Code of Practice update to be published October 2021 - background paper

Details about this paper

Area(s) of strategy this paper relates to:	The right information
Meeting:	Background paper
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Output from this paper

For information or decision?	For information
Recommendation:	Authority members are asked to review the background information within this paper and provide feedback where relevant on the issues identified in section 3 of the paper. A paper will be coming to Authority at its July 7 meeting with recommendations for decision.
Resource implications:	Within budget
Implementation date:	We are preparing for publication in October 2021, dependent on Secretary of State approval. We will keep Authority members and clinics informed in advance of the publication date and will present the Code for approval at the July 2021 Authority meeting.
Communication(s):	Code of Practice, Chair's Letter and Clinic Focus article

1. Overview

What is the HFEA Code of Practice?

1.1. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) covers the use and storage of sperm, eggs, and embryos for human application, as well as all research involving the use of human and admixed embryos. Publication of the Code of Practice is a statutory duty and helps licensed clinics to comply with the Act.

1.2. We periodically review the Code to ensure that it:

(a) reflects the law and regulatory practice

(b) is fit for purpose, and

(c) makes our regulatory requirements clear.

What is changing in the October 2021 update?

1.3. The purpose of this paper is to provide Members with background information and early sight of the proposed changes to the next version of the Code of Practice, and to give you an opportunity to provide feedback before we finalise the draft guidance. We will present the new draft guidance for approval at the Authority meeting in July. Following this meeting, we will have a tight turnaround to lay the new Code in Parliament before the Summer recess for approval by October, when we intend to publish these changes.

1.4. The focus of this update is to incorporate legal changes that have come into force since the last update in 2019, and to provide additional guidance that seeks to build upon and clarify areas of existing HFEA guidance. This update will not be introducing or changing any existing areas of policy. Members should note that the legislative changes have already come into force and clinics have been notified of these changes through our regular clinic communications in Clinic Focus and Chairs Letters. We are therefore particularly interested in your feedback on the policy areas identified in section 3 of this paper below.

1.5. The legislative changes are:

- Amendments of the HFE Act brought about by EU Exit, which impact import and export of gametes and embryos and traceability requirements, among others.
- Amendments of other legislation, including the Medical Devices Act 2002 (as amended), which has introduced new requirements for the marking of medical devices,.
- Introduction of the 2020 Coronavirus Storage Regulations which amend the 2009 Regulations.

1.6. Other updates that will provide clarification and build upon our existing guidance are on:

- The definition of a family as it applies to the 10-family limit
- Use of electronic consent
- Medicine's Management
- Witnessing
- Legal parenthood in cases where relationships breakdown and patients return for treatment using previously stored gametes or embryos

1.7. This update will also incorporate other guidance provided in Chair's letters and Clinic Focus articles since the last Code update to ensure that all our guidance is in one place. This includes guidance on:

- **How to calculate the correct storage periods for gametes or embryos received from abroad**
- **Disclosure of medical records of a deceased patient**
- **Exporting gametes and embryos in surrogacy arrangements**
- **Clarification on calculating storage periods for gametes and embryos**

1.8. We will also update the terminology for PGD and PGS which is outdated and inconsistent with the version adopted by the sector or available on HFEA website. It will be updated to PGT-M and PGT-A. To note however that while the terminology used across the sector has changed and these changes to the Code will reflect that, the language of the statute has not changed, and refers only to 'embryo testing'.

1.9. The Competition and Marketing Authority (CMA) has drafted guidance for fertility clinics on consumer law to help them understand and comply with their obligations. The CMA plan to publish in Spring 2021 a final version of the consumer law guidance. We will highlight this guidance in the Code and consider whether any additional guidance is required.

Stakeholder engagement

1.10. In December 2020, we circulated a survey to clinics and other stakeholders through the Clinic Focus newsletter to ask for comments on areas of the guidance that we will update. We received 54 responses from a wide range of clinic staff including from 17 PRs.

1.11. We also engaged with the Professional Stakeholders Group (PSG), the Association of Fertility Patient Organisations (AFPO) our Licensed Centres Panel (LCP), as well as other stakeholders on relevant issues at their online meetings. All of this has provided valuable feedback on the areas we will update, raising important considerations which have helped us with the development of the guidance. A summary of the feedback from the stakeholder engagement in relation to the issues we are addressing is presented below.

2. Legislative changes to this Code update (for information only)

EU Exit

2.1. **The Human Fertilisation and Embryology Act 1990 (HF&E Act)** continues to apply UK wide, however with some amendments resulting in certain provisions applying in relation to Northern Ireland (NI) only and, in some instances, to Great Britain (GB) only. We are updating the Code of Practice to reflect these changes and to make it clear for centres what requirements apply to centres in GB only, NI only or to both GB and NI.

2.2. **The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020** have also introduced new requirements depending on whether imports or exports are undertaken by a centre in NI versus in GB. We will be reflecting that the guidance on the Single European Code is now a requirement for centres in NI only. There have been amendments to our legislation on other aspects of traceability and adverse incidents, as

well as other pieces of legislation detailing the marking of medical devices and data protection, as EU GDPR is brought into UK law as UK GDPR.

Extended storage of gametes and embryos due to COVID-19

2.3. Due to the COVID-19 pandemic and fertility clinics being temporarily closed in April 2020, an amendment to the 2009 Regulations, **The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020**, came into force. Provided certain conditions can be satisfied, this amendment allows patients to extend the statutory storage period of their gametes or embryos to 12 years instead of 10.

2.4. New guidance will be introduced to explain the amendment to the 2009 Regulations and the two-year extension of storage periods.

3. Clarification of existing HFEA guidance – to be added to this Code update

3.1. Several policy areas have been identified since the last update to the Code or Practice where additional clarification would be beneficial to the sector and help our Inspectors to work with clinics to address non-compliances. An overview of these policy areas and the reasons for the additional clarifications are outlined below.

Definition of a 'family' for the existing 10-family limit policy

Background

3.2. Our guidance states that donor gametes should not be used to create more than 10 families (or any lower limit specified by the donor). The 10-family limit policy is to take account of the perceived psychological impact on donor-conceived children of having a high number of genetically related siblings, and to limit the risk of consanguinity. In general we know that most donors do not reach the 10-family limit in the UK, and we are not intending to revise this upper limit in this update to the Code.

3.3. However, we have received enquiries from clinics and patients about what we define as one 'family' under the current 10-family limit guidance. This question generally arises when a couple who conceive a child using donor sperm separate and one or both parties return to the clinic seeking further treatment using the same donor, either by themselves or with a new partner. We get asked whether conceiving a child using the same donor would create an additional 'family' under the 10-family limit, or whether it would create an extension to the existing family. This is an important question particularly if the donor has already been used to create 10 families in the UK.

3.4. Taking into account the policy intentions behind the 10-family limit, and that when the Authority last reviewed this policy in 2011 members noted that the policy allowed for the creation of genetically related siblings, we have provided individual responses that advise that a child born as a result of the above scenario would not constitute an additional family. Our intention is therefore to provide clarity in line with the individual responses we have previously used.

Stakeholder feedback

3.5. We have sought feedback on whether additional guidance on this would be useful. We spoke to various stakeholder representatives from the Project Group on Assisted Reproduction (PROGAR), the Sperm, Egg and Embryos Donation (SEED) trust, the Donor Conception Network, clinics who offer donation, donor sperm banks and the British Infertility Counselling Association (BICA). We also included some questions on this topic in our Code of Practice survey.

3.6. The feedback suggested that there are a variety of interpretations of what is meant by a 'family' under the 10-family limit and that additional guidance would be useful. A third of respondents to the survey reported that their clinic had come across scenarios where it was unclear if using a donor would create an additional family.

Proposed additions to the Code of Practice

3.7. We propose introducing new guidance that will make it clear that if a couple with a donor-conceived child separates and one or both individuals subsequently returns for treatment, alone or with a new partner, using gametes from the same donor will be considered one family, not a new family.

3.8. We propose adding the following definition of 'family' under the 10-family limit into the Code of Practice:

A 'family' is defined as the patient to be treated and their partner (if they have one) and any existing legal child or children of either individual, and will include any child that may be born provided the child will be a genetic sibling or half sibling of the existing donor-conceived child, and will share at least one legal parent with the existing donor-conceived child. The 10-family limit only applies to donor treatment carried out at UK licensed clinics.

3.9. We will also make it clear that if a patient has treatment abroad using donor gametes resulting in a donor-conceived child, subsequent treatment using the same donor in the UK will not be considered a new family even if that donor has already been used to create 10 families in the UK. This is because the child will be a genetic half or full sibling for the existing child.

Electronic consent

Background

3.10. New technology and the introduction of electronic consenting (e-consenting) platforms, as well as the effect of COVID-19 and the increase in virtual consultations, has increased the use of and demand for e-consent in UK fertility clinics.

3.11. The Code currently only briefly covers aspects that are relevant to the use of e-consent. Guidance note 5 on consent states 'centres should ensure that if consent forms are signed outside of a clinic, a documented process should be in place to ensure that they are signed by the correct person, have been correctly completed and the consent is valid'. We do not currently give any guidance in the Code of Practice on how clinics should introduce e-consenting platforms, and how e-consent should be taken to ensure it is valid.

3.12. We issued a Clinic Focus article on e-consenting to provide guidance to the sector in September 2019. A number of Authority members were involved in the drafting of this new guidance. In September 2019, the HFEA also updated **General Directions 0007 (version 8)**, which clinics must comply with when using electronic consenting methods. We informed the sector that the Code will be updated to include guidance on the requirements that must be met where clinics intend to use electronic methods of recording consent and to expand on the particular issues it raises. We therefore intend to incorporate this new guidance and add more detail on this policy in the next Code of Practice update.

Stakeholder feedback

3.13. E-consenting platforms are increasingly used by UK clinics. Over half of respondents to our Code survey stated that their clinic currently uses e-consenting platforms. Many also stated that they had experienced challenges with the introduction of this form of consenting. This includes challenges with:

- ensuring the correct person is completing the consent
- making sure demographic information is correct
- ensuring patients were fully informed before completing a consent i.e. a face to face discussion is still necessary

3.14. There were also concerns raised that some staff and patients struggle with the technology, highlighting the importance of training. Twelve respondents out of the 28 who answered this question said that the electronic consenting platform they are using allow consent forms to be automatically pre-populated (autofill). To further develop and understand this guidance, we have consulted with centres who currently use e-consenting platforms, as well as the director of a platform being used by the sector.

Proposed additions to the Code of Practice

3.15. We are proposing to add guidance on e-consent as a method of obtaining consent and what we expect from clinics to ensure the e-consenting platform they use is secure. This will incorporate the guidance in General Direction 0007 which was previously approved by the Authority. New guidance will include the requirement for centres to have IT resources and training in place before introducing e-consent, and the requirement for patients to have secure access to centre staff when completing consent forms on electronic consenting platforms who can answer any questions.

3.16. Centres may use a patient's first name(s), surname, date of birth and NHS/CHI/HCN/passport number as previously recorded on their electronic medical record (EMR) to pre-complete the 'About you' or About your partner' sections of HFEA consent forms. These details should be confirmed as correct by the centre and the patient whilst completing consent forms. However, centres should not pre-complete any other portion of consent forms on behalf of the person giving consent that relates to decision about their treatment.

3.17. When introducing an electronic consenting platform, centres should evaluate the reliability of the electronic consenting platform making sure the platform is fully validated, quality assured, and risk assessed. They should also have a documented procedure in place to provide training for staff to ensure they are competent at using the relevant electronic

consenting platform and adhere to clinic procedures when taking consent electronically, and they should retain the capability for taking consent in a paper form and ensure that staff are competent.

3.18. Centres should ensure that any electronic consenting platform used has inbuilt security measures and provides an individual account for each person that is required to complete consent forms that cannot be accessed by any other person. The centre must ensure that the account has an appropriate level of security, for example multifactor authentication. Patients should only be provided with the information and consent forms that are relevant to their specific treatment, which should replicate the title (including the acronym) and wording of the current version of the relevant HFEA form, including the most up to date version number and date.

3.19. The electronic consenting platform should also enable the person giving consent to sign the consent form using a qualified electronic signature and that only the person providing consent should be able to sign the form. Additionally, the platform must have the capacity to record the time and date that a consent form was signed, and it must not be possible for anyone with access to the consent form to make amendments to the consent form.

3.20. Centres should also have contingency plans in place in the event of there being no access to the electronic consenting platform, including the ability to take paper-based consent.

Medicine's management

Background

3.21. Since 2013/2014 the HFEA has overseen the management of medicines. Although not a requirement of the HFE Act 1990 (as amended), we came to regulate this as a result of an agreement with the Care Quality Commission (CQC) to reduce the regulatory overlap of clinics that were both licensed by the HFEA and registered with the CQC.

3.22. Medicine's management is an area in which we have seen a high number of non-compliances on inspection, with an average of 34 medicines management non-compliances per year (2015-2019). Providing additional guidance in the Code of Practice should raise awareness of the duty to comply with the relevant regulations, best practice, and professional body guidance to attempt to reduce the number of non-compliances.

Proposed additions to the Code of Practice

3.23. We propose expanding the current guidance on medicines management to include references to relevant legislation, best practice, and professional body guidance including:

- highlighting the importance of compliance with legislation
- ensuring the safe management of medicines including controlled drugs, and the need to demonstrate good governance and accountability
- having processes in place to investigate, analyse and report incidents involving controlled drugs, and
- having procedures for the monitoring and auditing the management and use of controlled drugs.

3.24. We will also refer to the legal requirements for the controlled drugs register entry, including how recording should be done and how/where the drug register should be kept. We will

highlight that centres should be aware of and comply with waste management regulations relating to the disposal of controlled drugs, and staff competency in the management of medicines should be regularly reviewed and assessed.

Witnessing

Background

3.25. Currently our witnessing guidance requires that centres use a patient's or donor's full name and one or more additional identifier, one of these being date of birth to uniquely identify and label each sample of gametes and embryos. This is to ensure that there is no misidentification of gametes and embryos. There have been cases where a patient or donor have had the same name and date of birth, and not using a third identifier may result in a risk of misidentification of a sample. Many clinics already routinely use three identifiers to reduce this risk.

Stakeholder feedback

3.26. Only 20% of respondents to our clinic survey said that they only use two identifiers, with the majority suggesting that requiring three identifiers would not have a significant impact on practice or cause any risks or challenges.

Proposed additions to the Code of Practice

3.27. We will update our guidance to say that to uniquely identify each sample of gametes and embryos, centres should use the patient's or donor's full name and *two other* identifiers (the patient's or donor's date of birth, hospital number, NHS number/CHI number or patient/donor code).

3.28. Additionally, there is currently no guidance in our Code about witnessing protocols to follow when donor gametes or embryos are allocated to a patient. We will therefore also include a witnessing step to follow when donor gametes or embryos are allocated to a patient.

Legal parenthood in cases when relationships breakdown and patients return for treatment using previously stored gametes or embryos

Background

3.29. All clinic staff have a responsibility to ensure they understand legal parenthood and the implications for their patients. In the past we have seen considerable errors in legal parenthood which have now been largely resolved in the sector. However we know that legal parenthood can still be complex, particularly when relationships break down and patients return for further treatment. An example we get asked about is where couples have treatment and complete the relevant legal parenthood consent forms, then subsequently separate and are left with embryos in storage. Patients can be unclear on who can decide what happens to the remaining embryos, and what the parenthood implications are.

Proposed additions to the Code of Practice

3.30. We provide detailed guidance in the Code in the Legal Parenthood guidance note. However, to further address questions we receive about patients whose relationships breakdown and return for treatment, we propose expanding our guidance. We intend to

clarify the legal parenthood implications when a woman with an unmarried male partner or unmarried female partner returns for subsequent treatment.

3.31. We will also add guidance for all couples on how to ensure that the patient's partner consents to her treatment, whether married or not. Where appropriate and taking account of confidentiality, centres should attempt to contact the partner and ask him or her to provide written confirmation about whether or not he or she consents to the proposed treatment and to being treated as the legal parent of any child that may result from his or her partner's treatment.

3.32. Additionally, we will specify that any embryos in storage may only be stored and used in accordance with the consent of the egg and sperm providers whose gametes were used to create the embryos, and a woman can only withdraw consent to her partner being the child's legal parent if donor sperm or embryos are used in the treatment and the woman and her partner are not married or in a civil partnership.

4. Next steps

4.1. The Authority is asked to note the background information for the next Code of Practice update and use this as an opportunity to ask questions and provide feedback before we finalise the draft guidance. More detail on the proposed changes will be provided in an Authority paper in July along with the amended guidance notes.

4.2. If you want to discuss any of these issues further, please get in touch with Emily Tiemann, Regulatory Policy Manager, at **emily.tiemann@hfea.gov.uk.**