

## The HFEA in Context

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### Abstract

While the regulatory role of the HFEA, its independence, and its shortcomings are debated in the context of a fiscal economic crisis, the larger sociological importance of the Authority may be overlooked. Harder to calculate than its annual budget, and more elusive than its technical remit as a licensing body, the cultural value of the HFEA as a historical and symbolic entity that was born out of a pioneering debate unique to the UK must be included in a discussion of its future role. Against its perceived shortcomings as an expensive and outdated Quango is the importance of the Authority as a public instrument for enhancing the future of translational bioscience. From this point of view the HFEA is crucial not only to ensuring the successful realisation of a domestic bioscience agenda, but to protecting the international reputation of UK.plc as a best-practice model of publicly-supported bio-innovation.

### Commentary

The scientific and technological origins of human *in-vitro* fertilisation are numerous and varied, and some are more than a century old, such as the first successful embryo transfers in mammals conducted by Walter Heape in Prestwich in 1890, not far from where Louise Brown was born just under a century later. The ability to investigate the very earliest stages of mammalian development *in vitro* has long held a fascination for scientists and the general public alike, promising as it does not only the potential for greater understanding, but for greater control of the basic biological processes involved in human reproduction. This sector of scientific innovation is equally strongly associated with public concern (Turney, 1997). As late as 1971, Robert Edwards and Patrick Steptoe were denied funding for their research into IVF due to a combination of logistical, professional and ethical obstacles that rendered their proposed research programme unacceptable to the MRC (Johnson et al., 2010). But the goal of achieving human IVF had already become so tangible it was only a matter of time before someone succeeded. And it was no coincidence that the first viable IVF offspring were born in the UK, where a uniquely accomplished community of developmental biologists had the benefit of being trained in highly interdisciplinary university research centres, such as the one at Edinburgh led by Conrad Waddington, where both Bob Edwards and Anne McLaren, among others, began to mix together genetics and development biology in new and dynamic ways (Johnson, 2011). These new experimental frontiers offered possibilities to improve both basic science and translational applications in ways that are still just becoming visible today.

Another of Waddington's innovations, in addition to his high quality support staff, his famously popular refectory, and his bespoke animal husbandry facilities, was his establishment of the first science studies unit in the UK (or perhaps anywhere) at Edinburgh. He also took a keen interest in modern art, and his famous epigenetic landscape remains influential because of its unique visual encapsulation of a complex biological reality (Robertson, 1977). Waddington was a strong supporter of animated public debate about the ethics of science, as were many of his contemporaries and colleagues, including Naomi Mitchison (who dedicated some of her science fiction to Anne McLaren), Julian Huxley, Joseph Needham, Charlotte Auerbach, and J B S Haldane, among others,

who defied C P Snow's 'two cultures' thesis by combining basic science with art, philosophy, and social science (Hughes, 2008).

When Robert Edwards and Patrick Steptoe succeeded in delivering the world's first test-tube baby in 1978, few would have imagined this technology would become such a vast and over-subscribed global reproductive service industry in less than three decades. No one predicted that as many as five million 'miracle' babies would have been born by 2012, or that IVF would become a new norm of social life. Some of the early discoveries associated with the ability to culture human embryos in glass, such as the likelihood of deriving human cell lines to cure degenerative disease, were considered 'biologically impossible' until the late twentieth century. And as that century becomes more distant, it is ever clearer that IVF is likely to be seen in retrospect as one of its most significant technological accomplishments (Henig, 2004). As well as changing the future of human reproduction, IVF has expanded into a technological platform that supports and enables a huge range of pure and applied scientific research projects, from cloning and regenerative medicine to preimplantation genetic diagnosis and the derivation of new cellular models of human disease.

The involvement of the UK public in a challenging and lengthy conversation about how best to regulate and govern human fertilisation and embryology is, like much of the UK science that enabled IVF, comparatively anomalous. The UK is unique in its ability both to have held a lengthy public and parliamentary debate over the issues raised by technologically assisted conception, and to have successfully passed a comprehensive Act of Parliament governing the use of new reproductive technologies such as IVF. Moreover, the philosophical basis for these laws is highly unusual. Eschewing the polarised question of the moral status of the human embryo, Mary Warnock, working in close partnership with Anne McLaren, and with the implicit blessing of the scientifically-trained Prime Minister of the time, Margaret Thatcher, devised a different strategy. Above all, they sought a workable policy basis for regulating human fertilisation and embryology that would not only pass muster in Parliament, but would be sustainable in the long term. Using highly pragmatic reasoning, they sought a law which, as Warnock put it, would inevitably not appear 'right' to everyone, but would be 'alright' to enough people that it could command a workable majority opinion (Warnock 1985). The resultant legal framework is essentially sociological at root. It is based on an exchange: in exchange for allowing controversial research on human embryos, such research would be overseen by a licensing body, and subject to the very strictest sanctions (i.e. criminal law).

Warnock and McLaren faced a difficult challenge, as did the other early architects of the HFEA. They needed a licensing body that would strictly enforce the will of Parliament in law, while also helping to change the law when necessary. As anyone could plainly see from the very first incarnation of the HFEA in 1991, it would have to satisfy many conflicting masters, including Parliament, the general public, the scientific community, the medical profession, the courts, the media and various religious communities, among others. It was always obvious that the Authority would be vulnerable to challenges from well-resourced, and highly articulate patients, such as Diane Blood, who sought to defy its sanctions by appealing to the public with unusually tragic circumstances (Deech and Smajdor, 2007). To be consistent and logical in its enforcement of the law would inevitably require the decision to take unpopular actions from time to time. The Authority must be strict and reliable in its duties of surveillance, evaluation and licensing, while remaining flexible and innovative in the face of a rapidly expanding and diversifying assisted conception sector, as well as unforeseen developments in basic science. To deliver a much-needed service to the public, the Authority would

need to expand, while in order to minimise the burden on the public purse, it would need to be self-financing.

Ironically, the argument that the HFEA cannot continue in its present guise is a back-handed measure of its success. Even the claim that new reproductive technologies have now become routine is a measure of the comparative ease with which the techniques of IVF, gamete donation, preimplantation genetic diagnosis, intracytoplasmic sperm injection, cryopreservation, surrogacy, and even cloning have been normalised. As in the airline industry, excellent safety records are never as visible as catastrophes. It would be surprising if there were not incidents that have brought the authority of the HFEA into question, although on the whole these have been few and far between. What is particularly difficult to see in the wake of how comparatively well managed and thoughtfully regulated the rapid technologization of reproduction has been in the UK over the past two decades is how unusual it is to have an HFEA at all.

In contrast to the view that IVF and its ilk have simply become more normal and routine, however, is the fact that they have also become more complex and radical. IVF may be a technological imitation of natural biological conception *in vivo*, but it is hardly the same thing. As anyone who has undergone it can testify, IVF is not at all 'just like' what is now referred to as spontaneous or unassisted conception. 'Routine' IVF involves a complete rebooting of the female endocrine system using powerful pharmaceutical drugs whose long-term effects on either female IVF patients or their offspring will only be fully understood over time. Time will also be necessary to fully characterise the epigenetic effects of culturing embryos in various proprietary media, or the imprinting errors associated with IVF, some of which are now known to be heritable. The rapid routinisation of ICSI may well be 'normal' in a clinical sense, but what its biological sequelae may turn out to be remains an open question. And although comprehensive and systematic documentation of the increasingly large population of technologically conceived offspring is the only way to ensure thorough clinical follow-up, few countries outside the UK and Scandinavia keep accurate, if any, medical records of such children. The rapid privatisation of the assisted conception industry has posed, and will continue to pose, very substantial social, political, ethical and economic challenges in the future – not to mention biological and medical ones. As we already know from the massive spike in multiple births following the introduction of IVF, the costs of private sector mis- or mal-practice are largely met by the NHS, or other national equivalents. As we can predict from the huge increase in demand for assisted conception services worldwide, this commercial sector will soon be a multi-billion pound market. As Debora Spar (2004) asks in her prescient book, *The Baby Business*, the question of what kind of market this should be remains a nettle few governments are willing to grasp. Should it be completely free, so that anyone can sell their eggs or sperm to the highest internet bidder? Is it ethical for large numbers of Indian women to be encouraged to rent their wombs to wealthy foreign nationals – some of whom do not collect their 'Google babies' if they are born with abnormalities? What responsibilities do powerful countries such as the UK bear in the context of the increasingly global, international, economically stratified and financially lucrative business of baby-making?

As the planning work continues for the new UK Centre for Medical Research and Innovation (UKCMRI) at King's Cross, it is clear that public participation in new pathways of biological research will be crucial to their success domestically, while also key to the ability of the UK to brand itself internationally as a research leader in what *The Economist* has called 'the age of biology'. Probably one of the most important lessons of all that we have learned from the success of the HFEA is how to integrate science, medicine and society through successful policy. This is a famously elusive goal

at the same time that, as a series of reports from that of Walter Bodmer in 1985 onwards has shown, it is an increasingly central priority for the British government. IVF was not only a crucible for a new science of baby-making: it also gave birth to a new form of public debate, for which the UK is now seen as a best-practice model internationally. It is telling that the Bodmer Report was published in the midst of what the sociologist Michael Mulkay (1997) has called 'the great embryo debate' in the UK. The pioneering debate over human fertilisation and embryology that began in the UK in the wake of the birth of Louise Brown is itself a very distinctive species of British invention, which has, over the past three decades, expanded through debates over stem cells, cloning, and most recently human-animal chimeras (a debate that was so mild it hardly even compares to those that took place in the 1980s: e.g. Theodosiou and Johnson, 2011). All of the new applications in regenerative medicine and tissue engineering will require unique forms of consent, consultation and policy innovation. Biobanking on a newly explicit scale of public participation is probably one of the most important means of furthering translational science and medicine. The claim that the HFEA is an outdated and expensive Quango overlooks its accumulated and incalculable value as a public good. At a time when biological science is increasingly intimately interfaced to public trust and participation, the unique importance of the HFEA as a cultural, as well as a civic, resource should not be underestimated. Indeed, to the extent that the UK gains advantage by its ability to offer credible and persuasive evidence of accountability in the all-important bioscience sector, and currently enjoys an almost unparalleled degree of public support for highly experimental work on human embryos, the HFEA is nothing short of a national treasure.

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