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REVIEW ARTICLE

Time-Line in HFEA Developments and Regulatory Challenges: 20 Years of Overseeing Fertility Practices and Research in the UK

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Abstract In the wake of political upheaval, the Human Fertilisation and Embryo Authority (HFEA) has faced increasing insecurity over its future as a pivotal regulatory body of fertility practices in the UK. HFEA regulates activities by means of licensing, audit, and inspection of fertility centers and maintaining the Code of Practice, which ensures the optimum undertaking of licensed activities by fertility centers. In 2009, amendments to the 1990 Act came into force representing an amalgamation of cumulative proposals, debates, and changes in legislation, which have shaped the world of reproductive medicine. The medical world has, in many cases, adapted to righteous political and social demands, and continues to evolve at a rapid rate. The HFEA has faced many regulatory challenges and changes, and through this study, we aim to provide an overview of some of these changes, particularly those during the last 10 years and the implications that they may have had to fertility practices.

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Introduction

Since the birth of Louise Brown in 1978, who was conceived through in vitro-fertilization (IVF) treatment, pioneered by Nobel Laureate Professor Robert Edwards, there have been revolutionary changes globally in medical intervention strategies, treatment, and research of sub-fertility. As fertility figures continue to rise, the Human Fertilisation and Embryology Authority (HFEA), which regulates fertility practices in the UK, has evolved and introduced the Code of Practice (CoP) which incorporates standards, which are central to HFEA's regulatory function. The updated 8th CoP of 2010 reflects the HFEA Act and incorporates the regulations imposed by the European Union Tissue and Cell Directive (EUTCD) of 2004. The original HFEA Act 1990 was amended in 2008, and as of October 2009, the HFE Act 2008 came into force representing an amalgamation of cumulative advances, proposals, debates, and changes in legislation which have shaped the world of reproductive medicine.

In light of very recent political remodeling, the role of HFEA has been questioned and indeed threatened. With the Public Bodies Act, the HFEA stood to lose its regulatory powers with its ultimate dissolution. Over time, HFEA has proved itself invaluable and indeed critical for the regulation of fertility practice. This article aims to provide an

overview of these advances and changes, which have taken place in the Western World and the implications that they may have had to fertility practices.

The HFE Act 1990, further amended in 2008, was an Act of Parliament passed in response to public concern about the implications of assisted reproductive technology on the perception and value of human life and family relationships. The HFEA was established with the aim of regulating and supervising the use of gametes and embryos for human clinical and research application. It also enforced obligations that ensure quality and safety standards, record and give information to patients and clinicians, offer counseling, and take into account the welfare of children who are born following fertility treatment. The HFEA regulates activities covered by HFE Act by means of licensing, audit, and inspection of fertility centers, and by maintaining a CoP, which aims to ensure optimum undertaking of licensed activities by fertility centers.

In 1992, the Disclosure of Information Act made it legal for the Human Embryology and Fertilization authorities to disclose information at the patient's will. If the patient indicated a desire to have his/her information disclosed to his/her parents, the government deemed it legal for the patient's parents to receive information from the HFEA authorities. www.legislation.gov.uk.

Section 156 of the broad legislation 1994 Criminal Justice and Public Order Act, banned the use of aborted embryos for reproduction. Uneasy about the consent issues associated with aborted embryos, the government passed the law with the hope that the role of women in reproduction would not be undermined. www.legislation.gov.uk.

In 1997, stimulated by public interest in "dolly the sheep," the Government along with the Human Reproductive Cloning Act 2001, banned implantation of cloned embryos in women in 2001. This government action was in response to the judicial ruling that the HFEA Act did not clearly state that human embryos could not be developed through cloning techniques. However, this legislation was only applicable for implanted embryos. The government, in the same year extended the HFE Act to allow for therapeutic cloning, but only for research. www.legislation.gov.uk.

HFEA has confronted many challenges and responded appropriately. The TOFT Report 2004 scrutinized the vulnerabilities of the HFEA's regulatory function and the clinical safety systems [1]. The Report was commissioned in light of four adverse events, which occurred in 2002 at Leeds Teaching Hospital NHS Trust involving the use of incorrectly identified gametes and lapses of storage systems. The report concluded that the events were the consequence of a combination of systems failure and human error, and the recommendations were aimed at risk management, inspection, witnessing processes, and funding. HFEA responded to this seriously and developed a stricter and more robust risk management system. An incident alert system was implemented whereby the fertility sector could be privy to and learn from mistakes. Changes to practice made it mandatory for two members of staff to be witnesses of the checking systems as part of a formal process, along with the patient's signatures to confirm sample identity. Clinical governance and inspection procedures were also enhanced with the addition of unannounced inspection visits and improving selection and training for external inspectors. With greater government funding and liaison, the HFEA was able to implement and strengthen their regulatory responsibilities.

In 2004, the UK and HFEA hit the headlines by being the first regulatory body in the world to officially sanction the use of preimplantation tissue typing to produce "Saviour siblings" where children would be created to save an existing child. The first reported use of preimplantation genetic diagnosis (PGD) and tissue typing was in the USA in 2000, and the HFEA followed with its first interim policy in 2001 [2, 3]. Initially, the PGD technology was used cautiously, to exclude affected embryos with a particular genetic condition. In the next 3 years, after full consideration of the ethical, medical, and technical issues, the HFEA concluded that tissue typing should be available, subject to appropriate safeguards, in cases where there is a genuine need for potentially life-saving tissue and a likelihood of therapeutic benefit for an affected child [3].

With the government's decision to remove donor anonymity in July 2004, coupled with changing standards from the European legalization, the HFEA faced new expectations and review, which prompted the production of the sperm, egg, and donation (SEED) report of April 2005 [4]. This represented the most thorough review of donor-assisted conception regulation since the HFEA Act 1990. It focused on measures to secure a safe and reliable service for those requiring treatment and to donors and children born as a result. Minimizing the risk of disease transmission from the affected gametes could be prevented by suitable medical and laboratory screening; however, professional standards on this matter, in the form of clear, concise, evidence-based guidelines, were not available at this time, and therefore, it was deemed necessary that these should be produced and adhered to.

Based on a thorough research, it was concluded that the selection of donors based on physical attributes, both limited the availability of potential donors and had little effect on the welfare of the produced child. Therefore, in response, the HFEA revised its selection process to be case based, taking into account individual issues presented at the time. Ambiguity over and expectations on the number of children produced per donor led the HFEA to cap the number of "families" produced from a single donor to 10.

In 1993, the HFEA considered the issue of donation payment, amid concerns of reduction of donors if payment

stopped, and following a consultation at this time, continued the flat rate of £15 per donation plus additional reimbursements [4]. In the 2005 SEED report, in line with the EUTCD [5, 6], the HFEA agreed that donors may only be reimbursed for expenses incurred in connection with the gamete donation and that egg-sharing "benefits in kind" should be limited to two recipients, with discounted treatment being the only benefit offered. In 2005, the compensation for donation consisted of loss of earnings to a maximum £250 plus traveling expenses. However, more recently, in 2011, the monetary gains from egg donation have become more lucrative, with a fee of £750. The HFEA has had to defend their decision against the counter argument of "egg trade" as it was felt that this substantial sum could be viewed as a financial inducement leaving the patients vulnerable to both exploitation and abuse [7].

With evolving attitudes, public expectations, and advances in technology, the HFEA contemplated the extended use of PGD for additional inherited diseases and sought public opinion in its "Choices and Boundaries" document published in November 2005, before decision making [8]. At this time, serious diseases such as cystic fibrosis, Huntington's disease, and familial adenomatous polyposis Coli (FAP) were screened using PGD, but before 2004, when the HFEA first issued a license for FAP, the matter of the child not being affected at birth by the disease provoked debate and criticism. Screening for other diseases including ovarian and breast cancer and hereditary non-polyposis colorectal cancer came under question. Opinion was sought since only 5–10 % of these cancer cases have an inherited gene, have variable penetrance and a later age of onset. Further, there were questions of a potential treatment being available for these cases. With large deviation in ethical, social, and medical opinions, there was no consensus gained from public view, but after full consideration, the HFEA, in 2006, authorized the use of PGD for these diseases on a case-by-case (i.e., for a particular condition and for a particular individual) basis [9]. In 2007, HFEA added a range of diseases applicable for PGD and granted the University College Hospital a license to carry out PGD for homozygous familial hypercholesteraemia [10].

The emotive figures, which emerged through research, of the possible prevention of 126 IVF twin deaths, had they been singletons, motivated the development of the **"**One Child at a Time Report**"** published in 2006 [11, 12]. With the increasing fertility figures, success rates, and public demand and expectation, the risk profile was also noted to be expanding disproportionately. In 2005, around 1.5 % of births and 1.8 % of babies born in the UK were as a result of IVF or IUI, but the single greatest health risk associated with fertility treatment was multiple births, with IVF accounting for 1 in 5 of all multiple births. Individual autonomy balanced with public health, needed to be weighed in the decision and policy review. In addition, the number of NHS-funded cycles offered, the cost per cycle, the cost implications of multiple births, and the number of transferred embryos needed to achieve success were all complex and multifactorial variables, all of which required careful consideration [11].

On December 4, 2007, the HFEA called for a professionally led, evidence-based national strategy to reduce the number of multiple births [12]. The aim was to reduce multiple births rates (MBR) from 25 to 10 % over a 3-year period while preserving success rates with a coordinated change, set to occur in 2009. The "One Child at a Time" report had established that this could potentially be achieved using elective single embryo transfer eSET [12], and in 2007 the Authority made the decision allowing clinics to adopt their own strategies for the utilization and implementation of eSET as an outcome-based policy. Each center had put in place their own "multiple birth minimisation protocol" with the expectations to improve annually from 2009 such that in April 2011 it was expected that the multiple pregnancy rate was no more 10 % for any given center [12]. In collaboration with professional bodies, patients and clinics, this formed a national strategy. To achieve the targets the National Strategy Stakeholder Group produced guidelines published in the Human Fertility Journal to aid clinics in the use of eSET with recommendations on appropriate patient selection [13]. Additional guidance was given suggesting appropriate days for embryo transfer. The Association of Clinical Embryologists (ACE) standardized embryo grading system, improved patient education and guidance on frozen embryo transfer and cryopreservation policies. With promising results to date, years 1 MBR of 25 % and 2 MBR of 20 % targets were both met and in fact, exceeded. As of October 2012 the maximum multiple birth rate at 10 %, came into effect [14]. The clinics, which fail at maintaining a lower MBR of 10 % may have to face increased regulatory and inspection burden and financial penalties.

With the growth of embryo research, the HFEA had licensed 33 egg research projects, in 2007, the HFEA authorized egg donation purely for research [15]. Before this, only those undergoing IVF treatment were able to donate eggs for research. Rather than the use of "surplus eggs," non-patient egg donation for research was to be allowed under the same rules as those for donation for treatment, with strong safeguards in place to ensure prevention of coercion and appropriate consent in line with the Helsinki Declaration and the GMC guidelines.

To ensure that HFEA remained at the forefront of new technology, the Horizon Scanning Panel, an international panel was set up in April 2005 with the aim of gaining early knowledge and a global expert insight of new

developments within this field. The panel considered and evaluated many boundary-pushing techniques within embryo research and treatment [16]. The techniques which were reviewed and evaluated at this time was the use of germinal vesicle transfer (GVT) whereby the nucleus in the germinal vesicle stage is removed and transferred into an enucleated donor egg with the aim of reducing the risk of mitochondrial diseases and those related to advancing maternal age [16]. The other technologies, which were evaluated, were that of in vitro maturation (IVM) of the oocyte before standard IVF or ICSI protocols, gene chip technology, and microarrays as a specific way to detect mutations and other chromosomal abnormalities to compliment or replace PGD. Vitrification was also examined as an alternative to the semi successful cryopreservation to increase the efficacy of both storage and donation [16].

With this being an extremely fast paced arena of research, it was only a matter of time before the discussion focused on the use and production of "artificial" in vitro derived gametes. The Horizon Scanning Panel in 2005 concluded that the most likely source of these gametes would be from embryonic stem cells, a technique that would involve cell nuclear replacement [16]. The advantages were simple, that no donor would be needed and therefore the child would be genetically related to both parents. It could be applied so that individuals in same sex relationship could have a child and one person could have a child alone, as the stem cells could be differentiated into either sperm or oocytes.

In practice at that time, there were no regulatory prohibitions from the HFEA 1990 Act as the techniques applied, affected the oocyte rather that the embryo, and a license was only needed to both store and mix the gametes. With the anticipated huge demand, came the contentious and sensitive ethical issues. The Department of Health raised the ethical and the potential safety issues in its review and prohibited its use. The Government proposed that the amended HFE Act "Should contain a regulation making power giving Parliament flexibility to introduce the use of in vitro derived gametes in the future if so desired" [16]. More recently, under the amended Act 1990, it was decided that in vitro derived gametes are precluded for treatment use but can continue to be used in research without the need of a HFEA license unless an embryo is to be created from the in vitro derived gametes.

In 2005, stem cells derived from embryos were being used in research to explore the pathogenesis and possible therapies of several diseases. Prompted by the incongruous demand for research and limited supply of human embryos, two independent research groups submitted to the HFEA in November 2006 their proposals to derive stem cells from human embryos created from animal gametes [17]. Previously hybrid embryos had been created but were not permitted to develop past the 2-cell phase; however, this proposition was for the use of somatic cell nuclear transfer (SCNT) with development of the embryo to the blastocyst stage to produce specific embryonic stem cells. Most countries, including the UK, had not formed specific legalization concerning the production of human/animal hybrid embryos and a debate took place as to whether these embryos should be regarded as human as the law was far from explicit. Confirmation that they were human meant that the decision fell under the remit of the HFEA. Before granting licenses, the HFEA held a public consultation during 2007 [17], preempting the bioethical considerations that interspecies embryo production would elicit. It also sought literature review, scientific consultation and worked in close liaison with the Government's Stepwise Programme.

The Government White Paper 2006, proposed a ban of the creation of all types of hybrids and chimera embryos in research, but with a caveat, the HFEA's regulatory power continued allowing the HFEA to permit and license certain types of research. The HFEA in September 2007, after deliberation over the matter, stated "this is not a total green light for human animal cytoplasmic hybrid embryo (HACHE) research but recognition that this area of research can, with caution and careful scrutiny, be permitted" [17]. Two applications, one from Kings College London and the other form Newcastle, which fulfilled strict standards deemed necessary and met the standards required by HFEA, were subsequently granted a 1 year license for HACHE research.

With independent and conflicting legalization across the world, varying levels of regulation for fertility treatment and research, coupled with intensive worldwide exchange of gametes and embryos, the EUTCD 2004 set out to establish a homogenous approach for Europe. It was integrated and implemented into UK law on July 5, 2007 largely via the quality and safety for Human Applications Regulations 2007 [18]. It sought to standardize safety and quality for human tissues and cells intended for human application. The process was staggered, but importantly, many of the UK clinics had already met and exceeded the standards set in advance of the Directives absorption into the HFE Act, therefore little adjustment was required.

The HFEA under the EUTCD was expected to extend its remit. The HFEA had to investigate serious adverse events and if necessary, inspect third party premises to ensure safety and quality. In addition, the EU proposed that by 2008 the Member States were to establish a process by way of a single unique European coding and donor identification system. In January 2008, however, the HFEA expressed its concerns stating that it would be "burdensome on centers, require the purchase of costly new equipment and could threaten the viability of gametes and embryos currently in storage" [18].

With the extensive EUTCD aiming to ensure health protection within the European Union and consistent high expectations, many clinical services previously unaffected were now impacted by the new, extended regulatory role of the HFEA. Treatments, which necessitated the processing of fresh gametes which were previously unregulated, were now required to have a HFEA license under the European Directive. This affected clinics offering gamete Intra-Fallopian Transfer (GIFT) and artificial insemination. It was also necessary to obtain a HFEA license for the handling of fresh gametes and nonmedical fertility services such as Internet sperm providers. Despite this, there remained, the potential for abuse. This was exemplified by the first criminal conviction in 2008 when an online sperm website continued to "trade" without a license, and therefore, failed to comply with or respect the HFEA.

With this increasing demand for gametes and application of human gametes, coupled with several vulnerabilities, the HFEAs existence was deemed fundamental and central. Therefore again in 2008, with the revised definition of "gamete," came a critical modification in the HFEAs regulatory practice. With the definition extended to include immature eggs and sperm at all stages of development including precursor tissue, there were major implications for the storage of testicular and ovarian tissue for use in fertility preservation. This was not, however, the first change related to immature gametes, since in 2007, the revised regulations for the use of IVM came into force. IVM is a technique where immature gametes retrieved from the ovary are matured in the laboratory. This technique is now coupled with IVF and ICSI licensing. IVM is deemed advantageous on certain clinical grounds, such as in women who are at a very high risk of developing ovarian hyperstimulation syndrome with the use of ovarian stimulation medications which are used during standard IVF treatment. The technique allows for more clinical autonomy and choice when deciding on the most appropriate fertility treatment without the submission of an independent application [19].

As evidenced over time, HFEA has had to face many challenges and adapt. In line with scientific advances and the social attitudes elicited as consequence, a modernized and updated Human Fertilisation and Embryo Bill was introduced into the House of Lords on November 8, 2007 [20]. The Bill aimed to ensure that the law was fit for the twenty-first century practice with reflection of the UK as a forefront country in reproductive technology and research. In February 2008, the Bill was passed in the House of Lords and in the same month moved to the House of Commons. Despite much opposition and being subject to a great debate, the House of Commons passed the HFEA Bill with a majority vote of 355–129, and it received Royal Assent on November 13, 2008. Overall, it was felt that the bill "Would provide clarity and assurance to patients, researchers, the medical profession and the public for years to come" [20].

The framework of the 1990 Act was to remain as the foundation; however, many aspects required amendment to cover the matters and concerns that were not envisaged when the original Act was drawn up. The Human Fertilisation and Embryo Act 2008 encompasses the new concept of parenthood with the removal of **"**need for a father," and movement toward the paramount "welfare of the child" and responsible parenting being on the forefront. Previously the clinical responsibility toward the child was related to "the need for a father" for the child but now the emphasis has shifted to the importance of the wellbeing of the child. As a result, there is recognition and an equivalent provision for same sex couples and unmarried heterosexual couples. Since 1st September 2009, it is possible for both female partners to be included on the birth certificate.

With the ever increasing scope and meaning of "embryo" further clarification was desirable with assurance given that creation of all embryos, despite the means, would be subject to strict control and regulation. With the increased complexity, careful attention is now required even with the basic concepts of "gametes" and "embryo" and new definitions have been given to encompass the changes in technology and biological potential. With the ongoing controversy over the provisions of licensing for interspecies embryos, and the 1990 Act not explicitly addressing the issue, coupled with the interim 2006 Governmental White Paper intending the ban of interspecies embryos, motivated the HFEA to make a conclusion. The Act pledged and clarified that the creation of human/animal embryos is to be permitted for the purposes of research thereby allowing the embryo supply dilemma to be sidestepped [20].

With the new HFEA Act, the HFEA CoP also required substantial revision with new expectations in both conduct and outcomes for clinical practice. The 8th HFEA CoP superseded the 7th CoP and came into force in October 2009. The objectives and requirements of the 8th CoP may seem vast but are thoroughly justified considering that they were not only proposed to ensure safety and efficacy of clinical practice, but were also concerned with procedures which raise fundamental ethical and social questions. To ensure maintaining high standards, all centers are now required to have their licenses reviewed and renewed to comply with the new legislation.

The HFEA, via its Act 2008, 8th CoP and ongoing appraisals such as the 2009 Hampton Review [21] generates an appropriate model of regulation for the use and development of reproductive technologies, providing evidence and justification as to its pivotal role in the UK fertility field. Despite consistent maintenance of standards since its establishment with the 1990 Act, the HFEA's

position as a Government Arm's Length Body has not been secure. Initially, in 2006, it was proposed that the HFEA should be merged with the Human Tissue Authority (HTA) as "part of a wider Government aim of minimising and modernising the bureaucracy that goes with the provision of public services" [20]. The proposed Regulatory Authority for Tissue and Embryology (RATE) was deemed to be beneficial, as it would minimize the risk of overlapping functions, allow for the continuity of provision while achieving savings by way of increased effectiveness and efficiency [20]. With strong objections at this time, the counter augments highlighting the different remits and areas of expertise of the two organizations with the consideration of patient safety and public confidence, the Government dropped the proposal.

More recently, motivated by the current financial climate faced by the NHS, again the questions surrounding the position of HFEA resurfaced. In July 2010, the Government published its Arm's Length Body Review with the aim to reduce the NHS administration costs by 45 % and to abolish Arm's Length Bodies that do not need to exist [22]. With synergistic functions performed by the HFEA, HTA, and Care Quality Commission (CQC), it was proposed that the HFEA could be merged and its identity was lost. The Government introduced the Pubic Bodies Bill in 2010 to reshape and reorganize regulatory bodies including HFEA and HTA. Fragmentation and disbandment of the HFEA and HTA with the responsibilities moving to the CQC and Human Research Authority (HRA) were the original proposition. The main motive appeared to be financial with savings in the order of £180 million by 2014/15 estimates. Furthermore, with IVF no longer being considered experimental or "new," it was suggested that several HFEA functions are now superfluous and have been superseded, and moving away from one sole regulatory body may be overall more beneficial in preventing marginalization of the sector.

The Public Bodies Bill received Royal Assent on December 14, 2011 and was subject to much heated debate. On June 28, 2012 the Government launched a public consultation to seek views on the initiative [22], which closed on September 28, 2012 and HFEA retorted with its own response [22]. The government expressed in favor of the transfer of all functions to the CQC except those relating to research, which would go to the HRA as it would keep the regulatory functions intact, but reduce duplication and enhance transparency. HFEA argued the need to retain a dedicated coherent regulatory body, which maintains public trust, and further their already ongoing efforts to reduce expenditure. Since 2010, HFEA has made significant headway, and the total expenditure for the HFEA has been reduced by 25 %.

Although initial attempts to win reprieve for HFEA appeared futile and with a final decision in the lifetime of this coalition government being thought unlikely, the HFEA welcomed the news on the January 25, 2013 that, following consultation, the Department of Health had decided that the HFEA was to be retained. The majority of respondents (75 %) favored preservation of HFEA but stressed the necessity of further streamlining. The decision is therefore conditional on a further independent review on the delivery of further efficiencies, which would report to Government in April 2013 with contemplation of a potential merger with the HTA at that time [23].

In this 2-year interim period of much vulnerability, HFEA have continued their research and most recently launched a consultation document investigating the latest IVF technique with mitochondrial replacement designed to avoid serious mitochondrial disease [24]. This only further verifies that despite inquiry and anxiety, the HFEA remain wholly dedicated to the field of reproductive medicine.

Conclusion

On the 1st November 2010 the HFEA and the 1990 Act celebrated its 20th Anniversary. In the wake of political and financial upheaval the HFEA has faced increasing insecurity over its future as a pivotal regulatory body of fertility practices in the UK.

Since 1987, with the first Governmental White Paper, through tight regulation and steady nonwavering standards we have seen some tremendous milestones within the fertility world. It remains to be seen what further advances will come about and the role the HFEA will play, but to date, the figures demonstrating 138 licensed clinics and research establishments and over 200,000 "IVF babies" being born in the UK, reflects proudly the HFEAs and the UKs unprecedented reputation as a pioneer in the regulation process and a leader in reproductive technology respectively.

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