

HFEA PRACTICE GUIDANCE NOTE

LIMITATIONS ON THE USE OF GAMETES (OR EMBRYOS CREATED USING GAMETES) FROM AN INDIVIDUAL DONOR

It is intended that this note will be incorporated into the 7th edition of the *Code of Practice*.

A failure on the part of any person to observe any provision of the *Code* shall not itself render the person liable to any proceedings, but—

- (a) a licence committee shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be “proper” or “suitable”, take account of any relevant provision of the *Code*, and
- (b) a licence committee may, in considering, where it has the power to do so, whether or not to vary or revoke a licence, take into account any observance or failure to observe the provisions of the *Code*.

– Human Fertilisation and Embryology Act 1990, s.25 (6)

Purpose of this Guidance

To ensure that gametes (or embryos created using gametes) from an individual donor are not used to produce children for more than 10 families as a result of licensed assisted conception services.

Relevant legal and licensing provisions

This guidance is designed to assist centres:

- to comply with HFEA policy that gametes (or embryos created using gametes) from an individual donor should not be used to produce children for more than 10 families as a result of licensed assisted conception services. Notwithstanding the foregoing, gametes (or embryos created using gametes) from an individual donor may be used in any licensed assisted conception treatment for the purpose of producing a genetically-related sibling for an existing child of the family of the woman to be treated.
- to comply with the following standard licence condition:
“That the provisions of Schedule 3 to this Act [The Human Fertilisation and Embryology Act 1990] shall be complied with.” (HFE Act 1990, s.12(c))

where the number of families that may be produced using a particular donor's gametes is given as a condition of consent given under paragraph 5 of Schedule 3 to the 1990 Act ("Use of gametes for treatment of others").

Terms used in this guidance

Family – the woman to be treated and any person together with whom she is proposing to receive treatment, and any legal child of that woman or of any person with whom she is proposing to receive treatment, at the time at which treatment is to take place

Primary centre – the centre which keeps an overall record of the number of children born and embryos created using the gametes or each donor and from which authorisation must be sought for the use of gametes (or embryos created using gametes) from a particular donor. For each donor there will be one primary centre. This centre will usually be the centre at which the donor was recruited. In the case of imported gametes this may be the centre importing the gametes

Secondary centre – a centre using donated gametes or embryos, the outcome of which must be reported to a primary centre

Relevant outcome – either a live birth or the creation of embryos which are placed in storage and available for subsequent transfer

Relevant treatment situation – any of the following situations:

- having begun a treatment cycle (e.g. begun ovarian stimulation)
- having received treatment (insemination or embryo transfer) and awaiting confirmation of pregnancy
- having a confirmed ongoing pregnancy
- having embryos created using donor gametes and not yet transferred (e.g. placed in storage)
- having received treatment but being lost to follow-up

Procedure

1. All **secondary centres** using gametes (or embryos created using gametes) from a particular donor must report **relevant outcomes** to the **primary centre** for that donor.
2. When the **primary centre** becomes aware that **six** families have had a **relevant outcome** using gametes (or embryos created using gametes) from a particular donor, the **primary centre** should notify all **secondary centres** having or using gametes (or embryos created using gametes) from that donor within two working days.
3. Thereafter, unless they are used to treat a family who has an existing child using that donor, **secondary centres** should only use the gametes (or embryos created using gametes) from that donor subject to specific

authorisation from the **primary centre**. (Treatment cycles already in progress when the notification is given may continue.)

4. When using gametes (or embryos created using gametes) from a particular donor subject to specific authorisation from a **primary centre**, a **secondary centre** should report to the **primary centre** each time a woman enters or leaves a **relevant treatment situation**.
5. A **primary centre** should ensure, when giving specific authorisation to a **secondary centre** for the use of gametes (or embryos created using gametes) from a particular donor, that no more than 10 women in total have *either* had a **relevant outcome** *or* are in a **relevant treatment situation** at any one time as a result of treatment using gametes (or embryos created using gametes) from that donor.

Responsibilities of primary centres

It should be the responsibility of the primary centre for each donor:

- to determine whether the donor has been registered previously with the HFEA and to ensure that, before their gametes (or embryos created using their gametes) are released or supplied for use in treatment, each donor is registered with the HFEA in accordance with the relevant Directions;¹
- to ensure that the HFEA and secondary centres are supplied with appropriate information in accordance with relevant Directions² and, in addition, that secondary centres:
 - are provided with a copy of the donor's consent form
 - are informed of the number of other centres having or using gametes (or embryos created using gametes) from that donor, and
 - are informed of the number of families that are in a relevant treatment situation;
- to ensure that there is an appropriate, identified contact at the primary centre and an adequate means of communication for the management of the use of the gametes (or embryos created using gametes) from each donor and that secondary centres are aware of these arrangements;
- when six or more families have had offspring as a result of treatment using gametes, or embryos produced using gametes, from an individual donor, to authorise the use of a donor's gametes (or embryos created using a donor's gametes) only if a live birth outcome could not result in exceeding the limit of 10 families (or lower limit as specified by the donor). Primary centres should take into account the number of families in a relevant

¹ Currently General Directions D.2004/3 and, where gametes have been imported from abroad, in accordance with the conditions of the Special Directions authorising their import.

² Currently General Directions D.1999/1 and D.2001/1

treatment situation when considering whether to authorise a use of a donor's gametes (or embryos created using a donor's gametes);

- to respond to requests from secondary centres to use the gametes (or embryos created using gametes) of a donor in a timely manner and to approve the subsequent use of the gametes (or embryos created using the gametes) in a fair and reasonable manner.³

Responsibilities of secondary centres

It should be the responsibility of a secondary centre

- to ensure that there is an appropriate, identified contact at the secondary centre for the management of the use of gametes (or embryos created using gametes) from donors and that the primary centre for each donor is aware of this arrangement;
- to inform prospective recipients of gametes (or embryos created using gametes) from donors of the number of families that may have children as a result of treatment using the gametes (or embryos created using the gametes) of that donor and of the possible impact on their treatment of arrangements for ensuring that the limits are not exceeded;
- to advise the primary centre when, as a result of treatment using gametes (or embryos created using gametes) from a donor, a patient has a relevant outcome (*i.e.* live birth or embryos placed in storage for subsequent transfer);
- when instructed by the primary centre that six relevant outcomes have occurred as a result of treatment using gametes (or embryos created using gametes) from a particular donor:
 - to inform the primary centre of the number of patients at that centre currently in relevant treatment situations;
 - to use **only** the gametes (or embryos created using gametes) from that donor in subsequent treatment (not including transfer of embryos already in storage) subject to the specific authorisation of the primary centre;
 - to inform the primary centre, within two working days of coming into possession of the relevant information, when, as a result of treatment using gametes (or embryos created using gametes) from that donor, a patient enters or leaves a relevant treatment situation;
- to advise the primary centre for each donor when gametes (or embryos created using gametes) from that donor are supplied to another licensed

³ A primary centre might, for example, authorise a secondary centre to use a given donor's gametes on a named-patient basis until that patient has completed or withdrawn from treatment, or for a certain quota of patients to be treated (*i.e.* being in a relevant treatment situation) at each centre at any one time.

centre and to inform that centre of the arrangements for managing the use of the donor's gametes (or embryos created using gametes) in accordance with this guidance.

EXPLANATORY AND SUPPLEMENTARY INFORMATION

NB This information is not part of the guidance

The HFEA's recent SEED Review identified difficulties in ensuring that the use of donor gametes (or embryos created using gametes) remains within the current limit of 10 live birth events per donor.

It is important that all donors should have confidence that the limitations they have specified or agreed to for the use of their gametes and embryos will be observed. Identifiable donors, who could potentially be contacted by donor-conceived offspring in the future, will have additional reasons for wanting the limit to be observed. This assurance will also be important to recipients and donor-conceived people, who have no control over the number of other families with whom they might share a genetic link through donor-conception.

In future, donors will be asked to consent explicitly to the use of their gametes (or embryos created using gametes) to produce no more than a maximum of 10 families. **Centres should not produce children for more than 10 families using gametes (or embryos created using gametes) from an individual donor.** In some cases, depending on the number of donor-conceived siblings in each family, this could mean marginally more treatments using gametes (or embryos created using gametes) from a particular donor than under the previous limit of 10 live birth events. **In all cases donors are free to restrict the use of their gametes to fewer than ten families or place other conditions on their consent.** If this is the case, clinics should always ensure that the conditions are complied with; failure to comply with the conditions of a donor's consent is a breach of licence.

The guidance has been developed in consultation with patients, clinics and others, to ensure that the limits are not exceeded and that the donor's consent is not breached. It is also designed to protect the interests of patients so that embryos in storage created using donated gametes need not be discarded when the prescribed limit is reached as a result of another patient's treatment.

When the donor has specified a lower limit

This guidance should be adapted if the donor has specified a limit of fewer than 10 families by replacing the number of six live births, which triggers the

introduction of enhanced controls by the primary centre, with $n-4$ (where n is the maximum number specified by the donor).

Implementation

Centres to whom this guidance applies are expected to implement the guidance from April 1, 2006.

Inspection

Where appropriate, HFEA Inspectors will review compliance with this guidance on the part of licensed centres from April 1, 2006. Routine register reports will be compiled prior to the inspection of centres which recruit donors or provide treatment using donated gametes or embryos created using gametes. The information from these reports will allow inspectors to focus their attention on particular aspects of practice.

Evaluation

It is proposed that one year after implementation of the new guidance a report will be compiled from information contained on the HFEA's register to compare instances where the HFEA guidance has been exceeded prior to and subsequent to the introduction of new guidance. Feedback from clinics will be sought and an assessment will be made of whether any revision to the guidance is desirable.