

RESEARCH ARTICLE

The Value of Life and Reproductive and Professional Autonomy

Lucy Frith 

Professor of Bioethics and Health Research, Centre for Social Ethics and Policy, University of Manchester, Manchester, UK
Email: lucy.frith@manchester.ac.uk

Abstract

This article considers John Harris' work on autonomy, specifically reproductive autonomy, outlined in *The Value of Life* and developed throughout his career. Harris often used the concept of reproductive autonomy to make the case for liberal approaches to developments in reproductive and genetic technologies. Harris argued that reproductive autonomy should be highly valued, and therefore we need compelling arguments to justify limiting it in anyway. When discussing reproductive autonomy, Harris focused mainly on restrictions on the potential users of reproductive technologies autonomy, that is, prospective parents. This article extends the discussion of autonomy and the appropriate limits to individuals exercising their autonomy to medical professionals working in this area. Given reproductive technologies have become part of routine medical practice, this article considers whether the current restrictions on both patients and clinicians, as imposed by regulators and professional guidelines, remain ethically justified.

Keywords: Human Fertilization and Embryology Authority (HFEA); medical professionalism; professional autonomy; reproductive autonomy; reproductive technologies

Introduction

This article considers John Harris' work on autonomy, specifically reproductive autonomy, outlined in *The Value of Life* and developed throughout his subsequent work. Harris often used the concept of reproductive autonomy to make the case for liberal approaches to developments in reproductive and genetic technologies. Harris argued that reproductive autonomy should be highly valued, and therefore we need compelling arguments to justify putting any limitations on it. According to Harris, a commonly raised objection to new developments in reproductive technologies, is that they might produce harmful consequences in the future, and on these grounds, they should be prohibited or carefully regulated. However, Harris often claimed that the reasons given were rarely strong enough to provide justifiable grounds for limiting reproductive autonomy. Hence, prospective users' autonomy should be respected as the harms that might be engendered by using these technologies are usually not seriously harmful to others, or to society, and that these harms are "rarely real and present, but rather future and speculative."¹ When discussing reproductive autonomy, Harris focused mainly on restrictions on the potential users of reproductive technologies autonomy, that is, prospective parents. In this article, I will extend the discussion of autonomy and the appropriate limits to individuals exercising their autonomy to medical professionals working in reproductive technologies. Medical professionals' autonomy is restricted by

This article will develop an argument that we need to be cautious about dismantling the regulatory protections provided by legislation in jurisdictions like the United Kingdom. Although regulations could be changed to allow for the greater exercising of both reproductive and professional autonomy, there still needs to be careful oversight of reproductive technologies.

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regulations and legislation and/or professional guidelines, such as welfare of the child considerations or guidelines on the number of embryos replaced in an in vitro fertilization (IVF) cycle,² and this in turn restricts the options available to users of reproductive technologies and hence their reproductive autonomy.

This article will discuss Harris's arguments about reproductive autonomy in the light of technological developments and the increase in the use of reproductive technologies over the last 40 years since the publication of *The Value of Life*. Given reproductive technologies such as IVF, egg freezing, donation of gametes and embryos and associated genetic screening and diagnostic techniques have become part of routine medical practice, are many of the restrictions placed by regulators on both users' and practitioners' autonomy in this area still ethically justified? This article will explore this question by using the example of the recent proposals for law reform in the United Kingdom. The legislation and the associated codes of practice in the U.K. place substantial limitations on both the reproductive autonomy of potential users of reproductive technologies and on medical professionals who work in the field. The legislation that governs this area is the Human Reproduction and Embryology (HFE) Act 1990, and the amendments introduced in 2008. The act established the Human Fertilization and Embryology Authority (HFEA) to regulate and license reproductive technologies. The HFEA is responsible for developing codes of practice and has held public consultations on various ethically contentious issues, such as mitochondrial DNA replacement treatment. In 2022, the HFEA announced it would begin a process of considering how the HFE Act might be reformed. This article will look at the proposals to reform the HFE Act and the implications this has for the oversight of reproductive technologies.

This article will argue that we need to be cautious about dismantling the regulatory protections provided by the HFE Act. Although regulations could be modified to allow the greater exercising of both reproductive and professional autonomy, there still needs to be careful oversight of reproductive technologies.

Terminology

I will use the term "reproductive technologies" to denote medical techniques developed to create babies/children such as IVF, gamete, egg and sperm, and embryo donation, and intracytoplasmic sperm injection. These techniques are sometimes termed medically assisted reproduction (MAR). I will use the term "recipients" to mean those either individually or in couples who may wish to use these techniques to form a family, and "clinicians" to mean members of the medical profession who specialize in this area. Although this article will focus on medical professionals, many of the concerns and issues will also affect other healthcare professionals working in fertility, such as embryologist, nurses, and so forth. This article will also focus predominantly on the U.K. context, but the arguments about regulation and professional autonomy are relevant for all jurisdictions.

John Harris and Reproductive Autonomy

Autonomy has been a central theme in much of Harris' work and discussed in some detail in the *Value of Life*. In the *Value of Life*, as the title suggests, Harris considered what might make life valuable and establish the importance of "respect for persons," which is "the starting point of morality." Central to his idea of respect for persons, is respecting peoples' wishes, and from this follows his consideration of autonomy. "Respect for the wishes of others is central to any claim to accept that their lives are valuable because, as we have seen, for each individual life has unique value and that value is determined by what the individual wants to do with his or her own life. Because it is we who give our lives value, that value is in pawn to our freedom to pursue our own objects in our own way."³ Harris goes on to say, "Unless the value of our lives is to be undermined, the only constraint on our freedom to do as we please should be the familiar proviso that what we please to do does not harm others or does as little harm to others as it is possible for us to do."⁴ This is the familiar Millian view of liberty, there should be a presumption toward liberty, decisions should be free from interference

unless they will cause serious harm to others. In other words, the burden of proof should reside with those wishing to restrict choices, employing liberty limiting principles to assess how far liberty should be restricted in a particular situation.⁵ Edgar Dahl, for example, sums up this argument when he says: “each citizen ought to have the right to live his life as he [sic] chooses so long as he [sic] does not infringe upon the rights of others. The state may interfere with the free choices of its citizens only to prevent serious harm to others.”⁶ As Harris states, “the burden of proof is not on those who defend liberty but on those who would deny it.”⁷

Harris calls this the democratic presumption. In liberal democracies the freedom of citizens should not be interfered with unless there are very good grounds for doing so. Harris applied this concern with liberty and what might constitute unwarranted restrictions on individual autonomy to the area of reproductive technologies, and used, in many places in his work, this as a starting point to question whether restrictions in the form of legal prohibitions or regulatory limitations, were ethically justified. “At the heart of these questions is the issue of whether or not people have rights to control their reproductive destiny and, so far as they can do so without violating the rights of others or threatening society, to choose their own procreative path.”⁸ Harris, in applying autonomy concerns to reproduction, talks about reproductive liberty and procreative autonomy in different places, and it appears that there is no substantive distinction between these two terms.

Reproductive autonomy—as I shall call it in this article—is argued to be a special kind of autonomy. It is claimed that reproductive choices are special kind of choices, “integral to a person’s sense of being,”⁹ and any restrictions therefore require a more robust justification than other less important choices.¹⁰ Hence, there is a belief that the more important the particular choice, the stronger the case for restricting it has to be. Harris outlines the importance of reproductive autonomy and its relationship to the fundamental right to reproduce in a 2006 paper.¹¹ Given its importance, Harris contends that the level of evidence of harm needed to justify restricting reproductive choices should be higher than the level needed to justify other less important choices. Further, as reproductive choice is very important, allowing people to exercise is a good in itself, and this good could outweigh the production of a certain level of harm. Harris argues that when weighing up whether to allow developments in reproductive technologies, we must not be swayed by, arguably, irrelevant considerations such as objecting on the grounds that we might not do these things ourselves or things that we find disgusting or abhorrent: “Those who would exercise reproductive liberty do not have to show what good it would do, rather those who would curtail freedom have to show not simply that it is unpopular, or undesirable, or undesired, but that it is seriously harmful to others, or to society, and that these harms are real and present, not future and speculative.”¹²

Harris employs these arguments in his discussion of human reproductive cloning. Drawing on the defense of procreative liberty advanced by Gerald Dworkin, Harris argues, “Dworkin’s arguments suggest that human dignity and indeed democratic constitutions may be compromised by attempts to limit procreative autonomy, at least where greater values cannot be shown to be thereby threatened. [I have] argued that no remotely plausible arguments exist as to how human cloning might pose significant dangers or threats or that it may compromise important human values. It has shown that there is a *prima facie* case for regarding human cloning as a dimension of procreative autonomy that should not be lightly restricted.”¹³

Harris’ concern with autonomy and how far and in what way it can be reasonably limited or curtailed continues to be a dominant focus in medical/bioethics. There have been criticisms of the focus on individual autonomy, and whether these kinds of concerns should trump other moral imperatives, such as beneficence.¹⁴ There have also been developments in thinking about autonomy, such as relational autonomy¹⁵⁻¹⁶ that consider the person in their wider context. Edward S. Dove et al. define relational autonomy as: “Relational autonomy can be viewed as a conception of autonomy that places the individual in a socially embedded network of others.”¹⁷ For the purposes of this article, I do not want to question Harris’s definition of autonomy, or whether the liberal project of championing individual autonomy and specifically, reproductive autonomy, needs to be revisited. Rather, I want to consider how debates over autonomous action in this space have changed since Harris published *The Value of Life*, and how current regulatory debates, in the United Kingdom, are raising concerns over the extent of the restrictions on professional autonomy, for medical practitioners who work in this area. Hence, I will

extend the discussion of autonomy and the appropriate limits to individuals exercising their autonomy to medical professionals working in fertility practice.

Concepts of Professional Autonomy and Relationship with Reproductive Autonomy

As Harris notes, legal prohibitions limit the reproductive autonomy of individuals, those who wish to use reproductive technologies, such as reproductive cloning, but they also limit the autonomy of clinicians. If we are concerned about potential recipient's autonomy, then the ability of practitioners, fertility clinicians, to practice autonomously directly affects what options recipients will be offered. Ethical debates over reproductive technologies tend to focus on individual recipients and the effect of regulatory structures on them and concerns related to people created by these techniques, with less attention paid to clinicians' professional autonomy. Although the focus of Harris's work has been on the importance of the ability to exercise reproductive autonomy for recipients, I will consider arguments about in which circumstances it is acceptable to restrict medical professionals' autonomy. It is important to clarify that I am talking about members of the medical profession's professional autonomy, not their ability to exercise their own personal autonomy on clinical or ethical matters.¹⁸

There is not space in this article to go into a discussion of what constitutes a "profession" nor how the medical profession has developed and changed historically. There is also considerable debate about the medical professions' right and ability to self-regulate and I will not revisit that here. However, one feature that frequently arises when people talk about professions and what distinguishes a profession from other forms of employment role, is the moral nature of the endeavor and their autonomous nature. The Oxford English dictionary definition of a profession, states members of a profession, "profess a commitment to competence, integrity and morality, altruism, and the promotion of the public good within their domain. These commitments form the basis of a social contract between a profession and society, which in return grants the profession *the right to autonomy in practice* and the privilege of self-regulation." (Emphasis mine)¹⁹

The, building on this concept of the autonomy of professions, the argument I will advance is:

1. The medical profession is held to be a moral one, comprising of moral values (principles).
2. As members of the profession, clinicians are expected to act according to the moral values (principles) of medicine.
3. Clinicians are accountable and face censure if they do not act in this way.
4. In order to be able to be held accountable, clinicians must have professional autonomy, moral agency to make moral decisions.
5. Therefore, for medicine to be a moral profession, clinicians must have professional autonomy.

I will not go into all the premises of this argument in depth but summarize the key points, namely that medicine is a moral profession and that some form of professional autonomy is necessary for this to be realized in practice. Taking medicine as a moral profession first, in many accounts of what medicine is and what makes it a profession, is a claim that medicine is a moral endeavor that is based on particular moral values and duties. In a report published in 2005, the Royal College of Physicians (RCP) defined medical professionalism as follows, "[m]edical professionalism signifies a set of values, behaviors and relationships that underpins the trust that the public has in doctors." And argued that, "these values, which underpin the science and practice of medicine, form the basis of a moral contract between the medical profession and society."²⁰

Accounts of medical professionalism often start with the question of what norms are binding on doctors by virtue of their membership of their profession? What are the norms without which medicine, in John D. Arras's words, "would cease to be a going concern."²¹ Arras gives the example of confidentiality, as a norm that makes the trust relationship between the doctor and the patient possible. Hence, most accounts of medical professionalism incorporate notions of a commitment to ethical practice, however grounded, based on fiduciary responsibility and trust. For example, Rosamond Rhodes²²

account of medical professionalism grounds this distinctive form of professional morality in Rawlsian theory,²³ and develops a contractarian constructivist account. The concept of public reason is central to Rhodes' Rawlsian account. She argues that in medicine the success of public reason is often more apparent than in political deliberation. This idea that there can be a common standard of "reason" is coupled with Rawls' recognition that there are some elements in society that have a distinctive character and autonomy, and therefore act from their own principles. Rhodes argues that while Rawls may not have had medicine in mind, "medicine is clearly a part of society that is ethically autonomous."²⁴

Building on these two elements, Rhodes attempts to construct the principles that should govern the social institution of medicine, as Rawls outlined the principles that should govern political institutions. These principles, for Rhodes, are drawn from, "the distinctive character and autonomy of the profession [of medicine]."²⁵ The principles that Rhodes outlines are found in many different sets of ethical codes for doctors. She argues that "there is genuine consensus on the core content of the professional responsibilities of physicians"²⁶ and gives the example of the consistency of the principles she lists to those found in "The Medical Professionalism Project."²⁷ Thus, these are the principles that underpin medicine as a moral profession and other professions such as law are based on different, although sometimes overlapping (e.g., confidentiality) moral commitments.

In this account, the moral principles that underpin medical professionalism are coupled with a consideration of the autonomy of medicine. What precisely professional autonomy means in practice is open to debate, but it seems that any robust conception of medical professionalism, has to incorporate some form of commitment to professional autonomy, or the values that underpin the delivery of healthcare would be fostered only by organizations not the professionals within them. Medical professionals should be able to act as moral agents and this requires them to have agency and autonomy. As my argument suggests, we hold clinicians to account, and therefore, as ought implies can, they must be able to make autonomous choices, to be held to account in this way.

There have been critiques of the value of professional autonomy in medicine. For example, in the RCP report of 2005, they state that their definition of medical professionalism does not include any mention of autonomy because, "autonomy ... suggests the right to self-governance, an appeal to personal authority—that is, the right to pursue a practice that is entirely self-generated. Clearly, that is not a value we wish to recommend. The doctor should tailor his or her care to the expressed needs of the patient in the light of a body of reliable scientific evidence."²⁸ The tenor of this report is that the values of the autonomous authoritative clinician are of a past era, and values of teamwork and patient-centered care should replace them.

This criticism trades on a potential confusion over what professional autonomy means,²⁹ as Rhodes says, exercising professional autonomy is not the same as exercising individual autonomy, we do not expect clinicians to act according to their own personal moral codes, but the codes of the medical profession.³⁰ Rhodes sees this as a kind of ethical standard of care, and this would be established, using the tools of public reason, by discussions drawing on the relevant evidence and ethical principles that all competent clinicians would recognize as relevant considerations on which to base their judgment. Hence, in this sense a clinician's individual autonomy is restricted by their professional obligations, but individual clinicians should be able to exercise professional autonomy—not restricted by organizational policies or regulations.

Whether medicine can be argued to be a moral profession has also been questioned. Medicine was traditionally seen as a moral profession in the work of Everett Hughes for example. The medical profession was seen to have a set of moral values that it adhered to, and doctors were granted their privileged status on the grounds that they would be moral in their everyday undertakings.^{31,32} This notion of medical professionalism began to be heavily criticized in the 1960s and 1970s. It was argued that any notion of professional ethics was a cynical ploy, doctors' supposed altruism was really a mask for their own self-interest.^{33,34} However, since the 1990s, there has been a change in the tenor of the sociological literature and medical professionalism began to be reunited with the notion that medicine has certain values (such as altruism) that are central to its functioning in society, as outlined above. Eliot Freidson, for instance, in a latter work,^{35,36} argues that medical professionalism serves an important social function in ensuring that the professions maintain high standards of work and trustworthiness.

Freidson argued that there are now “three logics” for viewing the distribution and organization of healthcare:

- “1. By market forces—where healthcare is traded like any other commodity.
2. By large social organizations—insurance companies or the NHS, bureaucracies that seek to manage healthcare.
3. By the professions themselves with a commitment to the standard of their work and a public service ethos.”³⁷

In his view, it is this third way of organizing healthcare that is preferable. We need to bolster medical professionalism in order to best ensure a more ethical and publicly trustworthy health service. William M. Sullivan exemplifies this trend in arguing that medicine cannot function unless the public has trust in it as an institution, “the root of the public’s trust is the confidence that physicians will put patients’ welfare ahead of all other considerations....It is the function of medicine as a profession to safeguard and promote this trust in the society at large.”³⁸ These arguments for giving the moral character of the medical profession a central role and ensuring some kind of professional autonomy are brought together in the World Medical Association’s (WMA) Seoul declaration, “The WMA reaffirms that professional autonomy and clinical independence are essential components of high-quality medical care and the patient-physician relationship that must be preserved. The WMA also affirms that professional autonomy and clinical independence are core elements of medical professionalism.”³⁹

Clearly, what counts as professional autonomy, and how far clinicians can rightly exercise it is a contentious issue. There are certainly many claims that medical professional autonomy has declined over the last 50 years,⁴⁰ and that this is not a bad thing.⁴¹ However, this section has sought to demonstrate that there are arguments for valuing some form of professional autonomy, as without that medicine as a moral endeavor is hard to substantiate. If we go back to reproductive autonomy, a form of autonomy that was seen as particularly important, we can now add professional autonomy, as a form of autonomy that should be valued, and that any moves to restrict it, need to be robustly justified.

Current Regulatory and Good Practice Restrictions in MAR

Since the publication of the *Value of Life* both scientific developments and the landscape in which reproductive technologies operate have changed significantly. The regulatory imperative in this area, partly prompted by the ability to create embryos outside the body, and the perceived view that as reproductive technologies involve the creation of life, this is an area that merits special regulatory and legal oversight, is still prevalent both in the United Kingdom and internationally. The approach taken to regulating this area in the United Kingdom, as with other jurisdictions such as Victoria Australia, is therefore one of comprehensive legislation. The 1990 HFE Act, revised in 2008, governs most aspects of reproductive technologies in the United Kingdom.⁴² Such legislation gives those working in this area and those wishing to access fertility services less room for autonomous choice. For instance, the choice of sex selection for social reasons is not available in the United Kingdom but is available in other countries. In other jurisdictions, such as the federal system in the United States, professional guidelines such as those issued by the American Society of Reproductive Medicine (ASRM), guide practice, alongside some state-specific regulation. However, arguments have been made that these guidelines and their voluntary nature are not sufficient to adequately regulate this area.⁴³

What was once seen as a cutting edge experimental and futuristic technology, IVF is now a routine treatment for fertility issues. The use of IVF has increased ninefold since 1991 in the United Kingdom.⁴⁴ Not only has the use increased, but the success rates for treatments have improved. IVF now has an average birth rate using fresh embryo transfers of 22% per embryo transferred in 2021, which has increased from 8% per embryo transferred in 1991. The scientific landscape has also changed; for example, mitochondrial donation in treatment was allowed by the U.K. parliament in 2015, and preimplantation genetic testing for monogenic disorders or chromosomal structural rearrangement

(PGT-M and PGT-SR) is now used to screen embryos for serious inherited illnesses. Scientific developments, such as womb transplants and in vitro derived gametes continue to challenge the boundaries of acceptable ethical practice and scientific possibility. Hence, in this regard, although the issues might have changed, the debates and controversy over how we balance the good of society, the reproductive autonomy of potential recipients, scientific freedom, and professional autonomy are still pertinent and no less significant than they were when the Value of Life was first published in 1985.⁴⁵

Now that many reproductive technologies have become part of routine medical practice, are the restrictions placed by regulators on both users and professionals' autonomy still ethically justified and does this area merit such "special treatment"? To consider these questions I shall look at the proposals for reform of the HFE Act put forward by the HFEA in 2023, and the response to this consultation from the main professional body that represents fertility clinicians (and other fertility professionals), in the United Kingdom, the British Fertility Society (BFS).

Reform of the HFE Act

In the early 2020s,⁴⁶ there was a growing consensus that modernization of the HFE Act was well overdue. The chair of the HFEA, Julia Chain, in speeches given in 2021 and 2022, outlined areas that needed attention to ensure that the Act could be "future proofed."⁴⁷ Chain noted that fertility treatment and embryo research "had originally been considered so distinct, that it required its own regulatory regime." A review of the HFEA in 2023 by the Department of Health and Social Care, reiterated that the HFEA should continue to regulate this area and not have its functions transferred to other bodies.⁴⁸ Chain commented that the HFEA were, "delighted that this discrete and specialized area of medical practice and scientific research should continue to be separately regulated by us at the HFEA."⁴⁹

There are two areas of the proposed reforms that are relevant for this article, the HFEA's proposals on how to manage scientific developments and patient protection and safety. In terms of scientific developments, the planned reforms would, arguably, fit well with Harris's concerns that undue caution is being exercised and reproductive autonomy restricted disproportionately. The consultation states: "The question is not whether a new treatment is 'safe,' but whether the evidence suggests it is 'sufficiently safe' given the potential benefits to the patient." The HFEA's proposals recognize that this is a fast-changing area and that the approval of new developments needs to be more agile, and suggest, "The Act should explicitly give the HFEA greater discretion to support innovation in treatment and research."⁵⁰

On patient protection and safety, the HFEA consultation puts forward the suggestion that "The HFEA should have a broader and more proportionate range of regulatory enforcement powers." In addition, "The Act should be revised to include an overarching focus on patient protection." The consultation goes on to state, "This proposal is intended to reflect the wider context of fertility treatment in the United Kingdom today, where the majority of patients pay for the treatment themselves (which is very unusual in U.K. healthcare) and consideration is not only about medical care and treatment, but as others have noted, about patients as consumers."⁵¹ These proposals are driven by the changing landscape of fertility provision that includes greater non-NHS (public) funding of fertility treatment, privately operated clinics that are often part of large international groups, greater use of online services and advice, and online advertising. This has led to those using fertility services becoming consumers, not just recipients of medical treatment. Hence, there are two imperatives in these proposals, first that this area still needs distinctive and dedicated laws and regulation, and second, that some extension of the HFEA's powers is necessary, underpinned by a more general concern with patient protection and safety.

I shall now consider the BFS's response to the consultation document,⁵² to show how this professional organization sees some of the requirements and powers that the HFE Act gives the HFEA as an unwarranted restriction on their members' professional autonomy. The question here is not a generalized one about the external regulation of the medical profession, or how modern medicine with its increasing use of guidelines and protocols (both in state funded and insurance funded systems), is reducing clinicians' professional autonomy. Rather, it is whether fertility clinicians are facing specific

restrictions of their practice, their professional autonomy, over and above what a doctor in another specialty might face and if this warranted.

It is certainly the case that current regulatory practice in the United Kingdom adds an extra layer of regulation and it is argued that this is burdensome for clinicians and restricts their professional autonomy in an unnecessary way. Sebastian Sethe and Alison Murdoch⁵³ consider how IVF is regulated compared to abortion and conclude that IVF is overregulated and trace the historical reasons for this. There have been various articulations of this view by the BFS before their consultation response, in which they raise an overriding concern that any extension of the HFEA's functions should not duplicate other existing regulatory mechanism, such as the Care Quality Commission. The specific details of existing regulatory structures are only relevant to an English setting, so I will not explore these in depth, but the principle that regulatory mechanisms sit over and above those required for all medical professionals is relevant in other regulatory regimes. A key area that the BFS response highlights is how patient autonomy is currently unduly restricted and, although not put in this way explicitly, professional autonomy. "Patient autonomy is limited by the legislation and its implementation, for example, 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, for example, antenatal screening decisions are made by the patient after appropriate information and counseling. 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."⁵⁴ They go on to say, "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, European Society of Human Reproduction and Embryology [ESHRE], ASRM) allows this flexibility and an individualized approach. Justification for practice outside professional guidelines may be required but the guidelines are not designed to be obligatory."⁵⁵ These two quotes exemplify the BFS's concern that their practice and hence what is available to patients, is unwarrantedly restricted in some instances by the HFE Act and the HFEA's COP that sits alongside it.

How Should We Regulate Reproductive Technologies?

Given the criticisms of the HFEA, as noted above, and the various attempts over the years to either restrict or abolish the HFEA and move some of its functions to other bodies, such as the Human Tissue Authority,⁵⁶ how should this area be regulated? One solution would be radically curb the power of the HFEA and rely on the regulations that govern all medical practice to provide oversight of this area. However, there are benefits to having such regulatory regime and a body like the HFEA fulfills important functions. As Victoria English points out, the HFEA:

- (i) protects patients,
- (ii) allays public concerns,
- (iii) provides an environment within which scientific progress can flourish, and
- (iv) protects IVF practitioners against claims of unethical behavior.⁵⁷

Hence, it can be argued that having such a regulatory regime actually protects professionals and gives reproductive technologies a social license. As we have seen with events in the United States over the Alabama constitution giving full moral status to the embryo and the consequent failure of bills to protect IVF practice in the US senate,⁵⁸ reproductive rights and the continuation of related reproductive services cannot always be assumed. The debate in the United Kingdom is not whether to regulate through an all-encompassing piece of legislation, but what the scope and parameters of this piece of legislation should be.

To consider the impact of the regulatory framework on fertility clinicians' professional autonomy, it could be argued that some of the HFEA guidelines, for example, those on single embryo transfer, are

based on current clinical opinion and evidence, so that a “reasonable medical professional” would agree with implementing these guidelines. However, a central tenant of professional autonomy is being able to exercise one’s judgment, based on ethical and clinical standards of care for the patient’s benefit,⁵⁹ and binding guidelines do not allow that possibility. It might now the time to allow clinicians more professional autonomy to determine what is an acceptable treatment regime for a particular patient and recognize that guidelines that are enshrined as compulsory directives might not always provide the best care in particular individual circumstances. Further, since the inception of the HFEA in 1991 a considerable body of professional guidance and guidelines, such as those from ASRM and ESHRE have grown up and these can perform the role of setting good practice standards, as is the case in other areas of medicine.

Despite this, there is still a role for specific regulation in this area, even though it is argued that, as many reproductive technologies are now routine medical treatment, it no longer requires such specialized oversight. The issue here is how “routine” treatment is defined and what counts as yet unproven or experimental technologies? While we might be confident that IVF without preimplantation genetic diagnosis is routine, what about the use of donated gametes with IVF? While again, this is a well-established procedure, it still raises complex regulatory and ethical issues.⁶⁰ Further, taking the example of gamete donation again, technological advances in tangential areas, such as direct-to-consumer genetic testing, that enable people to find and search for donor relatives outside regulatory structures, can have profound effects on the practice, that were not foreseen, and hence regulators need to be attentive to and have the authority to respond to such developments.⁶¹ Hence, I would argue that the HFEA needs to be able to have oversight of the changing landscape of reproductive technologies. However, as per the BFS response, in doing this, careful consideration needs to be given to ensuring that functions of the HFEA do not unnecessarily duplicate other regulatory measures and, further, do not needlessly restrict professional autonomy. Professional autonomy needs to be added to the range of competing interests and factors to be taken into account when regulating this area, so that when regulations, policies and directives are developed, the effect on clinical practice and the implications for professional autonomy are carefully considered and become an explicit part of the risk–benefit analysis.

Conclusion

Reproductive technologies have always been and are likely to continue to be an ethically contentious area and there will never be consensus on these issues. At the level of policy approval of new scientific developments, the HFEA is cognizant of the criticism that scientific developments are so rapid that statutory instruments might not be agile enough to allow timely approvals and hence could stall developments that could benefit patients. The proposals put forward in the HFEA’s consultation response could go some way to address this. Adding professional autonomy to the range of competing interests and factors that need to be considered when regulating this area, could open up different avenues of risk–benefit analysis, and make explicit the connection between the reproductive autonomy of potential users and the professional autonomy of those who provide the services. If we are concerned with reproductive autonomy, we should also be concerned with (medical) professional autonomy, as the two go hand in hand, and this, arguably, has not been given sufficient attention in the debates over how to regulate reproductive technologies.

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Notes

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