Annex I: Summary of changes to the Code of Practice in October 2018

Main updates

Leadership

Guidance note 1: Person Responsible

Guidance note 2: Staff

We believe that good leadership improves the care provided to patients and that we need to set a regulatory framework which encourages leadership within licensed centres. In this update, we are introducing new guidance to include explicit reference to leadership capability including:

- requiring the Licence Holder to provide evidence that any proposed Person Responsible (PR) has the necessary authority and autonomy to carry out the role to the best of their abilities. This is particularly important where the PR is not the sole owner of the clinic.
- requiring evidence that the PR has 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 care provided to patients
- holding the PR accountable for the overall performance of the centre by requiring clear responsibilities, roles and systems of accountability to support good governance, and requiring evidence that appropriate action is taken following all forms of feedback from the HFEA or patients.

Patient support

Guidance note 2: Staff

Guidance note 3: Counselling and patient support

Guidance note 23: The quality management system

As part of our strategy for 2017-2020, we aim to improve the emotional experience of care before, during and after treatment or donation. Many clinics already do an excellent job in supporting their patients, but this is not universal. We have introduced new guidance to help strengthen support to patients by staff at all levels, in every clinic. We hope to raise standards of patient care by proposing that all clinics set out a policy outlining how patients, donors and their partners will receive appropriate psychosocial support from all staff before, during and after treatment. We have also placed more emphasis on enhancing the support offered to patients throughout the Code.

Information provision to patients

Guidance note 4: Information to be provided prior to consent

We want to ensure that patients receive good quality, unbiased information before giving consent to treatment and/or storage, including the same standard of information for emerging or unproven treatment add ons as they are given for established treatments.

We have redrafted our guidance to make the following key changes:

- a new structure to our guidance breaking down requirements into focused subheadings
- explicit requirements for information relating to treatment add ons
- centres to provide information about the effectiveness of treatments and treatment add ons
- encouragement for centres to display their success rates ‘per embryo transferred’ to provide easier comparison to HFEA statistics presented in this format.

Implications of treatment and consent

Guidance note 4: Information to be provided prior to consent

Guidance note 12: Egg sharing arrangements

Guidance note 14: Surrogacy

Guidance note 20: Donor assisted conception

We have updated our guidance to ensure that where a person chooses not to take up the offer of counselling, the implications of treatment must be discussed as part of their preparation for treatment. Given that emotional issues may surface during the discussion of implications, a qualified counsellor is best suited to having these discussions, even in those cases where the offer of counselling has been declined. Where a qualified counsellor is not available, the PR should be able to assure themselves that the member of staff leading the discussion is sufficiently skilled, knowledgeable and experienced.

In cases involving third party donation and surrogacy arrangements, our expectation is that the discussion of implications should be delivered by a qualified counsellor.

Counselling

Guidance note 2: Staff

Guidance note 3: Counselling and patient support

We have updated guidance on what the appropriate competence for a counsellor includes, by adding that counsellors should prove specialist competence in ‘infertility’ counselling, a specialism within the generic counselling role which is not currently specified by the Code. We have also updated the term ‘general’ with ‘generic’, noting that a generic counsellor is the term more commonly used to describe a non-specialist counsellor. Finally, we have added that counselling should be ‘accessible’, broadly interpreted for the needs of the individual.

Extension of storage

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Guidance note 17: Storage of gametes and embryos

We want to clarify guidance on when it is possible to extend storage of gametes and embryos. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 introduced the same criteria for both gametes and embryos to allow extension of storage when someone is prematurely infertile or is likely to become prematurely infertile, in the written opinion of a registered medical practitioner. Current guidance is being misinterpreted and relied on by some clinics to allow the extension of storage for gamete providers beyond the intended circumstances. The guidance on storage of gametes and embryos has been 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, and
- when to obtain patients' consent for extension of storage.

Consent

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

We want clinics to have processes in place to ensure consent is informed, taken properly and given by the right person. We have updated our guidance to ensure that:

- consent is given at the clinic where possible
- and where a patient cannot attend the clinic to give consent, there is a documented process in place for ensuring consent has been given by the right person
- clinics are satisfied as to the evidence of patients' legal relationships to each other (needed to be able to discuss consent and the implications for legal parenthood), and
- where the partner of a patient has not visited the clinic, or does not return for subsequent treatment, the clinic takes reasonable steps to find out if the partner still consents to treatment and do not commence treatment until they are satisfied that the partner consents to the treatment.

Surrogacy

Guidance note 3: Counselling and patient support

Guidance note 6: Legal parenthood

Guidance note 8: Welfare of the child

Guidance note 14: Surrogacy

Guidance note 30: Confidentiality and privacy

With increased enquiries from clinics about surrogacy, we want to make sure that our guidance clearly sets out what clinics should consider when treating people entering into such arrangements. We want clinics to ensure that both the surrogate (and her husband or partner, if she has one) and the intended parents, understand the arrangement and its implications for them, and that they are suitable candidates to enter into a surrogacy arrangement and are offered appropriate emotional support throughout.

We have updated our guidance on surrogacy:

- to ensure that all intended parents and surrogates fully understand the implications before entering into a surrogacy arrangement, we state that implications should be discussed separately with the surrogate, her husband or partner (if she has one), the intended parents, and in a joint session together
- to more explicitly emphasise the responsibility of the clinic to be satisfied that a surrogate is a suitable candidate for surrogacy
- to ensure that both surrogates and intended parents give careful consideration to the medical, emotional, legal and practical issues involved in surrogacy, and to the implications of surrendering the child after the birth

- adding that the centre should weigh up all the evidence before deciding whether to treat individuals seeking a surrogacy arrangement and seek out further information (for example from the GP) when there is any doubt over suitability
- to include 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.
- to update terminology throughout the Code e.g. removing references to 'surrogate mother' and 'commissioning couple', replacing these with 'surrogate' and 'intended parents'
- to put in provision for clinics to take into account that implications discussion and counselling around surrogacy may have already taken place elsewhere
- to specify that the surrogate's partner (if she has one) should be included in the discussion of implications and the offer of counselling – this is particularly important where the surrogate is in a legal relationship
- to add that the surrogate should be informed of 'the risk of the intended parent(s) not wanting to parent any child born and/or not wishing to make a parental order application after a child is born'
- to add that 'all centre staff should demonstrate their understanding of their centre's SOP for surrogacy and associated protocols before they are involved in the treatment of surrogacy patients'
- to note that there is both a risk of surrogate deciding to parent the child herself and a risk of surrogate refusing legal transfer of parenthood
- to make clear that the welfare of the child assessment applies to both surrogates and intended parents (and partners where they have one), and
- to add links to the two new Department of Health and Social Care Guidance documents: 'Care in surrogacy' and 'The Surrogacy Pathway'.

Screening

Guidance note 11: Donor recruitment, assessment and screening

Guidance note 20: Donor assisted conception

Our changes to guidance on screening requirements focus on those relating to Nucleic Acid Amplification 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 (standard blood test). However, the Code of Practice also stated that donors of gametes and embryos should be screened in accordance with current professional body guidance which recommends that the 180 day quarantine period should still be observed when NAT testing is used in addition to serology.

In order to provide some clarity on this matter, a meeting was held 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 recently released a blood, tissue and cell donor selection criteria report, and it was agreed that SaBTO produce an addendum to that report with recommendations relating to gamete donor screening when NAT testing is used in addition to serology.

SaBTO has published its recommendations and the HFEA Code of Practice refers to those recommendations to be clear about NAT testing and quarantine expectations.

The professional societies support the decision for the HFEA Code of Practice to refer to the SaBTO recommendations even though there is some conflict with the guidance set out in their combined 2008 report[1].

The main recommendations which have been incorporated into the HFEA Code of Practice are:

- where NAT testing is used in addition to serology, centres should quarantine sperm for a minimum of three months, and
- centres should screen all egg donors by NAT testing in addition to serology.

Egg sharing

Guidance note 12: Egg sharing arrangements

We have reviewed guidance on egg sharing 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.

The guidance no longer refers to deferral of treatment as an 'exceptional' circumstance and makes clear that where deferring treatment to the egg provider is appropriate, egg or embryo freezing should be offered where possible.

We have also 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.

OHSS

Guidance note 4: Information to be provided prior to consent

Guidance note 15: Procuring, processing and transporting gametes and embryos

Guidance note 27: Adverse incidents

General Directions 0011

Ovarian hyperstimulation syndrome (OHSS) is a potentially serious side effect which can develop in reaction to the drug treatment necessary for IVF. Several changes have been made to support improvements to the prevention, care and follow up of patients affected by OHSS.

These changes include:

- that all 'severe' and 'critical' cases of OHSS must be reported to the HFEA, irrespective of whether these involved a hospital admission. This brings our reporting requirements into line with OHSS severity classification set out in the relevant RCOG Green Top Guideline, which doesn't include hospital admission nor its duration
- a new form to help to simplify 'severe' or 'critical' OHSS reporting to HFEA which will require centres to complete this within 25 working days
- that clinics' OHSS documented procedures should cover establishing if any patients have experienced OHSS as part of the routine follow up, and that procedures should also be in place to cover prevention of OHSS in line with BFS guidelines

[1] Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society and Royal College of Obstetricians and Gynaecologists (2008) 'UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)', Human Fertility,11:4,201 — 210

- signposting to the RCOG information leaflet to patients about OHSS which outlines what patients should do if they develop OHSS
- that fertility clinics should establish and maintain clinical information and data sharing agreements with local hospitals around OHSS admissions.

Data protection

Guidance note 4: Information to be provided prior to consent

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

Guidance note 11: Donor recruitment, assessment and screening

Guidance note 25: Premises, practices and facilities

On 25 May 2018 the General Data Protection Regulation (GDPR) came into 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 20 million 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 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.

The main changes affect guidance note 30 (confidentiality) where we have added guidance 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 signpost them to regulatory guidance published by the Information Commissioner's Office.

Import and export of gametes

Guidance note 16: Imports and exports

The Human Fertilisation and Embryology Act 1990 (the 1990 Act) was amended as of 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the 2018 Regulations) to incorporate procedures for verifying the standards of quality and safety of imported gametes and embryos into the UK from tissue establishments outside of the EU, EEA or Gibraltar. A Chair's letter was sent to all centres in April informing them that they were required to comply with the requirements with immediate effect.

We have amended our guidance to include the changes brought in by the new EU Directive on import, and was included in the consultation for information only. We will 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.

Single European Code

Guidance note 15: Procuring, processing and transporting gametes and embryos

Guidance note 19: Traceability

The 2018 Regulations also incorporate a range of new legal requirements on standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It is now necessary for traceability, to establish a unique identifier and apply it to tissues and cells (including reproductive cells) distributed in the EU (this will be done by way of a Single European Code). The SEC will provide information on the main characteristics and properties of those tissues and cells. The Authority approved amendments to General Direction 0006 on the SEC in March and a Chair's letter was sent to all centres in April informing them that they were required to comply with the requirements with immediate effect.

Data submission

Guidance note 32: Obligations and reporting requirements of centres

General Directions 0005

The forthcoming new HFEA data submission system provides an opportunity to define 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 new General Direction, backed up by modest changes to the Code of Practice.

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 (obligations and reporting requirements of centres) has been 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.

Corrections, clarifications and minor amendments

The following corrections and minor clarifications have been made:

- correcting reference in 11.18 and 11.34(l) of the Code
- changing the word 'gender' to 'anatomical sex' in 29.6
- changes to guidance note 23 (quality management system) to facilitate a more cohesive understanding of incident and audit investigations in addition to the management of risks within centres
- adding reference to updated EU Tissues and Cells Directive to guidance note 15 (Procuring, processing and transporting gametes and embryos)
- changing the word 'clinical' to 'medical' in the 'staff to be involved in scientific services' section in guidance note 2 (staff)

- correcting references in 33.24 and 33.26 of the Code