



Proposals for the revision of the Human Fertilisation and Embryology Act 1990 as amended

British Fertility Society

2023

About the British Fertility Society

The British Fertility Society (BFS) is the leading multi-disciplinary professional body for those working in the field of fertility in the UK.

The objectives of the BFS are

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

Development process

1. On her appointment in 2021, Julia Chain, the Human Fertilisation and Embryology Authority (HFEA) Chair, indicated that the **Human Fertilisation and Embryology Act 1990 as amended** (HFEAct) needed to be modernised as it no longer reflected the needs of the service, medical practice and scientific developments. It was proposed that the HFEA would prepare a document for submission to the Department of Health and Social Care (DHSC) by the end of 2022. It was anticipated that a review would take place in the subsequent few years.
2. In late 2021, the BFS responded by asking its Law Policy and Ethics (LPE) Special Interest Group to undertake a review of the legislation and make proposals for change.
3. The HFEAct was reviewed to identify themes that needed further consideration. This was presented to the BFS Executive in January 2022.

4. A consultation paper was prepared that outlined the issues in the HFEAct that required review. This was sent to all BFS members for their views in July 2022. The responses were published in November 2022. They demonstrated strong support for legislative reform in several areas.
5. The HFEA carried out a consultation in March 2023 to which the BFS responded based on the BFS consultation responses and the LPE's discussions.
6. Since early 2023, the LPE has had many meetings to discuss detailed proposals for revision of the HFEAct. A clear distinction was made between concerns about the legislation and concerns about its implementation. The primary aim was the legislation but, since some of the implementation is based on the HFEA's interpretation of the legislation, there is inevitably some overlap.
7. The LPE is a multidisciplinary Special Interest Group including clinicians, nurses, scientists, lawyers, counsellors, sociologists and a bioethicist. The issues were considered from the perspective of the various stakeholders to ensure that opinion and interests of everyone were reflected in the proposals.
8. The proposals have been grouped into nine Chapters representing the themes that have been identified. They represent a reference point. Precise legislative changes are not identified since this will be decided by the government but the intention behind this document is to clearly present the problems that need to be addressed.
9. The document prepared by the LPE Special Interest Group was further reviewed by the BFS Executive Committee and by members who had volunteered to be further involved after the BFS' consultation.

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Chapter 1

Consent to creation, use and storage of embryos and gametes

1.1. Aims

- 1.1.1. To reduce the burden for patients in the completion of multiple complex consent forms and hence to improve patient understanding.
- 1.1.2. To avoid unnecessary duplication between the medical consent forms and the HFEA forms that patients are required to complete.
- 1.1.3. To avoid duplication and potential contradiction between the HFEA, other regulators and professional organisations with respect to standards for information provision and consent taking.

1.2. Background

- 1.2.1. The provisions in the legislation relating to consent were drafted in 1990 to reflect practice within the healthcare system at that time. Since then the procedures for consent have now been established in other regulation and legislation.
- 1.2.2. The consent procedures required in the HFEAct result in the duplication of consent which has the potential to be conflicting and result in legal problems.

1.3. Relevant Sections of HFEAct

- 1.3.1. Schedule 3 prescribes the processes required for “Consents to use or storage of gametes and embryos.”
- 1.3.2. Schedule 3 paragraph 2 (1) states that “A *consent to the use of any embryo must specify one or more of the following purposes- (a) use in providing treatment services to the person giving consent or that person or another specified together.*”
- 1.3.3. Specific provisions in Schedule 3 of the HFEAct 1990¹ relating to clinical procedures are summarised below.
 - Paragraph 1 (1) Consent must in writing and, where possible, signed by the patient.
 - Paragraph 2 (1) Consent to the use of an embryo must specify that the purpose is to (b) provide treatment services to persons not including the person giving consent, (ba) embryology training, or (c) research.
 - Paragraph 2 (2) Consent for storage must specify the maximum storage if less than ‘10’ years, and the decision about posthumous use.
 - Paragraph 2 (5) Consent may be varied or withdrawn.
 - Paragraph 3 (1) The person giving consent must be given (a) an opportunity to receive proper counselling about the implications and (b) must be provided with such relevant information as is proper.
 - Paragraph 5 Consent from both the donor and recipient of gametes for treatment of others is required.
 - Paragraph 6 Embryos may only be created and used with effective consent and for the purposes for which consent is given.
 - Paragraph 8 Embryos must not be stored without effective consent and must be stored in accordance with that consent.

¹ <https://www.legislation.gov.uk/ukpga/1990/37/schedule/3>

Paragraph 9, 10 and 11 relate to complex provisions for storage of embryos and gametes, and posthumous use and storage where consent is not required as the person is under the age of 18. These are uncommon events.

Paragraph 11A to 11D) relate to the renewal of consent to storage of gametes and embryos.

1.4. **Other relevant legislation**

1.4.1. The fundamental principles of consent for medical treatment are well prescribed elsewhere – DHSC,² NHS³ British Medical Association (BMA),⁴ General Medical Council (GMC),⁵ Care Quality Commission (CQC)⁶.

1.4.2. All healthcare services are regulated under the Health and Social Care Act 2008. <https://www.legislation.gov.uk/ukpga/2008/14/contents>. Inspection and registration with the CQC is required. Licensed fertility services are exempt from regulation under this legislation (Schedule 1(4)(3)(i)). Nonetheless, the HFE Act duplicates most of the principles of care under this legislation.

1.4.3. Human Tissue Act (HTA) <https://www.legislation.gov.uk/ukpga/2004/30/contents>. Covers the removal and storage of human tissue but it excludes embryos and gametes for fertility treatment and research (Section 4(2ZA)).

1.5. **Relevant HFEA documentation**

1.5.1. The HFEA forms that must be completed where relevant are given in <https://portal.hfea.gov.uk/knowledge-base/consent-forms/>.

1.5.2. The HFEA applies 129 Standard Conditions to treatment and storage licences. <https://portal.hfea.gov.uk/media/e40fpefa/standard-licence-conditions-gb-1-july-2022-onwards-treatment-and-storage-licences.pdf>.

1.6. **Service provider perspective**

1.6.1. The number and complexity of forms that are required to be completed are demonstrated in the checklist provided by the HFEA. This is unnecessarily confusing and risks inadvertent error.

<https://portal.hfea.gov.uk/media/lxmbp5pc/2022-07-01-record-of-information-provided-before-obtaining-consent-male-or-sperm-provider-v4.pdf>.

1.6.2. Some clinics may prefer to use forms provided by the HFEA whilst others consider that patients may benefit by using forms consistent with their own clinic management e.g. each clinic will have different procedures for administering the stored embryos and ensuring correct consent. Currently this flexibility is not available. Thus, the HFEA forms may not be adequately drafted for all users.

² <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>.

³ <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>.

⁴ <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>.

⁵ <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>.

⁶ <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent>

- 1.6.3. Documenting the patient's consent to medical treatment encompasses all parts of the procedure including medication, the surgical procedures (egg retrieval and embryo transfer), and the use of retrieved cells. Duplication of consent to create embryos on HFEA forms is an unnecessary burden for clinics and patients.
- 1.6.4. The requirement for consents to be given in writing does not reflect the potential benefits of digital technology.

1.7. Patient perspective

- 1.7.1. For each patient there are 24-26 HFEA forms that may need to be completed. Excluding the 9 Statutory notices related to the recent change in storage period, the total number of pages related to consent to treatment and storage is **106**. It is an unnecessary burden for patients. They are unlikely to read and understand them all, resulting in a risk of error. Any reduction in this number would be beneficial.
- 1.7.2. Few patients understand the legal significance of the HFEA forms, and most do not read them in detail. The more complex the forms they are required to complete, the greater the chance of misunderstanding and error.
- 1.7.3. Patients accept that the forms they sign giving consent for medical treatment is standard procedure in medical practice. As a fundamental part of the clinical treatment, the medical consent form must include consent to the creation, use and storage of embryos.
- 1.7.4. Patients must complete the HFEA WT Form or HFEA MT Form⁷ at the start of treatment. These forms relate not only to the consent to the creation, use and storage of embryos, but also rare events of posthumous use and legal parenthood. Removing the requirement for consent to the creation, use and storage at the start of treatment, would allow consent to be taken for these other circumstances more appropriately i.e. consent for storage and posthumous use is only needed for the 30% of patients who have embryos to store. Consent to storage, including provisions for posthumous use and use if the patient loses mental capacity, could be taken at any time before storage to allow for clinic practice and individual patient circumstances.

1.8. Legal perspective

- 1.8.1. Section 11 of the HFEAct states that the HFEA may grant licences to clinics for the purpose of treatment, storage of gametes and embryos, and research. In accepting the licence, the clinic takes legal responsibility for compliance. The HFEAct in Schedule 3 section 2 (1) states that patient consent must be given for the specific 'purpose' of the use of the embryo, but this is not the responsibility of the patients. The intentions of the legislation are not clear.
- 1.8.2. For fertility treatment, two people must agree to a procedure involving a single embryo in which they both have an interest. The HFEA requires that consents are taken on separate forms by each partner. In other circumstances e.g. a house purchase, both parties would sign on a single form. Separate forms give a potential for confusion and error particularly in relation to embryo storage. Inconsistent consents may result in legal dispute.

⁷ <https://portal.hfea.gov.uk/knowledge-base/consent-forms/>.

- 1.8.3. The Act does not specify that a specific form must be used for recording consent for the creation, use and storage of embryos. This is required by an HFEA Directive. As such, some beneficial changes may not need legislative revision.
- 1.8.4. The time limit for embryo storage does not require specific consent unless the patient requests that it is less than 10 years. Embryos may thus be stored legally without stating a specific time period.

1.9. Ethical perspective

- 1.9.1. It is unethical to carry out a medical procedure without proper informed consent. In medical practice, it is accepted that flexibility is justifiable to account for different clinical and patient circumstances. Inflexibility may be considered unethical and detrimental to the best interest of some patients.
- 1.9.2. The HFEAct uses terminology related to parenthood (mother and father) and gender (man and woman) which is now out of line with current social opinion.

1.10. Political perspective

The requirements of the Regulator's Code, which reflects government intentions for regulators, needs to be considered when the consent processes are reviewed.⁸

1.11. Proposed changes to the HFEAct

1.11.1. Where the HFEAct and the Code of Practice (COP) duplicate standard procedures for taking consent for medical procedures that are already provided by the law, BMA, GMC and NHS, these are redundant and could be withdrawn.

1.11.2. Where consent to the creation and use of embryos in the HFEA forms duplicates consent given in required medical consent forms, the HFEA consent forms should be withdrawn.

1.11.3. The Act should allow consent to be obtained and stored electronically.

1.11.4. Remove from Schedule 3 paragraph 2 (1) of the Act the requirement for patients to state the specific 'purpose' of the use of the embryos. This removes the need for these sections on the WT and MT forms. These forms could then be replaced with more appropriately targeted and timely forms related to consent and withdrawal of consent for storage, and provision for posthumous use.

1.11.5. Consideration should be given to remove the absolute power of the HFEA to determine the design and content of their forms. These should be tested externally for readability and comprehension including patient review. Consultation with service providers is vital to ensure compatibility with clinical practice.

1.11.6. Legislation should use gender neutral terminology. Documentation for patients should be appropriately flexible to reflect individual preferences.

⁸ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/913510/14-705-regulators-code.pdf.

Chapter 2

Posthumous use and storage of embryos and gametes

2.1. Aims

- 2.1.1. To simplify the procedures for recording decisions about posthumous use.
- 2.1.2. To reduce the likelihood of legal challenge related to posthumous use.
- 2.1.3. To ensure that the interests of the remaining partner and potential children are considered.
- 2.1.4. To simplify the procedure of recording legal parenthood after posthumous use.

2.2. Background

- 2.2.1. The requirements for taking consent for posthumous use are unnecessarily complex and require simplification. The consequences of the badly drafted forms and the ambiguous requirements for counselling results in patients not recording their wishes clearly. The problems have arisen both due to patient and clinic errors.
- 2.2.2. Implementation of the legislation relies on written consent on prescribed forms. In regulatory practice these are the only acceptable method of obtaining and/or proving consent. This is not consistent with the more flexible procedures for taking consent in other healthcare situations.⁹
- 2.2.3. Posthumous use relates to stored gametes and embryos. Since embryos may be stored for many years, a consent taken at the time of initial storage may not be relevant as social circumstances change. Where consents have not been updated accordingly, this has resulted in distress of the surviving partner and subsequent legal challenge, at significant cost to the clinics, the HFEA and the claimant.
- 2.2.4. The HFEAct 1990 Schedule 3 paragraph 2 (2) (b) requires that consent must state what is to be done with the embryos should the person giving consent die or lack capacity. The HFEAct 1990 does not limit the options for “what is to be done” although their subsequent use must be for a prescribed purpose (Schedule 3 paragraph 2 (1)). The HFEA consent forms are often amended in an attempt to account for all possible options resulting in increasingly complex forms. A more flexible approach would better meet patients’ needs.
- 2.2.5. There are precedents for different procedures for posthumous use in other circumstances e.g. for organ or tissue donation, legislation allows donation unless an opt-out decision has been made. Intentions can be prospectively recorded by registering on the NHS Organ Donation Register. The surviving family or a nominated representative may still overrule the decedent’s intent.
- 2.2.6. Although one partner may die during the few days that an embryo is growing in the laboratory during in the initial treatment, the validity of consent needed to continue with transfer of the embryos is not clear in the HFEAct.

2.3. Relevant sections of the HFEAct

- 2.3.1. Schedule 3 paragraph 2 (2) (b) requires that consent for storage of gametes and embryos must state “what is to be done” with the gametes or embryos if the person giving consent dies.

⁹ <https://www.bma.org.uk/media/2481/bma-consent-toolkit-september-2019.pdf>

2.3.2. A detailed review of the current legal framework is given by Mrs Justice Theis in the reported case of *Jennings v HFEA*, paragraphs 23 to 29.¹⁰

2.3.3. Provisions for parental status after posthumous use are given in HFEAct 2008 Section 39 (where the partner's sperm was used), Section 40 (where donor sperm was used) and Section 46 (where a female partner had died). The partner of a child conceived posthumously may be entered on the birth register if certain other conditions are met, such as consent having been given by the man (whether using his sperm or donor sperm) or consent from the female partner to be so named on the birth certificate and the woman elects in writing, not later than 42 days from birth that the man/female partner is to be so named on the birth certificate, but will not be the legal parent for any other purpose.

2.4. Other relevant legislation

The Human Tissue Act 2004 Part 1, Section 4 provides for consent to be given by a nominated representative of a decedent.¹¹ Although this Act does not apply to gametes, it provides a precedent that a nominated representative may be an appropriate person to understand the intentions of the decedent.

2.5. Relevant sections of the HFEA Code of Practice

2.5.1. Chapter 5 includes consent procedures related to posthumous use (paragraphs 5.21, 5.24 and 5.25.) it is advised that consent for storage should be taken at the same time as consent for use. This should include consent for posthumous use.

2.5.2. There are 13 HFEA forms that must be used to complete the requirement for consent for posthumous use of gametes or embryos. Only selected forms will be required for each patient. (MT, WT, WPT, GS, MGI, WGI, RE, RG, RE(TP), RG(TP), SPP, PBR, PP). <https://portal.hfea.gov.uk/knowledge-base/consent-forms/>.

2.6. Patient, partner, donor, family perspective

Stored embryos

2.6.1. At the time of fertility treatment, the possibility and consequences of death are so far from the mind of patients that entering into a meaningful discussion and reaching reliable decisions about posthumous use is highly unlikely. After treatment, if there are remaining stored embryos or gametes, a possible early death will still be remote for a young adult. The chance of dying in the next year for a 30-year-old is ~0.05%. The leading causes of death in 20–35-year-olds in the UK are suicide, injury and accidental poisoning which are largely unpredictable and unforeseen events.¹² It is not surprising therefore that the average age at which a person writes a will in the UK is 58 years. Most

¹⁰ <https://www.judiciary.uk/wp-content/uploads/2022/06/Jennings-v-HFEA-judgment-220622.pdf>.

¹¹ <https://www.legislation.gov.uk/ukpga/2004/30/contents>.

¹² <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/causesofdeath/articles/leadingcausesofdeathuk/2001to2018>

- people do not take out life insurance until they have the responsibility of children.
- 2.6.2. Whilst it is essential that patients must consider the options for posthumous use, the expectation of a fully informed and considered decision must be realistic.
 - 2.6.3. It is the responsibility of the patient to ensure that their consents to posthumous use reflect any change in their social circumstances. Legislation needs to recognise that, despite the best intentions, this does not always happen.
 - 2.6.4. The HFEA attempt to predict all the possible circumstances surrounding an unexpected death. Their consent forms reflect their decisions about options that might be available. The underlying assumptions are that affirmative consent must be given for all possible posthumous circumstances. This assumes that the forms include all possible scenarios (see below). A more flexible interpretation of the HFEAct may reflect the complexity of current family structures.
 - 2.6.5. A Court has recently agreed to a husband's request for the posthumous use of an embryo in a surrogate where his wife (the donor) died unexpectedly and where she had not signed the relevant consent forms giving her consent for the use of the embryo with a surrogate, finding that she was not given the opportunity to sign the relevant form and if she had been given such opportunity, the court found that it could infer from all the evidence that she would have given her consent <https://www.judiciary.uk/judgments/jennings-v-hfea/>. The main issue with female patients being able to effectively give their consent to a surviving partner posthumously using an embryo with a surrogate, is that the HFEAct 1990 requires the additional donor screening tests required prior to donation, which comes at an additional cost and may, therefore, deter patients from giving this consent. In addition, the court found that the HFEA forms relating to the giving of posthumous consent were "far from clear" (paragraph 88) This is a further example of inflexibility that is potentially detrimental to best patient care.
 - 2.6.6. The HFEA requires that both partners complete separate forms. Consents may conflict but be unnoticed or unresolved. Thus the opportunity for discussion is missed. Using a single form to record separate decisions might be beneficial to ensure that both partners are aware of the decision that the other has made and facilitate a joint decision.

Stored gametes.

- 2.6.7. The circumstances are different when gametes are stored e.g. prior to cancer treatment. It is more appropriate to consider long term life expectancy at that time.
- 2.6.8. It is the responsibility of the person who has gametes stored, to ensure that the documented consents remain consistent with their wishes as the social circumstances change e.g. when there's a new partner. Although written evidence may have been recorded elsewhere, use of the gametes with a partner is only permitted if the appropriate HFEA forms have been completed.

2.7. Legal perspective

There have been many legal problems related to posthumous use. These are illustrated in the following cases.

2.7.1. Absence of consent

The most well-known case is the judicial review brought by Diane Blood whose husband Stephen was admitted to hospital with meningitis and fell into a coma.¹³ The couple were not having fertility treatment so there were no consents in place for the use or storage of Mr Blood's sperm. Samples were extracted from him before he died, but the HFEA determined that – in the absence of consent – the storage of the samples was unlawful. For the same reason, the use of the sperm by his widow would also be unlawful and the HFEA did not agree to export the sperm abroad. Mrs Blood judicially reviewed this decision and whilst she was unsuccessful at first instance, the Court of Appeal permitted the exportation of the samples to Belgium where she was successfully treated. The case is notable for clarifying the strict requirements of the 1990 Act and licence conditions in relation to consent. Although the court did not doubt Mrs Blood's evidence about what her husband would have wanted and the uncontradicted evidence that they had discussed the possibility of artificial insemination, the consent requirements were incontrovertible.

2.7.2. Variation of consent

A similarly strict approach was adopted by the Court of Appeal in the case of Mrs U and the Bristol CRM.¹⁴ Mr and Mrs U completed their *pro forma* HFEA consent forms, and both consented to posthumous use. The clinic had a policy of not providing posthumous treatment, so Mr U was asked to change his form or transfer the sperm to another clinic. He amended the form, withdrawing his consent to posthumous use, and his sperm was stored. He subsequently died and Mrs U asked to be permitted to use the stored samples in treatment. The court expressed its sympathy for Mrs U but would not look behind the unambiguous, informed and capacious consent provided by her late husband.

2.7.3. 'Mosaics' of consent

Happier outcomes were achieved by the applicants in two more recent cases, Elizabeth Warren and SB.¹⁵ Both cases turned on their ability to provide evidence enabling the courts to conclude that there was sufficient evidence of consent, notwithstanding that HFEA forms had not been completed.

Beth Warren's husband had sperm stored and had consented to a series of incremental storage periods to match the availability of NHS funding. He had named Beth as his partner and consented to posthumous use of his sperm. However, he died before he was able to complete another extension of storage form. The court considered evidence from Beth, the families, and the documentary evidence of her husband's wishes, and Beth's Article 8 rights under the Human rights Act. The court was satisfied that it was right and proportionate to allow

¹³ R v HFEA *ex parte* Blood [1997] 2 All ER 687

¹⁴ [Mrs U v Centre for Reproductive Medicine \[2002\] EWCA Civ 565](#)

¹⁵ [Warren v CARE Fertility & HFEA \[2014\] EWHC 602 \(Fam\)](#) and [SB v University of Aberdeen & Ors \[2020\] CSIH 62](#)

the stored samples to remain in storage for up to 55 years notwithstanding the absence of a further consent form.

SB's husband JB had sperm stored before he met his wife. He had consented to the use of his sperm in IUI, but not IVF. JB died before a planned consultation for IVF treatment. JB had amended his will, directing his executors to ensure that his stored samples be available to SB. The court found that the combination of the forms and the direction in the will constituted valid consent for the purposes of the HFEAct 1990.

2.8. Ethical perspective

- 2.8.1. There have been many publications about the ethical issues¹⁶ of posthumous conception and these are not discussed at length here. The main ethical considerations include:
 - 2.8.1.1. autonomy of the decedent; although different from autonomy of the living, wishes given before death are respected in some legal situations.
 - 2.8.1.2. beneficence and justice for their partner.
 - 2.8.1.3. consideration for the embryo as a potential child.
- 2.8.2. It is recognised that some people are fundamentally opposed to posthumous conception and find it ethically unacceptable. Nonetheless, Parliament's decision, as implemented in the HFEAct 1990, is that posthumous use of embryos and gametes is permitted. The option for a patient to object to posthumous use in all circumstances could be retained.
- 2.8.3. The HFEAct 1990 places overriding emphasis on written consent. This was an understandable response to some of the fears at that time. Legal challenges have found that this rigid consent process is no longer suited to provide the compassionate and humanitarian response that is needed in many difficult and varied family circumstances.
- 2.8.4. A Will documents the distribution of a person's property after their death and is rarely challenged. The final decision about posthumous organ donation is usually made by relatives. A critical difference with stored embryos is that responsibility for decisions about their use directly involves two people. Whilst both remain alive, joint agreement is required. On the rare occasions when this has not been achievable, a court decision has been sought e.g. *Evans v United Kingdom*¹⁷. When one partner unexpectedly dies, there is no opportunity for couples to make a considered response to the unanticipated event. Their opinions on posthumous use could have changed but it will no longer be possible for the decedent to alter a previous written decision. The law, as implemented, offers no flexibility.
- 2.8.5. The current regulation requirements for consent for posthumous use of embryos must be specific as to how they may be used. s. Even if the intention of the decedent is clear, the final decision remains with the surviving partner. A decedent's desire that the embryo may be transferred, and a child be conceived may not be fulfilled because the surviving partner does not consent. Therefore, the 'consent' of the decedent only has moral weight

¹⁶ Angela K. Lawson, Julianne E. Zweifel & Susan C. Klock (2016) Blurring the line between life and death: a review of the psychological and ethical concerns related to posthumous-assisted reproduction, *The European Journal of Contraception & Reproductive Health Care*, 21:5, 339-346, DOI: [10.1080/13625187.2016.1203892](https://doi.org/10.1080/13625187.2016.1203892)

¹⁷ <https://academic.oup.com/icon/article/6/2/317/737023>

because it cannot be enforced. Conversely, if the decedent's consent form has stated that the embryos may not be used after the decedent's death, this is upheld in law and the rights of the remaining partner to be a parent are ignored. In both cases, the result is that the embryo is not transferred and there will be no child. Ethically therefore, the consent process under current regulation has flaws. A more flexible approach that takes account of the wishes of the decedent and the interests of the surviving partner and the potential child may be preferable.

- 2.8.6. The storage of gametes presents different problems from embryos. Most are never used for treatment, and, for some, the storage is an affirmation of hope for the future life rather than an immediate desire for parenthood. Gametes are usually stored in anticipation of potential infertility often when there is no current partner. Strict adherence to HFEA form completion, may not represent beneficence and justice for a new partner where an oversight has resulted in out-of-date forms. Again, a more flexible approach is needed.
- 2.8.7. For the child, there is a subtle but potentially significant difference between a posthumous conception and a posthumous embryo transfer. The unique embryo was created when the decedent was alive whereas the gamete used after death was an earlier part of the creation of the individual. The child may feel that they did, at some very early brief time, have two parents.

2.9. **Political perspective**

Inflexible legislation that results in successful legal challenges is a strong indication of poor legislation and a need for change.

2.10. **Proposed changes to the HFEAct**

- 2.10.1. Implementation of the legislation could require that a person nominates another person to decide what should happen if they die. An alternative option to object to all posthumous use could be retained. Examples for consideration are:

*If I die or lack capacity to vary or withdraw consent whilst my embryos/gametes are in storage, the decision about what to do with the embryos/gametes will be made by -----
---- (partner/parent/other?). I understand that this could result in the birth of a child, and I may be named on the Birth Certificate.*

Or

I do not want my embryos/gametes to be kept in storage or used after my death or mental incapacitation and that in the event of my death or mental incapacitation they will be destroyed.

- 2.10.2. The form to be used for this purpose should be simplified. The use of multiple forms should be avoided and both parties should use the same consent form.
- 2.10.3. Since the above suggested changes at 2.10.1 and 2.10.2 may not require legislative change, they could be considered without delay.
- 2.10.4. Whilst reviewing legal parenthood provisions in the legislation, posthumous use of embryos and gametes should be included.

Chapter 3 **Legal Parenthood**

3.1. Aims

- 3.1.1. To ensure that a child has a correct, complete, and permanent record of their legal parents on their Birth Certificate.
- 3.1.2. To remove discrimination against those who choose not to be married/civil partners.
- 3.1.3. To ensure that legislation is consistent with social and family norms in 2023 and flexible for future evolution.
- 3.1.4. To reduce the number of legal problems that have resulted from the implementation of the Legal Parenthood provision in the HFEAct 2008.
- 3.1.5. To remove the responsibility for clinics to give legal advice about legal parenthood, parental responsibility and Birth Registration.

3.2. Background

- 3.2.1. Legislation in relation to parenthood in the UK for children conceived through assisted reproduction has grown from the social norms of 1990. The original legislation only catered for heterosexual couples having children together (with preferential treatment for those who were married). Since then other family forms have been transplanted onto the existing legislation (such as civil partners and same-sex parents), resulting in a complex set of legislative rules which seek to cater for a broad range of specific situations individually.
- 3.2.2. In most cases following natural conception or any licensed treatment involving a different-sex couple using their own gametes (or donor eggs), the woman giving birth and the biological father will be the child's legal parents and may be named on the birth certificate. No consent for legal parenthood is required.
- 3.2.3. When donor sperm is used by couples who are married/civil partners, the parenthood of the non-birthing parent is conferred by operation of law. No positive consent for legal parenthood is required, but it can be negated if an absence of consent to the conception is shown.
- 3.2.4. When donor sperm is used by couples who are not married/civil partners, implementation of the HFEAct 2008 requires the completion of specific HFEA forms by each partner giving notice to the person responsible at the UK fertility clinic where treatment will take place of their intention that the non-birthing partner will be a legal parent. If not completed before the embryo transfer or artificial insemination, the partner is not the legal parent. That partner can only be named on the Birth Certificate if the HFEA Legal Parenthood forms have been signed and both partners agree. It is this situation that is problematic.
- 3.2.5. There is no option to change the status of a sperm provider from 'treatment' to 'donor' for a stored embryo. Thus, if an embryo is created and stored for treatment but then no longer needed for that couple, it can be donated to others for treatment, but the legal parenthood of the man could be at issue. If the recipient couple are married or in civil partnership, they would be the legal parents. But if the recipient is a single woman, the sperm provider would

legally be the parent of a resulting child, which is unlikely to be what he or the single woman wants.

- 3.2.6. Additional complexities arise where the woman carrying the child is acting as a surrogate, where patients are in complex relationship situations (for example still married but conceiving with a new partner) and where patients are transgender (given that there is no provision in the Act to govern the legal parenthood status of someone who has legally changed gender, but the wording of the legislation is gendered throughout).

3.3. Relevant sections of the HFEAct

- 3.3.1. Provisions for legal parenthood were made in the HFEAct 2008 Part 2. <https://www.legislation.gov.uk/ukpga/2008/22/part/2>.
- 3.3.2. Sections 33-55 in this Act relate to the legal parenthood of people conceiving through assisted reproduction (both in fertility clinics and otherwise) and cover a range of different situations.
- 3.3.3. Section 33 clarifies that the woman carrying the child (and no other woman) is the mother of the child. The remaining sections relate to the parenthood status of fathers and second female parents and provide a mechanism for reassigning parenthood to the intended parents in a surrogacy arrangement via a parental order.
- 3.3.4. Section 41(1) confirms that a sperm donor who has provided the required consent required by paragraph (5) of Schedule 3 HFEAct 1990 (i.e. to donation through a UK licensed fertility clinic), is not to be the legal father.

3.4. Other relevant legislation

- 3.4.1. The Family Law Reform Act 1987 (Section 27) states that the married parents of a child conceived using donor sperm are the legal parents unless it is proved that consent was not given to the insemination.¹⁸ Positive consent is not needed.
- 3.4.2. The Birth and Deaths Registration Act 1953, requires that the birth of a child must be registered within 42 days (21 days in Scotland). Only the legal parents of the child can be named on the Birth Certificate.

3.5. Relevant Sections of the HFEA Code of Practice.

- 3.5.1. The HFEA Code of Practice (COP) Chapter 6 relates to legal parenthood. Sections 6.10 and 6.11 require that in cases where they are required, the HFEA Legal Parenthood forms must be completed by both partners before sperm and egg transfer, embryo transfer or insemination takes place.
- 3.5.2. Legal Parenthood Consent forms are given at <https://portal.hfea.gov.uk/knowledge-base/consent-forms/>.

3.6. Patient, partner, donor and family perspective

- 3.6.1. The law on parenthood can be extremely complex and has not kept pace with the growing diversity of family structures and personal identities.
- 3.6.2. Current legislation often does not adequately safeguard the legal parenthood of those who intend to be a child's legal parent (and then become a parent in all real terms) and discriminates against couples who choose not to marry/be

¹⁸ <https://www.legislation.gov.uk/ukpga/1987/42/section/27>.

civil partners where this determines the legal parenthood of the birth person's partner.

- 3.6.3. A gamete donor donating through a UK licensed clinic will have completed forms to confirm that they will not be the legal parent of the child. This provision should remain.
- 3.6.4. The use of known sperm donors is increasing, particularly among same sex couples and single women. The role that such donors may wish to play in the life of a subsequent child is not considered in legislation. Where a single woman uses a known donor, before treatment is provided in a licensed clinic, it must be decided whether the sperm provider is to be treated as a donor or a legal parent. A more flexible approach is needed in the interest of the child.
- 3.6.5. Modern family structures are complex and may involve the desire for there to be 3 legal parents e.g. a same-sex couple and a sperm donor. Parental responsibility can be given to more than 2 adults but there can only be 2 legal parents.
- 3.6.6. When an embryo that has been created as part of treatment but is no longer needed for that couple, it may be donated to a third party. Currently there is no option for the sperm provider to change his status to donor. This could result in his being the legal parent if the embryo is donated to an unmarried/non-civil partnered woman.
- 3.6.7. There is no provision in the legislation for transgender parents, resulting in bizarre outcomes (e.g. someone who is legally male having to be registered as a mother rather than a father or parent) and inconsistency (it being possible to nominate someone who has a gender recognition certificate making them legally male as a father in certain circumstances but not others).

3.7. Legal perspective

- 3.7.1. There have been more than 50 reported judgments from the High Court Family Division since 2015 involving cases in which fertility clinics have retrospectively identified that the HFEA forms (WP and PP), which create legal parenthood for unmarried couples conceiving through sperm donation, have not been completed correctly. The errors include missed signatures, forms completed the wrong way around, errors in the details completed and missing forms. In all, minor administrative errors have jeopardised legal parenthood because of the hard deadline the law creates in relation to the documentation that must be in place prior to embryo transfer or artificial insemination. Judges have had to apply considerable legal gymnastics to achieve legal parenthood in line with what was clearly intended and in the child's best interests, at considerable expense, delay and most importantly stress to patients.
- 3.7.2. The HFEA advises single women conceiving with donated embryos to seek legal advice due to the "lack of clarity in the law regarding the parenthood status of a man who donates embryos created with his sperm for his and his partner's treatment." The current law creates unnecessary confusion and obstacles to both patients' treatment and donation choices.
- 3.7.3. Where a woman is separated from a spouse, she can experience obstacles to proceeding with fertility treatment (with either donor sperm or with sperm from a new partner) due to the legal rule that her spouse is presumed to be the father or second legal parent unless his/her lack of consent to the conception is 'shown.' It is often unclear to clinics whether they need to involve and notify

the woman's spouse to verify a lack of consent, and if not whether it is possible to treat the woman or couple.

- 3.7.4. If the Legal Parenthood forms are not correctly completed by both partners before treatment, then entry of both partners on a Birth Certificate is not valid. This is contradictory legislation.
- 3.7.5. It would be simpler if, for all relationship options, legal parenthood were grounded in the intention to be a parent. Where a child is conceived through artificial insemination or the transfer of an embryo, the legal parents are the people who intend to become the child's parents at that time, as documented in the medical consent form or through other evidence. This would remove discrimination against those who are not married or in a civil partnership and enable more flexibility for the law to reflect increasingly diverse family forms and the lived realities of the children conceived within them.
- 3.7.6. There have been recent cases requesting an option of more than 2 legal parents, for example, a same-sex female couple intend to co-parent with the child's genetic father, so that there are 3 people who intend to be the child's parents at the moment of conception. If the Person Responsible (PR) is given notice of such an intention, then the interests of the child in such a relationship should be recognised in law.
- 3.7.7. Transgender men (who are legally male for all purposes following the issue of a gender recognition certificate) who conceive through fertility treatment and give birth to a child must (following the case of *McConnell v Registrar General (2020)*) be registered on their child's birth certificate as the 'mother'. However, transgender men whose partner gives birth can be nominated to be the legal 'father' of a child conceived with donor sperm. This inconsistency is a feature of the law which was not written with these circumstances in mind and fails to provide adequately for transgender parents who are increasingly commonly conceiving children. There would be advantages to giving parents the option of being registered on their child's Birth Certificate as the child's mother, father, parent, or gestational parent so as to more appropriately reflect their own identity and their relationship with their own child.
- 3.7.8. In surrogacy cases, the law forces the spouse of a surrogate to become a legal parent and to be named on the birth certificate of a child who he or she does not consider to be theirs. It also denies the recognition of intended and biological parenthood for the child's intended parents.
- 3.7.9. Following a Law Commission review, proposals have been made by the Law Commission of England and Wales and the Scottish Law Commission to the Government as to how the law on surrogacy could be revised. This is considering some of the issues related to legal parenthood that are reviewed here. Rather than trying to micromanage legal parenthood conditions in the HFEAct for every possible social situation, a more fundamental review of parenthood and Birth Registration is needed.
- 3.7.10. The legal parenthood forms required by the HFEA are retained by the clinic for 30 years. Since such forms may be the only record relating to legal parenthood, there is concern that the duration and security of storage is not adequate to protect the long-term interests of the family and child.

3.8. Service provider perspective

- 3.8.1. The COP effectively requires clinics to be experts in the law related to legal parenthood despite acknowledging that this area can be highly complex, and

some patients should be advised to take legal advice. Most clinics believe that this is outside their area of expertise and feel very uncomfortable at being required to make such decisions.

3.8.2. The completion of unnecessary forms is an unwarranted regulatory burden.

3.9. **Ethical perspective**

3.9.1. Where legislation in relation to the parents of children conceived by some licensed fertility treatments is different to that of others or to natural conception, this is potentially discriminatory.

3.9.2. The legislation still uses the terms 'mother' and 'father' based on the original terminology in the 1990 Act. This causes unnecessary potential discrimination and it is not appropriate to modern families. The importance of the legislation is to determine who are the legal parents of the child. This is irrespective of gender-related terminology.

3.9.3. Patients sign consent to medical treatment that includes the intended purpose of the treatment. Intent indicates a purpose (to have treatment) to achieve a specific aim, and the intention (to be parents). Consent for intent and intention are clearly related in clinical practice but, in relation to legal parenthood, the HFEAct only considers that consent to intention is legally binding.

3.9.4. The need to involve High Court judges sitting in the Family Court to determine who is and is not a legal parent should be unnecessary where the dispute is not between the parents but with errors in completing forms.

3.10. **Political perspective**

The number of legal challenges implies that the legislation is imperfect.

3.11. **Society perspective**

Most women giving birth now are not married¹⁹ although two thirds were within co-habiting relationships. Family relationships are much more complex than 1990 and even 2008. Extended kinship patterns are now generally accepted in society in the UK and there is no evidence that this is detrimental to children. Legislation is often slow to react and, where legislation attempts to regulate evolving kinship structures, it is likely to fail in a democratic society where individual autonomy is valued. Legislation related to parent and children relationships must remain flexible to be able to reflect future social change.

3.12. **Proposed Changes suggested to the HFEAct**

3.12.1. Legal parenthood conditions must not discriminate against unmarried/non-civil partnered women and their partners.

3.12.2. Sections 33-55 HFEAct 2008 should be reviewed. A more flexible approach to legal parenthood is needed than the current unnecessarily complicated procedures that bases legal parenthood entirely on a signature at a specific time. In dispute resolution, the intention stated in the medical consent forms and other evidence should have equivalent weight.

¹⁹

<https://www.statista.com/statistics/294571/live-births-in-england-wales-uk-by-age-and-marital-status-of-mother/#:~:text=In%202021%2C%20there%20were%20approximately%20304%2C120%20live%20births,2021%2C%20by%20marital%20status%20of%20mother%20%28in%201%2C000s%29.>



- 3.12.3. If there is a wider review of the law on legal parenthood and birth registration as part of consideration of any Surrogacy Bill, then fertility treatment should be part of such a review.
- 3.12.4. There should be an option for change of status from legal parent to donor to enable donation of stored embryos to an unmarried/non-civil partnered recipient.
- 3.12.5. Clinics are required to store legal parenthood documentation for 30 years. Since this may be the only legal document relating to the child's parents, this is not adequate or safe. Clinics may be stand-alone providers of fertility services and subject to market forces including the possibility of clinic closure. An alternative record depository is required, which provides secure and reliable storage.

Chapter 4

Research, Training and Innovation

4.1. Aims

- 4.1.1. To ensure that, if patients wish to donate their embryos to research, legislation facilitates and does not inhibit this.
- 4.1.2. To make a clear distinction in the legislation between basic science research and clinical research.
- 4.1.3. To ensure that the process of regulation of embryo or gamete research is appropriate and consistent with the regulation of research in other scientific and healthcare situations.
- 4.1.4. To future-proof legislation for rapidly developing scientific and medical advances.
- 4.1.5. To clarify the intention of legislation related to training which is a necessary part of professional development.

This review does not include research based on the HFEA Register of Information.

4.2. Background

- 4.2.1. In 1990 there was significant ethical uncertainty about the status of a human preimplantation embryo. Research on the embryos raised concerns not only about the embryo but also about the implications for individuals and society should embryos that have been used for research also be used for treatment. Thus legislation placed restrictions on research. While the Act has allowed the UK to play a leading role in embryo-based research, difficulties have now arisen where the scope of the legislation is not defined.
- 4.2.2. The HFEAct defines the embryo based on scientific knowledge that has developed rapidly. It now becomes necessary to review the definition so that the scope of the legislation is appropriate.
- 4.2.3. Many embryos that were initially stored for the purpose of clinical treatment are no longer required by the patients. These embryos are a valuable resource for research that would benefit future patients. For patients who want to donate their embryos for research, the current legislation makes this donation very difficult.
- 4.2.4. There is now significant overlap in the considerations required by the HFEA in approving a research licence application and the considerations of the Research Ethics Committee. These need to be revised to avoid duplication.
- 4.2.5. Many of the processes in IVF treatment may influence the quality of the embryo. Thus every stage of the clinical process is potentially within the scope of the research restrictions. The HFEAct prohibits an embryo created under a research licence from being used in treatment, effectively prohibiting some clinical research. This has a detrimental impact on innovation and research to develop improvements in clinical embryology.
- 4.2.6. A problem has been identified in relation to the training of clinical embryologists. The legislation requires specific consent from patients for the use of their gametes or embryos for the purpose of training. Again it is the lack of definition of the scope of the term training that has the potential to cause significant disruption to service provision should it be challenged legally.

4.3. Relevant Sections of HFEAct

- 4.3.1. Research on human embryos can only be carried out with a Research Licence provided by the HFEA (Section 11 and Section 15).
- 4.3.2. Sections 3 and 4 state the “*Prohibited procedures*” involving embryos and gametes.
- 4.3.3. Section 3ZA sets out the embryos and gametes that are “*permitted*” for use in treatment.
- 4.3.4. Section 15(2) gives power to the HFEA to decide the information to be recorded and retained about research.
- 4.3.5. Section 15(4) HFEAct 1990. “*No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such research.*”
- 4.3.6. Schedule 3 paragraph 2 (1) states “*a consent to the use of any embryo must specify one or more of the following purposes- (c)use for the purpose of any project of research*”.
- 4.3.7. Schedule 2 paragraph 3 (5) requires the HFEA to be satisfied that the use of embryos is necessary for the purpose of the research.
- 4.3.8. Schedule 2 paragraph 3A (1) requires the HFEA to assess whether the research activity is “*necessary or desirable*”.
- 4.3.9. Schedule 2 paragraph 3A (2) (a) – (h) sets out the wide-ranging principal purposes for which research is permitted.

4.4. Other relevant legislation

- 4.4.1. Embryos and gametes are excluded from regulation under the Human Tissue Act 2004.
- 4.4.2. UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research in the UK. HFEA licensed research must be compliant with these principles. The HFEA has cooperation agreements with the HRA (Section 9.18).²⁰

4.5. Relevant HFEA documentation

- 4.5.1. The consent for treatment forms (i.e. [WT and MT](#)) include a section to record consent to the use of gametes or embryos for training purposes.
- 4.5.2. Chapter 22 of the Code of Practice (COP) gives detailed requirements of the consent process, information to be given to the donor and the management of the research. (<https://portal.hfea.gov.uk/media/it1n3vpo/2022-07-01-code-of-practice-2021.pdf>).
- 4.5.3. The HFEA applies 89 standard research licence conditions. <https://portal.hfea.gov.uk/media/bqpbvjyk/standard-licence-conditions-gb-1-july-2022-onwards-research-licences.pdf>

²⁰ https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf.

4.6. Basic science research

This section considers scientific research where embryos will not be used for treatment. There are 103 centres licensed for treatment in the UK, and 9 centres with HFEA research licences. Only 4 centres have both treatment and research licences. Other researchers are dependent on the donation of embryos from clinics that only have treatment licences.

4.6.1. Patient perspective

Several studies have demonstrated that patients are willing to donate their surplus embryos to research. Despite this, most surplus embryos are discarded because of the regulatory difficulties in donation. The current situation is limiting patient choice.

4.6.2. Researcher perspective

- 4.6.2.1. Researchers in this field are targeted by those who are fundamentally opposed to embryo research. Working within an approved HFEA research licensed clinic provides some protection against legal challenge. The system of research licensing could be improved but must be retained.
- 4.6.2.2. The lack of availability of human embryos for research is a major roadblock to scientific development. The HFEA interprets that the consent taken must be specific to the individual research project rather than the broad “Principal Purposes” in Schedule 2 paragraph 3A (2). This causes prohibitive administration problems as the person taking consent must have detailed knowledge of the science of the project. Where the research and treatment centres are distinct, the ability to comply with the required consent procedures is limited. The HFEA’s interpretation also requires that a research licence must specify the precise scientific objective. Thus, if the centre has more than one objective for the use of donated embryos, a separate research licence must be approved. This is unnecessarily bureaucratic, uneconomical, and inefficient.
- 4.6.2.3. The process of obtaining consent for donation of embryos for research needs Research Ethics Committee (REC) approval. Many of the HFEA licence conditions duplicate those of REC e.g. serious adverse events and reactions that must be reported to the HFEA are also reported to REC, or differs from REC guidance e.g. the licence condition that requires that “The centre must ensure that a designated individual, who is not directly involved in the patient’s treatment is available to discuss with the patient the project of research and the possibility of donating material to the project.”
- 4.6.2.4. The process of applying for an HFEA Licence is given in <https://www.hfea.gov.uk/about-us/applying-for-a-research-licence/>. This includes peer review, a fee, an inspection, and review by the Licence Committee. The justification for this complex process is unclear. The HFEA expects to complete 90% of the applications within 4 months. For comparison, REC is required to give an opinion within 60 days.
- 4.6.2.5. The HFEAct defines an embryo but it does not define what is not an embryo. This was not a problem in 1990 but scientific developments require this further definition e.g. are cells grown from an induced



pluripotency stem cell line that have molecular embryonic features covered by the HFEAct? This needs clarification.

- 4.6.2.6. There are arguments to support the potential scientific benefit of culturing embryos for more than 14 days. To future-proof the legislation, it is appropriate to consider giving the Secretary of State the ability to make regulations to change this time limit if appropriate.
- 4.6.2.7. Basic science research is often a collaborative approach between more than one laboratory, such that differing expertise is applied. Legislation requires all research to be carried out on a licensed premises. This is inefficient and unnecessary.

4.6.3. Service provider perspective

- 4.6.3.1. Complying with the requirements for the donation of embryos for research requires each clinic to arrange and fund local agreements and approvals e.g. local REC approval and staff to take consent. There may be no direct benefit for the clinic arranging the donation (other than the clinic with the research licence), thus effectively inhibiting embryo donation. These burdensome procedures need to be simplified.
- 4.6.3.2. The requirement for consent to the use of embryos in training is ambiguous in the legislation. An embryologist or clinician who has not completed professional accreditation is considered to be 'in training'. It is unlikely that legislation intended to restrict professional training or require that patient consent is needed for the procedures to be carried out by accredited staff only.
- 4.6.3.3. Patients should be made aware of individual clinic procedures related to training e.g. a teaching hospital may have medical students whilst a small private clinic may only have fully accredited staff. This should be clear in clinic specific information but consistent with other healthcare provision, and should not require written consent.

4.6.4. Legal perspective

Legal challenges have been made to the regulatory process of a research licence award rather than against an individual research project. Simplification of these processes may avoid future such challenges.

4.6.5. Ethical perspective

- 4.6.5.1. The HFEAct reflects the majority of society's opinion that embryo research is ethically acceptable.
- 4.6.5.2. The principles underpinning ethically acceptable medical research refer to individuals and society. Although the embryo has a unique status, many consider that the preimplantation embryo is a group of cells not an individual. It may now be appropriate to adjust the focus of ethical concern onto the patients that wish to donate the embryos rather than simply the embryos.
- 4.6.5.3. The HFEAct requires the HFEA to decide if the proposed research is "*necessary or desirable*" for one of the specific principal "*purposes*". REC has a wider remit and must consider the benefit or harm to individuals or society in its review of a research application. Nonetheless, these considerations are similar. REC must also approve participant recruitment process, participant information sheets and consent forms. Some regulatory requirements assigned in the HFEAct for the HFEA are now duplicated by REC. Simplification of research regulation could be achieved if it were decided that REC consideration primarily related to the donors, whilst the HFEA research licence confirmed that the purpose of the research is consistent with one of the permitted "*principal purposes*" of research specified within the HFEAct and that the use of human embryos is necessary for that purpose.
- 4.6.5.4. The procedures required by the scientists that involve manipulating these cells are determined by the scientific aims. Since the HFEAct already prohibits procedures on embryos that are ethically unacceptable,

it is difficult to justify the need for any further regulatory oversight of the detailed scientific procedures that would be used during the research e.g. genetic manipulation of research embryos raises no more ethical concerns than the study of embryo nutritional requirements. A requirement for the HFEA to consider only what is legal in relation to the scientific methods would simplify the licence application process.

- 4.6.5.5. There are strong arguments to support the establishment of an Embryo Research Bank. This would be beneficial for the patients who wish to donate their embryos, and scientists who have approved research projects. It is anticipated that the information and consent forms that will be used will be approved by an appropriate REC. Consideration should be given to allowing embryo donors to specify some exclusion criteria.

4.6.6. **Political perspective**

Embryo research in the UK has a leading international profile. It is important that this is maintained.

4.7. **Clinical embryology research and training**

4.7.1. **Patient Perspective**

- 4.7.1.1. Best patient care requires properly designed clinical trials. Patients are disadvantaged in the UK because legislation does not support such trials under the HFEAct.
- 4.7.1.2. Patients are often willing to be recruited into clinical trials and many have been participants in studies where the research does not involve the embryo e.g. trials of medication prior to egg collection. Participation is voluntary, requires consent and is subject to REC approval.

4.7.2. **Researcher and Service Provider perspective**

- 4.7.2.1. There is no clear regulatory pathway in the HFEAct for clinical research e.g. the study of pregnancy rates using different embryo biopsy needles. Ideally, such a study should be a randomised controlled trial with REC approval. This is clearly both research and treatment. The HFEAct does not consider this type of clinical research and it is not clear if it is permitted. This uncertainty is inhibitory to good research and innovation.
- 4.7.2.2. The consequence is that clinics have adopted less rigorous and statistically weak comparisons e.g. retrospective comparison of unrandomised use, or based their practice on research outside the UK, or adopted practices that have not been subject to appropriate assessment.

4.7.3. **Legal Perspective**

Where there is legislative void (e.g. clinical research is not considered), this will result in an inevitable risk of legal challenge.

4.7.4. **Ethical Perspective**

- 4.7.4.1. There are established procedures for innovation and the introduction of a pharmaceutical product or medical device in clinical practice. These

are regulated by HRA and MHRA. They involve phased procedures from a small Phase 1 study to obtain early safety data, to Phase 3 involving a multi-centre study in a wider group of patients to compare with existing technology. Examples in the fertility sector would include embryo visualisation chambers (e.g. Embryoscope) or embryo freezing technologies. Where the HFEAct inhibits these established research pathways, revision is needed.

4.7.4.2. There is concern at the suggestion to introduce a new specific regulatory process by the HFEA for clinical research based on Sandbox regulatory structures in IT and business. There is already an ethically accepted and proven regulatory pathway for medical research. The introduction of a new regulatory pathway requires an explanation of why current procedures are inadequate, and justification that a new system would be an improvement.

4.7.5. **Political Perspective**

The HFEAct was drafted without consideration of the need for clinical embryology research. It is likely that this was an oversight that now needs to be corrected. IVF was pioneered in the UK and good quality clinical research is vital if the UK is to retain its international position in this field of medicine.

4.8. **Proposed changes to the HFEAct**

4.8.1. **Basic science, non-clinical, research**

4.8.1.1. The requirement that an HFEA research licence is required for basic science embryo research should be retained. To simplify and avoid duplication with REC, award of such a licence could be limited to the following considerations,

- The research must be within the “principal purposes” stated in the HFEAct.
- If the project had been supported by expert independent peer review (as expected by REC), no further peer review by the HFEA should be required.
- Inspections for the purpose of auditing embryos in storage for research should be permitted but would not be required routinely.
- In relation to embryo donation, the project must have approval of an HRA constituted Research Ethics Committee.

4.8.1.2. The requirement that the HFEA must determine if a research activity is “necessary or desirable” should be removed.

4.8.1.3. The requirement that research be carried out only on the licence holder premises should be reviewed.

4.8.1.4. The definition of an embryo in the HFEAct must also include what is not an embryo. Research on cells that are not defined to be an embryo, would not need an HFEA research licence.

4.8.1.5. The consent requirements should clarify that consent is for the “principal purposes” within the legislation and not the individual projects of research. Such a change could permit a more generic consent to enable the establishment of an Embryo Research Bank (virtual or physical) for distribution of embryos to those with a valid research licence.

4.8.1.6. The research prohibitions within the HFEAct e.g. culture time limit, should remain but with the ability of the Secretary of State to make amendments if indicated.

4.8.1.7. Where the HFEAct prescribes regulatory procedures for research that are the same as those required by REC and the Health Research Authority (HRA), legislation should be simplified. The HFEA should not be required to duplicate decisions about research that have been made by REC and HRA.

4.8.1.8. Legislation should require that the HFEA’s regulatory process, in particular the timescale for reaching decisions, should be consistent with practice by other research regulators. Reducing complexity and removing duplication could make this easier for the HFEA to achieve.

4.8.2. **Clinical research**

4.8.2.1. Clinical research, including research in clinical embryology, should be permitted under a treatment licence if:

- The embryos are “permitted” embryos, and,
- The research project is approved by an HRA constituted REC.

4.8.3. **Training**

There should not be a requirement in the HFEAct to obtain consent for training where that training is part of professional development.

Chapter 5

The Person Responsible and Licence Holder

5.1. Aims

- 5.1.1. To ensure that accountability for compliance with the provisions in the HFEAct is consistent with other areas of healthcare.
- 5.1.2. To ensure that the role of the Person Responsible (PR) reflects the separation of managerial and professional structures in organisations in the healthcare sector in 2023 and going forward.
- 5.1.3. To ensure that the duties of the PR under the HFEAct are realistic and deliverable.

5.2. Background

- 5.2.1. The HFEAct grants a licence to the Licence Holder (LH). The primary point of contact for the regulator (HFEA) is the Person Responsible (PR). This system was appropriate in 1990 when fertility clinics were small, and the managerial structure was consistent with a single clinical leader. Now many clinics are within much larger organisations either within an NHS Trust or a private company.
- 5.2.2. The way in which the role of the PR is defined is too vague and too broad. The PR duties are extensive, covering both managerial and professional accountability. It is generally acknowledged that, for many clinics, this is not achievable by one person. Furthermore, some duties of the PR require the ability to fund developments, and this may not be within the control of the PR.
- 5.2.3. There is no formal procedure for appointing the PR, but they must be approved by the HFEA and complete an HFEA training programme. This is a unique system in healthcare management and is no longer consistent with expected quality assurance procedures. Many fertility clinics have now established Quality Management systems with UKAS accreditation and appropriately trained managers. This could be used as the basis of an alternative model.
- 5.2.4. The perceived liability of the PR is that they carry a potential criminal liability for non-compliance with the HFEAct and regulatory requirements. Whilst it was clarified that regulatory liability under the Act commonly lands on the PR, *criminal* liability under the Act lands on whomsoever commits the offence (which might happen to be the PR, but they are not liable solely by virtue of their statutory role)²¹.

5.3. Relevant Sections of the HFEAct

- 5.3.1. Section 16 relates to the grant of a licence and the required qualifications and experience of the PR. It also requires the HFEA to determine that “*the*

5.1.1. ²¹ 200304050 D5, Neutral Citation Number: [2004] EWCA Crim 785, IN THE SUPREME COURT OF JUDICATURE, IN THE COURT OF APPEAL (CRIMINAL DIVISION) ON APPEAL FROM CROWN COURT AT SOUTHAMPTON HHJ BOGGIS QC].

applicant is a suitable person to hold a licence” and, if it “is satisfied that the character of that individual is such as is required..” (16(2) (cb)).

- 5.3.2. Section 17 of the HFEAct states the duties of the PR.
- 5.3.3. Section 18 (2) *states that the authority may revoke a licence if ..(b) “it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17, (c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence, (g) “it is satisfied that the person responsible ceases to be a suitable person to supervise licence activities.”*
- 5.3.4. Sections 19, 19A, and 19C sets out the procedures in relation to licensing decisions made to the PR and LH.
- 5.3.5. Many other sections refer to decisions which must be made by or given to the PR.

5.4. Other Relevant Legislation and regulation

- 5.4.1. The Health and Social Care Act 2008 is the legislation under which the CQC was established. Since the HFEA undertakes duties that would otherwise be carried out by the CQC, it is relevant to understand accountability under that legislation. The licence is granted to a ‘registered manager’. The assessment process is given in <https://www.cqc.org.uk/guidance-providers/registration/registered-manager-application/apply-new-registered-manager>.
- 5.4.2. The Human Tissue Act 2004 is the legislation under which the HTA was established. Since the HFEA undertakes duties that would otherwise be carried out by the HTA, it is relevant to understand accountability under that legislation. The licence is granted to a ‘designated individual’.
- 5.4.3. The APBI (Association of British Pharmaceutical Industry) prescribes the duties and required qualifications of the Qualified Person that must then be approved by the MHRA. <https://www.abpi.org.uk/careers/working-in-the-industry/manufacturing-and-supply/quality/qualified-person-qp/>.

5.5. Relevant HFEA documentation

- 5.5.1. The HFEA provides the key behaviours and role description of the PR. <https://www.hfea.gov.uk/media/2993/person-responsible-role-description-and-key-behaviours.pdf>.
- 5.5.2. Chapter one of the Code of Practice (COP) relates to the PR.
- 5.5.3. The HFEA specifies the process for appointment of a PR including a required assessment document. <https://www.hfea.gov.uk/about-us/applying-for-a-clinic-licence/>. The LH is usually expected to be a person with managerial responsibility in the organisation.
- 5.5.4. COP guidance expects that the PR “*should have enough understanding of scientific medical legal social ethical and other aspects of the centre’s work to be able to supervise its activities properly*” and that the PR “*has the managerial authority and capability necessary to perform their duties.*”

5.6. Service Provider Perspective

- 5.6.1. The PR role has become synonymous with a leadership position within this healthcare sector. Whilst not intending to diminish the PR responsibilities, this needs to be reviewed. The regulatory functions of the PR are more consistent with those of a quality manager (QM) than a leader of the service provision. A

QM must effectively be independent of the service providers so that activities can be challenged when necessary. In order to establish a cultural change in the role of the PR, consideration should be given to changing the name.

- 5.6.2. The provision of fertility services includes several duties, some of which may be conflicting e.g. the provision of contracted NHS services, the provision of individual private care contracts, financial control, compliance with regulations, and maintaining professional standards. In most clinics, there will be several individuals working within a formal management system to carry out these duties. The HFEAct does not reflect this complexity in its assigned duties for the PR.
- 5.6.3. In relation to their individual patient care, professionals are accountable for their practice to their professional regulators. Where there are systemic problems, this is likely to compromise care for many patients. In such circumstances it is expected that the organisation may be accountable. This needs to be reflected in the legislation.
- 5.6.4. NHS management systems provide separate structures for individual professional accountability and the organisational management. The current PR role combines both professional and managerial accountability. Thus, the HFEAct is not consistent with general healthcare structures within which the PR may also be working. Under a QM system, there should be a management structure that provides leadership and accountability for each profession. The quality manager would be responsible to ensure that there is a structure, but would not be responsible for professional activities.
- 5.6.5. In relation to their individual patient care, professionals are accountable for their practice to their professional regulators. Where there are systemic problems, this is likely to compromise care for many patients. In such circumstances it is expected that the organisation may be accountable. This needs to be reflected in the legislation.
- 5.6.6. The decision that the HFEAct requires the HFEA to make a subjective assessment about the suitability and character of the PR is archaic and no longer consistent with regulation in a complex healthcare setting. Consideration could be given to the objective procedures adopted elsewhere e.g. CQC requires a personal reference, Disclosure and Barring Service check and criminal records check. It is helpful for the HFEA to provide guidance on the duties of the PR in relation to the legislation although this guidance is provided for all practitioners in the COP.
- 5.6.7. The experience, particularly in large clinics, is that the role of the PR is too extensive and complex for a single individual. Thus, the ability to appoint a deputy PR would spread the workload and enable succession training.
- 5.6.8. In some healthcare settings, there is corporate liability for regulatory non-compliance. If a revised legislation introduced an option for the regulator to impose fines, this should be a corporate not PR liability.

5.7. Legal Perspective

It is essential that there is an individual(s) or organisation that is accountable for compliance with the regulatory requirements. If the duties prescribed in legislation are neither realistic nor deliverable, non-compliance is unlikely to be upheld if challenged in court.

5.8. Proposed Changes to HFEAct

- 5.8.1. The duties of the PR prescribed in the HFEAct should be realistic and deliverable taking account of the various, and potentially conflicting, professional, and managerial structures within fertility clinics.
- 5.8.2. The requirement for the HFEA to assess the suitability and character of the PR should be removed from the HFEAct.
- 5.8.3. There should be the option for there to be a deputy PR should the workload in an individual clinic indicate that this is needed.
- 5.8.4. Serious consideration should be given to fundamentally changing the role and name of the PR to facilitate a cultural change and be consistent with that in other healthcare regulatory systems e.g. CQC or ABPI.

Chapter 6 **Enforcement and Sanctions**

6.1. Aims

- 6.1.1. To protect patients undergoing licensed fertility treatment by providing appropriate enforcement and sanctions to ensure compliance with the HFEAct whilst ensuring that they do not restrict good practice.
- 6.1.2. To ensure that enforcements and sanctions in the HFEAct are appropriate to the non-compliance and are proportionate and not unduly punitive.
- 6.1.3. To ensure consistency with the enforcements and sanctions that are used in other healthcare sectors.

6.2. Background

- 6.2.1. In a democracy, the purpose of legislation is to provide a governing framework that reflects the opinions of society. Where legislation prohibits an action, it may be appropriate to apply criminal sanction for non-compliance. The HFEAct prohibits some practices in relation to embryos and applies criminal sanction. Compliance with these prohibitions has been achieved without the need for prosecution.
- 6.2.2. Legislation may also set standards for professional practice, either directly or by empowering standards to be set by a regulator. Enforcing and applying sanctions for non-compliance with a regulator's requirements is more difficult. Both the HFEA and clinics have faced significant problems and review is needed.
- 6.2.3. There are now multiple legislative and regulatory requirements for medical practice. Consistency of both enforcement and sanctions is necessary to avoid overregulation and potential for contradiction, whilst retaining public confidence and patient safety.

6.3. Relevant Sections of the HFEAct

- 6.3.1. Section 41 gives the Offences and Sanctions. The sanctions are imprisonment <10yr and/or fine as a consequence of contraventions of serious prohibitions, for example,

- Section 3(2) Transfer an embryo or gamete that is not permitted.
- Section 3A Keep or use embryo after primitive streak (14 days), place embryo in animal, keep or use any embryo in which regulations prohibit keep or use.
- Section 4A (1) Store gametes without a licence.
- Section 3(3) Do anything which cannot be authorised by a licence.

6.3.2. Section 41(2) and 41(3). The sanctions are <2years imprisonment and/or fine (summary conviction <6months and/or fine) as a consequence of contraventions of regulatory requirements, for example,

- Section 3(1) Person creates an embryo without a licence.
- Section 3(1A) Person keeps embryo without licence.
- Section 3(1B) Person distributes embryo without licence.
- Section 4(1)(a) Person stores gametes without a licence.
- Section 4(1)(b) Person uses gametes for treatment of woman without a licence.
- Section 4(1A) Person procures, tests, processes, distributes gametes without a licence.
- Section 4(3) Person places gametes in woman without a licence.
- Section 24(5D)
 - Person fails to provide information held in accordance with a licence as required under Directions.
 - Provides false or misleading information in relation to the grant of a licence.
 - Disclosed information in contravention of section 33A.
 - Disclosure of any information that is not allowed.
 - Fails to comply with sections 19B(3)(a) or 20B(3)(e).
 - Failure to give evidence or documents if required in regulations about a procedure in relation to the determination of applications under the Act.
 - Gives or receive money for gametes that is not authorised.

6.3.3. Non-criminal sanctions include the following.

- Section 16: the HFEA may or may not grant a licence.
- Section 18 and 18A: the HFEA may revoke or vary a licence if the HFEA is “satisfied” that a circumstance described in any of sections 18(2)(a) to (f) has been met.
- Section 19C: the HFEA can revoke or immediately suspend a licence if it has reasonable grounds to suspect that there are grounds to revoke a licence.
- Section 13: the HFEA has considerable discretion under the HFEAct to determine what, if any, additional conditions should be attached to a centre’s licence.

6.3.4. Schedule 3B relates to the powers given to the HFEA for Inspection, Entry, Search and Seizure.

6.4. Other Relevant legislation

Below is a selection of the other regulations which may apply sanctions to those providing licensed fertility treatment services. provision.

- 6.4.1. Professional organisations may suspend or revoke a licence to practice/registration.

- 6.4.2. General medical Council .²²
- 6.4.3. Nursing and Midwifery Council ²³
- 6.4.4. Health and Care Professions Council²⁴
- 6.4.5. Care Quality Commission ²⁵
- 6.4.6. Advertising Standards Authority ²⁶
- 6.4.7. Human Tissue Act 2004 ²⁷
- 6.4.8. The Health and Social Care Act 2008 (Regulated activities),²⁸
- 6.4.9. The Sentencing Act 2020 gives a standard scale for fines applied by courts.²⁹

6.5. **Patient, partner, donor, family perspective**

- 6.5.1. Those receiving treatment, donating gametes, or participating in research expect that clinics will comply with both legislation and regulation. It is also expected that proportionate sanctions will be imposed if non-compliance is found. It is not expected that sanctions would have a negative impact on their treatment.
- 6.5.2. People may make a complaint about their individual care and this process is set out by the HFEA (<https://www.hfea.gov.uk/contact-us/making-a-complaint-about-a-fertility-clinic/>). This is separate from enforcement and sanctions considered by the HFEAct, but compliance with regulation would be taken into consideration in relation to resolution of an individual complaint.
- 6.5.3. A sanction that might be applied to a service provider, must take account of the implications for patients under their care. Thus, the relative harm of noncompliance with regulation must be balanced against the consequences of the sanction e.g. closing or restricting a service or imposing a fine that compromised the service, may result in poor care or severe disruption to patients' treatment.

6.6. **Legal perspective**

- 6.6.1. Legislation should be sufficient to ensure that regulators have powers to ensure compliance with their required procedures so that the interests of both patients and society are upheld.
- 6.6.2. Where legislation prescribes enforcement and sanctions, these must be appropriate to avoid the risk of challenge by any of those affected.
- 6.6.3. The HFEAct was enacted because of specific political concern related to the human preimplantation embryo. Recent debate has suggested that the HFEAct should be revised to reflect concern for the interest of patients. The HFEAct already contains some elements of patient protection, many of which

²² <https://www.gmc-uk.org/concerns/information-for-doctors-under-investigation/our-sanctions>.

²³ <https://www.nmc.org.uk/concerns-nurses-midwives/hearings/sanctions-info/#:~:text=If%20a%20panel%20of%20the%20Fitness%20to%20Practise,public%20confidence%20in%20the%20professions%20and%20the%20NMC>

²⁴ <https://www.hcpc-uk.org/resources/policy/sanctions-policy/>

²⁵ <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/offences>

²⁶ <https://www.asa.org.uk/codes-and-rulings.html>

²⁷ Section 8(3) gives the penalties for a person guilty of an offence.
<https://www.legislation.gov.uk/ukpga/2004/30/section/8>

²⁸ Section 23 states the penalties that may be applied.
<https://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents>

²⁹ <https://www.legislation.gov.uk/ukpga/2020/17/section/122/enacted>.

are duplicated in other healthcare regulation. Further specific legislation related to patient care requires evidence of necessity.

6.7. Service provider perspective

- 6.7.1. The primary focus of clinics must be on the safety and welfare of patients and potential children. Sanctions are supported where this is found to be compromised. Where clinics face sanctions for actions that have no bearing or effect on, or may even compromise patient safety or welfare, these must be justified.
- 6.7.2. There is a significant burden for clinics in ensuring compliance with multiple regulatory processes from different organisations.
- 6.7.3. A regulatory requirement to adhere to fixed protocols may make compliance easier for the clinic to implement and the regulator to confirm. Conversely, where standards have been set that are particularly rigid, this can inhibit the development of innovation and improvements to patient care.
- 6.7.4. The withdrawal or suspension of a licence can be a consequence of failure to comply with any of the HFEA licence conditions including COP guidance. Therefore, clinics must comply with the COP related to the conduct of their professional activity. If the COP conflicts with professional guidance or other legal requirements, this will effectively penalise good medical/embryology/nursing/counselling practice. There is an important distinction between guidance and a legal requirement. Where legislation requires a regulator to provide guidance on medical practice, this should be, in relation to enforcement, consistent with guidance provided elsewhere e.g. NICE.
- 6.7.5. A criminal sanction sets a high bar for compliance. Section 20 provides a right to reconsideration of a licensing decision and section 20(A) requires the HFEA to have an Appeals Committee. If legal advice is needed, an appeal can be very expensive and slow and not available for most NHS clinics. This is a disincentive to challenge licence decisions even if they are not considered to be appropriate by the clinic.
- 6.7.6. Where an individual clinic fails to comply with regulations that are accepted by other clinics, this is an indication of potential bad practice, and it may be justified to apply sanctions.
- 6.7.7. Not all regulatory requirements are inevitably or obviously correct and it is sometimes appropriate to challenge the regulation. Where non-compliance has been found to be a consistent problem over several clinics, consideration should be given to the possibility that the regulation may need to be reviewed.

6.8. Ethical perspective

- 6.8.1. The government on behalf of society passed legislation to reflect concerns about the creation, use and storage of human embryos. Some absolute prohibitions have been applied and it is ethically justified that the legislation also provides the means whereby these are upheld.
- 6.8.2. Improvements can be made by use of sanctions that prevent or prohibit bad practice. Conversely, punitive sanctions can have the opposite effect by inhibiting change and innovation where this could improve patient care. From the ethical perspective that considers both benefit and harm, these outcomes must be balanced.

- 6.8.3. Patient autonomy is limited by the HFEAct. There is a professional responsibility to respect patient autonomy. Enforcement and sanctions are of concern where a more flexible approach would not be harmful and could be beneficial for an individual patient.
 - 6.8.4. The HFEA have proposed that they should have powers to impose fines for non-compliance. Although potentially an attractive option, there are ethical concerns. The amount of fine should be appropriate to the breach of regulations and, to ensure equity, should be consistent with fines imposed for similar non-compliances in other healthcare sectors. A fine will have different consequences on dissimilar service providers e.g. a private clinic may easily pay a fine whilst an NHS service might be seriously compromised.
 - 6.8.5. The ability to challenge or appeal is vital if the regulatory system is to be fair and equitable.
- 6.9. Proposed Changes suggested for HFEAct**
- 6.9.1. Criminal sanctions should be reserved for very serious breaches of the regulations. The criminal sanctions for non-compliance with the regulatory process should be removed.
 - 6.9.2. Sanctions applied for non-compliance with regulator processes should be consistent with sanctions in other health care provision.
 - 6.9.3. The option for introduction of fines imposed by the HFEA for regulatory non-compliance should be considered, but must include evidence of the potential to improve compliance without compromise of patient care.
 - 6.9.4. The appeal process needs to be revised and simplified to improve the ability to challenge regulatory non-compliance decisions.

Chapter 7

The HFEA Register

7.1. Aims

- 7.1.1. To ensure that patients understand the data that is retained on the Register, its purpose and who has access to it.
- 7.1.2. To ensure that the data on the Register is compliant with the Data Protection Act 2018.
- 7.1.3. To ensure that there is appropriate access to data on the Register.

7.2. Background

- 7.2.1. The Warnock Report considered that there was a need for the HFEA to keep a Register for two main reasons. The first was so that children would be able to obtain some information about their genetic origin. The second was to collect information about service provision. There was very little scientific or clinical information available about the licensed services in 1990, whereas there is now significant evidence of practice methods and treatment outcomes.
- 7.2.2. There has been a limited revision of the data held on the Register since 1990. The data items currently collected are given in the Data Dictionary. https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.hfea.gov.uk%2Fmedia%2F1whgthz4%2F2021-08-16-uk-art-data-dictionary-v3_7.xlsx&wdOrigin=BROWSELINK. This data includes identifying information about patients, donors and children born from treatment, information about the service provider, details of the treatment provided, and treatment outcomes. The Register keeps a record of gametes and every embryo in storage.
- 7.2.3. The BFS reviewed each data field collected for the Register. This review was based on the principles that were later enacted in the Data Protection Act 2018. The BFS recommendations were published in 2013. [<https://pubmed.ncbi.nlm.nih.gov/23517429/>]. The McCracken Report recommended (Recommendation 6) that these BFS recommendations be adopted. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216947/Justin_McCracken_report_of_review_of_HFEA_and_HTA.pdf. The HFEA's response was given in <https://www.hfea.gov.uk/media/1512/ifq-recommendations-for-data-submission-and-publishing.pdf>. Minutes of the related Authority decisions are <https://www.hfea.gov.uk/media/1590/january-2015-minutes.pdf>. The HFEA's new data submission process (PRISM) went live in late 2021.

7.3. Relevant Sections of the HFEAct

- 7.3.1. Section 31 of the HFEAct 1990 relates to the Register of Information. <https://www.legislation.gov.uk/ukpga/1990/37/section/31>. It effectively enables the HFEA to collect any information about the provision of licensed treatments.



7.3.2. Sections 33A and 33B relate to the requirements for disclosure of information from the Register.

7.4. Other Relevant Legislation

7.4.1. The Human Fertilisation and Embryology (Disclosure of information for Research Purposes) Regulations 2010.

<https://www.legislation.gov.uk/ukxi/2010/995/contents/made>.

7.4.2. The Data Protection Act 2018 includes the principles that protect personal data.

<https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>. This includes the requirements that the information be:

- used fairly, lawfully, and transparently.
- used for specified, explicit purposes.
- used in a way that is adequate, relevant, and limited to only what is necessary.
- accurate and, where necessary, kept up to date.
- kept for no longer than is necessary.
- handled in a way that ensures appropriate security, including protection against unlawful or unauthorised processing, access, loss, destruction or damage.

7.5. Relevant HFEA documentation

Data collection is considered in Chapter 32 in the HFEA Code of Practice. This covers the procedural and governance issues related to the recording of required information, its storage and upload to the HFEA Register.

7.6. Patient, partner, donor and donor conceived perspective

7.6.1. Patients are generally aware that medical data is held centrally as well as in their clinical records. Most patients are unaware of the specific personal data that is held on the Register and there is little evidence on their views about access to the Register. One study indicated that patient knowledge of the Register was very limited.³⁰

7.6.2. Data that is required for the purpose of genetic tracing is held on the Register. This relates to conceptions where donated gametes or embryos were used. Donor conceived individuals may request this information from the age of 18. It is critical for those for whom this is relevant that the data is accurate, safe and accessible when required.

7.7. Access to the Register

7.7.1. HFEA

7.7.1.1. The HFEA audits the data on the Register, and this is published in an annual report. This primarily relates to a summary of service provision and treatment outcomes.

<https://www.hfea.gov.uk/about-us/publications/research-and-data/>.

7.7.1.2. The HFEA also uses selected analysis from the Register data to provide outcome data for individual clinics. This is presented as a benefit for patients when choosing a clinic to attend, but more thorough and detailed analysis is needed for accurate clinic comparisons.

7.7.1.3. The HFEA accesses the Register to provide answers to government questions and for Freedom of Information enquiries.

³⁰ BMJ Open 2019;9:e026469. doi: 10.1136/

7.7.1.4. The HFEA holds the Register and thus is the only body that has access to the entire dataset including identifying information about gamete donors and those receiving treatment. This is required for genetic tracing by those conceived from treatment using donated gametes.

7.7.2. Non-identifying data

7.7.2.1. Access to the anonymised data is freely available. <https://www.hfea.gov.uk/media/2682/guide-to-the-anonymised-register.pdf>. The data is presented in a format that protects against the identification of individual patients by suppressing or aggregating some fields e.g. age is given in age ranges not the precise age. This is useful but may limit detailed analysis.

7.7.3. Identifying data

7.7.3.1. Regulations in 2010 permit the disclosure of Register data for the purpose of research if the patient has given consent to the disclosure for the purpose of research.³¹ To access this more precise information, a request is made to the HFEA Register Research Panel (RRP) and there must be approval of a Research Ethics Committee (REC). The principles underpinning the RRP considerations are not published. There may be some overlap in decisions made by the RRP and REC. There is a fee for the provision of this type of information. The Regulations do not permit the disclosure of either identifying or non-identifying information that relates to the provision and use of donor gametes for treatment, which limits potentially important audit of gamete donation.

7.7.3.2. The HFEAct requires patient consent for disclosure of data held on the Register for research. There is a precedent by which researchers may apply for access to identifiable information on other healthcare databases, even without patient consent because it is recognised that access may be justified in the public interest.³²

7.7.4. There have been requests for additional data to be collected on the Register specifically for research i.e. for hypothesis driven study. An example is the comparison of culture media that is used in treatment. This is not prohibited within the HFEAct because of the very wide remit given to the HFEA to determine the data collected but extending this activity to the HFEA would require consideration of resources and funding. Independent scientific review would be needed to determine if the use of the Register would be the optimal method to address the research question. This would be a new function for the HFEA and needs clarification in the HFEAct.

³¹ The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 Section2(3). <https://www.legislation.gov.uk/uksi/2010/995/made>

³² <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>.



7.8. Service Provider Perspective

- 7.8.1. The retention of a national database of fertility treatments is supported by the service providers as being an important resource.
- 7.8.2. Maintaining the Register has been a significant burden for the HFEA, and the associated problems have placed commensurate and corresponding burden on clinics. There have been significant problems for clinics, particularly in relation to the transition from paper to digital related documentation.

7.9. Legal Perspective

- 7.9.1. There is a risk of legal challenge under the Data Protection Act 2018. Thus, there would be a benefit to be gained from an independent review of the data collected and stored to ensure compliance.
- 7.9.2. Consideration should be given to prescribing in the legislation more specific instructions for the information to be held on the Register. For example, Section 13(2) could be redrafted for specific purposes i.e.
 - 7.9.2.1. To provide objective evidence for inspection and licensing.
 - 7.9.2.2. To provide collated national data for service monitoring.
 - 7.9.2.3. To collect data required to establish legal parenthood and genetic identity.
 - 7.9.2.4. To carry out external, ethically approved and funded research.

This would facilitate the assessment of each data field collected for compliance with the Data Protection Act 2018.

- 7.9.3. The HFEAct's restrictions on access to the data is more limited than in other areas of healthcare. A review is needed to ensure that the legislation reflects current political intentions.
- 7.9.4. The new Surrogacy Bill proposed a Register of surrogacy treatments, many of which will be in HFEA licensed clinics. The implications of the overlap between this and the HFEA Register must be considered to be economic, efficient and effective.

7.10. Ethical Perspective

- 7.10.1. The retention of personal data on a central national database has the potential for ethical concern. This is addressed under the Data Protection Act 2018. <https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>.
- 7.10.2. The government has provided guidance related to the ethics of data collection. <https://www.gov.uk/government/publications/data-ethics-framework/data-ethics-framework-2020#how-to-use-the-data-ethics-framework>.
- 7.10.3. Access to healthcare databases does not always need Research Ethics Committee (REC) approval. (https://www.hrdecisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf). Where a database has been collected for the specific purposes of service evaluation or clinical audit, REC approval is not required. If data is collected solely for the purpose of hypothesis driven research, REC approval should be obtained prior to data collection.
- 7.10.4. It is important that patients can decide who has access to the medical data. The HFEAct requires each patient to make an 'opt-in' decision at the start of treatment for the use of their data on the Register. National data policy allows individuals to opt out of use of their data for research and planning purposes at any time after their treatment. <https://digital.nhs.uk/services/national-data-opt-out>. The rationale for these differences needs to be reviewed to ensure that policies are consistent with public opinions in 2023 and beyond.
- 7.10.5. It is important, particularly in this healthcare sector, that complete records are kept. Nonetheless there are circumstances where retention of identifying information should be reconsidered e.g. for those who did not

conceive and hence where tracing for genetic identity is not needed. To maintain a national database that identifies those who are infertile is not justified. Where the HFEAct requires the Register to collect identifying information, justification for the retention of all the identifying information needs to be reviewed.

- 7.10.6. Irrespective of whether consent for the use of data is an opt in or an opt out procedure, the consent given must include details of the use to which the data would be put. If such information is not provided, such consent may not be ethically acceptable.

7.11. Proposed Changes to the HFEAct

- 7.11.1. The Register must be compliant with the Data Protection Act 2018. The HFEAct should be reviewed to identify whether there is conflict with the legislations and, if so, should be resolved.
- 7.11.2. The HFEAct should be revised to give the HFEA specific indications for the collection of data for the Register.
- 7.11.3. The HFEAct and the Regulations should be reviewed to ensure that access to data on the register is consistent to access to other databases in the healthcare systems.

Chapter 8

Duplication of Regulatory Functions

8.1. Aims

- 8.1.1. To avoid duplication of regulatory requirements and procedures.
- 8.1.2. To avoid duplication of the provision of professional standards.
- 8.1.3. To reduce the financial burden on clinics and patients caused by over regulation.

8.2. Background

- 8.2.1. In 1990 IVF was a novel procedure and there were no related clinical or embryology standards. Thus the role was given to the HFEA to document standards.
- 8.2.2. In 2023 the landscape is very different, there are standards set by professional organisations for all aspects of fertility services. Although HFEA now generally defers to standards set by professional organisations, this is not reflected in the legislation. Thus, there is unnecessary duplication.
- 8.2.3. Clinics providing licensed fertility treatments are regulated by the HFEA not the CQC nor HTA. Nonetheless, there are similarities between the functions of the CQC, HTA and HFEA. The CQC and HTA do not set professional standards and the justification for this additional role for the HFEA in the HFEAct should be justified.
- 8.2.4. Care is needed to ensure that any extension of HFEA functions does not result in a further duplication of legislation and regulation.

8.3. Relevant Sections of the HFEAct

- 8.3.1. Section 8 of the HFEAct relates to the general functions of the authority.
- 8.3.2. Section 8ZA states that the functions must be carried out “*effectively, efficiently and economically.*”
- 8.3.3. Section 8C states that the authority may contract out its functions.
- 8.3.4. Section 8(1)(c) states that the HFEA shall “*provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so,*”
- 8.3.5. Section 11 gives the function to the authority to grant licences for treatment storage and research.
- 8.3.6. Sections 23 & 24 enable the HFEA to make Directions (delegated legislation).
- 8.3.7. Section 25 requires the authority to “*maintain a code of practice giving guidance about the proper conduct of activities carried on or in pursuance of a licence under this Act..*”. Section 25 (2A) (6) states that “*a failure on the part of any person to observe any provision of the code shall not in itself render the person liable to any proceedings but.... The authority may in considering where it has the power to do so whether or not to vary or revoke a licence take into account any observance of or failure to observe the provisions of the code.*”

8.4. Other Relevant professional standards and regulation

Some of the relevant other organisations/pieces of legislation are given below.

8.4.1. Professional Standards

- 8.4.1.1. General Medical Council (GMC) – Regulates doctors and their medical practice, and there is a dedicated subspecialty accreditation for Reproductive Medicine.
- 8.4.1.2. Nursing and Midwifery Council (NMC) – Regulates nurses' and midwives' clinical practice, and there are dedicated groups and documented standards specifically for fertility (for example the Senior Infertility Nurses Group and training logbook documents and pathways).
- 8.4.1.3. Health and Care Professions Council (HCPC) – Regulates health and care professions, including biomedical and clinical scientists (andrologists and embryologists), supported by a network of specialist teams, advisory committees and partners.
- 8.4.1.4. Genetic Counsellor Registration Board (GCRB) – Oversees the standards of practice in genetic counselling by systems of professional accreditation. In 2019 the GCRB register was transferred to the Academy for Healthcare Science (AHCS). GCRB members are included in the AHCS public register of Practitioners accredited by the Professional Standards Authority.

8.4.2. Legislation

Health and Social Care Act 2008

8.4.3. Regulators.

- 8.4.3.1. Medicines and Healthcare products Regulatory Agency (MHRA) – This accredits, regulates and licenses all medicines prescribed to fertility patients, as well as all devices used in a clinical environment and the embryology laboratory.
- 8.4.3.2. International Organization for Standardization (ISO) – ISO develops international standards to ensure that products or services or systems meet specific requirements, and its certification is used widely in the UK for testing laboratories.
- 8.4.3.3. Care Quality Commission (CQC) – The CQC regulates and inspects health and social care services. Its role is to ensure that clinical practices provide people with safe, effective and high-quality care, and to encourage those providers to improve. It carries out this role through checks during the registration process, as well as through inspections and monitoring.
- 8.4.3.4. Competition and Markets Authority (CMA) – The CMA has produced a guide to help patients understand what their consumer law rights are at the different stages of considering and undergoing fertility treatment, and it has the power to enforce the law and the standards it sets and fine clinics which do not comply.
- 8.4.3.5. Advertising Standards Authority (ASA) – The ASA investigates complaints made about ads, sales promotions or direct marketing, and deciding whether such advertising complies with its advertising standards codes.
- 8.4.3.6. Home Office – Regulates and licenses the procurement, storage and distribution of controlled drugs used in the fertility clinics.

- 8.4.3.7. Information Commission Officer (ICO) – Oversees the handling of information and data rights, including medical data for fertility patients and clinical staff. It has the power to fine clinics.
- 8.4.3.8. Independent Sector Complaints Adjudication Service (ISCAS), and other ombudsmen – ISCAS provides independent adjudication on complaints about independent healthcare providers.
- 8.4.3.9. Human Tissue Authority (HTA) – The HTA regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. It is also involved with the approval of organ and bone marrow donations from living people. Its remit excludes gametes and embryos.
- 8.4.4. Research
The Health Research Authority (HRA) – The HRA ensures that research in the UK is ethically reviewed and improved and also coordinates and standardised research regulatory practice.

8.5. HFEA related documentation

The HFEA states that “*The Code of Practice is the ‘rule book’ for clinics and is updated regularly to help clinicians understand and comply with their legal requirements as a licensed centre.*” It provides “... *guidance notes on key topics including storage of gametes and embryos, donation, legal parenthood, import and exports, traceability and others*”. The COP provides 3 sections in each Chapter. The first gives the obligatory requirements and includes the legislation (reflecting Parliament’s intentions) and/or HFEA Directions (reflecting HFEA decisions). The second are the obligatory licence conditions determined by the HFEA. The third is guidance which are recommendations.

8.6. Patient, partner, donor, family perspective

- 8.6.1. It is expected that all healthcare services are regulated to ensure that appropriate standards are met. Those receiving treatment should have access to the regulator if they have concerns about the standard of care provided. The pathway for such complaints should be clear and directed to the regulator that has the authority and ability to take appropriate action.
- 8.6.2. Some provisions in the HFEAct duplicate and contradictory to other standards in healthcare. For instance, patient autonomy is limited by the legislation and its implementation e.g. the conditions for which embryos may be tested to exclude serious abnormality must be determined by the HFEA (Schedule 2 paragraph 1ZA (2)). Patient autonomy is respected in other similar situations e.g. antenatal screening decisions are made by the patient after appropriate information and counselling. If a pregnancy is then terminated, the clinical practice is regulated by the requirement to adhere to professional standards and must comply with the Abortion Act 1967, but patient autonomy is respected.
- 8.6.3. Duplication in legislation and regulation gives rise to potential gaps in the service pathway as one regulator may assume that another regulator covers a particular aspect of care. This is a potential risk to patient care.
- 8.6.4. The HFEA has the power under Section 8(1)(c) to give advice to patients about their treatment. The scope of this potential advice is not limited and could duplicate or conflict with advice given by the clinic. Such advice is available elsewhere for patients <https://www.nhs.uk/conditions/infertility/> and for service providers in <https://cks.nice.org.uk/topics/infertility/>. Whilst it is

important that such advice is available, too much advice can be confusing. Furthermore the sources of the information provided must be robust, provided by those with relevant knowledge and, where possible, evidence based.

8.7. Legal perspective

- 8.7.1. Where legislation describes an activity that is also covered by other legislation or regulation, there is a risk of conflict. There is then a risk of legal challenge.
- 8.7.2. Where legislation requires a regulator to set standards, regulate against these standards, and implement sanctions, this has the potential to place inappropriate power in the hands of the regulator. This may be difficult where the constitution of the regulator may not be suitable (the HFEA has a lay majority). In relation to healthcare provision, standards are set by professional societies and implementation of these standards would be enforced by the appropriate regulator.

8.8. Service provider perspective

- 8.8.1. The provision of fertility treatment is now a routine medical practice worldwide. In 1990 there were no professional organisations setting standards in the field of assisted conception, and it is understandable that Parliament required standards to be provided. It is no longer appropriate that an authority consisting of a majority of lay members is still required to set standards of professional practice.
- 8.8.2. The Code of Practice (COP) relates to both legally obligatory requirements and guidance for good practice. Compliance with procedures given under guidance in the COP is expected. The effect is that the guidance has become obligatory. This has the potential to remove the flexibility that is sometimes needed in the best interest of the patients. Guidance drafted by professional bodies (BFS, ESHRE, ASRM) allows this flexibility and an individualised approach. Justification for practice outside professional guidelines may be required but the guidelines are not designed to be obligatory.
- 8.8.3. Service providers must be accountable to the many standards and regulations listed in (4) above. This is important for optimal patient care. Duplication of regulations can be confusing and unnecessarily burdensome. If all aspects of regulation in the fertility sector become an HFEA function, there is a risk that this healthcare sector and its patients may face disproportionate oversight and /or diverging standards. This could result in discrimination to patients requiring fertility treatment compared with those requiring other medical treatment.
- 8.8.4. Those working in fertility clinics who have appropriate professional accreditation (see 4.1), will have achieved the required knowledge and skills. Their practice must be consistent with their professional guidelines. The duplication of guidance on professional practice in the COP is unnecessary and potentially conflicting e.g. 25.30 (pre-op assessments), 25.21 (controlled drug management), 25.17 (management of potential laboratory hazards), 25.15 (counselling facilities).
- 8.8.5. Guidance on when to use established procedures should be outside the remit of a regulator e.g. Code of Practice 21 (ICSI).
- 8.8.6. The evaluation of novel techniques is of particular concern in this sector. Within the NHS, procedures are funded on a cost-effective basis and decisions on provision are based on local resources. This does not necessarily apply within the private sector where decisions may be made by the patients who are paying for treatment. The HFEA has adopted a role in the evaluation of novel techniques e.g. PGT-A, thus duplicating and potentially conflicting with decisions made by professionals, researchers, funders, and patients. Clarification is needed as to whether Parliament intended this to be a function of the regulator.
- 8.8.7. The taking and giving of consent is essential for all medical care under professional guidelines and the Health and Social Care Act 2008. In the HFEAct, the procedure for giving consent Schedule 3 paragraph 3 (1) states that “*Before a person gives consent under this schedule-... (b) he must be provided with such relevant information as is proper.*” Interpretation of the term ‘proper’ would, in other healthcare settings, be a decision made by those caring for the patient and be dependent on the individual patient needs. Inclusion of this requirement in legislation results in detailed requirements in the COP (Chapter 4). This duplicates other guidance about the taking of



consent, is unnecessary and may not be in the best interest of individual patients.

8.9. Ethical perspective

- 8.9.1. Patient autonomy is an important consideration in all healthcare provision. The impact of duplication in regulation and oversight has the potential to place even more restrictions on patient autonomy. There is a risk that service providers may prioritise compliance with the regulatory requirements over medical judgment and not act in the best interest of their patients.
- 8.9.2. There is a need for specific legislation related to ethical considerations about the preimplantation human embryo.
- 8.9.3. The HFEAct already places a regulatory burden on the fertility sector that is disproportionate to the risk to patients compared to other health care services. Consideration is needed to determine whether this burden is unnecessary and potentially discriminatory.
- 8.9.4. A unique feature of the fertility services in the UK is that they are largely within the private sector and treatment is not covered by health insurance. This is difficult in a society within which the culture of the NHS is embedded. Regulation of the private healthcare provision sector is provided by the CQC but does not include patient costs which are determined by the market <https://www.cqc.org.uk/sites/default/files/20210809-how-cqc-regulates-independent-healthcare-services-august-2021.pdf>. The lack of NHS treatment for some patients is not within the remit of the HFEA and should not influence their regulatory decisions i.e. advertising and costs are the remit of the ASA and CMA and should not be duplicated by the HFEA.
- 8.9.5. There is a financial cost for all stakeholders in the regulatory process. In a risk v benefit analysis this must be taken into account where there is duplication.

8.10. Proposed Changes to the HFEAct

- 8.10.1. Where the HFEAct requires the HFEA to determine the “proper” practices of professional care or duplicates general standards and guidelines provided elsewhere, these requirements should be removed.
- 8.10.2. The scope of the advice that may be provided by the HFEA needs review to ensure that it does not unnecessarily duplicate advice given elsewhere.

Chapter 9

Confidentiality and Consent to Disclosure

9.1. Aims

- 9.1.1. To remove the stigma associated with infertility that is implied by the strict secrecy and confidentiality provisions in legislation.
- 9.1.2. To reduce the burden on patients to complete multiple HFEA forms.
- 9.1.3. To clarify the distinction between disclosure of data on the HFEA Register and disclosure of medical records.
- 9.1.4. To simplify the legislative requirements for access by researchers to digital databases such that they are consistent with current ethical practice and technical possibilities within the healthcare sector.

9.2. Background

- 9.2.1. In 1990, infertility was associated with shame and failure, and those who had difficulty conceiving often kept it secret from family and friends. Thus, the HFEAct reflected Parliament's intention to ensure confidentiality.
- 9.2.2. Patients expect that clinical records are confidential, and this basic principle now underpins all medical care regulation. Duplication of this principle in the HFEAct is unnecessary.
- 9.2.3. The HFEAct includes strict access restrictions not only (justifiably) to the HFEA database but also to medical records. This can prevent doctors who are providing IVF treatment from obtaining advice from doctors in other specialities and thus has the potential to be detrimental to patient care.
- 9.2.4. The criminal sanction provided in the HFEAct for breach of confidentiality regulations is not consistent with sanctions related to breaches of confidentiality in other healthcare settings.
- 9.2.5. The HFEAct requires that data cannot be disclosed without patient consent. Consequently, the HFEA provides forms (Consent to Disclosure (CD) forms) that must be completed by all patients before treatment.³³ Patients are generally unaware of the data held on the Register database. Without this knowledge, the validity of giving consent to disclosure is ethically dubious.
- 9.2.6. In 1990, healthcare records were held in a paper form. In 2023, healthcare records are held in a digital form and that brings ethical and practical challenges. The HFEAct does not acknowledge the legal consequences.

9.3. Relevant Sections of HFEAct

- 9.3.1. Section 31(2) states that the HFEA shall hold a Register and prescribes a general list of the information that the HFEA may hold. The Register may contain any information relating to the provision of identifiable individual treatment services, procurement, and distribution of sperm, the keeping of gametes, the use of gametes and the use of an embryo. It also includes data about a child born from treatment.
- 9.3.2. Section 33A (1) "Disclosure of Information" relates to information that is, or could be, on the Register. It states that "*no person shall disclose information falling within section 31(2) which the person obtained...in the person's capacity as - (a) a member or employee of the Authority, (b) any person*

³³ <https://portal.hfea.gov.uk/knowledge-base/consent-forms/>

exercising functions of the Authority, (c) any person engaged by the Authority to provide services to the Authority, (d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c), (e) a person to whom a licence applies, (f) a person to whom a third party agreement applies, or (g) a person to whom directions have been given.” Although mainly relating to disclosure by the HFEA, (e) extends this to the clinic records.

- 9.3.3. Section 33A (2) (a-t) & (3) state the many situations in which disclosure is permitted without consent.
- 9.3.4. Section 33B prescribes the consents required to permit disclosure of this data.
- 9.3.5. Section 41 (5) states that contravention of Section 33A is an offence liable to two years imprisonment or a fine or both.
- 9.3.6. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 relate to disclosure of information by the Authority of information that the Authority holds. They prescribe procedures required to permit the disclosure of information on the Register for research. The HFEA cannot give identifying information from the Register for research if the individual has refused to give consent for research.
<https://www.legislation.gov.uk/ukxi/2010/995/contents/made>.

9.4. **Relevant sections of the HFEA Code of Practice**

Guidance note 30 relates to Confidentiality and Privacy.

<https://portal.hfea.gov.uk/knowledge-base/read-the-code-of-practice/>.

9.5. **Other relevant legislation or regulation**

Service providers must comply with the professional standards of practice in relation to confidentiality.

- 9.5.1. <https://www.england.nhs.uk/wp-content/uploads/2019/10/confidentiality-policy-v5.1.pdf>.
- 9.5.2. <https://www.health-ni.gov.uk/sites/default/files/publications/health/user-info-code2019.pdf>.
- 9.5.3. <https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---confidentiality-good-practice-in-handling-patient-information---70080105.pdf>.
- 9.5.4. <https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf>.

9.6. **Patient perspective**

- 9.6.1. Infertility is a private issue but there is no evidence now that patients or society associate it with shame or stigma. Legislation that encourages secrecy about fertility treatment is inappropriate.
- 9.6.2. Patients expect, and service providers must ensure, that all information about a consultation or treatment held within clinical records is confidential. This basic principle underpins all medical care and is not dependent on HFEAct provisions.
- 9.6.3. Legislation provides for the disclosure of information in the event of a healthcare emergency, but it is in the best interest of patients that clinic staff are able to discuss their care with other healthcare providers even if it is not in an emergency. Unlike other healthcare situations, the HFEAct currently prohibits this unless specific written consent has been given.

9.6.4. There is little evidence available about the patient knowledge of the HFEA Register. Information about the data held on the Register is provided on the HFEA website but it is highly unlikely that this will be seen by patients.
<https://www.hfea.gov.uk/about-us/data-research/>.

9.6.5. Consent to disclosure of data requires completion of Consent to Disclosure (CD) forms by each partner before the start of IVF treatment. These are part of the <106 pages of HFEA forms that must be completed in addition to standard medical treatment consent forms. This is a significant burden on patients at the time of a stressful procedure. Removal of the requirement to complete the CD forms would remove 10 pages.

9.7. Service provider perspective

9.7.1. The HFEAct effectively requires clinical records related to licensed treatments to be maintained separately from the patients' general medical records. Inability to have a single set of notes for review by other relevant healthcare providers, even when within the same hospital, leads to potential risk of important medical information being missed. This can lead to compromised patient care. The combining of clinical records would be efficient, economical and provide data access consistent with optimal healthcare.

9.7.2. Provision of healthcare services is multidisciplinary. Patients with complex comorbidities, need referrals for fertility treatment and aftercare, and require input from several healthcare providers outside the licensed centre. Thus, it is not always possible to keep information about fertility treatment from the general medical records and an inadvertent breach of the regulations may be unavoidable.

9.7.3. The requirement for completion of the CD forms and their retention is an additional burden for the service provider. In the current system, all patients must agree or disagree to disclosure. Considering very few patients currently disagree to disclosure there should be a presumption of agreement. An opt-out option could be made available if needed. This would be less burdensome for patients and clinics.

9.8. Legal perspective

9.8.1. The HFEAct places non-disclosure restrictions on the HFEA Register and, possibly by default, on the medical records from which the Register data was obtained. It is unlikely that this was the political intention.

9.8.2. Clinics are subject to healthcare confidentiality regulations, but the HFEA is an arm's-length body. Their Register is outside the NHS and thus not directly within the NHS regulatory procedures. Thus, there is a need for legislation to ensure that the confidentiality requirements apply to those working within the HFEA.

9.8.3. Section 41 imposes criminal sanctions for non-compliance with non-disclosure regulations. This offence of breach of specific confidentiality regulations in fertility care is not consistent with sanctions related to breaches of confidentiality in other healthcare settings.

9.9. Ethical perspective

9.9.1. The perceived desirability of secrecy has resulted in the practice of confidentiality. It is recognised that secrecy is potentially harmful in the context of family and social relationships. Parliament agreed to the removal of

anonymity for gamete donors based on this principle and the HFEAct was amended accordingly. The legislation gives a conflicting message if the provision of fertility treatment itself must remain secret. Information related to fertility treatment may be sensitive but no more than some other areas of medical care. Continuing confidentiality conditions based on a specific sensitivity related to infertility is neither justifiable nor sustainable.

- 9.9.2. Considering both benefit and harm, it is relevant that requests for access to identifying information have been very infrequent. For the benefit of these few studies, all patients had the additional burden of being required to complete a CD form. An opt-out option may be less harmful whilst achieving the same outcome.
- 9.9.3. There is concern about the validity of a consent to disclosure given that there is little information provided about the data held, the limits of and purpose to which any data obtained may be used.
- 9.9.4. Patients are aware that the National Health Service holds significant digital data about their care. Although there is evidence of patient and public concern about the use of such data outside the NHS, there is no significant concern about the use of patient data for audit and research within the NHS.
- 9.9.5. The HFEA Register is available in an anonymised format for Open Access. Patient consent for researchers' access to this anonymised database is not required.
- 9.9.6. The HRA (Health Research Authority) provides guidance for researchers and those who hold large databases about ethical issues related to access to such data. While patient consent should always be obtained if practically possible, there are circumstances when it is ethically appropriate to access identifying information on databases without consent. Researchers can apply to the CAG (Confidential Advisory Group) for advice and approval if appropriate.³⁴ This option, which is appropriate in other medical care scenarios, is effectively prohibited by the HFEAct.
- 9.9.7. It is ethically acceptable that a clinic which provided previous patient care may write to that person about a research project without that person's prior consent. This would require Research Ethics Committee approval. Additional requirements within the HFEAct to obtain consent to contact are not justified.
- 9.9.8. It is inefficient and potentially conflicting that ethical issues relating to access by researchers to databases containing identifying clinical data are overseen by two separate regulators (HFEA and HRA). Given the greater experience of the HRA in the ethical issues related to balancing the interests of the patient, society, and researchers, it may be more appropriate if access to the HFEA Register for research were primarily within HRA regulation.

9.10. Researcher perspective

The principal reason for researchers wishing to use identifying patient information is linkage to NHS databases in the interests of patient health, society, and healthcare provision. The HFEAct has been a significant barrier to such research in the UK.

³⁴ <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-cag-applicants/>

9.11. Political perspective

- 9.11.1. The proposed changes to the HFEAct are to reflect modern society and changed attitudes towards infertility. The removal of the excessive requirement of secrecy is expected to be welcomed.
- 9.11.2. The proposed changes will not reduce the confidentiality that is critical in medical records. They will bring them in line with practice elsewhere in the health service.
- 9.11.3. Patient care may be improved if the HFEAct facilitates research by enabling better linkage with NHS data.

9.12. Proposed changes to HFEAct

- 9.12.1. To ensure that patient care is not compromised, disclosure from the Register (Section 33A) should be redrafted to relate only to the HFEA and their subcontractors. It should not apply to those in the healthcare sector who have legitimate access to this information from clinic records.
- 9.12.2. The offence associated with the disclosure of information should be appropriate to those who can obtain data from the Register e.g. HFEA. Such offences should not apply to disclosure from medical records.
- 9.12.3. To simplify access to patient data whilst retaining appropriate confidentiality, consideration could be given for the guardianship of the Register to be within NHS Digital. It would then be subject to confidentiality, governance, and accessibility consistent with all NHS data.
- 9.12.4. Consideration should be given for an opt-out option for those who do not consent to identifying information being disclosed from the Register rather than the current opt-in option. Such a decision could be given digitally and directly to the HFEA.