

Code of Practice update

Strategic delivery:

Safe, ethical
effective treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting	Authority
Agenda item	11
Paper number	HFEA (24/01/18) 868
Meeting date	24 January 2018
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Output:

For information or decision?	For information
Recommendation	The Authority is asked to note the areas of guidance being reviewed as part of the next Code of Practice update and the plan for stakeholder engagement.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	
Organisational risk	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
Annexes	

1. Introduction

- 1.1. The Authority is required to publish a Code of Practice to provide licensed clinics and research establishments with guidance on how they should carry out licensed activities in line with legislation. The Code of Practice is reviewed regularly to update existing, or incorporate new, requirements. Although we call it a Code of Practice update, the policy decisions involved can lead to other regulatory tools such as General Directions, consent forms and best practice guidance, being updated too.
- 1.2. At a previous meeting the Authority was made aware that a new, major update was in preparation, looking at a number of policy areas and at the format and structure. This paper provides a summary of the areas of the Code that will be revised and the engagement processes that will help shape the work. We aim to launch a new 9th edition of the Code of Practice for 1 October 2018.

2. Areas of guidance

- 2.1. The following areas of guidance are being reviewed as part of the next update. The areas of focus arise in part from a desire to ensure that the Code better supports the Authority's strategic ambitions for 2017-20, and in part from enquiries we have received from inspectors and clinics, policy projects, and from general discussions.

Information provision to patients

- 2.2. As part of promoting safe, ethical and effective treatment, one of the aims of the HFEA 2017-20 Strategy is to increase patients' understanding of the science and evidence base behind treatments and added extras known as treatment add ons. We have already produced clear, evidence based information about treatment add ons for the HFEA website, we now want to make sure that clinics are providing patients with similarly clear, evidence based information about the treatments they are offering through updated guidance in the Code of Practice.

Donor screening and quarantine requirements

- 2.3. Donor screening and quarantine requirements are an area that the sector has long struggled with, in part due to conflicting or unclear guidance from a variety of professional bodies or organisations. We aim to provide greater clarity in this area, particularly in respect of different interpretations of guidance relating to quarantine requirements for donor sperm when Nucleic Acid Amplification (NAT) testing is used.

Egg sharing

- 2.4. When the Code of Practice was updated in April 2017, the guidance on egg sharing was changed to explicitly rule out "egg giving". This is when a woman undergoes two cycles of stimulation and the eggs from one cycle are kept, and one set are donated. However, the guidance does make a provision for "exceptional circumstances" where all eggs could be "given", rather than

shared, if undergoing treatment at this time would be harmful for the egg giver, and freezing the eggs is not possible. We have been asked to consider whether there are enough examples of what could constitute “exceptional circumstances” for this to be useful, and whether this provision could still be harmfully misinterpreted.

- 2.5.** We are also reviewing our guidance on egg sharing after concerns raised last year about the way in which some clinics have promoted their egg sharing arrangements. Our own inspections into these allegations concluded that there was “some evidence of an overly informal culture about the provision of information to patients in relation to donation treatment” and that there is “work to do to further emphasise the special nature of egg donation and egg sharing”.

Obtaining and retaining electronic consent

- 2.6.** Practice in clinics is changing and the NHS is going paperless in 2020. We are considering how we should update our guidance to reflect this, with consideration to the law and its stance on written consent.

Consent to data research

- 2.7.** We are currently looking at ways to increase the proportion of patients that consent to the use of their identifying information for use in research. One strand of this project is to consider whether guidance in the Code of Practice on consent to disclosure to researchers could be improved to support clinics seeking consent from patients.

Extending storage for gamete providers

- 2.8.** Current guidance in the Code of Practice is sometimes misinterpreted by clinics and relied on to allow the extension of storage for gamete providers in circumstances where the regulations do not envisage extended storage. We aim to clarify guidance in this area.

Leadership

- 2.9.** The Authority has already signalled its desire to see greater leadership in clinics to improve the quality of care. As part of that work we aim to review our Code of Practice guidance on the responsibilities of a Person Responsible (PR) and leadership more generally within the clinic. (There are other elements to this work which sit outside of the Code of Practice update including a training programme, revised PR Entry Programme test, and updated inspection tools.)

Implementing the EU Directive on import and export of gametes or

embryos

- 2.10.** The purpose of the new Directive is to ensure that there are procedures for verifying the standards of quality and safety of gametes and embryos that are imported into the UK from non-EU establishments. The importing relationships will need to be approved by the HFEA, and as a result we will need to amend the requirements in the Code of Practice on factors which the clinic will need to reassure itself before importing or applying to establish an importing

relationship. We are also reviewing the policy on compensation and consent requirements for overseas donors in parallel to introducing the requirements of the Directive.

Emotional support

- 2.11.** Improve the emotional experience of care, before during and after treatment or donation, is one of the Authority's key strategic aims. We have established a project to identify the key constituents of a service that offers good emotional support and consulting, and we are collaborating closely with a range of external stakeholders to identify good practice and different ways of sharing and promoting it across the sector. Various potential outputs will be explored with stakeholders during the course of the project, including updated Code of Practice guidance.

Other

- 2.12.** In addition, we will be addressing a range of minor issues that have been identified since the last update through enquiries we have received from inspectors and clinics, and from general discussions. We will conduct an audit of issues raised in Clinic Focus articles, Chair's or Chief Executive's Letters published since the last time they were reviewed as part of a Code of Practice update, and check that external links within the Code, for example links to professional body guidelines, are up to date.
- 2.13.** We are also 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 will check that guidance is where it should be, that it isn't too lengthy and that it is written in plain language. We will also assess whether any guidance can be removed or if anything should be added, for example reintroducing a glossary of terms.

3. Engagement plan

- 3.1.** We have established a working group comprising a range of clinic and laboratory staff, including nurses, embryologists, quality managers, doctors, counsellors and administrators. The function of the group is to advise the Executive in developing the next edition of the Code of Practice, to comment on draft sections of the Code, and to provide feedback and suggestions on the format, structure and usability. The working group have met in December and January, and will meet again in March.
- 3.2.** We will be holding workshops in February in London, Edinburgh, Manchester and Bristol to hear stakeholders' views on the various areas of guidance under review, and on the format, structure and usability of the Code.
- 3.3.** We will also be adding some questions to our Opinion Leader stakeholder survey, asking for more general feedback on the Code and our regulatory tools.
- 3.4.** A draft version of the Code will be circulated in April for around four weeks to allow stakeholders to comment, and the Authority will receive a paper on the

outcomes of the workshops and engagement so far in May. All proposed changes will then be presented to Authority in June for approval. Subject to sign off by the Secretary of State the new version of the Code will go live in October 2018.

4. Recommendation

- 4.1.** The Authority is asked to note the areas of guidance being reviewed as part of the next Code of Practice update and the plan for stakeholder engagement.