Legislation in the UK

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Z. P. Nagy et al. (eds.), *In Vitro Fertilization*, https://doi.org/10.1007/978-3-319-43011-9_66

Learning Objectives

- To provide an overview of the history of legislation of ART in the UK
- To explain the structure and functions of the HFEA
- To describe the legislatory framework that centres must work within
- To discuss how centres are assessed for compliance and describe the process of licensing of centres by the HFEA

66.1 History of Legislation in the UK

66.1.1 The Warnock Committee

Although the birth of Louise Brown in 1978 was a major breakthrough in the treatment of the infertile couple [1], it raised many ethical concerns with both professionals and the general public. In response, a committee was established in 1982 in the UK to inquire into the technologies of in vitro fertilisation (IVF) and embryology and to form the principles of future regulation. Chaired by Mary Warnock, the terms of reference were to 'consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations' [2]. The findings, which considered all processes involved in IVF, donor insemination and surrogacy, were published in the Warnock Report in 1984. The report concluded that the human embryo should be protected by law by giving it a special status outside the human body; however, research of human embryos could be permitted under certain circumstances. Other recommendations included the provision of counselling and ensuring patients give informed consent prior to treatment commencing. A key proposal was to establish an authority to regulate both research and treatment [2]. The first step to meeting the 60-plus recommendations in the report was for the Medical Research Council and the Royal College of Obstetricians and Gynaecologists to establish an interim licensing authority to provide a framework for inspection.

66.1.2 Founding the HFEA and the HFE Act 1990

Following the Warnock Report, the government undertook an extensive public consultation. The findings led to the publication of a government white paper, 'Human Fertilisation and Embryology: A Framework for Legislation', in 1987. The act drafted following this paper received royal assent on 1 November 1990 and paved the way for the establishment of the Human Fertilisation and Embryology Authority (HFEA) in 1991. This executive, nondepartmental public body was the first statutory body in the world and had the remit under the legislation to regulate IVF clinics through the licensing of:

- The creation of human embryos outside the body and their use in treatment and research
- The use of donated gametes and embryos
- The storage of gametes and embryos

The HFEA is comprised of a chair and members. The members who are appointed via the Appointments Commission are from diverse backgrounds and have the scope to determine policies and review treatment and research licence applications. Several committees support the process by providing advice on specific aspects, for example, the Audit and Governance Committee oversees corporate governance, risk, audit arrangements and financial matters and the Scientific and Clinical Advances Committee reviews and provides recommendations on recent developments. The HFEA is also obliged to provide information to the public, particularly those having treatment and donating gametes or embryos or those who are donor conceived. For this process to work efficiently, the HFEA maintains a formal register of information which records all treatments and donor information. The information held on this register can be used for research purposes depending on the type of consent provided by the patient.

66.1.3 Changes in Legislation 1991–2016

Although the 1990 legislation remained in force until the amended act in 2008, there have been various changes to the UK regulations over the years. This included allowing the storage periods for embryos to be extended in certain circumstances in 1996 and extending the purposes for which embryos could be used in research to include 'increasing knowledge about the development of embryos, increasing knowledge about serious disease and enabling any such knowledge to be applied in developing treatments for serious disease' in 2001.

A major change which impacted greatly on centres was the removal of anonymity from gamete and embryo donation which came into force in April 2005. This change permitted donor-conceived children access to the identity of their sperm, egg or embryo donor upon reaching the age of 18. This change raised concerns regarding the impact of this on donor recruitment, but although initially studies showed an overall trend in a decrease in recruitment, other studies have reported that over a longer time period, they were able to meet demand for recipient cycles [3]. At this time, payment for donation was not permitted, so in 2010 the HFEA started to review the legal and ethical issues surrounding payment and undertook a public consultation to formulate a new policy which came into force on 1 April 2012 [4]. This policy allows centres to compensate egg donors £750 per cycle and sperm donors £35 per centre visit with the flexibility for a donor to claim more if higher expenses are incurred, and receipts are produced as evidence.

In 2004, new EU regulations regarding common safety and quality standards were introduced to enable easier movement of tissues between members of the EU. UK centres had until 2007 to comply with the introduction of Directive

2004/23/EC [5] and the Commission Directives 2006/17/EC [6] and 2006/86/EC [7]. The HFEA was nominated as the competent body to assess centre compliance. The directives encompassed donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.

Technology advances rapidly in assisted reproduction technology (ART), and in 2004, it became apparent that scientific developments and changes in public attitude necessitated a review of the 1990 Act. After public consultation and a review by the House of Commons Science and Technology Committee, the government published the white paper [8]. Following this, the draft bill was published in 2007, and after scrutiny the new bill received royal assent in November 2008.

The HFE Act 2008 [9] is divided into three parts:

1. Amendments to the Human Fertilisation and Embryology Act 1990
2. Parenthood
3. Miscellaneous and general

The main new elements of the 2008 Act [9] are:

- Ensuring that the creation and use of all human embryos outside the body – whatever the process used in their creation – are subject to regulation
- A ban on selecting the sex of offspring for social reasons
- Removal of the previous requirement within 'welfare of the child' of the child's 'need for a father'
- Allowing for the recognition of both partners in a same-sex relationship as legal parents of children conceived through the use of donated sperm, eggs or embryos
- Enabling people in same-sex relationships and unmarried couples to apply for an order allowing for them to be treated as the parents of a child born using a surrogate
- Changing restrictions on the use of data collected by the HFEA to make it easier to conduct research using this information
- Provisions clarifying the scope of legitimate embryo research activities, including regulation of 'human admixed embryos' (embryos combining both human and animal material)

Statutory storage limits for gametes and embryos increased within the new act from 5 to 10 years. It also became possible to extend the storage of gametes and embryos up to a maximum of 55 years provided that at each 10-year checkpoint, the centre obtains a written opinion from a registered medical practitioner that the person to be treated (or one of the people who provided the eggs or sperm) is or is likely to become prematurely infertile.

66.2 Code of Practice

Section 25 of the 1990 Act requires the HFEA to maintain a code of practice to provide guidance to centres in order for them to comply with the regulatory requirements when providing licensable activities. The first edition was published in 1991; the latest edition, the ninth edition, was published in January 2019. The code comprises of 33 guidance notes, each one describing the mandatory requirements, the HFEA interpretation of the mandatory requirements, best practice guidance and other relevant legislation, professional guidelines and information [10]. This comprehensive document is well used by centres and forms the basis of any procedures and processes which are carried out in a licensed centre. The 33 guidance notes are as follows:

1. Person responsible
2. Staff
3. Counselling and patient support
4. Information to be provided prior to consent
5. Consent to treatment, storage, donation, training and disclosure of information
6. Legal parenthood
7. Multiple births
8. Welfare of the child
9. Preimplantation genetic screening (PGS)
10. Embryo testing and sex selection
11. Donor recruitment, assessment and screening
12. Egg sharing arrangements
13. Payments for donors
14. Surrogacy
15. Procuring, processing and transporting gametes and embryos
16. Imports and exports
17. Storage of gametes and embryos
18. Witnessing and assuring patient and donor identification
19. Traceability
20. Donor-assisted conception
21. Intra-cytoplasmic sperm injection (ICSI)
22. Research and training
23. The quality management system
24. Third-party agreements
25. Premises, practices and facilities
26. Equipment and materials
27. Adverse incidents
28. Complaints
29. Treating people fairly
30. Confidentiality and privacy
31. Record-keeping and document control
32. Obligations and reporting requirements of centres
33. Mitochondrial donation

Centres use the Code of Practice to check their own compliance and for reference for many different clinical situations. In recent years, there has been much focus towards witnessing and minimising multiple births. The implications of inadvertent mixing of gametes or embryos resulting in the birth of a child with the 'wrong' genetic parents are catastrophic. It is therefore a mandatory requirement that centres have robust contemporaneous witnessing procedures and documentation in place to double check both the identity of patients and their samples throughout the treatment pathway. Electronic witnessing can be used, but a full risk

assessment must be conducted, and certain conditions such as double manual witnessing must occur when gametes are inseminated at embryo transfer or when samples are put into or removed from storage.

An expert report published in 2006 [11], which highlighted that multiple pregnancy was the biggest risk to the health of the mother and child during ART, led to the HFEA producing a policy and integrating the requirement for a multiple birth minimisation plan into the Code of Practice. The policy adopted a stepwise approach with the target being reduced over a period of 4 years. Centres are currently obliged to ensure their multiple birth rates do not exceed 10% and to perform regular audits to evaluate the effectiveness of their policies. Although after a legal challenge the licence condition (T123) had be to be removed, the HFEA remains committed to reducing multiple birth rates, and centres who do not meet the target are invited to attend a management review at the HFEA to discuss the issues.

The most recent Code of Practice focusses on the leadership role of the person responsible and introduces the concept of a patient support policy which ensures centres provide emotional support to patients before, during and after treatment.

66.2.1 Licensing and Inspection of UK Centres

In order to carry out assisted reproduction techniques in the UK, centres must be inspected by the HFEA to assess compliance against the HFE Act 1990 (as amended). The compliance cycle is 4 years with an inspection within every 2 years. An initial or renewal inspection has a planned agenda and is usually conducted with between two and four inspectors over 1–3 days depending on the size of the unit. Prior to the inspection, centres are asked to complete a self-assessment questionnaire which is analysed by a risk tool alongside other general performance measures. The focus of inspection is always on the quality and safety of patient care and protection of the embryo. Inspectors will directly observe practice, interview patients and check records. An interim inspection is often unannounced and will be focussed around specific themes. More frequent targeted inspections may be carried out if specific concerns are raised. In 2013, the HFEA extended its remit to include the inspection of surgical procedures in England to prevent centres being inspected by the Care Quality Commission (CQC) as well as the HFEA. This helped to reduce regulatory burden on centres and to streamline the regulatory process.

Once an inspection is complete, a report is produced, and the licensing decision whether to grant a licence is made by the licensing committee. Clinics do hold the right to appeal through the Appeals Committee. The HFEA also continually monitors a centre's performance through a risk tool which focusses on six key areas: incorrect identification of gametes or embryos; cross infection of gametes, embryos or patients; consent failures; damage or loss of gametes or embryos; multiple pregnancy; or incorrect or incomplete information on donors. The system also analyses a centre's success rates, multiple pregnancy rates, submission of critical donor information, payment of fees and incident reporting. Reporting incidents is a statutory requirement. Incidents are defined by the HFEA as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, or loss or damage to patients, their embryos and/or gametes, or to staff or a licenced centre, including serious adverse events and serious adverse reactions'. Once received, the HFEA will grade the severity of an incident and determine what further action is required.

If a centre is non-compliant and there is a risk to patients, donors, gametes or embryos, then a formal process commences through the executive licensing panel using the guidance from the compliance and enforcement policy. Ultimately, a licence can be revoked.

66.2.2 Recent Changes

Although in 2015 the UK parliament voted to permit the use of mitochondrial donation for the purpose of avoiding the inheritance of severe mitochondrial disease, the expert panel reporting to the HFEA recommended that the safety and efficacy of the technique required further evaluation. The further 2016 review [12] provided comprehensive evidence in order for the HFEA to determine whether the technique could be used in clinical practice. The report concluded that clinical treatment could proceed cautiously in restricted circumstances with further research being conducted. On 15 December 2016, the HFEA permitted the use of this technology.

Section 33 in the Code of Practice outlines the specific criteria which must be complied with for treatment to be undertaken. Individual cases of maternal spindle transfer (MST) or pronuclear transfer (PNT) have to be submitted to the HFEA's Statutory Approvals Committee for authorisation.

66.2.3 Other Accreditation Schemes

Many clinics seek to optimise their services and comply with the HFEA requirement to have a demonstrable quality management system by choosing to be ISO9001:2015 certified. Diagnostic andrology services must also be certified to ISO15189:2012 or equivalent. The professional bodies relating to reproductive medicine produce best practice guidelines and provide comprehensive training and validation programs. In the UK, embryologists are trained via the master's-level Scientist Training Program in order to attain state registration.

66.3 Conclusion

The HFEA provides a unique comprehensive regulatory mechanism for ART. The framework drives standards and ensures high-quality patient care. Although seen by some as

burdensome, the regulations provide protection to both patients and embryos, and they have served to reassure the patient that this sensitive and ethically challenging area of medical practice is performed ethically.

Review Questions

1. Following the Warnock Report, the HFE Act received royal assent on 1 November 1990 and paved the way for the establishment of the Human Fertilisation and Embryology Authority (HFEA) in 1991. The HFEA regulates IVF clinics through the licensing of?

2. What major change in legislation in 2005 had impacted on donor treatments, and what further change in 2012 was made to help encourage people to come forward to donate?

3. The HFEA licences centres through an inspection process; describe the inspection cycle.

4. What are the current statutory storage periods for gametes and embryos, and under what circumstances can the storage period be extended?

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