1. Introduction

1.1 Origins and functions of the HFEA

Medical intervention or research which aims to alleviate infertility or reduce the risk of inherited abnormality intrudes upon the most sensitive parts of our existence and our most private relationships. The Human Fertilisation and Embryology Authority (HFEA) was established by an Act of Parliament in response to deep public concern about the implications which new techniques for assisted reproduction might have for the perception and valuing of human life and family relationships.

The Human Fertilisation and Embryology Act 1990 (HFE Act) (as amended by the Human Fertilisation and Embryology Act (Quality and Safety) Regulations 2007) covers all uses of sperm, eggs and embryos for human application and all research involving the use of live human embryos. It imposes obligations upon centres to maintain appropriate standards of quality and safety, to give and record information, provide counselling and take account of the welfare of the children born as a result of certain fertility treatments.

The Authority’s principal task is to regulate those activities covered by the HFE Act. It does this by means of a system of licensing, audit and inspection. Section 25 of the HFE Act requires the HFEA to maintain a Code of Practice giving guidance about the proper conduct of licensed activities and the proper discharge of the functions of licensees. The standards and guidance contained in this document are central to the HFEA's regulatory function.

1.2 Principles underlying the Code of Practice

The Act recognises that, while those seeking assisted reproductive treatment deserve, and can expect, proper consideration of their medical and social needs, licensed treatments may result in children who would not otherwise have been born and whose interests must be taken into account. The object of the HFEA Code of Practice is therefore wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions.

In framing the Code of Practice, the HFEA has been guided both by the requirements of the HFE Act and by:

- the respect which is due to human life, appropriate to each stage of development;
- the right of people seeking assisted reproductive treatment to fair and reasonable consideration of their request in the context of current legal, clinical and ethical guidelines laid down for the type of treatment requested;
- the duty of the HFEA and licensees to deal with others without unfair discrimination, whether direct or indirect, in particular on grounds of gender, marital status, race, religion, age, sexual orientation or disability;
1. Introduction

- a concern for the welfare of any child who may be born as a result of treatment services (including the need of that child for a father), and of any other child who may be affected by the birth, which cannot always be adequately protected by concern for the interests of the adults involved; and
- a recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.

The HFEA recognises that these considerations may sometimes conflict and has sought to reconcile them in a way which is both practicable and in accordance with the spirit and intentions of the HFE Act (as amended). The HFEA’s aim is to support the best clinical and scientific practice, while guarding against the undoubted risk of exploitation of people at a time when they may be particularly vulnerable.

1.3 Compliance and enforcement

The Code of Practice is regularly reviewed and amended in light of experience and to keep pace with both the latest developments in legislation, clinical practice and evolving public concerns. In response, in particular, to new European legislation covering the handling, testing and storage of gametes and embryos in treatment, this seventh edition is arranged in two main divisions, Standards and Guidance:

- Division I (Standards) contains a set of agreed, common specifications for relevant aspects of an assisted conception service or research project involving the use of human embryos. Conformity to standards will be mandatory insofar as they express a legal requirement or a condition of licence. Evidence of conformity with these standards will be sought during an HFEA inspection and will be considered by HFEA licence committees in considering whether to grant, renew, vary or revoke a licence.
- Division II (Guidance) gives further information concerning the manner in which licensable activities are expected to be carried out and the functions and responsibilities of licensees discharged. The guidance is intended to assist licensees to meet the criteria set out in legislation and specified in the HFEA Standards, and thereby to ensure good practice in the provision of treatment services or the conduct of research. Compliance with the guidance may, and in certain circumstances must, be taken into account in determining whether a licence should be varied or revoked.

The standards have been developed in collaboration with UK bodies representing the professions involved in providing assisted conception services. Both the standards and guidance have been subject to extensive public consultation.

In addition to the standards and supporting guidance, this new edition of the Code also contains references to the underlying legislation and licence conditions by which requirements are enforced, as well as extensive cross references between the two divisions.
G.2. Use of unlicensed services and facilities

G.2.1 General

G.2.1.1 Where facilities or services provided by a third party are used in the course of a treatment process, the Person Responsible should be satisfied that the procedures of the provider are capable of integrating with the centre’s own quality system. In particular, a third party provider’s procedures should:

(a) allow for audit of the entire service and for full traceability of samples; and

(b) include an emphasis on minimising cross contamination (where relevant); and

(c) follow relevant professional guidelines; and

(d) ensure that adverse incidents are reported and any gametes and embryos affected are capable of being effectively recalled.

Related Information
HFEA Third party guidance note

G.2.1.2 A third party agreement should be made in accordance with any licence conditions imposed by the Authority. Specifically, the documentation for third party agreements should include:

(a) the full name and address, and other relevant contact details, of the third party; and

(b) a full and accurate description of the nature of the service to be provided; and

(c) the details of the person who is responsible for managing the arrangement between the centre and the third party; and

(d) information about how often the agreement will be reviewed and by whom;

(e) a summary of the responsibilities of the third party and detailed procedures which specify the activities to be carried out and by whom they are to be carried out; and

(f) specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety; and

(g) the procedure for communicating any test /diagnostic results to the commissioning centre, including procedures for sign off and confirmation that the result applies to the correct sample.
G.2. Use of unlicensed services and facilities

G.2.2 Transport and satellite arrangements

G.2.2.1 Where any part of treatment takes place in a satellite or transport centre, the licensed centre providing the licensable treatment must ensure that the treatment process complies with the requirements of the HFE Act, the HFEA Code of Practice and Directions made by the HFEA. Particular attention should be given to requirements covering information, counselling, the welfare of the child and confidentiality. The licensed centre should put in place effective procedures to ensure that that relevant information about these requirements, and any changes to these requirements, is communicated to satellite or transport centres in a clear and timely manner. The requirements should form the basis of a third party agreement.

G.2.2.2 All centres with satellite or transport arrangements should also hold third party agreements.

G.2.3 Patients producing sperm samples at home

G.2.3.1 Centres should normally only store or use sperm which has been obtained directly from the provider, from another licensed clinic, from a centre with which the licensed centre has a transport arrangement, or imported pursuant to Directions from the HFEA. In exceptional circumstances the centre may use sperm produced by a man at home. In these circumstances, the centre should:

(a) take all reasonable steps to satisfy itself that the sperm has been produced by that man; and

(b) take all reasonable steps to satisfy itself that the sperm has been produced not more than two hours previously; and

(c) take all reasonable steps to satisfy itself that the sperm has not been subject to subsequent interference; and

(d) formally record these matters in the patient records.
G.8.2.5 If it is possible that the question of treatment with donated gametes or embryos derived from them may arise, the centre should raise the matter with the person(s) seeking treatment before the beginning of their treatment cycle.

G.8.3 Management of iatrogenic risk

G.8.3.1 The centre should not use gametes or embryos in treatment where those gametes or embryos have been exposed to a material risk of contamination or damage which might cause harm to recipients or to resulting children. If in any doubt about these risks, the centre should seek expert advice.

G.8.4 Use of embryos created using intracytoplasmic sperm injection (ICSI)

G.8.4.1 The centre should not transfer to a woman embryos created by ICSI along with embryos created by any other method of insemination unless there are exceptional reasons for doing so and then only in accordance with the conditions of the centre’s licence. Where a mixed transfer takes place the centre should explain the exceptional circumstances in the patient notes and record it in accordance with the relevant Directions.

G.8.5 Management of risks arising from multiple embryo transfers

G.8.5.1 Where a woman is to receive treatment using her own eggs, or embryos created using her own eggs, whether fresh or previously cryopreserved:

(a) where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used;

(b) where the woman is aged 40 or over at the time of transfer the centre should not transfer more than three eggs or three embryos in any treatment cycle, regardless of the procedure used.
G.8. Use of gametes and embryos in treatment

G.8.5.2 Where a woman is to receive treatment using donated eggs or embryos, or using embryos created with donated eggs, the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the woman's age at the time of transfer and regardless of the procedure used.

G.8.5.3 Where a woman is to receive treatment using her eggs or embryos that have been screened for aneuploidy, the centre should not transfer more than two embryos in any treatment cycle, regardless of the woman's age at the time of transfer.

G.8.5.4 Some patients have a higher risk of a multiple pregnancy. These risks can be reduced with greater use of single embryo transfer (SET) in suitable patients. To this end, all licensed centres should have an effective documented strategy to minimise multiple births (the 'strategy').

The purpose of this strategy should be to reduce the annual multiple birth rate resulting from treatments undertaken by the centre. In particular, the strategy should ensure that the percentage of all live births, following treatment at that centre in any one calendar year, does not exceed the maximum rate specified by the Authority and set out in relevant directions.

The strategy should set out the circumstances in which the Person Responsible would consider it suitable practice to recommend SET to a patient. In setting out such circumstances, the centre should give proper consideration to relevant professional guidance.

G.8.5.5 If more than one embryo is transferred to a patient, and that patient fulfilled the SET criteria outlined in the centre's strategy, the centre should record this fact in the patient's records, with:
• an explanation as to why that patient did not have SET
• evidence that the patient was informed of the risks of a multiple pregnancy before the procedure.

The centre should regularly carry out documented audits to assess its progress in reducing its multiple birth rate and to help evaluate the effectiveness of its strategy. To assist with this process, centres should keep a summary log of all cases where more than one embryo was transferred to any patient who met the SET criteria outlined in the centre's strategy.
G.8. Use of gametes and embryos in treatment

**G.8.6 Ensuring the limitations on the use of gametes from an individual donor are not exceeded**

**G.8.6.1** All centres using gametes (or embryos created using gametes) from a particular donor that were not obtained directly from the donor by that centre should notify the primary centre for that donor each time a new patient has either:

- a live birth as a result of treatment using that donor's gametes; or
- embryos created using that donor's gametes which are placed in storage and available for subsequent transfer.

**G.8.6.2** When a primary centre for a particular donor becomes aware that six families have had either:

- a live birth as a result of treatment using that donor's gametes; or
- embryos created using that donor's gametes which are placed in storage and available for subsequent transfer;

the primary centre should notify all other centres having or using gametes (or embryos created using gametes) from that donor within two working days. 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 in which recipients have already begun or undertaken any form of medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given should be allowed to continue.

**G.8.6.3** When using gametes (or embryos created using gametes) from a particular donor subject to specific authorisation from a primary centre, a secondary centre should notify the primary centre each time a woman enters or leaves a relevant treatment situation. Relevant treatment situations are:

**Related Information**

British Fertility Society and Association of Clinical Embryologists - Elective Single Embryo Transfer: Guidelines for Practice’ (2008) CH (08) 03 Implementation of the multiple births, single embryo transfer policy

Direction D.2008/5: Multiple births minimisation strategy
G.8. Use of gametes and embryos in treatment

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

G.8.6.4 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 at any one time:

(a) have had a live birth as a result of treatment using that donor's gametes; or
(b) have embryos created using that donor's gametes which are placed in storage and available for subsequent transfer; or
(c) are in an ongoing relevant treatment situation as a result of treatment using gametes (or embryos created using gametes) from that donor.

G.8.7 Sex selection for social reasons

G.8.7.1 The centre should not, for social reasons:

(a) select embryos of a particular sex, or
(b) separate sperm samples, or use sperm samples which have been separated, for the purpose of sex selection.

G.8.7.2 Due to concerns about the reliability of the technique, sperm that has been subject to gradient methods of sperm sorting for sex selection should not be used for medical reasons.

G.8.8 Mixing of gametes and embryos

G.8.8.1 It is expected that women will not be treated with gametes, or with embryos derived from gametes, of more than one man or woman during any treatment cycle.
A. Appendix A - Standard licence conditions

A.5.4 The Centre shall ensure that the following core requirements are included in any Third Party agreement, namely:

(a) full address and named contact details of the Third Party, and nature of the service to be provided,
(b) identification of person(s) responsible for managing arrangement between the Centre and the Third Party,
(c) provision setting out how often the agreement will be reviewed and by whom,
(d) summary of the responsibilities of the Third Party and detailed procedures with regard to each party’s respective responsibilities,
(e) any specific criteria that the service provided by the Third Party must meet, particularly in relation to quality and safety,
(f) description of how any test/diagnostic results are relayed to the commissioning Centre, including sign off and confirmation that the result applies to the correct sample.

A.5.5 The Centre shall keep a complete list of agreements referred to in paragraph A.3.1 that they have established with Third Parties and such agreements shall specify the responsibilities of the Third Parties under any agreed procedures. Copies of these agreements shall be made available to the HFEA upon request.

Related Information
Directive 2004/23/EC, Art.24(3)-(5)

A.5.6 The Centre must ensure that it is made a condition of any third party agreement referred to in paragraph A.3.3.1 above that the Third Party will meet the requirements of the relevant licence conditions and the Standards set out in the HFEA Code of Practice.

Related Information
Directive 2004/23/EC, Art.21(5)
HFE Act 1990, s.19(1)(f) (as amended)

A.5.7 The Centre shall establish, implement and comply with documented procedures to ensure that, in the event of termination of activities for whatever reason, stored gametes and embryos shall (subject to the consent of the Donor) be transferred to another licensed Centre.

Related Information
Directive 2004/23/EC, Art.21(5)
A.6 Requirements for procurement of gametes and embryos (Schedule 3A)

A.6.1 The Centre must ensure that all persons to whom the licence applies who are authorised to procure gametes or embryos, or both, have successfully completed a suitable training programme.

Related Information
Directive 2006/17/EC, Art.2(2)
HFE Act 1990, Sched.3A, para.5 (as amended)

A.6.2 The Centre must ensure that it has written agreements with all staff or clinical teams responsible for Donor selection unless they are employed by the Centre. The written agreements must specify the protocols and procedures to be followed to assure compliance with the selection criteria for Donors as referred to in the licence condition at A.7 below headed “Selection Criteria and Laboratory Tests Required from Donors of Reproductive Cells”

Related Information
Directive 2006/17/EC, Art.2(3) and (4)

A.6.3 The Centre shall establish, implement and comply with Standard Operating Procedures (SOPs) for the verification of:

(a) Donor identity,

(b) the details of Donor or donor family consent or authorisation,

(c) the assessment of the selection criteria for Donors,

(d) the assessment of the laboratory test required for donors.

Related Information
Directive 2006/17/EC, Art.2(5)

A.6.4 The Centre shall also establish, implement and comply with Standard Operating Procedures describing the procedures for procurement, packaging, labelling and transportation of gametes, embryos or tissue/cell samples to the point of arrival at the Centre or, in the case of direct distribution, to the Centre responsible for their application or, in the case of tissue/cell samples to the laboratory for testing.

Related Information
Directive 2006/17/EC, Art.2(5)

A.6.5 The Centre must ensure that procurement takes place:
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