-recipient relationship, the future role of the donor in the offspring's life, and what information will be disclosed to the offspring. Marshall particularly refers to the importance of obtaining informed consent from recipients,
donors, and the donor's partner to ensure that the decision to be a donor has been voluntary and free from manipulative and coercive influences.  

3.29. As noted in the Authority paper in December 2009, both Australia and New Zealand ban the creation of embryos between close genetic relatives and issue guidance to clinics regarding the handling of requests for intra family donation. This guidance aims to ensure consent is freely given and that all parties have considered the implications of family donation and understand the importance of informing any children about their origins.

3.30. The American Society for Reproductive Medicine published an Ethics Committee Report in 2003, which looked at inter family donation. The report recommended that all assisted reproduction treatment programmes should develop policies and procedures for dealing with requests for the use of family members as donors or surrogates. The report also found that some forms of intra family donation should be rejected on the grounds of consanguinity or because of a lack of free, informed consent.

**Pooled donation**

3.31. Discussions at the workshop and ad hoc discussions with clinics more generally, reveal that ‘pooled donation’ is often offered as an alternative to direct donation to a family member. In cases where a potential donor recipient’s family member wishes to help, but does not wish to donate directly to their relative, the potential donor could donate their gametes to an unknown recipient, and by doing so their family member would be prioritised to receive donor gametes from an unknown donor.

3.32. One clinic stated that around half of sisters preferred to ‘pool’ their donation, rather than donate directly to their sister; although another clinic reported no great demand for pooled donation. It was noted that this was a good option for a brother who wishes to help his genetic sister, without donating to her directly.

3.33. Importantly, pooled donation may present a benefit to people wishing to help a family member conceive, but who, at the same time, do not wish their relative to raise their genetic child.

**Key messages**

3.34. Evidence gathered via the clinic survey, workshop and literature review tend to reinforce the conclusions of ELAC in October 2009, that there are important differences between intra family donation and other types of donation, which may affect how clinics deal with cases of intra family donation.

3.35. These differences include:

- The potential to mix gametes of close genetic relatives

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• Possible pressure on the donor to consent to donation
• Life long implications for donor, recipient, resultant child and wider family around telling the child about their origins and managing the genetic/social relationships in the family

3.36. Clinic staff tend to agree that there are additional considerations and assessments which should be taken into account to address the more complex dimensions of intra family donation. These might include:

• Safeguards to prevent mixing gametes of close relatives
• Safeguards to ensure donor consent is free and informed
• Implications counselling for donor, recipient and wider family
• Adequate time to reflect on implications of family donation
• Considerations of alternatives to family donation – e.g. pooled donation
• Ability to refer to a clinical ethics committee where there is concern within clinical team regarding intra family donation

Consultation options: mixing of gametes

3.37. In order to address the concern regarding the mixing of gametes between close relatives, the below consultation options are suggested.

3.38. The first option suggests sticking with the status quo, given that there are no known incidents of mixing of gametes between close relatives, and this issue is currently caught by the welfare of the child assessment.

3.39. The second option would address this issue through directly applying the current prohibitions on sexual relationships between close relatives, to the mixing of gametes between close relatives as a result of donation.

3.40. The third option recognises that a direct transcription of the sexual offenses prohibitions to the mixing of gametes between close relatives would also prohibit mixing of gametes between non-genetic relatives. This option proposes that prohibitions on the mixing of gametes between relatives should reflect the legal prohibitions on sex and marriage between close relatives only where there is also a close genetic relationship.

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<tr>
<th>Option 1: Status quo</th>
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<tr>
<td>No additional guidance needed; clinics must fulfil current mandatory requirements regarding welfare of the child assessments</td>
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<th>Option 2: Mirror sexual offences legislation</th>
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<td>Prohibitions on the mixing of gametes between relatives should reflect the legal prohibitions on sex and marriage between relatives</td>
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<th>Option 3: Mirror sexual offences legislation, genetic relatives</th>
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<td>The third option recognises that a direct transcription of the sexual offenses prohibitions to the mixing of gametes between close relatives would also prohibit mixing of gametes between non-genetic relatives. This option proposes that prohibitions on the mixing of gametes between relatives should reflect the legal prohibitions on sex and marriage between close relatives only where there is also a close genetic relationship.</td>
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Prohibitions on the mixing of gametes between relatives should reflect the legal prohibitions on sex and marriage between close relatives only where there is also a close genetic relationship.

**Consultation options: non-prohibited intra family donation**

3.41. In order to address the concerns regarding intra family donation, the below consultation options are suggested.

3.42. The first option suggests sticking with the status quo; this recognises that intra family donation is a long established practice which clinics have developed strategies for dealing with within HFEA current guidance on counselling, consent and welfare of the child.

3.43. The second option recognises the additional issues engaged in intra family donation, and would entail issuing guidance to clinics which reflects the current thinking on best practice based on the analysis of the evidence identified above.

3.44. The third option again recognises the additional issues engaged in intra family donation, but rather than issuing prescriptive guidance, gives clinics the freedom to implement their own strategy, which recognises the issues outlined in the analysis of evidence above.

3.45. The fourth option recognises that the HFEA may not be in the best position to issue guidance on the counselling needs of people involved in intra family donation, and encourages the profession to issues expert guidance on this issue.

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<th><strong>Option 1: Status quo</strong></th>
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<td>No additional guidance necessary; clinics must apply current guidance on consent, counselling, provision of information and welfare of the child.</td>
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<th><strong>Option 2: HFEA guidance</strong></th>
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<td>Clinics must offer implications counselling to recipients, donors both separately and together, and to the wider family (e.g. existing children of the donor), before donation takes place. Counselling should address: free informed consent; implications of telling the child of their donor origins and managing the lifelong relationship. Donors and recipients should be given adequate time to reflect on their decision and, alternatives to family donation should be explored in full.</td>
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<th><strong>Option 3: Strategy</strong></th>
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<td>Clinics offering donation services must have a strategy in place to deal with cases of donation between family members which addresses the following issues:</td>
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<td>- Safeguards to ensure donor consent is free and informed</td>
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<td>- Implications counselling for donor, recipient and wider family</td>
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<td>- Ability to refer to a clinical ethics committee where there is concern within clinical team regarding intra family donation</td>
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Option 4: Professional guidance
HFSA invite the British Infertility Counselling Association to produce professional guidance to counsellors on how to address cases of intra family donation.

Recommendations to the Committee

3.46. ELAC is asked to consider the evidence surrounding intra family donation and provide recommendations to the Authority on whether the options identified above are the right ones to publically consult on.

4. Conditional donation

Background

4.1. During the evaluation of SEED policies, undertaken in 2009, conditional donation emerged as an additional theme. As outlined in the December 2009 Authority paper, interviews with clinic staff indicated that it is relatively common for donors to restrict the use of their donor gametes or embryos to, for example, married heterosexual couples, or people of a particular faith.

4.2. 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.

4.3. The Authority referred this issue to ELAC for consideration and agreed it should be included in the review of donation policies.

Legislation

4.4. The HFE Act 1990 (as amended) appears to permit conditional donation: Schedule 3, paragraph 2(1)(ii) provides that a person’s consent to the use of any embryo may ‘specify conditions subject to which the embryo may be so used.’ Paragraph 2(2) makes similar provision in relation to the storage of any gametes or embryo.

4.5. The HFEA consent forms for donation ask: ‘Do you have any restrictions that you would like to apply to any of your [answers giving consent], e.g. use for a named recipient?’ The main intention of this question is to allow donors, who are donating to someone they know, to restrict the use of their donation exclusively for the treatment of that recipient. However, donors may use this field to specify other conditions which reflect their personal views.

4.6. In addition, because of the potential uncertainty in law relating to legal fatherhood of donated embryos, the HFEA has issued guidance stating that “One way of avoiding this potential uncertainty, is for a couple donating an embryo (or a man donating an embryo created during
treatment with his partner) to consider placing a condition on the use of the donated embryo. The woman could, for example, state that the embryo should only go to a woman who is in a legally recognised relationship that gives legal parenthood to her husband or civil partner or who has consented to another person being the second parent to her children."

**Position under the Equalities Legislation**

4.7. The following is a summary of the advice legal counsel has provided on conditional donation:

- The Equality Act 2010 which became an Act of Parliament on 8 April 2010, prohibits service providers from discriminating by treating people less favourably because of various protected characteristics, including race, religion or belief, and sexual orientation (cl.13(1), 27(1)-(2)). For the purposes of the Equality Act a treatment centre is considered a service provider however it is unlikely that a donor would be considered a service provider and nor would a donor be considered to be performing a public function. For these reasons, the duty not to discriminate will therefore not apply directly to a donor.

- The Equality Act also requires public bodies (eg, the HFEA), in carrying out their functions, to have regard to the need to:
  - eliminate unlawful discrimination;
  - advance equality of opportunity between persons who share a relevant protected characteristic and those who do not; and
  - foster good relations between persons who share a relevant protected characteristic and those who do not (cl.143).

- The attachment of conditions to donations might result in a treatment centre discriminating against persons because of a prohibited characteristic, contrary to the requirements of the Equality Act. For example, if the choice of donors at a centre is more limited for heterosexual couples than lesbian couples, because of conditions imposed by donors limiting the use of some donated material on the basis of sexual orientation, this may be found to constitute unlawful direct discrimination in relation to a service.

- Our existing guidance to centres, highlighting that donors can specify that the gametes or embryos should not be used for the treatment of single women, is permissible. The Authority does not discriminate against single women in issuing guidance that recommends donors be informed of the legal uncertainty regarding donating to single women, outlined in paragraphs 4.4 - 4.6.

- It is up to the Authority to decide whether to issue further guidance on this issue. The correct focus of any guidance issued would be upon the potential risk for treatment centres if they were to accept donations subject to discriminatory conditions (ie, conditions which specified a particular class or classes of persons identified by reference to the
protected characteristics defined in the Equality Act). In deciding whether to issue guidance, the Authority may wish to consider the scale of the problem being identified and the risks involved in taking a view of the law in relation to a statute outside its core area of competence and involving the application of rules which may be amenable to varying interpretations. In order to mitigate this risk the Authority should, at least, discuss any proposed guidance, before formal consultation, with the Equalities and Human Rights Commission to gauge its views.

4.8. The Executive has approached the Equalities and Human Rights Commission to meet to discuss how conditional donation fits within the spirit and letter of the law around Equalities and Human Rights legislation. This meeting has not taken place yet; the Executive will update both ELAC and the Authority once it has.

**Prevalence and current practice**

4.9. The HFEA Register only holds information on restrictions regarding family limits, so until the results of the clinic survey were received, the Authority only had anecdotal information about the prevalence of conditional donation. The survey results indicate the following:

- At the majority of centres no donors, or a very small proportion of donors, place restrictions on the characteristics of recipients who can use their gametes/embryos in treatment. Only one centre documented that the majority of donors at their centre place these types of restrictions on their donation.

- The most common restrictions appear to be that gametes or embryos cannot be used in the treatment of single women, same sex couples, people of a particular sexuality or older women. Some centres also reported having experienced incidences of restrictions relating to the following factors: age of recipients, religion, marital status, geography, physical characteristics and education.

- The majority of centres feel that donors should be permitted to place restrictions on the use of their donation. Reasons given included that the donor has a ‘right’ to choose and feel comfortable with who receives their donation, the removal of donor anonymity has resulted in contact between donor and donor conceived, and allowing conditional donation may increase donor supply.

- The vast majority of centres have not declined to recruit/use a donor who wished to place restrictions of their donation.

- Some centres, which do not agree with donors placing restrictions on their donation, feel that donation should be a gift that is not prescriptive.

- Centres were asked if potential recipients are informed that their choice of donor is limited, or that no donor is available, because they fall outside the restrictions set by the donor. Of those that responded 65% state that potential recipients are not informed that
their choice of donor is limited.

- Answers indicated that centres have not experienced a problem with donor imposed restrictions and informing recipients of these conditions (as either the clinic does not accept donors who place restrictions or that they have enough donors to provide choice for most of the recipients).

- The majority of centres feel that the waiting time for treatment with donor gametes/embryos would not be increased if donors were not permitted to place restrictions on the use of their donated gametes or embryos.

4.10. The Donation Review Advisory Group (constituted of clinicians, researchers and other stakeholders) highlighted that recipients may wish to place restrictions on who they would like as donors and that some donor restrictions may be based on features unrelated to the type of recipient, but rather features such as the location of the recipient or recipients having single embryos transfers etc.

**International comparison**

4.11. The Executive asked 32 regulators in other jurisdictions for information about their donation policies (the majority of whom are Competent Authorities to implement the requirements of the EU Tissues and Cells Directive: [http://www.eurocet.org](http://www.eurocet.org)).

4.12. Of the 5 countries which responded to questions about conditional donation 3 (Portugal, Croatia, Sweden) do not permit conditional donation or have no provisions to specifically allow it (i.e., donors give informed consent unconditionally in general to the act of donation and do not donate to one particular patient or type of patient). The Swedish regulator stated that the only exception to this is donation to a close friend or relative.

4.13. In Finland and New Zealand donors are permitted to place conditions on their donations.

4.14. This is set out in Section 17 of the Finnish Act on Assisted Fertility Treatments. The conditions can be included in the donor consent document and may, for example, stipulate that the donor’s gametes can only be used in the treatment of one particular woman or couple. It is up to the clinic to decide whether to accept the donation under the conditions set by the donor.

4.15. The Reproductive Technology Accreditation Committee (RTAC) Code of Practice, in New Zealand, requires that donors must be informed that they have the option of placing boundaries, subject to any relevant legislation, on the use of their gametes. The New Zealand Fertility Services Standard (planned for implementation this year and which will replace the RTAC Code) has a similar provision.

4.16. The Advisory Committee on Assisted Reproductive Technology (ACART) is currently undertaking work to advise the Minister of Health on informed consent as it applies to assisted reproductive treatment, and that work
includes looking at the issue of donors being able to set conditions.

**Ethical issues**

4.17. The Ethics Committee of the American Society for Reproductive Medicine has concluded that the principal argument for allowing donors to place restrictions on their donation is that a donor is autonomous and has the right to specify the type of person to receive this gift, but clinics can find this ethically unacceptable. They felt that, on the other hand, directed egg donation may not be practicable owing to the shortage of egg donors and in some situations the direction could be contrary to clinic policy.

4.18. When referring to the traditional model of anonymous organ donation, it is suggested that selection of categories of recipients undercuts the altruistic principle of donation. Consequently, directed donation is not part of the anonymous organ donation process. The Committee, therefore, suggest that it is ethically acceptable to select recipients in anonymous gamete donation without regard to the donor’s preferences, and donors should be counselled to this effect.

4.19. Guido Pennings on ‘Should donors have the right to decide who receives their gametes?’ remarks that giving donors the right to direct their gametes to certain groups of recipients goes against the general rule that donors relinquish all rights and duties and may run counter to the rules of distributional justice. On the other hand, he argues that the allocation right can be supported by the principle of autonomy and by the donor’s interest in and contribution to the process. The position is taken that the donors should have the right to direct their gametes to categories accepted as relevant by the moral and religious communities in their society. They should not be given the right to add their own categories to the exclusion list. If donors are not allowed to allocate their gift, they should at least be informed as to which categories of recipient are treated by the hospital to enable them to decide whether they want to donate gametes.

4.20. Two perspectives have been gleaned from discussing this issue with stakeholders. Given that the potential for future contact between the donor and any children born donors may feel it is important to ensure their offspring will be raised by people who broadly share their value system. On the other hand some may feel that donation should be altruistic, that discrimination is wrong and, even if conditions are placed in the donation, it is not possible for donors to ensure that the recipients share the same value system throughout the upbringing of the child (ie, married couples may get divorced, single women may get married and people may reveal a different sexual orientation).

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Key messages

4.21. Conditional donation may not be as commonplace as anticipated, with the majority of centres indicating that no donors, or a very small proportion of donors, place restrictions on the characteristics of recipients who can use their gametes/embryos in treatment. The most common restrictions placed on donations appear to be that gametes or embryos cannot be used in the treatment of single women, same sex couples, people of certain sexuality or older women.

4.22. In general the arguments for allowing conditional donation come down to donors being autonomous and a having the right to contribute to specify the type of person to receive this gift (eg, people who hold similar values). This argument is perhaps heightened by the fact that, following the removal of anonymity, donors may have contact with children born as a result of their donation. However, it is argued that conditional donation undercuts the altruistic principle of donation and may place centres at risk of breaching Equalities legislation.

4.23. Any guidance issued on conditional donation needs to be in line with the Equality Act. The Authority’s position will need to focus on centres’ responsibilities in terms of equality, rather than donor’s (ie, the potential risk for treatment centres if they were to accept donations subject to discriminatory conditions).

4.24. A decision to revise guidance on conditional donation does not have to entail public consultation on what guidance should look like. ELAC may wish to consider that, in light of the information gathered to date, there is sufficient evidence to recommend to the Authority that a specific approach to guidance on conditional donation is adopted, without publically consulting.

Consultation options

4.25. Therefore, the following consultation options are recommended:

4.26. **Option 1**: No additional guidance is necessary as licence conditions and guidance on treating donors and patients fairly are already outlined in the Code of Practice (guidance note 29). Centres may continue recruiting donors who place any types of conditions on their donation.

4.27. **Option 2**: Continue to permit conditional donation if it does not relate to characteristics protected by the Equality Act (eg, known donation, geographical location of recipient, method of treatment) or if there is another valid basis (eg, the legal uncertainty surrounding embryo donation). Provide guidance to centres ensuring they are aware of the requirements of the Equality Act and suggesting they refer to these requirements when deciding whether or not to recruit donors who place conditions on their donation (ie, they will need to judge whether or not this will result in them providing a service which discriminates on the basis of one of the protected characteristics).

4.28. **Option 3**: Prohibit centres from recruiting donors who wish to place conditions on their donation (with the exception of conditions which relate
to known donation and fatherhood following embryo donation).

**Recommendations to the Committee**

4.29. ELAC is asked to consider the legal advice and evidence surrounding conditional donation and provide recommendations to the Authority on:

- whether conditional donation is an issue which would benefit from public consultation or whether it is more appropriate for the Authority to decide on its position, following consideration of the legal advice and consultation with other relevant bodies; and

- whether the options identified above are the right ones to publically consult on, subject to advice from the Equalities and Human Rights Commission (if public consultation is recommended).

5. **Donor treatment as motivation for people to travel abroad**

5.1. As you will see from Annex 1, as part of the clinic survey we took the opportunity to ask clinics about the prevalence and motivations of people seeking fertility treatment abroad and the level of support provided by clinics to such patients.

5.2. The survey suggests that access to donor treatment is the main driver for people travelling abroad - 100% of respondents said that people travel abroad due to easier access to treatment with donor gametes or embryos. If a shortage of donor gametes is a key reason why people travel abroad, this adds to the evidence that there is a severe shortage of donor gametes within the UK. Whilst the Donation review is not intended to address the UK shortage of donors directly, it may be something the Authority wish to bear in mind whilst considering broader policies around donation, insofar as they may impact on supply.

6. **Recommendations to the Committee**

6.1. The Committee is asked to consider the recommendations outlined at paragraphs 3.46 and 4.28.

7. **Next steps**

7.1. The Authority will discuss these issues, together with ELAC’s advice and further evidence, at their meeting on 7 July.

7.2. A further paper will be taken to the September Authority meeting with consultation options on compensation to donors and the donor family limit. A consultation document, regarding all of the donation policies under review, will be drafted and presented to the Authority in October. A public consultation will then take place from November to January.
Annex 1
Clinic survey

Background

In April 2010, the HFEA sent out an online, anonymous, survey to all licensed centres in the UK; 31 responses were received, 29 of these centres perform treatment using donor gametes or embryos (44% response rate from donor treatment centres).

The survey explored the experience and attitudes of centres around:

- Intra family donation
- Restricted donation
- Donor family limit
- The release of donor codes
- Donor motivations and barriers to donation
- Cross border reproductive care

The survey results surrounding donation and cross border reproductive care have been summarised below.

Type of respondents

The majority of responses received were from unit managers (12 responses) and the centres’ Person Responsible (10 responses).

A further breakdown of the responses is provided below:
Intra family donation

*Frequency of requests*

Centres were asked how frequently they receive requests for treatment using gametes donated by a recipient’s family member. The majority of centres state that they receive a request for intra family donation once a month (nine responses) or once every three months (six centres). Only one centre has never received a request for intra family donation.

A further breakdown of the responses is provided below:
Types of intra family donation

Centres were asked to document the types of intra family donation they have witnessed. The most common type of intra family donation is sister to sister donation; 23 out of 28 centres state this type of intra family donation as the most frequent.

The second and third most frequent type of intra family donation is brother to brother (13 responses) and father to son (8 responses). Less frequent types of intra family donation include:

- Cousin to cousin - 7 responses
- Daughter to mother - 3 responses
- Niece to Aunt - 3 responses
- Mother to daughter – 2 responses
- Step brother to step sister in law – 1 response
- Sister in law to sister in law – 2 responses

Frequency of treatment

Centres were asked how frequently they perform treatment using gametes donated by a recipient’s family member. Of those that responded, 11 (39.3%) perform treatment involving intra family donation once every three months and 5 centres (17.9%) perform this type of treatment once every six months. Two centres (7.1%) have never performed intra family donation.
A further breakdown of the responses is provided below:

![Bar chart showing the frequency of donation requests between family members]

**Declined requests**

Centres were asked whether they had ever declined a request for donation between family members and, if so, the reasons why. Of those that responded, 21 (75%) state they have declined a request for donation between family members.

A further breakdown of the responses is provided below:
In the additional comments provided, centres documented reasons for turning down a donor including:

- Age of the donor (3 responses)
- Medical reasons (4 responses)
- Ethical/social reasons including (majority of responses):
  - Undue pressure on the donor
  - Potential egg donor hadn’t had own children
  - Suspicions surrounding the motivations of donors
  - Lack of understanding of the full implications of treatment
  - Ethical objection to intergenerational donation

**Motivations surrounding intra family donation**

Centres were asked what the reported motivations of people seeking treatment with a family member’s eggs or sperm are. Centres reported a mixture of motivations for intra family donation (each centre was able to select more than one motivation).

The following is a breakdown of what centres felt the main motivations to be:
Of the centres which specified motivations outside of the options provided, one centre felt that some intra family donations may be opportunistic i.e., the donor may have approached the recipient offering to donate.

Another centre stated that NHS commissioning in their area does not allow egg sharing as a source of donor eggs for NHS funded treatment (therefore, presumably, increasing the number of patients which consider use of eggs donated by a family member).

A centre which selected all of the presented options for reported motivations stated that the reasons for intra family donation are usually multifactorial but the most common motivation is lack of unknown donors. However, one centre stated that motivations for intra family donation are not always known.

The one centre which has never had a request for donation between family members obviously did not respond to this question.

**Additional assessments**

Centres were asked if there are any additional assessments or considerations they take, in the case of known family donation, which would not be an issue with unknown donation or non-family known donation. Of those that responded, 16 (57%) do carry out additional assessments or considerations, 12 (43%) do not.
A breakdown of the responses is provided below:

In the additional comments provided, the majority of centres require that the recipient and donor (and their partners) undergo implications counselling. Some centres require the donor and recipient to be counselled separately, some require joint counselling and some require both.

One centre stated that extra consideration needs to be given to the welfare of the child assessment, within the context of each different intra family donation.

The documented reasons for these extra measures included:
- to ensure pressure of coercion and occult financial inducement is excluded
- to work out how the donor and recipient feel with respect to continuing involvement in any potential child’s life
- to ensure all parties understand the implications of being related
- to ensure social acceptance within the family
- the need to take into account the family dynamics eg, the effect on the donors own children
general unease around intergenerational donation.

**Restricted donation**

*Proportion of donors who place restrictions*

Centres were asked what proportion of donors place restrictions on the characteristics of recipients who can use their gametes/embryos in treatment. Of those that responded, 17 (68%) state that no donors, or a very small proportion of donors, place restrictions on the characteristics of recipients who can use their gametes/embryos in treatment. Only one centre documented that the majority of donors place these types of restrictions on their donation.

A further breakdown of the responses is provided below:

![Pie chart showing distribution of restrictions](chart.png)

**Type of restrictions**

Centres were asked what, commonly, are these restrictions. The most common restrictions appear to be that gametes or embryos cannot be used in the treatment of same sex couples (9 responses), people of certain sexuality (7 responses), single women (4 responses), or older women (3 responses).

Some centres also reported having experienced incidences of restrictions relating to the following factors: age of recipients, religion, marital status, geography, physical characteristics and education.

**Should donors be permitted to set restrictions?**
Centres were asked if, in their opinion, donors should be permitted to place restrictions on the use of their donated gametes or embryos. Of those that responded, 18 (72%) felt that donors should be permitted to place restrictions on the use of their donor gametes or embryos. Seven centres (28%) state that donors should not be permitted to place restrictions on the use of their donated gametes or embryos.

A further breakdown of the responses is provided below:

In the additional comments provided, centres documented reasons permitting donors to place conditions on their donation, including:

- The donor has a ‘right’ to choose and feel comfortable with who receives their donation (4 responses)
- Anonymity legislation has resulted in contact between donor and donor conceived (3 responses)
- Donor supply may decrease (3 responses)
- Only in terms of restricting the number of families (1 response)

Centres that do not agree with donors placing restrictions on their donation provided the following reasons:

- Donation should be a gift that is not prescriptive (2 responses)
- The centre should decide (1 response)

Are recipients’ informed of restrictions?
Centres were asked if potential recipients are informed that their choice of donor is limited, or that no donor is available, because they fall outside the restrictions set by the donor. Of those that responded, 15 (65.2%) state that potential recipients are not informed that their choice of donor is limited.

A further breakdown of the responses is provided below:

In the additional comments provided, most centres have not experienced a problem with donor imposed restrictions and informing recipients of these conditions (six responses) as either the clinic does not accept donors who place restrictions or that they have enough donors to provide choice for most of the recipients.

One centre stated that a couple went to another clinic because of donor imposed restrictions and another centre state that recipients were ‘disappointed’ when informed of the restrictions.

**Would waiting times be increase?**

Centres were asked if the waiting time for treatment with donor gametes/embryos would be reduced if donors were not permitted to place restrictions on the use of their donated gametes or embryos.

The majority of centres (66.7%) state that waiting time for treatment with donor gametes/embryos would not be increased if donors were not permitted to place restrictions on the use of their donated gametes or embryos. A minority of centres state that waiting times would be increased (16.7%) or were unsure what the effect would be on donor waiting lists.

A further breakdown of the responses is provided below:
Declining donors

Centres were asked if they have ever declined to recruit/use a donor who wishes to place restrictions on their donation. The vast majority of centres (20 responses) have not declined to recruit/use a donor who wished to place restrictions of their donation.

A further breakdown of the responses is provided below:
Donor Family Limit

Reasons for restricting donation to fewer than 10 families

Centres were asked the reasons (if any) donors give for restricting the use of their gametes/embryos to fewer than 10 families.

The reasons given included:

- Considering future contact with children born from their donation
- Egg donors prefer to only donate to one family
- Religious/ethical reasons
- Medical reasons
- Restricted to known donor
- Number of half siblings for children of donor
- Some donors do not restrict the use of their gametes

Declining donors

Centres were asked if they had ever declined a donor because they were unwilling to donate their gametes for the use of ten families. The majority of centres (19 responses) have not declined to recruit a donor for that reason. Only one centre had declined to recruit/use a donor because they wished to restrict the number of times their gametes were used.

A further breakdown of responses is provided below:
In the additional comments provided, centres do not decline donors on the basis of limiting the use of their donation for the following reasons:

- Donors do not place a limit of the number of families, except for known donors (two responses)
- Donors are recruited on the assumption that they will donate to ten families due to the financial cost for the centre (one response)
- Although donors restricting the use of their donation is not cost effective for the centre, the donor is not declined because of the general shortage (two responses)

**Donating to more than ten families?**

Centres were asked that given that, in the majority of cases, donor sperm is used for 10 families, would donors extend the use of their gametes/embryos to more than 10 families. The majority of centres (17 responses) considered that, in their opinion, donors would extend the use of their gametes/embryos beyond 10 families.

A further breakdown of responses is provided below:
The release of donor codes

Proportion of parents of donor conceived children which request donor codes

Centres were asked to provide an approximation of the number of parents of donor conceived children which request donor codes. Of those who responded the majority (81.8%) state that none or a very small proportion of parents of conceived children which request donor codes. Two centres (9.1%) state that the majority of parents ask for this information.

A further breakdown of responses is provided below:
Proportion of donors which request their donor code

Centres were asked to provide an approximation of the number of donors which request their donor code. Similar to the proportion of parents of donor conceived children who request donor codes, the majority of centres (76.2%) state that none or a very small proportion of donors ask for their donor code.

A further breakdown of responses is provided below.
Should donor codes be released upon request?

Centres were asked whether, in their opinion, donor codes should be released upon request. Of those that responded, 7 (35%) do not agree donor codes should be released upon request and seven (35%) do not know whether donor codes should be released.

A further breakdown of responses is provided below.

Centres provided a mixed response to whether donor codes should be released upon request; seven centres (35%) were not in favour of releasing donor codes; six centres (30%) were in favour of releasing this information; and seven centres (35%) not knowing whether donor codes should be released.

The documented reasons given for not releasing donor codes included the risk of donor identification and breaching donor confidentiality. Centres in favour of releasing donor codes provided reasons including a desire for greater openness and access to information, beneficial in particular for recipients rather than for donors.

Donor motivations and barriers to donation

Donor motivations

Centres were asked, from their experience, what was the biggest motivation for people to donate. Of those that responded, 50% of centres state that helping a stranger to have a family was the biggest motivation for people to donate. Centres also state that helping a friend or family member to have a family (six responses) and discounted fertility treatment (three responses) are motivating factors for people to donate. No centres state that financial compensation would be the biggest
motivational factor for donation. A further breakdown of the responses is provided below:

In the additional comments provided, centres state that there is a mixture of motivations for people to donate; however wanting to help a stranger have a family i.e. for altruistic reasons is the biggest donor motivation.

**Barriers to donation**

Centres were asked, from their experience of queries from potential donors (who have not gone on to donate) what is the main barrier to donation. According to centres the main barrier to donation is the hassle/disruption of donating (seven responses) and the lack of anonymity with the potential to be contacted by the child when they reach 18 (seven responses). A further breakdown of the responses is provided below:
In the additional comments provided, centres state that sperm donors are often unaware of the commitment involved and the number of samples needed and consider the financial compensation to be inadequate. Two centres state that lack of anonymity is a barrier to donation.

**Cross border reproductive care**

*Increase in people seeking treatment abroad*

It was put to centres that there has been a perceived recent increase in UK patients seeking fertility treatment abroad; centres were asked if this was also their experience. Of those that responded, 22 centres (100%) state that this was their experience.

*Motivations of people seeking treatment abroad*

Centres were asked about their perceptions of why people seek treatment abroad. Of those that responded, 22 centres (100%) state that easier access to donor gametes and embryos is the main motivation for people seeking treatment abroad.

A further breakdown of the responses is provided below (centres could chose more than one category).
In the additional comments provided, four out of the seven centres identified shorter, or no, waiting times as the primary reason for going abroad. One centre stated that, in the case of egg donation, it may be the only option for patients. Two centres stated that people travelled abroad to access anonymous donors. One centre stated that people go abroad due to higher success rates for egg donation, stating that centres abroad have amassed more experience than centres in the UK, due to a larger number of donors.

**Level of support provided**

Centres were asked about the level of support they provide to patients considering treatment abroad. Of those that responded 11 centres (50%) provide no support to patients considering treatment abroad. Seven centres (31.8%), however, state that they participate in joint care arrangements with a clinic abroad.

A further breakdown of the responses is provided below (centres could chose more than one category).
In the additional comments provided, several centres expressed concern regarding risks to patient safety through making independent arrangements to travel abroad, with no support from a UK centre.

“If they are going to go abroad then we’d sooner it be with a clinic that gives safe treatment, limiting the number of embryos replaced. The patients also receive much needed support in a clinic setting once home”

“We believe in providing a high level of support for patients travelling to vetted centres only. We think patients travelling abroad without support are very vulnerable and often do not know how to assess appropriate care and ensure high standards for gamete [donation] are met.”

One centre stated that they get involved in the technical side of the treatment process such as taking blood and providing scans, but do not get involved with treatment arrangements. Two centres stated that they provide ‘informal support’ to patients seeking treatment abroad. Four centres stated in their additional comments that they provide no assistance to people wishing to seek treatment abroad, one stated that they do not recommend centres abroad because they are outside UK regulation; one NHS centre stated that it did not have the staffing capacity to provide such support.