Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

Chief Executive's introduction

Dear colleagues,

We want to hear your views on the changes we are making to theHFEA Code of Practice. The purpose of the new edition is to provide all staff at licensed clinics with a clear and up-to-date reference point about the HFEA's expectations in relation to interpreting the law that governs all our work.

We published the last edition of the code in 2009 and have been producing regular updates since then. This new edition includes some wide-ranging revisions, particularly in the areas of support for patients and leadership in relation to patient care and clinic activities. It also brings the code up to date to in light of EU Directives coming into force in Spring 2018 and anticipating the Department of Health and Social Care's intention to update the law in relation to surrogacy and applications for parental orders. The new edition also incorporates all the directions given by Chair's and Chief Executive's letters and Clinic focus articles since we last incorporated them comprehensively in 2015.

The focus on leadership that runs throughout the new edition is applicable to staff at licensed clinics in all roles and we look forward to continuing to support leadership in teams to reflect their multidisciplinary needs more widely. We are beginning with planning a new programme of engagement with persons responsible across 2018. We will be inviting all PRs to attend a new meeting for the sector for topical discussion with us, continuing professional development and networking, which we hope will become an annual event helping PRs to share their good practice with their peers and to continue their work to drive up standards across the sector as a whole.

Revising the current code has offered a welcome opportunity for us to engage with all those involved in delivering fertility treatment and other stakeholders to develop a shared understanding of what these changes will mean to clinical and research practice. Staff from licensed centres across the UK have shared examples of their good practice in raising the overall standards of care and support that all patients can expect, for which we thank them.

Given the new EU Directives that came into force in April 2018, several months earlier than the Government had expected, some of the elements referred to in the draft code will already be in force at the time of consultation and our detailed guidance on these will have been given separately in a Chair's letter. We have included the new guidance here for information only. We will, of course, seek feedback on how effective that guidance has been in future consultations on the code once clinics have had time to work with the new requirements.

We also ask whether there are any other important areas that we could provide guidance on that are not included in this new edition, which we can then address in future.

Thank you to those people who have already given us your views and to those who took part in the workshops to inform the changes set out in this consultation. The consultation period runs for six weeks until 1 June 2018. We hope you will respond as your feedback is important.

Yours sincerely,

Peter Thompson
Chief Executive, HFEA

Human Fertilisation & Embryology Authority

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Background to the consultation on the Code of Practice 2018

We produce the Code of Practice to help clinics comply with the legal requirements set out in the Human Fertilisation and Embryology Act.

To help inform the development of this draft code, we convened a Code of Practice review working group made up of clinicians, embryologists, counsellors and nurses and other key stakeholders delivering licensed fertility services to patients. From the outset of this work in December 2017, this group have met to represent to us the views of the core professional audience for this new edition of the Code of Practice.

We have further engaged directly with relevant professional and regulatory bodies, patient groups and licensed clinic representatives on relevant areas of the draft code.

We also commissioned specific legal advice on particular issues and have discussed the relevant policy principles and issues at Authority meetings with our board members and Chair, Sally Cheshire, who also outlined some of this work at our recent annual conference.

One of the most valuable approaches to us in the development of this draft code has been the open workshops we held in early 2018. At these workshops in London, Edinburgh, Manchester and Bristol, we sat down to talk through these proposed changes with over 100 attendees gathered from all disciplines and working at all levels of clinical care and research practice. The discussions that arose were incredibly valuable to us and directly informed the revised drafting in the code presented here for consultation, changes to the relevant Directions, and our policy thinking. Thank you to all who attended those.

One of the striking outcomes of the workshops was the commonality of themes and often quite strong consensus on the proposed direction of travel that arose. While we will take account of all views, and this consultation forms an important part of doing that openly, we hope that the support we have heard thus far at the workshops for principles in the new code around patient support, leadership and information provision, including around treatment add ons, for example, reflect our ongoing efforts to build a two-way, listening regulatory relationship, engaging with the sector well in advance of and outside of the set points for formal public consultation.

We hope that the sections of the code that we are consulting on here set out the standards that we expect licensed centres to meet. We welcome your comments on whether we have expressed these standards clearly, and whether the proposed regulatory approach will allow centres to follow our guidance.

The new code will look similar to previous codes in format and we hope that licensed centres will continue to find the familiar format easy to use. For improved ease of use of the code online, we will be taking steps to help centres with searching the code via our website and Clinic Portal.

The consultation runs from 23 April to 1 June and is available to comment online at Survey Monkey.

View the full draft of the 9th edition Code of Practice

To contact us about the consultation, or any other aspect of our work, please email enquiriesteam@hfea.gov.uk.

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General questions

This survey will guide you through several areas of guidance that have been reviewed as part of this new edition. We have included excerpts of the draft code throughout to enable you to answer questions and comment. Highlighted text draws your attention to an area of the guidance that has been amended or added. Where extracts from the code are not highlighted, this is all new text.

The areas of guidance we are amending are:

- leadership
- patient support
- information provision to patients
- extension of storage
- consent
- screening
- egg sharing
- ovarian hyperstimulation syndrome
- surrogacy
- general data protection regulation.

For information:

- import and export of gametes and embryos
- single European code
- other amendments including:
    - data submission
    - QMS
    - minor consent form changes
- format and usability.

You do not have to complete every question. There is space for any other comments at the end of each section.

*** 1. Personal details**

Name

Job title

Organisation

Human Fertilisation & Embryology Authority

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Leadership

Good leadership improves patient care. It therefore follows that if we are to ensure that all fertility patients receive high quality care, we need to set a regulatory framework which encourages good leadership. The proposed changes to the code below are designed to do just that, but they will not alone bring about the general improvement in leadership in the sector that we wish to see. We will also be looking at the training and support we can provide to persons responsible (PRs) in particular.

Guidance notes 1 and 2 set out our policy requirements of the PR, the Licence Holder (LH) and staff within centres. In previous editions of the code those requirements have been fairly narrowly focussed on the relationship between the PR and the LH (see HFEA guidance note 1: 1.1 and 1.2 below), the qualifications of the PR (1.3 and 1.4 below), the awareness and understanding of the legal obligations involved (1.6(a) below), and the need to participate in the various regulatory processes in place (1.6(b) and (c)). Requirements relating to the management of staff, their professional registration, training and other matters is set out in guidance note 2.

We want to be more ambitious in respect of the expectations we place on PRs and other staff within centres because we believe that improving leadership will continue to improve patient care. We propose a number of changes to guidance note 1 to include explicit reference to leadership capability.

Being a leader can be a lonely role and we want to see evidence that the PR will have the necessary authority and autonomy to carry out the role to the best of his/her abilities. This is particularly important where the PR is not the sole owner of the clinic. We propose amending 1.4 to place a requirement on the LH to provide evidence that any proposed PR will have that authority.

In a fast-moving field like fertility treatment, it is vital that PRs have an up-to-date understanding of their policy and legal obligations. To date, we have only assessed that understanding when the PR is first appointed. We propose amending 1.5(a) to refer to the need for all PRs to complete the PREP (person responsible entry programme) assessment; work is underway on revising PREP so that it is suitable for periodic refresher training and we will consult with the sector on the appropriate frequency and scope of any such reassessment.

A well-led clinic is one where staff are involved at all levels and in future we wish to see evidence that PRs have systems in place to ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. We have introduced 1.6 (a), (b) and (c), and a new requirement in guidance note 2 at 2.3, to that effect.

A high performing clinic is one where roles and accountabilities are clear and risks are well managed, and where the PR is responsive to feedback whether positive or negative. We propose making explicit those obligations by introducing a new section to guidance note at 1.7 below.

The licence holder and the person responsible

1.1 The licence holder and the person responsible should be separate individuals. Clinics operating within a hospital or other healthcare organisation may find it advantageous for a senior hospital manager to hold the post of licence holder.

1.2 It is the responsibility of the licence holder to inform the HFEA if the person responsible is unable to perform their duties. Where the centre no longer has a person responsible, the licence holder should seek the advice of the HFEA as soon as possible on continuing to provide licensable activities. Either the person responsible or the licence holder may apply for a licence or for its variation or revocation. However, only the licence holder may apply to a licence committee to vary a licence in order to designate another individual to be the person responsible.

Qualifications for the role of the person responsible

1.3 The person responsible should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. It is also important that the person responsible possesses integrity and leadership capability.

1.4 When applying to vary a licence in order to appoint a new person responsible, the licence holder must provide evidence that the proposed individual has the managerial authority and capability necessary to perform their duties.

1.5 The HFEA expects the person responsible to take any necessary specialist advice to allow them to run the centre professionally.

Responsibilities of the person responsible

Interpretation of mandatory requirements 1B

The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos.

1.6 The role of the person responsible should include:

(a) maintaining an up-to-date awareness and understanding of legal obligations
(b) responding promptly to requests for information and documents from the HFEA
(c) co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
(d) informing the HFEA of any change to their professional registration

1.7 The person responsible should ensure that:

(a) all staff maintain an up-to-date awareness and understanding of legal obligations
(b) all staff possess the competencies necessary for their role, and have access to learning and professional development
(c) all staff are encouraged, as appropriate, to contribute to discussions and decisions about improving patient care.

1.8 The person responsible is accountable for the overall performance of the centre and to that end should ensure that:

(a) there are clear responsibilities, roles and systems of accountability to support good governance
(b) appropriate action is taken following feedback from the HFEA, staff and patients, including through the outcomes of inspections, audits, patient complaints and feedback.

Centre staff

2.3 All staff should maintain an up-to-date awareness and understanding of legal obligations, and should support the person responsible in monitoring and improving the performance of the centre.

2. Do you think these new requirements clearly set out the expectations of a person responsible?

- ◯ Yes
- ◯ No
- ◯ Unsure

3. Any comments

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Patient support

Undertaking fertility treatment can be a distressing and anxious time for patients and their partners and we want to reduce the emotional burden. We know that emotional support for patients during their treatment is very important to their overall experience at clinics. Our aim is to improve the emotional experience for patients and donors and there partners, where applicable, before, during and after treatment or donation. We want to see a cultural shift in clinics to place a greater emphasis on the emotional aspect of patient treatment.

We think it is right to set clear expectations in the Code of Practice for clinics regarding the support they provide to patients. We recognise that many clinics do an excellent job in supporting their patients, but this is not universal. We hope to raise the standard of patient care across all clinics by proposing that every clinic sets out a policy on patient care outlining how it will ensure patients, donors and their partners receive appropriate psychosocial support from all staff they encounter before, during and after treatment. We also plan to guide and help clinics to improve their patient support in the coming months, which may include organising training workshops and publishing a patient support pathway and guidelines to support clinics in implementing their patient support policy.

New addition to guidance note 3: counselling

Patient support

3.17 The centre should develop a 'patient support policy', to outline how the centre ensures that patients, donors and their partners (where applicable) receive appropriate psychosocial support from all staff they encounter before, during and after treatment. Psychosocial support is delivered by all members of staff and includes, but is not limited to, access to counselling. All patients, donors and their partners (where applicable) should be treated with sensitivity and respect, and supported through all aspects of their treatment and, in particular, if they are suffering distress at any stage.

3.18 The policy should include:

a) a definition of patient-centred care and how this will be delivered at the centre

b) a statement regarding each individual staff member's responsibility for supporting patients and managing their expectations

c) a list of written and online information to be provided and how patients will be able to access this

d) what the centre will provide in terms of

   i) support groups
   ii) forums for patients to engage with each other
   iii) signposting to external groups and forums
   iv) other events/groups/open evenings etc

e) the expectations about how all staff will communicate with patients, donors and their partners

f) an outline of customised support interventions at different stages of treatment and for different types of patients

g) the annual programme of training that will be provided to staff on different aspects of patient support, including skills training, adapted as appropriate to reflect staff members' role within the clinic

h) feedback mechanisms for collecting data on the patient/donor experience, and

i) quality indicators for systematically monitoring and evaluating the centre's provision of patient support and patient care as contained in this policy.

3.19 Clinics should also refer to the HFEA's guidelines on patient support for further guidance on best practice.

4. Is the proposed guidance clear about what should be included in the patient support policy?

- ◯ Yes
- ◯ No
- ◯ Unsure

5. Can you foresee any difficulties in implementing a patient support policy in your clinic?

- ◯ Yes
- ◯ No
- ◯ Unsure

Amendments to guidance note 23: Quality management system

Quality policy and quality objectives

23.6 The quality policy is defined as:

'the overall intentions and direction of an organisation related to quality as formally expressed by centre management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning.' (International Organization for Standardization)

23.7 Centre management should ensure the quality policy includes a commitment to:

(a) providing a service that meets its users' needs and requirements. This should include ensuring that all staff who come into contact with patients, donors and their partners (where applicable) provide the good quality supportive care before, during and after treatment, as outlined in the centre's patient support policy
(b) meeting the provisions of this Code of Practice and statutory provisions and standard licence conditions
(c) continually improving the effectiveness of the quality management system
(d) upholding good professional practice, and
(e) ensuring the health, safety and welfare of all staff and visitors to the centre.

23.8 The quality policy should be:

(a) signed and issued by the person responsible
(b) communicated, understood and available throughout the centre, and
(c) reviewed for continuing suitability.

23.9 Centre management should establish documented quality objectives. These should:

(a) include objectives needed to meet users' needs and requirements, including their need for supportive care and treatment, from clinic staff, before, during and after treatment or donation (see GN 3 paragraph 3.14)
(b) be measurable and consistent with the quality policy, and
(c) be reviewed regularly.

Quality indicators

23.16 The centre should establish quality indicators for systematically monitoring and evaluating the centre's provision of emotional support and patient care generally.

Assessing user satisfaction

23.17 The centre should assess whether or not the service has met users' needs and requirements, including the extent to which they felt supported before, during and after their treatment or donation. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.

6. Any comments

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Information provision to patients

We want to ensure that patients receive good quality, unbiased information before they give consent to treatment and/or storage. We also want to ensure that patients receive the same standard of information for emerging or unproven treatment add ons as they do for established treatments such as IVF.

During Summer 2017 we ran a patient survey to find out how patients feel about the information they receive before giving consent. We explored the findings from this survey during a clinic workshop held in November 2017.

We have redrafted guidance note 4 - Information to be provided prior to consent - with the following key changes:

- a new structure breaking down requirements into focused subheadings
- explicit requirements for information relating to treatment add ons
- requirements for centres to provide information about the effectiveness of treatments and treatment add ons
- strengthened guidance relating to OHSS
- encouragement for centres to display their success rates 'per embryo transferred'.

The guidance relating to information for transgender patients in guidance note 4 has not been amended as part of this exercise so is not included in this consultation.

Information specific to the centre

4.2 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the centre's policy on selecting patients
(b) the centre's statutory duty to take account of the welfare of any resulting or affected child
(c) the expected waiting time for treatment
(d) fertility treatments available, including any treatment add ons which may be offered and the evidence supporting their use. Any information should explain that treatment add ons refers to the technologies and treatments listed on the treatment add ons page of the HFEA website (https://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/)
(e) the availability of facilities for freezing and storing eggs, sperm and embryos
(f) where patients freeze and store eggs, sperm or embryos the centre should provide information about future use including information about consent to posthumous use
(g) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
(h) the centre's complaints procedure.

7. Do you think that guidance in 4.2 includes all the relevant information that should be provided to patients about the centre?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want patients to receive clear and unbiased information about the nature of any treatments or treatment add ons which they are offered. We also want patients to receive information about the likely effectiveness of any proposed treatments or treatment add ons so they can make an informed decision about their treatment options.

Information about the treatment

4.3 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the likely outcomes of the proposed treatment (data provided should include the national live birth rate and clinical pregnancy rate, and the centre's most recent live birth rate and clinical pregnancy rate. Centres are encouraged to provide data per embryo transferred where relevant)
(b) the nature of the proposed treatment and any treatment add ons, including evidence of effectiveness. The centre should provide information in a lay format with reference to the HFEA website
(c) the implications of treatment, including for example, the possibility of a negative outcome which could cause distress or multiple pregnancy

8. Do you think that the requirements set out above in 4.3 (b) will be effective in ensuring that patients receive sufficient unbiased, evidence-based information about the nature and effectiveness of any treatment or treatment add on which they may be offered?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want to ensure that patients are informed of what to do and who to contact if they experience symptoms of OHSS. In the draft guidance we have focussed on the outcome rather than setting out exactly how clinics should go about informing their patients.

Information about the risks of treatment

4.4 Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

(a) the potential immediate and longer-term risks of the treatment and any treatment add ons used, including the risk to the patient and of any children conceived having developmental and birth defects
(b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment
(c) the possible side effects and risks to the woman being treated and any resulting child
(d) the possibility of developing ovarian hyperstimulation syndrome (OHSS). Any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS
(e) the nature and potential risks (immediate and longer-term) of using emerging or unproven treatments, including reference to the clinic's experience and wider evidence base
(f) the potential risk of emotional distress associated with negative outcomes both during and after treatment.

9. Do you think the requirements set out in 4.4 (d) will be effective in ensuring that patients are informed of what to do and who they should contact if experiencing symptoms of OHSS?

- ◯ Yes
- ◯ No
- ◯ Unsure

Any other comments

In 2016 the Authority decided to display HFEA birth rate statistics per embryo transferred. In this update to the Code of Practice we encourage centres to display their success rates in the same way.

Information about success rates

4.5 In line with the Advertising Standards Authority's Code, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.

(a) The information should include the most recent data available from the past three years.
(b) Centres are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information should not highlight a high success rate that is not statistically significant where it applies only to a small, selected group of patients.
(c) The data should show split by maternal age and, if appropriate, by treatment type.
(d) The information should provide raw numbers rather than just percentages.
(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
(f) The centre's published success-rate data should refer to the HFEA as the source of national information through its Choose a Fertility Clinic function.
(g) The information must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on choosing a clinic: https://www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/
(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

10. Do you think that the guidance provided in section 4.5 is sufficiently clear that clinics can understand what is expected of them in terms of success rates displayed on their website or any other material they produce?

- ◯ Yes
- ◯ No
- ◯ Unsure

11. Any comments

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Extension of storage of gametes and embryos

The guidance around storage of gametes and embryos is being amended to provide more clarity in respect of:

- when written consent is needed from a gamete provider
- the requirement for a medical opinion for extension of storage
- when to obtain patient's consent for extension of storage, and
- what is not considered premature infertility.

The changes are highlighted below in yellow.

Interpretation of mandatory requirements 17C

The law requires the centre to obtain written informed consent from a person before it stores their gametes or embryos created with their gametes.

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

In certain limited circumstances involving premature infertility, gametes and embryos can be stored beyond the statutory maximum storage period.

Gametes first placed in storage before 1 August 1991

Any gametes currently in storage which were originally placed into storage prior to 1 August 1991 i.e. prior to statutory regulation, can only continue to be stored if the original 10-year storage period was properly extended under the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (the 1991 Regulations) and has not expired. Any gametes in storage as at 31 July 2001 (10 years after the storage period was deemed to commence) and which were not eligible for extension of storage under the 1991 Regulations should have been allowed to perish. The Schedule to the 1991 Regulations sets out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period must be calculated from 1 August 1991.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage between 1 August 1991 and 1 October 2009

Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period ~~without the written consent of the gamete provider~~ if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied. The Schedule to these Regulations set out how long gametes can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the gamete provider's age on the date the gametes were provided. The storage period begins on the date that the gametes were stored. This has the effect that storage can continue beyond the gamete provider's 55th birthday but not beyond age 56.

Embryos first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period but only if both people whose gametes were used to bring about the creation of the embryo confirm in writing that they have no objection to the extension (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 are satisfied). The Schedule to these Regulations set out how long embryos can be stored beyond the statutory maximum storage period. The appropriate period is calculated by using the age of the woman being treated on the date that the embryo was first placed in storage.

For an online tool to calculate the appropriate storage period, see CE(16)02(a).

Gametes and embryos first placed in storage after 1 October 2009

Gametes or embryos first placed in storage after 1 October 2009 may continue to be stored beyond the statutory maximum storage period, to a maximum of 55 years, but only with the written consent of the gamete provider or the people whose gametes were used to bring about the creation of the embryo (and if the other conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') are satisfied). Gametes and embryos first stored earlier than 1 October 2009 may be stored for an extended period under the 2009 Regulations but only where the gametes or embryos are either still within the statutory storage period, or are being stored subject to a lawfully extended period under the 1991 or 1996 Regulations respectively.

For guidance about steps to take when consent is not required, see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

Extension of storage

Interpretation of mandatory requirements 17D

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009 ('the 2009 Regulations') allow gametes or embryos to be stored for longer than the

10-year standard storage period, up to a maximum of 55 years, provided that the conditions set out in those Regulations have been met.

There are two criteria that must be met; the first is that the relevant person(s) have provided written consent to the gametes or embryos being stored for longer than 10 years; and the second is that on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gametes, or in the case of embryos, one of the persons whose gametes were used to create the embryos, or the person to be treated, is prematurely infertile or likely to become prematurely infertile.

To meet the statutory requirements, the written consent to storage for a period of more than 10 years must be given before expiry of the original 10-year statutory storage period or, in the case of gametes or embryos which have already been stored pursuant to an extended period under the 2009 Regulations, before expiry of that extended period.

The written opinion on premature infertility must be provided by a medical practitioner who is registered with the General Medical Council and must be provided within 10 years from the date that the gametes or embryos were first placed in storage or, in the case of gametes or embryos which are being stored pursuant to an extended period under the 2009 Regulations, within 10 years of the date of the most recent medical opinion.

The statement from the medical practitioner must be renewed for every 10-year storage period beyond the initial statutory period.

17.16 The centre should inform patients wishing to store gametes or embryos for more than 10 years of criteria set out in the 2009 Regulations and how these must be satisfied. It is important that, in the case of patients who wish to store gametes or embryos for more than 10 years, centres take steps to satisfy the requirements of the 2009 Regulations before expiry of the patient's current storage period.

17.17 To satisfy the Regulations for extended storage periods, the centre should seek a written medical opinion to certify that one of the gamete providers, the woman who is to be treated with the gametes, or the person who the gametes or embryos have been allocated to, is prematurely infertile or likely to become prematurely infertile. This medical opinion should be obtained before expiry of the current storage period and needs to come from a medical practitioner registered with the General Medical Council (GMC). A medical opinion from an overseas medical practitioner who is not registered with the GMC does not satisfy the requirements of the 2009 Regulations.

17.18 The centre should seek the written medical opinion on premature infertility whilst the gamete provider is alive. However, if the gamete provider (who has provided consent to extended storage) dies before a medical opinion is in place, the medical opinion may be sought after death based on evidence that the person would have satisfied the premature infertility criteria when they were alive. Although the medical opinion may be provided after the gamete provider's death, it must nevertheless be provided within the relevant period; that is within the 10-year statutory storage period, or in the case of gametes or embryos that are being stored pursuant to an extended period under the 2009 Regulations, within ten years of the most recent medical opinion.

17.19 Whether a person is or is likely to become prematurely infertile is a clinical judgment taking into account all relevant considerations and information known to the clinician at the time. A woman who has reached menopausal age will not however be considered prematurely infertile and similarly, a same-sex couple will not be considered prematurely infertile.

17.20 Provided the provisions of the 2009 Regulations have been met, the centre can store the gametes and embryos for a further 10 years from the date the criteria are met. The centre can extend the storage period by further 10-year periods (up to the maximum of 55 years) if it is shown at any time within each extended storage period that the criteria continue to be met.

End of storage

Interpretation of mandatory requirements 17F

No centre may keep embryos or store gametes after the expiry of the statutory storage period, or after the end of any shorter period specified by the gamete provider(s). Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.

17.23 The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details, including that their gametes or embryos may be removed from storage if they do not keep their contact details up to date.

17.24 The centre should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the centre and patient to take any steps necessary to comply with the 2009 Regulations where extension of storage is an option for the patients. The centre should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options and to access appropriate advice. Options could include the donation of the gametes or embryos for research, training or for the treatment of others. If contact with the patient is not possible, the centre should record the steps it has taken in the patient's medical records.

12. Do you think that the changes to guidance note 17 are sufficient to provide clarity about these legal obligations?

- ◯ Yes
- ◯ No
- ◯ Unsure

13. Any comments

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Consent

It is important that when a patient gives consent that the clinic can assure themselves that the consent is informed and given by the right person. We think there should be more guidance in the Code for clinics to have processes in place to ensure consent is taken properly and is witnessed.

We propose to add an additional step to guidance note 5.11 ensure consent is taken properly:

Procedure for obtaining consent

5.11 The centre should ensure that consent is:

(a) given voluntarily (without pressure to accept treatment or agree to donation)
(b) given by a person who has capacity to do so
(c) taken by a person authorised by the centre to do so, and
(d) given at the clinic (with both parties if a couple is being treated) where possible, clinics should record why a patient is not able to sign at the clinic and should have a documented process for ensuring consent forms being signed outside the clinic are signed by the correct person

14. Is this addition feasible for clinics to carry out to ensure consent is given by the correct individual?

- ◯ Yes
- ◯ No
- ◯ Unsure

Our aim is to ensure that clinics have processes in place to ensure consent is taken properly and is witnessed appropriately, and that consent is informed and given by the right person.

Clinics also need to be able to satisfy themselves of the evidence of legal relationships such as marriage or civil partnership between a couple who are seeking treatment together. Clinics need a clear understanding of such patients' legal relationships to each other to be able to discuss consent with them appropriately, given the implications for legal parenthood.

5.13 Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. The centre should establish the relationship between a patient and their partner and a record of this should be retained in the patients' notes. If a patient's identity is in doubt or if a centre has reason to question whether the person is who they claim to be, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records. Centres should have a process in place to verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment, to ensure the patient and their partner are the same people they treated initially. The clinic should establish whether the patient and their partner's personal circumstances have changed in the period since their last treatment, for example, whether the couple has divorced or separated since their previous treatment and give consideration to whether any changes in their personal circumstances impact on consent.

In paragraph 5.15 of the Code of Practice, the guidance requires that where the partner of a patient has not visited the clinic or does not return for subsequent treatment, the clinic should take reasonable steps to find out if they still consent to treatment. We propose to make an addition that says treatment should not commence until the clinic is satisfied that the partner consents to the treatment.

15. Do you think that these additions will be effective in allowing clinics to be given evidence of the legal relationships between patients seeking treatment together as a couple in a marriage or civil partnership?

- ◯ Yes
- ◯ No
- ◯ Unsure

5.15 To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment or donation. If the partner of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, centres should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid. The centre should not commence treatment until it is satisfied that the partner in fact consents to the treatment.

16. Do you think that this guidance will be effective in ensuring that the clinic can avoid carrying out potentially unlawful treatment when a partner of a patient no longer consents to treatment?

- ◯ Yes
- ◯ No
- ◯ Unsure

17. Any comments

Human Fertilisation & Embryology Authority

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Egg sharing

The guidance on egg sharing has been reviewed to address an overly informal culture in some clinics on the provision of information to patients in relation to donation treatment and the special nature of both egg donation and egg sharing.

When the Code of Practice was updated in April 2017, our guidance on egg sharing was changed to explicitly rule out 'egg giving'. However, at 12.5 the guidance does make a provision for “exceptional circumstances” where deferring treatment to the egg provider is appropriate. We asked our working group and attendees at our regional workshops whether there are enough examples of what could constitute "exceptional circumstances" for this to be useful, or whether making this provision is confusing and could be harmfully misinterpreted.

Clinic staff felt that there are no "exceptional circumstances" where the egg provider should donate all the eggs collected in the initial cycle. If deferring treatment to the egg provider is appropriate, egg freezing should be offered where possible. In the very rare event that this is not possible, the centre can contact their inspector. This is reflected in the updated guidance below.

NB: Although we are proposing removing reference in 12.5 to the situation where the number of eggs collected is lower than is needed for a benefits in kind arrangement, this is already mentioned in 12.20 – "If too few eggs are collected for use in a benefits in kind agreement, the woman should be given the option of using or storing all the eggs for her own treatment, at the agreed discount."

Benefits

12.4 Centres may offer benefits in kind, in the form of reduced-price or free licensed services (for example, fertility treatment or storage) or quicker access to those services, in return for providing eggs or sperm for fertility treatment or mitochondrial donation.

12.5 If benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient’s treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.

In the exceptional circumstance where deferring treatment to the egg provider is appropriate, ~~the egg provider may choose to donate all the eggs collected in the initial cycle and receive the benefits in a subsequent cycle. This excludes cases where the number of eggs collected is lower than is needed for a benefits in kind arrangement. In this event, and where possible,~~ egg or embryo freezing should be offered where possible.

18. Do you think that this deletion is a feasible requirement?

- ◯ Yes
- ◯ No
- ◯ Unsure

Inspection findings have suggested that we should introduce guidance on the distribution of eggs in an egg sharing arrangement. We have introduced a requirement for centres to distribute eggs evenly between the provider and the recipient(s) and to be clear about who will receive the additional egg if an odd number is collected. This updated guidance can be found in 12.6, 12.22 and 12.30.

Benefits

12.6 In an egg sharing arrangement, centres should ensure that, where the minimum number of eggs required for the arrangement are collected, eggs are distributed equally between the egg provider and the recipient(s). Where an odd number of eggs is collected, the benefits in kind agreements should clearly set out who will receive the additional egg.

Agreement between a licensed centre and a gamete provider

12.22 The agreement should include full details of the proposed arrangements for distributing the eggs or sperm between the provider and recipient(s), including:

(a) the minimum number of eggs required for a benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

Agreement between a licensed centre and a recipient

12.30 The agreement should set out the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

(a) the minimum number of eggs required for the benefits in kind arrangement
(b) the number of recipients among whom the eggs or sperm will be shared (which for eggs should be no more than two, excluding the egg provider), and
(c) who will receive the additional egg where an odd number is collected.

19. Do you think that this addition is a feasible requirement?

- ◯ Yes
- ◯ No
- ◯ Unsure

We propose that, should the gamete provider choose not to have counselling, clinics should record the reason for refusal and discuss the implications of donation with the gamete provider. In addition, an agreement between the clinic and the gamete provider, and between the clinic and recipient, should confirm that the gamete provider and the recipient have received information about the treatment and donation.

This updated guidance can be found in 12.10, 12.19(e) and 12.27(e).

Consent

12.10 Centres should ensure that where a gamete provider elects not to have counselling, the implications of donation are discussed with the gamete provider. Centres should record that the implications of donation have been discussed and why the gamete provider has elected not to have counselling. The gamete provider should be given enough time to consider the implications of donating, before giving consent.

Agreement between a licensed centre and a gamete provider

12.19 The agreement should include a statement from the egg or sperm provider confirming that they have:

(a) had an opportunity to talk with a member of staff qualified to explain the procedures involved in providing gametes as part of a benefits in kind arrangement
(b) received verbal and written information about the treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice
(d) been offered counselling
(e) received information about the implications of the treatment and donation, and
(f) been made aware of the screening that will be done before treatment begins.

Agreement between a licensed centre and a recipient

12.27 The agreement should include a statement from the recipient confirming that she has:

(a) had an opportunity to discuss with an experienced member of the centre's staff the procedures involved in receiving eggs or sperm as part of a benefits in kind arrangement
(b) received verbal and written information about her treatment
(c) received all the appropriate information listed in the relevant parts of this Code of Practice (written information should be attached to the agreement)
(d) been offered counselling
(e) received information about the implications of the treatment and using donated gametes, and
(f) been informed about the screening that the egg or sperm provider has undergone and the limitations of that screening in avoiding transmissible conditions.

20. Do you think that this proposal will be effective in ensuring prospective gamete providers and recipients in a benefits in kind arrangement receive appropriate information prior to consent?

- ○ Yes
- ○ No
- ○ Unsure

21. Any comments

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Ovarian hyperstimulation syndrome (OHSS)

Ovarian hyperstimulation syndrome (OHSS) is a potentially serious side effect which some patients develop in reaction to the drug treatment necessary for IVF.

To support improvements to the care and follow up of patients affected by OHSS, changes to the Code of Practice in guidance notes 4, 15, 27 and Directions 0011 are proposed to clarify our expectations on this issue.

These changes aim to better inform patients about OHSS, support OHSS prevention, improve accuracy of reporting around OHSS and to highlight the part that information sharing with local NHS hospitals could play in this reporting.

To improve accuracy of reporting around OHSS:

All 'severe' and 'critical' cases of OHSS must be reported to the HFEA, irrespective of whether or not the patient's case has involved a hospital admission. This will bring our reporting requirements into line with the criteria for assessing and classifying the severity of OHSS, as set out in the relevant RCOG Green top guideline. Hospital admission and the length of time spent in hospital are not part of the RCOG's classification system and are not in themselves an indicator of severity.

To do this, we propose to remove the text 'requires a hospital admission and' from 27.1 of the Code of Practice, (which defines an 'adverse incident') and also 4 a) and 4 d) of Directions 0011 which make the same specification.

We will also provide a new form to help to simplify OHSS reporting to us, for use from October 2018, when the new edition of the Code of Practice comes into force. We propose that guidance note 27.8 will mention a requirement for centres to complete this reporting form for OHSS incidents (where there is a severity grading of 'severe' or 'critical'), within 25 working days.

Definitions

27.1 An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, anomalies or deficiencies in the obtaining or recording of consent, and ovarian hyperstimulation syndrome (OHSS) which ~~requires a hospital admission and~~ has a severity grading of severe or critical.

Reporting and timescales

27.8 When reporting cases of OHSS with a severity grading of severe or critical the centre must complete the OHSS form within 25 working days.

To help support good practice in OHSS management and prevention

Where appropriate, clinics' OHSS documented procedures should cover establishing if any patients have experienced OHSS as part of the routine follow up of patients. We propose that procedures should also be in place to cover prevention of OHSS. This would be in addition to the current requirement for documented procedures around the management of OHSS (where appropriate).

To do this, we will add the requirement to specifically include 'establishing if any patients have experienced OHSS', to 15.1 (h) of the Code of Practice under 'follow up after treatment'. Furthermore, at 15.1 (i) we propose to add 'prevention' to the existing wording, that requires documented procedures for the management of OHSS.

To support awareness around management of OHSS, and in determining of the severity of OHSS using the grading of 'severe' or 'critical', we will add a link to the Code of Practice (under 'Professional Guidelines') to the relevant 2016 RCOG guidelines: 'Ovarian Hyperstimulation Syndrome, Management (Green-top Guideline No. 5)', in guidance note 27.

To support awareness around prevention of OHSS, we will add a link to the Code of Practice (under 'Professional Guidelines') to the relevant 2014 BFS paper: 'British Fertility Society Policy and Practice Committee: Prevention of Ovarian Hyperstimulation Syndrome, 2014', in guidance note 15.

Clinicians have told us that good quality information giving about OHSS might be able to play a part in encouraging patients to self-report (suspected) OHSS to clinics. Our expectations in relation to informing patients about OHSS are currently set out at guidance note 4.4.(d) of the Code of Practice.

This states that "before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about: (d) ovarian hyperstimulation syndrome (OHSS). Any information provided should include what the woman being treated should do and who to contact if experiencing symptoms of OHSS."

While we do not propose to alter this wording at this stage, we note feedback from clinics that they would welcome the sharing of good practice around appropriate information giving. In particular, more specific guidance around how they should inform patients 'what to do and who to contact', or what should be included in this information. We will carry out further work in this area, with a view to clarifying expectations in future.

To help support appropriate clinical information sharing about the care of patients with OHSS

Within the broader aim of improving patient care, we note that accurate reporting of OHSS to the HFEA may be improved via fertility clinics and their local hospitals establishing and maintaining close clinical liaison. Such a relationship could help to raise awareness among local hospital staff that patients from the local clinic may present with OHSS. Fertility clinics could also seek to establish and maintain information and data sharing relationships with these centres.

Clinics should have in place procedures for maintaining clinical liaison with local hospitals around OHSS, including seeking to put in place written information and data sharing agreements. Where implemented, we would expect that these would provide that if a treating NHS team becomes aware that a fertility clinic's patient has been admitted with OHSS, the NHS team can share appropriate information about that episode with the fertility clinic in a timely way. (We do appreciate that a patient may not always attend their own local hospital, or the hospital nearest their fertility clinic, if they need to seek help in the event of OHSS, however.)

To work towards this outcome, guidance note 15.1 (i), already requires licensed centres to have documented procedures covering the prevention and management of ovarian hyperstimulation syndrome where appropriate. We propose to add "including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS, and seeking to put in place agreements around related appropriate information and data sharing".

Documented procedures: general

15.1 The centre should, where appropriate, have documented procedures that cover:

(a) superovulation regimes
(b) egg retrieval
(c) sedation
(d) resuscitation
(e) sperm aspiration
(f) gamete and embryo transfer
(g) insemination
(h) follow-up after treatment, including management of complications and establishing if any patients have experienced OHSS, and
(i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed centre's patients for OHSS, and seeking to put in place agreements around related appropriate information and data sharing.

22. Do you think that taken together, these proposed changes will be effective in supporting improvements to the care and follow up of patients affected by OHSS?

- ◯ Yes
- ◯ No
- ◯ Unsure

23. Do you think that taken together, these proposed changes will be feasible for clinics to implement?

- ◯ Yes
- ◯ No
- ◯ Unsure

24. Any comments

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Surrogacy

With surrogacy becoming more prevalent, we want to make sure that our guidance clearly sets out what clinics should consider when treating people entering into such arrangements. We want to ensure that both the surrogate and intended parents understand the arrangement and its implications for them, that they are suitable candidates to enter into a surrogacy arrangement and are offered appropriate emotional support throughout the process.

Some of the changes have been made to guidance on surrogacy in guidance notes 3, 8, 14 and 30.

We have added some new points to guidance note 3, which aim to ensure that all intended parents and surrogates receive implications counselling before entering into a surrogacy arrangement. Implications counselling should take place three times: for the surrogate (with the intended parents not present), for the intended parents (with the surrogate not present) and in a joint session for both the intended parents and the surrogate.

New subheading and requirements in guidance note 3: counselling

Implications counselling for surrogacy arrangements

3.7 The centre should ensure that any person intending to begin treatment as a surrogate has implications counselling (depending on their wishes, alone, or with a partner, if the surrogate has one). The implications counselling should be provided by a qualified counsellor. The intended parents should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the intended parent(s). This appointment should address potential risks and implications of surrogacy (including, but not limited to, risks to the surrogate's physical and mental health, legal implications, practical and financial matters and emotional impact on the surrogate and the surrogate's partner and/or family. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.8 The centre should ensure that any person intending to enter a surrogacy arrangement as an intended parent has implications counselling provided by a qualified counsellor. The surrogate should not attend this appointment and where practicable this appointment should take place on a date separate to any appointment to be attended by or with the surrogate This appointment should address potential risks and implications of surrogacy, including, relevant risks outlined in 3.7 and the risk of the surrogate not wishing to agree to the parental order being made once a child is born. This appointment should allow full opportunity for the intended surrogate to ask questions and discuss any concerns.

3.9 In addition to the separate implications counselling referred to at 3.7 and 3.8, the surrogate and intended parent(s) should attend a joint implications counselling session with a qualified counsellor. This should cover any relevant risks/considerations mentioned in 3.7 and 3.8. Both the intended surrogate and the intended parent(s) should have full opportunity to ask questions and discuss any concerns.

25. Do you think that the requirements set out above in 3.7- 3.9 will be effective in ensuring that surrogates, intended parents, and their partners, where applicable, fully understand the implications of entering into a surrogacy arrangement and have a sufficient opportunity to ask any questions and voice any concerns?

- ◯ Yes
- ◯ No
- ◯ Unsure

26. Are guidance notes 3.7-3.9 sufficiently clear about what a clinic needs to provide in terms of implications counselling for surrogacy arrangements?

- ◯ Yes
- ◯ No
- ◯ Unsure

We want both surrogates and intended parents considering a surrogacy arrangement to give careful consideration to the medical, emotional, legal and practical issues involved in surrogacy, and to the implications of surrendering the child at birth.

In addition, we have added into guidance note 8 the following guidance which more explicitly emphasises the responsibility of the clinic to be satisfied that a surrogate is a safe and suitable candidate for surrogacy.

We want clinics to weigh up all the evidence before deciding whether to treat individuals seeking a surrogacy arrangement and seek out further information when there is any doubt over suitability.

The welfare of the child assessment process for surrogacy arrangements

8.4 If the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one, to ensure the welfare of the child in the event of a breakdown in the surrogacy arrangement leading to the surrogate keeping the child). A Welfare of the Child form should be completed by the surrogate in conversation with the treating clinician at the centre.

8.5 The centre should satisfy itself that the information given on the Welfare of the Child form is complete and correct so that any decisions relating to the treatment provided to the surrogate are fully informed and take account of all relevant considerations. The centre should obtain any relevant medical records from the surrogate's GP and any other relevant organisations and use that information to verify the information provided in the Welfare of the Child form. Any omission, discrepancy or other concern which raises questions about the woman's suitability for surrogacy or which might impact on decisions relating to her treatment should be investigated by the centre and discussed with the surrogate.

8.6 The centre should use evidence it has gathered from the GP, surrogate and any other relevant sources to satisfy itself that the woman is suitable to act as a surrogate, taking into account all relevant factors (including, but not limited to, the surrogate's age, medical history, previous obstetric history, mental health, Body Mass Index etc.) Further information should be sought where required so that the treating clinician can make decisions having been fully informed of all relevant considerations.

27. Does the new text above offer appropriate guidance to help clinics ensure that a surrogate and intended parent are suitable to enter into an appropriate and medically safe surrogacy arrangement?

- ◯ Yes
- ◯ No
- ◯ Unsure

We have also added a new requirement for clinics to have in place a standard operating procedure (SOP) for surrogacy arrangements, alongside a written protocol for decision making for deciding or refusing treatment in the case of a surrogacy arrangement.

8.7 Centres should have a Standard Operating Procedure in place for managing treatments involving surrogacy. Whilst acknowledging that the decision to proceed with treatment involving a surrogate should be made on a case by case basis, the SOP must detail its processes and policies in relation to (but not limited to) the following aspects of a surrogacy arrangement:

(a) Legal parenthood in surrogacy
(b) Surrogacy agreements
(c) Counselling requirements
(d) Confidentiality and arrangements for sharing information, in particular, between the intended parents and the surrogate
(e) Assessment of the surrogate and procedure for when a surrogate is deemed unsuitable for treatment
(f) Ensuring provisions are made for the surrogate to be seen alone by a healthcare professional
(g) The handover of care of the surrogate, once a viable pregnancy has been confirmed

8.8 The SOP must include a written decision-making protocol setting out the range of factors that may be taken into account when assessing the surrogate's suitability. The protocol should require the treating clinician to document the evidence that he or she relied on when reaching a decision as to the surrogate's suitability or unsuitability and should detail how the decision should be communicated to the surrogate and the commissioning couple. The decision-making protocol should be used in every case of a proposed surrogacy arrangement and a record made of the decision-making process and outcome for each individual intended surrogacy arrangement.

28. Is the new guidance sufficiently clear about what is needed from a surrogacy SOP?

- ◯ Yes
- ◯ No
- ◯ Unsure

Guidance note 14 relates exclusively to surrogacy arrangements. We have added in some more detail to the guidance. We want to emphasise the special status of surrogacy arrangements due to the particular legal risks, the emotional pressure the surrogate may feel and the number of lives which may be affected by a surrogacy arrangement which breaks down.

Offer of counselling to those considering surrogacy

14.7 The centre should ensure that all those involved in a surrogacy arrangement receive proper counselling about the implications of the steps they are considering. The counselling requirements are outlined in guidance note 3.

14.8 The centre should encourage those involved in a surrogacy arrangement to reflect on their decisions before it obtains their consent. The centre should provide detailed information, advice and guidance and encourage questions. The centre should be satisfied that all parties fully understand all aspects of the surrogacy arrangement and are entering into the arrangement freely and voluntarily, before obtaining their consent. This should include testing the understanding of both the intended surrogate and intended parents and ensuring that information is provided clearly and at an appropriate level of complexity tailored to an individual's capacity to understand it.

14. 9 The centre should exercise particular caution and sensitivity when discussing and taking consents for surrogacy arrangements and be aware of the vulnerable positions of both the intended surrogate and intended parents and serious implications for all concerned of a surrogacy arrangement breaking down. The centre should be alert to any sign of coercion. The centre's role should be to protect both parties from entering into a surrogacy arrangement which it suspects may be unsuitable or unethical for any reason.

29. Does this guidance do enough to protect the interests and wellbeing of surrogates and intended parents?

- ◯ Yes
- ◯ No
- ◯ Unsure

30. Any comments

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Data protection

Data protection law is changing on 25 May 2018, when the General Data Protection Regulation (GDPR) will come in to force. This is the biggest reform of data protection law for decades and strengthens and upgrades the current data protection rules.

While the GDPR is EU law, the UK Government has confirmed that the UK will be implementing the GDPR in full and no immediate changes are expected post-Brexit.

The GDPR sets a higher standard for consent to process personal data and introduces much more severe penalties for organisations that get it wrong than under existing provisions, with fines of up to 20million Euros or 4% of worldwide turnover.

GDPR applies to all licensed centres (both NHS and private). All centres will need to make the necessary changes to bring practices and procedures in line with the new requirements of the GDPR.

GDPR is not part of our regulatory remit, but we want to make sure that clinics are alert to the upcoming changes and know where to go for more detailed advice on what they need to do to ensure they are complying with the new legislation.

We are proposing some amendments to the current Code of Practice. These include small changes to guidance notes 4, 5, 11, 25, but mainly affect guidance note 30 (confidentiality). In guidance note 30 we have added in text to inform clinics about the new GDPR legislation and what it means for them, to emphasise the new stricter financial penalties for getting it wrong and to to signpost them to the guidance published by the Information Commissioner’s Office (ICO), the UK's independent body set up to uphold information rights.

We have added the following to guidance note 30: confidentiality and privacy

The General Data Protection Regulation (EU) 2016/679 (GDPR)

30.14 The General Data Protection Regulation will be implemented in the UK on 25 May 2018. On that date a new Data Protection Act also entered into force, repealing and replacing the existing Data Protection Act 1998. Many of the requirements of the GDPR are similar to those in the Data Protection Act 1998 (DPA 1998) therefore, if centres are compliant with the DPA 1998, they are likely to be compliant with the GDPR. However, GDPR does introduce some new requirements and significant enhancements to existing requirements. GDPR introduces much more severe financial penalties for organisations that get it wrong. Each centre is responsible for ensuring that it complies with the new legislation.

30.15 GDPR introduces some new rights for individuals and enhances other rights, but in general an individual's rights under GDPR are not absolute and will only apply in certain circumstances. For example, although GDPR introduces a right for individuals to have personal data erased, that right does not apply if the processing of the individual's personal data is necessary to comply with a legal obligation. In other words, centres will not need to comply with a patient's request for erasure of their IVF treatment records given that it is a legal requirement, by virtue of General Direction 0012, that the centre retains those records for at least 30 years. Matters which raise questions about the application of GDPR and the HFE Act 1990 should be considered on a case by case basis and centres should consult the Information Commissioner's website for guidance and take their own legal advice where necessary.

30.16 GDPR applies to both NHS and private centres and all centres are expected to do an audit of their current Data Protection arrangements as against the new requirements of the GDPR to determine whether they are fully compliant, and where indicated, make the necessary changes to bring practices and procedures in line with the new requirements of the GDPR.

The audit should assess amongst other things, what and when personal data is collected, the legal basis for the processing of personal data (for example to fulfil legal obligations to report certain personal data, including data about treatment, to the HFEA or for employment purposes), where data is stored and what measures are in place to protect it, whether it is shared with third parties and why it is shared.

30.17 Centres should also review practices to ensure that all individuals (this includes patients and their partners, donors and members of staff) are provided with sufficient information about what the centre does with their personal data. Where indicated by the audit, centres should revise processes and procedures to ensure that they are fully compliant with all the individual rights set out in GDPR.

30.18 GDPR introduces a duty to report certain types of personal data breaches to the Information Commissioner. Centres must report notifiable breaches to the ICO within 72 hours of becoming aware of the breach, where feasible.

If the breach is likely to result in a high risk of adversely affecting individuals' rights and freedoms, centres must also inform the affected individuals without undue delay.

30.19 Centres should ensure that they have robust procedures for detecting and investigating any data breaches. This should include a clear procedure for staff to alert the PR of any personal data breaches and a procedure for notifying the ICO of reportable breaches. A record should be kept of any personal data breaches regardless of whether the centre is required to report the breach.

31. Is the new guidance sufficiently clear?

- ◯ Yes
- ◯ No

32. Any comments

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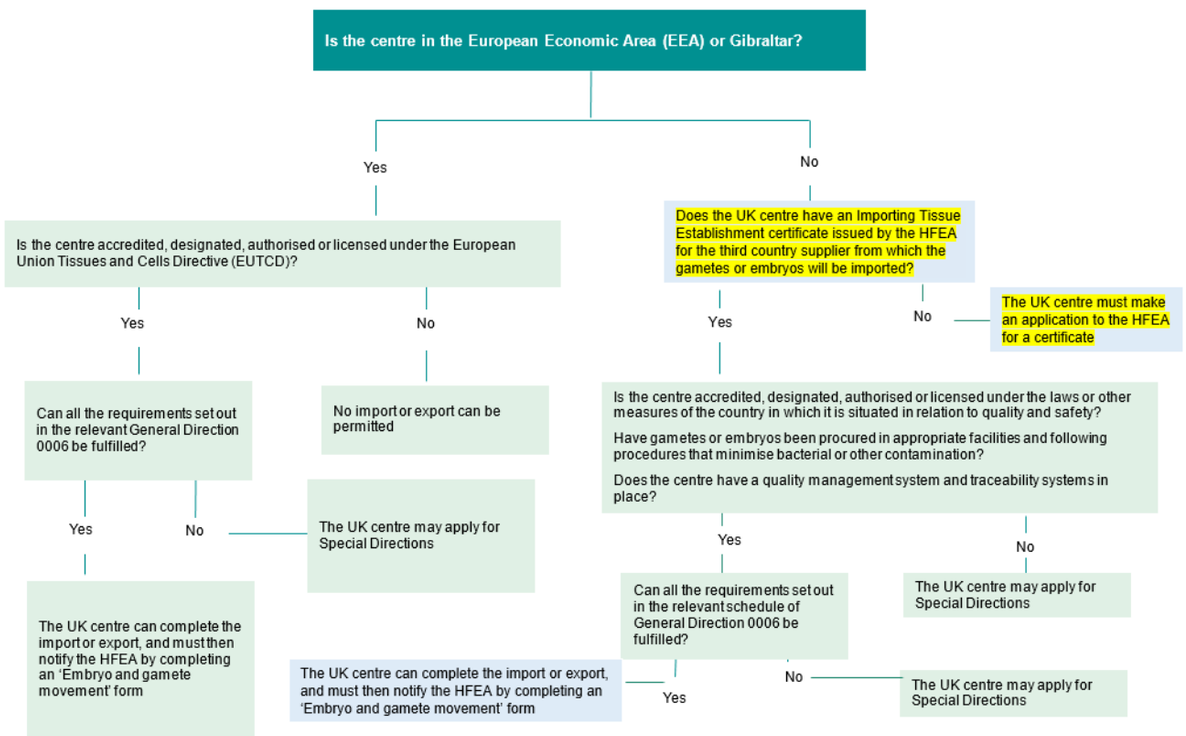
For information: EU Directives on the import and export of gametes

The guidance on the import and export of gametes (guidance note 16) has been amended to include the changes brought in by the new EU Directive on import. The Human Fertilisation and Embryology Act 1990 (as amended) now incorporates the requirements further to the passing of regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018). Clinics are required to comply with the requirements for importing from outside of the EU, EEA and Gibraltar.

We have included the new guidance here for information only. We will, of course, seek feedback on how effective that guidance has been in further consultations on the code once clinics have had time to work with the new requirements.

Updated decision tree



Updated interpretation of mandatory requirements

General Directions: evidence of compliance

Interpretation of mandatory requirements 16B

(a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

(b) Outside the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

(i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety

(ii) the centre has appropriate quality management and traceability systems, and

(iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

Where a centre wants to import from a third country supplier, the person responsible at the UK clinic must:

(i) ensure that, before undertaking any import from a third country supplier, the UK clinic has an Importing Tissue Establishment Certificate issued by the HFEA for the third country supplier it proposes to import from has a certificate

(ii) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety

(iii) provide the HFEA with the information specified in the relevant schedule to General Direction 0006 for ongoing imports

(iv) provide the HFEA with the documents specified in the relevant schedule to General Direction 0006 for one-off imports

(v) make available for inspection any documents specified in General Direction 0006

(vi) establish a written agreement with any proposed third country supplier that complies with the requirements set out in General Direction 0006.

When a certificate is issued to the Importing Tissue Establishment, the Person Responsible must:

(i) Seek written approval from the HFEA for any planned substantial changes to their import activities (i.e if it has previously only imported sperm and now wishes to import oocytes a written approval from the HFEA will be needed).

(ii) Inform the HFEA of their decision to cease their import activities in part or in full.

(iii) Inform the HFEA of any suspected or actual serious adverse events or reaction, reported to them by the third country supplier and which may influence the quality and safety of the tissues and cells they import.

(iv) Notify the HFEA of any revocation or suspension of a third country supplier's authorisation to export tissues and cells

(v) Notify the HFEA of any decision taken for reasons of non-compliance by the competent authority of the country that the third country supplier is based in where the quality and safety of imported tissues and cells are affected.

(vi) Notify the HFEA if a further import is anticipated for a couple on whose behalf a one-off import has previously been made whether by your clinic or any other clinic in the UK

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

No import of eggs or embryos that have undergone maternal spindle transfer (MST) or pronuclear transfer (PNT) is permitted to the UK.

33. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: the Single European Code

Guidance note 15 has been amended to include some guidance on the Single European Code (SEC). The Human Fertilisation and Embryology Act 1990 (as amended) now incorporates the requirements further to the passing of Regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018). Clinics are required to comply with the requirements.

Guidance note 19 has one minor addition that you should refer to guidance note 15 for details on the Single European Code.

Single European Code (SEC)

15.21 The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a SEC) providing information on the main characteristics and properties of those tissues and cells.

15.22 The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within and outside the UK. Movement of 'partner' embryos and gametes are exempt from the requirements.

15.23 A further exemption relates to where gametes and embryos are imported from a tissue establishment and not distributed thereafter (that is for use in that clinic). The SEC need not be applied in such cases.

15.24 The SEC is the unique identifier for tissues and cells distributed in the EU. It is made up of the following (six) features.

Donation identification sequence			**Product identification sequence**		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	**000123** HFEA Licensed Centre number	**00000000XX456** Clinic's donor registration 'number' – submitted to the HFEA currently in registering the donor, with zeros added	**E0000059** 1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	**001** If sperm, for example, is distributed to more than one TE	**20181231** Date of expiry of consent, for example, 31 December 2018
SEC GB000123000000000XX456 E000005900120181231					

15.25 There are three coding platforms permitted by the EU (and HFEA) one of which must be accessed to identify a product code.

1. The EU coding platform: https://webgate.ec.europa.eu/eucoding.
2. to ICCBBA ISBT128 https://www.iccbba.org (International Council for Commonality in Blood Banking Automation).
3. Eurocode international blood labelling system (IBLS) http://www.eurocode.org/.

15.26 Each coding platform provides tools to create a SEC. The EU coding platform contains detailed information on all Tissue Establishments in Europe in the Tissue Establishment compendium. If your clinic distributes embryos or gametes to a licensed clinic or tissue establishment, or similarly receives them, then you must access the EU coding platform to access the compendium.

15.27 The HFEA has a responsibility for ensuring the details of all UK HFEA licensed clinics on the compendium are current. We will do so further to changes we make to the Register of licensed clinics as part of our usual licensing activity.

15.28 We will check compliance at inspection, by sampling donor gamete and embryo movements into and out of the clinic to ensure the SEC has been applied appropriately.

15.29 Clinics identifying an error or change in relation to its details held on the EU Tissue Establishment compendium must notify their HFEA inspector as soon as practicable.

15.30 Clinics receiving gametes or embryos from a licensed clinic or tissue establishment without a SEC must note this is a serious adverse incident, and report it to the HFEA using the current incident reporting channel.

34. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: Screening requirements

Our changes to guidance on screening requirements (Guidance note 11) will focus on requirements relating to Nucleic Acid Technique (NAT) testing. Licence condition T53 currently states that quarantine of donor sperm is not required when NAT testing is used in addition to serology. However, the Code of Practice also states that donors of gametes and embryos should be screened in accordance with current professional body guidance which recommends that the quarantine period should still be observed when NAT testing is used in addition to serology.

In order to provide some clarity on this matter, we held a meeting with representatives from the relevant professional bodies and the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), which advises UK ministers and health departments of the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion or transplantation.

SaBTO has recently released a blood, tissue and cell donor selection criteria report and at the meeting we held it was decided that SaBTO would produce an addendum to this report with recommendations for gamete donor screening when NAT testing is used in addition to serology.

SaBTO is considering its recommendations and these will be incorporated into the HFEA Code of Practice and licence conditions. It is anticipated that these recommendations will include requirements for a shorter quarantine period for donated sperm when NAT testing is used in addition to serology, and recommendations for NAT testing of egg donors.

The exact details of SaBTO's recommendations will be added to this guidance note once they are available. Licence condition T53 will also be amended accordingly.

35. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: Other amendments

Consent forms

We are proposing some minor changes to our consent forms including:

- Wording will be added to section 3.1 of the 'Your consent to the storage of your eggs or sperm' form (GS form) informing clinics that the 'Your consent to the use of your sperm in artificial insemination' (MGI form) will need to be completed along with the GS form if patients want to consent for their partner to use their sperm in IUI or GIFT in the event of their death or incapacity.
- The introductory page of the 'Stating your spouse or civil partner's lack of consent' form (LC form) will contain a bullet point explaining that patients should make sure they have been told that the purpose of the form is to record, in their view, that their spouse and partner does not consent to their treatment, but it does not guarantee that their spouse or partner will not be the second legal parent.
- The 'Record of information before consent' will have a row for the 'Your consent to being registered as the legal parent in the event of your death' form' (PBR form).

36. Any comments

Quality management system

We have made some changes to our guidance on the quality management system guidance (guidance note 23) to facilitate a more cohesive understanding of incident and audit investigations in addition to the management of risks within centres.

Monitoring, evaluation and improvement

23.26 The centre's processes for monitoring, evaluation and improvement should:

(a) show that procedures and outcomes are satisfactory when judged against relevant professional standards
(b) show that the assisted conception processes are followed in a way that meets users' needs and requirements
(c) ensure conformity of the quality management system, and
(d) continually improve the effectiveness of the quality management system.

23.27 The centre should establish a documented procedure to identify and manage nonconformities and incident findings. These findings should be appropriately investigated and documented to include the following actions taken:

(a) remedial or immediate actions
(b) root cause analysis to determine the causes of nonconformities
(c) evaluating the need for action to ensure nonconformities do not recur
(d) promptly determining and implementing action needed
(e) recording the results of corrective action taken
(f) reviewing the corrective action taken and its effectiveness, and
(g) risk based thinking (preventive actions).

NOTE Action taken at the time of the nonconformity to mitigate its immediate effects is considered remedial or immediate action. Only action taken to remove the root cause of the nonconformities is considered corrective action. This is a reactive process.

23.28 The centre should establish a documented procedure to take risk based thinking (preventive action) to eliminate the causes of potential nonconformities and so prevent them happening. It should include:

(a) determining potential nonconformities and their causes
(b) evaluating the need for action to prevent nonconformities happening
(c) promptly determining and implementing action needed
(d) recording the results of preventive action taken, and
(e) reviewing any risk based thinking (preventive action) taken.

NOTE Risk based thinking (preventive action) is a way of actively identifying opportunities for improvement rather than reacting to problems or complaints when they happen. This is a proactive process as opposed to reactive.

37. Any comments

Data submission

Following the launch of our new submission system, we will have a new set of expectations and arrangements relating to good quality and timely data submission by clinics. We want to provide a transparent framework for clinics (and for the HFEA) about those expectations.

We seek to do this first by the rules of the proposed new General Direction, backed up by modest changes to the Code of Practice in its October 2018 update.

General Direction 0005 sets out mandatory requirements for clinics on collecting, recording and submitting information. The main changes to this version of the Direction are:

- To reflect the changes in the new submission system, we no longer refer to ‘forms’. Instead we refer to ‘information types’ detailed in the data dictionary, the purpose of each information type, and the deadline for submission.
- A reduction in the period allowed for correction of submission errors from two months to four weeks.
- Subtle changes in tone with more use of the word "must".
- A standardisation of submission deadlines so that they are always expressed in weeks.
- We no longer refer to the person responsible signing off a hard copy of their Choose a Fertility Clinic (CaFC) data before publication as we expect that this will be done electronically via Clinic Portal.

Guidance note 32 sets out obligations and reporting requirements of centres (along with presenting mandatory requirements from licence conditions and the act). It will be amended to reflect the changes in the new submission system - that we no longer refer to ‘forms’; and the process by which PRs will verify their data ahead of publication on CaFC.

38. Any comments

Human Fertilisation & Embryology Authority

HFEA Code of Practice 9th edition

For information: format and usability

We are using the opportunity of the 9th edition to make sure that the code is fit for purpose in today's clinic or laboratory, by gathering feedback on its format, structure and usability. We held user testing with our code working group and gathered further feedback on proposals in a survey and at the regional workshops.

Clinics' main frustration is with the search function on the website and Clinic Portal. We have now fixed the broken search function on Clinic Portal and are working towards improving the searchability of the entire code.

Overall, clinic staff wanted to keep the familiar format of the code with a few changes:

- making the link to Clinic Portal more prominent to encourage clinic staff onto the 'knowledge base' where they can find all guidance and news
- getting rid of the grouping of guidance notes to make them easier and quicker to find
- adding in abbreviations to aid searching the code eg, for professional bodies and other organisations
- reviewing our user guide to the code which explains the different types of guidance (currently in the PDF version of the code) and including it on the portal and website versions of the code
- providing more flowcharts to make it easier to explain particularly difficult guidance notes
- making the Chair's and Chief Executive's letters searchable by topic instead of by year
- marking Chair's and Chief Executive's letters as active or archived
- fixing all broken links.

39. Any comments or suggestions