Editorial

The changing face of IVF regulation

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Since the passing of the Human Fertilisation and Embryology (HFE) Act in 1990, technology has moved on apace and public opinion and social assumptions have also evolved. The Act has met with a number of legal challenges and has come under criticism for embedding prejudiced and discriminatory assumptions in the law.

In 2003, the UK's parliamentary Science and Technology Committee turned its attention to these issues, coming to the conclusion that the Act was outmoded and in urgent need of review: "we concluded that it was necessary to 'reconnect the Act with modern science.' The Department of Health's limp response was that the Government was keeping the Act 'under review.' We considered this statement to be inadequate, and on 24 October 2003, we announced our decision to embark on a review of our own" [1].

Perhaps galvanized by the Science and Technology Committee's zeal, in 2004 the government embarked on its own review of the Act. At the time of writing, the new Bill is still under debate, and the arguments raised by the first foray into this legislative area are being revisited, analyzed and subjected to renewed scrutiny. Ultimately, new legislation will be passed, updated and tightened to reflect scientific advances and social change.

Given that the approach to regulation in this area is changing, it is helpful to consider the circumstances in which the first Act was drawn up. For the first time, on 25 July 1978, a child conceived through IVF was born, an event that marked the beginning of a new era in human reproduction [2]. IVF was a highly experimental procedure and it seems plausible that it might not have been given the go-ahead had any regulatory body been in existence at the time. As it was, Louise Brown's birth presented legislators with a *fait accompli* in a regulatory vacuum.

Professional codes of conduct and self-regulation were put into operation to deal with these new techniques, but the novelty of the technology and the degree of public interest and concern that it raised meant that these professional regulatory frameworks were soon tested to the limits. The question of embryo research raised further difficulties: it was unclear how such research should be regulated, or indeed, whether it should be permitted at all. A feeling arose that the government should take some action to demonstrate that scientists were working within socially acceptable guidelines. With this challenge in mind, the government formed a committee chaired by the philosopher Mary Warnock.

The Warnock Committee's task was 'to consider recent and potential developments in medicine and science related to human fertilization 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' [3]. The Warnock Report was published in 1984 [4]. It suggested that the new technological developments needed closer and more formalized regulation than the existing professional codes could offer. After lengthy Parliamentary debate, the HFE Act was passed in 1990, based largely on the recommendations of the Warnock Report.

The Warnock Report has been widely praised for its pragmatism and insight, and its establishment of a sound ethical framework for embryo research and

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fertility treatment. However, since the passing of the HFE Act, controversies have continued to arise. As IVF has become more common and as new procedures and applications have been developed, regulatory questions have become more and more pressing. In the face of new developments, it has become necessary to define and constrain reproductive technologies within reasonable boundaries.

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The ongoing challenge for regulating reproductive technologies lies partly in the highly symbolic role that reproduction plays in our emotions and cultural values. But new reproductive technologies also raise pressing questions about fairness, justice and equity of access. Since the birth of Louise Brown, the place of IVF and other reproductive technologies in the NHS has come under intense scrutiny and local discrepancies in funding and eligibility criteria have been criticized severely.

In recent years it has become evident that the UK is particularly vulnerable to what has been termed the ‘unruliness’ of new reproductive technologies [5]. There are two primary reasons for this. First, there has been a failure to achieve uniform provision of IVF treatment on the NHS throughout the UK [6]. Guidelines issued by the NICE recommend that three cycles of IVF be provided to eligible patients, but these have not been put into practice throughout the UK. Patients’ distress at being refused treatment may be exacerbated by the knowledge that patients in neighboring areas are receiving these treatments. These discrepancies are widely perceived as arbitrary and unjust, and have been condemned strongly in the press [7,8].

It may be inevitable that financial restrictions play a part in determining who has access to new reproductive technologies, at least where such access is funded by the state; however, even if this issue could somehow be solved, there remains a second problem. That is the perception that access to new reproductive technologies is being restricted on specifically discriminatory grounds.

IVF clinicians are obliged by law to consider the welfare of children born as a result of treatment. But the welfare of children is a broad and contentious issue. Individuals may have widely varying ideas about what a child’s welfare entails and it is not always possible to achieve a consensus. The scope of clinicians’ interest and responsibilities in this respect is widely acknowledged to be poorly defined [9]. Is there any way of recognizing genuine welfare concerns, and separating them from mere prejudice and discrimination? If the answer to this question could be found empirically, life would surely be easier.

The prevailing trend in recent years has been to move away from overt value judgments and to focus more narrowly on objective grounds for legislation. Thus, where the Warnock Committee simply asserted that children do better with a mother and father, more recent approaches have sought empirical proof of such statements. A strongly libertarian view has been argued by some commentators, calling for unrestricted freedom, unless evidence of serious harm can be shown. The importance of avoiding discrimination is often raised in connection with this point. Sheila McLean, for example, argues that “whilst the state may have no general duty to facilitate reproduction through technology or the supply of a partner, once facilities are provided – for example through IVF and surrogacy programs – to deny access on the grounds of sexuality is to infringe the right on a discriminatory basis” [10].

Increasing weight has been given to the importance of avoiding discrimination since the passage of the Human Rights Act in 1998. Article 14 stipulates that the other rights outlined in the Act must not be applied on a discriminatory basis. This has been reflected in growing public and political awareness of this principle. In particular, the 2004–2005 Science and Technology Committee Report on Reproductive Technologies and the Law is highly critical of existing regulation and legislation specifically on the grounds that it is unjustly discriminatory [11]. The question of whether a prospective parent has a clinical need for treatment or whether the new technology will harm offspring has come to seem appropriate for legislators, while the deeper moral question of whether there is an intrinsic value in certain family set-ups is regarded as being irrelevant.

The move towards an evidence-based rationale for legislation was most apparent in the deliberations of the Science and Technology Committee and its report. This contrasts strikingly with the approach taken by the Warnock committee in the mid-1980s. At that time, it seemed self-evident that science must be constrained according to the moral concerns of the population. For Warnock, this was not purely about weighing the likely risks associated with a procedure since this ‘… could not provide a final or verifiable answer to the question whether it is right’ [12]. Emotional convictions were highly significant too: ‘Moral questions … are by definition questions that involve not only a calculation of consequences, but also strong sentiments’ [12].

By contrast, the Science and Technology Committee report repudiated the idea that freedom could be constrained on the grounds of emotional or moral convictions. The concept of personal individual freedom has gained weight since the publication of the Warnock Report, and the prospect of restricting freedom is now to be countenanced only with the greatest reluctance: “the foundation of legislation is to protect as far as possible the reproductive freedom of people wishing to have children. Any declared statutory policy can only erode the freedom of patients to make decisions in consultation with their doctors” [13].

Emotions have come to be regarded as being, at best, irrelevant, and at worst, detrimental to the task of achieving a reasonable approach to legislation. Harmful consequences are what count in drawing-up legislation, not gut feelings nor moral intuitions. If those who have concerns cannot provide proof of adverse consequences, the concern is represented as a groundless prejudice.

Perhaps partly because of this emphasis on reason, facts, objectivity and evidence, the role of ethics in relation to the drafting of legislation has become less clear in recent years. For example, the Report on the Draft Human Tissue and Embryos Bill published by a joint committee in August 2007, lamented the lack of explicit ethical principles and guidelines on which to base their deliberations. This report called for a specialist parliamentary ethics committee to be set up.

The interesting point here is that while previous parliamentary committees, most notably the Warnock Committee, regarded themselves as competent to debate, discuss and ultimately make decisions based partly on moral reasoning, the joint committee did not. Perhaps this was partly due to time constraints, but may have been partly because it is increasingly the case that it has become risky to express overt moral views that cannot be resolved empirically. The obvious benefit of the rational, evidence-based approach is that harmful consequences can, in theory, be objectively identified, quantified and analyzed in a way that more nebulous moral concerns cannot. Moreover, they are surely more stable over time.

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For example, only a few decades ago it was regarded as shameful and immoral to give birth to a child out of wedlock, yet many couples now choose not to marry and the stigma of illegitimacy has all but disappeared. In the mid-1980s, the assumptions of the Warnock committee about the desirability of certain family structures may have been in line with general social attitudes; however, 20 years later, views have changed. Undoubtedly some people still feel strongly about the need for a father, or the unsuitability of offering of fertility treatment to single women, but it seems fair to say that many people no longer feel these concerns. Having become aware of this kind of moral and emotional evolution during the relatively short period between the Warnock Committee’s report and the present day, current policy makers are understandably cautious about reflecting moral intuitions and gut reactions in the law.

Once laws are in place, it can become extremely difficult to amend or fine-tune them [14]. As technology continues to move on, the heated political debates and the legislative decisions that arise from them may become obsolete very quickly. It is in the public interest that parliamentary time is not wasted on the production of legislation that will inevitably be challenged and outmoded within a short space of time. Accordingly, esoteric ethical debates are avoided and a preference for light-touch legislation has been evident in many recent parliamentary documents, most notably the joint committee report on the Human Tissue and Embryos (draft) Bill and the government’s response to this report. Legal and regulatory restrictions are to be avoided unless demonstrably necessary to avoid harm.

This approach is very much in-keeping with the British empiricist tradition. Sheila Jasanoff, a Professor at Harvard, has said of the debates on embryo research and fertility treatments: “one is struck by the confidence of an empiricist culture persuaded that observable distinctions exist in the real world, that they can be witnessed in common, and that they accordingly form a stable basis for public policy” [15]. Yet Jasanoff’s comment seems to have an underlying note of skepticism: can it be that these observable distinctions are less than stable? Are we really likely to solve the problems of fluctuating moral and social beliefs by focusing more strictly on clinical facts and empirical evidence?

In the current social and political climate, those who wish the law to reflect a preference for ‘traditional’ families must now bolster their arguments with data showing that such families are in fact better for children. Conversely, those who argue in favor of more liberal interpretations of the family are likely to cite evidence showing that children are not harmed by ‘unusual’ family structures. Empirical data is thus a hotly contested prize and both sides claim it as their own.

Where conclusive proof is lacking or evidence is ambiguous, it is not empirical data that resolves the problem but whichever convictions hold sway at the time. Recent trends in moral and political thinking, such as the rise of individual rights and nondiscrimination as a principle, have attained primacy in our emotional and moral thinking. This being the case, what one can see in the deliberations over the past years is the evolution of value systems: emphasis on individual freedoms and entitlements has popularly superseded the weight placed on traditional and communal values.

Examples of this change can be seen in two comments, one from the Warnock report, and one from the Science and Technology Committee report of 2004/2005. Warnock’s approach reflected a belief in the public need for boundaries and a conviction that such boundaries serve to express and enforce moral beliefs that define our social identity: “in recognizing that there should be limits, people are bearing witness to the existence of a moral ideal of society” [16].

The Science and Technology Committee stipulate that: “… the state should intervene only in carefully defined and justified circumstances, where there are specific harms in reproductive decisions” [17].

It is appealing to think that today’s values and their reflection in law are somehow safer because they are founded on objective facts rather than moral ideals; but this is not entirely the case. Preventing harm may seem to be an admirably nondiscriminatory way of establishing legal boundaries, but the concept of harm itself has been called into question. It has recently been argued that prospective parents should be allowed to select embryos who will be deaf, on the grounds that the resulting children would not be harmed *per se* by this choice [18]. An emphasis on individual rights and freedoms is in fact inherently incompatible with the notion that harm is an objective and empirically verifiable concept.

A final point remains to be made concerning the limits of empiricism and objectivity in this area and the degree to which moral judgments are still inextricably entwined with supposedly factual or clinical decisions. Currently, NICE guidelines set out eligibility criteria that recommend the provision of IVF to healthy, fertile women whose (male) partners suffer from fertility problems [19]. A woman can thus receive treatment because she is unable to reproduce in the context of her relationship, rather than because of any specific physiological or medical fact pertaining to herself. This being the case, it is interesting to consider why single or lesbian women are deemed not to have a need for treatment according to NICE guidelines. After all, they too are unable to have children in the context of their relationships.

Fertility and infertility in the era of reproductive technology is defined not solely by clinical, but by social and moral beliefs. The norm of heterosexuality is embedded in the current interpretation of clinical need. The fundamental challenge facing current legislators is this: it is not only the welfare issue that seems to be entangled in subjective moral beliefs, but the very question of what constitutes infertility. As a result of this, it is simply not possible to excise all subjectivity, all emotion or all prejudice from legislation in this area. Attempting to do so may in fact mask some of the unquestioned moral assumptions that are nestling under the guise of clinical facts. A quasi-scientific language of facts and reason has become the medium in which current debates are embedded. Moral disputes are now often re-clothed as empirical disagreements, but the disagreements are still there.

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