Annex i: Summary of changes to the Code of Practice in 2023

Version 9.4

Legislative changes

Changes to the storage limits for gametes and embryos

User guide to the Code

Guidance note 1: Person responsible

Guidance note 3: Counselling and patient support

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 6: Legal parenthood

Guidance note 11: Donor recruitment, assessment and screening

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

Guidance note 17: Storage of gametes and embryos

Guidance note 22: Research and training

On 1 July 2022, the Health and Care Act 2022 came into force. This amended the Human Fertilisation and Embryology Act 1990 and means that new laws now apply to the storage of gametes and embryos. To support these changes, the HFEA has already published the Clinic Practical Guide alongside new consent forms, updated and new General Directions, a Chair's Letter, and other guidance. Amendments were also made to Standard Licence Conditions (SLCs). The Code of Practice has been amended to incorporate these new provisions, including:

- That different maximum storage periods apply depending on the purpose for which gametes or embryos are stored. For example, material stored for a patient's own treatment can be stored for up to 55 years with a renewal of consent every 10 years while donor gametes or embryos can be stored for up to 55 years without a renewal of consent.
- Details about the renewal of consent process and the new legal obligations that apply to clinics in relation to this process.
- New provisions that apply to patients wishing to store or use their gametes or embryos in the event of their death or mental incapacity.
- The specific law and guidance that applies during the Transitional Period (1 July 2022 – 30 June 2024).

Clinics should already be compliant with the 2022 storage laws. For more information, please see the Clinic Focus articles sent to all clinics in April 2022, May 2022 and July 2022.

Licences are being updated to reflect these changes to law as part of renewal or interim inspections, or when a clinic submits an application to vary licences.

Extension to acceptance of CE marked medical devices in the GB market

Guidance note 11: Donor recruitment, assessment and screening

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

Guidance note 17: Storage of gametes and embryos

Guidance note 26: 26. Equipment and materials

In a February 2023 **Clinic Focus article** we informed the sector that the deadline for manufacturers placing CE marked devices on the GB market was to be extended beyond 30 June 2023. Subsequently, amendments were made to the Medical Devices Act 2002 to implement this change.

As a result, despite the wording of the notes under Standard Licence Conditions (SLCs) T30, T51, T53, R59 and R67, clinics can continue to use CE marked devices placed on the GB market after 30 June 2023. The Code of Practice had been amended to include additional notes under the relevant SLCs.

For more information, please see: **Implementation of the Future Regulations** and **Regulating medical devices in the UK.**

Other changes

These changes will be added to the Code in order to build upon and clarify areas of existing HFEA guidance. These additions have been identified through enquiries with the sector and discussions with HFEA staff and stakeholders. It includes smaller additions, mostly incorporation of guidance or information previously communicated through our Clinic Focus newsletter.

Reference to Alternative Dispute Resolution (ADR) schemes

Guidance note 28: Complaints

Guidance has been updated in the following ways:

- To add that clinics should subscribe to Alternative Dispute Resolution (ADR) schemes.
- To make clear the options for self-funded and NHS funded patients.
- To include that clinics should provide information to patients about the routes to escalate complaints if they cannot be resolved by the centre.

Cancelling a benefits in kind arrangement

Guidance note 12: Egg sharing arrangements

We have clarified who bears the financial burden if a benefits in kind arrangement breaks down. The new guidance makes clear that gamete providers can withdraw or vary their consent up to the point of embryo transfer and clinics should ensure that gamete providers understand the implications of such a withdrawal. We also clarify what should be documented in patient information and in the agreement.

Counselling qualifications and equivalence

Guidance note 2: Staff

Guidance from an April 2022 **Clinic Focus article** has been incorporated to indicate that there is a list of professional counselling/accreditation schemes held by the British Infertility Counselling Association (BICA) Accreditation Board. We have added a link to the BICA counsellor accreditation scheme guidance handbook.

Pre-employment health screening

Guidance note 2: Staff

Guidance from a September 2022 **Clinic Focus article** regarding preemployment health screening for staff, including exposure prone procedures and added links to professional guidelines published by the Health and Safety Executive and the UK Advisory Panel for Healthcare Workers.

Provision of a chaperone for intimate examinations

Guidance note 3: Counselling and patient support

Guidance from an October 2021 **Clinic Focus article** regarding offering a chaperone to a patient who is having an intimate examination and added a link to the General Medical Council's (GMC) guidelines on this topic.

Medical and laboratory tests

Guidance note 11: Donor recruitment, assessment and screening

Guidance from a September 2022 **Clinic Focus article** regarding carrying out and documenting risk assessments for donors that do not meet the criteria for additional testing or professional body guidelines.

Safe-sedation practice

Guidance note 3: Premises, practices and facilities

Guidance from a September 2021 **Clinic Focus article** that provided information regarding the Academy of Medical Royal Colleges guidelines on safe sedation practice for healthcare procedures. This has been added to paragraphs 25.31-25.33 in guidance note 25 (Premises, practices and facilities), which can be seen in Annex iii.

E-consent platforms

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

Guidance from a February 2022 **Clinic Focus article** for centres using e-consenting platforms to ensure that their records are retained in line with **General Direction 0012**.

Rescue ICSI

Guidance note 21: Intra-cytoplasmic sperm injection (ICSI)

New professional body guidelines on the use of ICSI were published in August 2023. As a result, we updated guidance to indicate that rescue ICSI may be considered in line with those guidelines.

Corrections and minor clarifications

The following corrections and minor clarifications have been made:

- Revision control sheet updated to clarify the exact date that versions of the Code of Practice came into force.
- Link updated to the most recent version of our **Compliance and Enforcement policy**.
- Updated terminology regarding treatment of trans patients.
- Inclusion of Clinic Focus articles (including those mentioned above), Chair's Letters and other guidance under the 'Other legislation, professional guidelines and information' section of guidance notes.
- Minor amendments to wording, grammar or formatting to improve clarity but that do not change the meaning of guidance.