A Briefing on the Human Fertilisation & Embryology Authority (HFEA) Consultation *Modernising the regulation of fertility treatment and research involving human embryos*

Summary

The HFEA has launched a consultation into the potential revision of Human Fertilisation and Embryology Act 1990 ('the Act'). The consultation is open to all and we would **strongly encourage all concerned members of the public to make their voices heard**. The recommendations of the HFEA are extreme and many are highly unethical and illegal in most countries. These include proposals that:

- *the HFEA be freed from the requirement to make site visits every two years (question 12)*
- *the powers of the HFEA be increased in various ways (14, 15) including new powers over fertility services that do not involve* in vitro *fertilisation (17);*
- *the HFEA be given discretionary powers to extend licences indefinitely (19);*
- *consent for treatment be 'simplified' through a presumed consent ('opt-out') model (25);*
- *consent for research on embryos be broad and generic not only for specific research (27);*
- *the HFEA have powers to licence experimental treatments with no proven benefit (29);*
- *the Act be 'future proofed' to permit experimentation on human embryos or foetuses outside the womb without time limit (abolishing the '14 day rule') and to permit 'germline genome editing' for reproduction, subject only to secondary legislation (30).*

The HFEA proposals also include some positive changes on sharing information with donor-conceived offspring (21, 23) and sharing medical information with healthcare providers (26). However, even the positive proposals are weaker than they might be and all could be achieved without a revision of the Act. A revision of the Act would be a major distraction for the Department of Health and Social Care at a time when it needs to focus on the aftermath of the pandemic, on the massive increase in waiting times for routine procedures and on the crisis in social care provision.

For those who are concerned but have little time **we recommend** that you **do the consultation online** and state that you **strongly disagree with recommendations 25, 27, 29, 30.** The easiest thing is to leave all other questions blank. Or you may wish to answer the Personal Information section and then consider disagreeing with 12, 13, 15, 17, 18, and 22 and agreeing with 21, 23 and 26. There is no need to fill the comment boxes (20, 24, 28, 31) unless there is something you wish to say.

Unless you state your strong disagreement with the four questions in bold above (25, 27, 29, 30) you will tacitly be accepting these proposals. These potentially include experimentation on unborn children outside the womb up to viability, or on human-primate hybrids up to viability, without full parliamentary scrutiny, and without even the informed consent of the biological parents. The online consultation is available here, or you can complete the survey as a word document, and return to the HFEA by email at enquiriesteam@hfea.gov.uk. The deadline for responses is **5pm, 14 April 2023**.

Further considerations on the HFEA and the present consultation

What follows is background about some key moral principles, the character and remit of the HFEA and a more detailed analysis of the consultation questions. This fleshes out the brief outline given above and may also be of use for those who would like to consider further before responding or who would like to comment in the boxes provided (20, 24, 28, 31).

Status of the Embryo

A human embryo is the first stage in the life of a human being.[1] We were all embryos for the first few weeks of our existence. We each lived within our mother's womb before we were born. Most of us were also conceived within our mother's body but some were conceived *in vitro* and later transferred to the womb. To destroy a human embryo is to kill a human being in the first stage of his or her existence. If I had been killed as an embryo I would have been robbed of the whole of the rest of my life. Even though I would not have known about it (as I would not have known if I had been killed painlessly when I was a newborn infant), it would nevertheless have been a great injustice to me. It would have been homicide (as a matter of anthropology and ethics, if not one reflected in positive law). To conduct experiments on human embryos during or after which the embryo is destroyed is to conduct lethal experimentation on human subjects in the first stage of their existence. This not only ends their lives but also commodifies them. It is inhuman.

Neither the Human Fertilisation and Embryology Act 1990, nor the Warnock Report[2] on which it relied, adequately acknowledges the full human status of the embryonic human being. Had they done so then experimentation on human embryos would have been prohibited. Nevertheless, the Warnock Report and the Act both point to the 'special status' of the human embryo as a reason for having specific legislation and for having a regulator. The requirement for a licence prevents destructive use of human embryos except where this is 'necessary or beneficial' for fertility treatment or 'necessary or beneficial' for specific research purposes.

In UK law and regulation, there is a noticeable gap between the rhetoric of respect for the status of the human embryo and the practice of facilitating embryo experimentation.[3] Nevertheless, the principle of respect for the 'special status' of human embryo remains the stated basis for UK legislation in this area. This has been reiterated in many Parliamentary reports, for example:

> *'The starting point for consideration of the ethics of research on human embryos is the status of the early embryo'.*[4]

[1] This should not be controversial, but because the obvious sometimes stands in need of justification see, for example, the sustained analysis provided by S.B. Condic and M.L. Condic. *Human embryos, human beings: A scientific and philosophical approach*. Washington DC: CUA Press, 2018.
[2] M. Warnock, *Report of the Committee of Inquiry into Human Fertilisation and Embryology*. London: Her Majesty's Stationery Office, 1984.
[3] D.A. Jones, 'The "special status" of the human embryo in the United Kingdom: an exploration of the use of language in public policy', *Human Reproduction and Genetic Ethics* (2011) 17.1: 66-83.
[4] House of Lords Report from the Select Committee of the House of Lords, *Stem Cell Research*. London: HMSO.2002: 4.4.

> *'We have concluded that the embryo should be accorded special status in common with the Warnock Committee'.*[5]
>
> *'We acknowledge that the special status of the embryo means regulation of both research and treatment continues to be appropriate and desirable'.*[6]

It is striking that there is no statement in the present consultation by the HFEA on the status of the human embryo. It is also striking that there are no recommendations as to how respect for this status could be demonstrated and implemented more effectively. There is nothing, for example, on the imperative to replace the use of human embryos in research and to reduce the numbers destroyed where embryos continue to be used. This contrasts with efforts taken to reduce the extent of experimentation on nonhuman animals. Indeed, rather than reduce the destructive use of human embryos the consultation laments the lack of embryos available for experimentation.[7]

Effects on women and children

The consultation rightly seeks greater attention to be paid to 'patient safety'.[8] It is an indictment of the Act and of the HFEA that safety of those receiving fertility treatment has not been a significant concern hitherto. A key issue here is the safety of women. However, the consultation mentions 'women' only three times, twice in reference to documents not by the HFEA (the Cumberlege report on women who suffered avoidable harm from private and NHS healthcare, and the Women's Health Strategy)[9] and once to note that online sperm donation presents 'risks to a woman's health',[10] but that these could not effectively be tackled by a 'regulatory regime' such as that of the HFEA. The absence of any other explicit reference to the impact on women is both curious and concerning.

In one section of the consultation, the danger to a woman's health from Ovarian Hyperstimulation Syndrome (OHSS) is noted. However OHSS is described as a reaction to 'the drug treatment *necessary* for IVF'.[11] This description is inaccurate as stated, for IVF can be done without ovarian stimulation. Natural cycle IVF is not recommended by NICE because the success rate is higher with ovarian stimulation and there is insufficient research to provide evidence of the extent of the health risks of ovarian stimulation. Nevertheless, there is good reason to think that natural cycle IVF or mild ovarian stimulation carry less risk. To state that drugs that cause OHSS are 'necessary' for IVF is a self-fulfilling prophecy.

The Anscombe Bioethics Centre is not recommending IVF of any kind, but it is concerned about increasing the risks to women. It is not clear that new legislation is needed in order to uphold the ethical, human rights, and common law duty to protect patient safety, but it is reasonable to highlight safety especially where this consideration has been neglected in the past. Nevertheless, the HFEA recommendation in the consultation document is problematic in at least four respects:

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[5] House of Commons Science and Technology Committee. Fifth Report of Session 2004-05. *Human Reproductive Technologies and the Law*. London: HMSO, 2005: Vol. 1, para. 49.
[6] Joint Committee on the Human Tissue and Embryos (Draft) Bill. Report Volume I, HL Paper 169-I and HC Paper 630-I. London: HMSO, 2007: para. 105.
[7] HFEA 'Modernising the regulation of fertility treatment and research involving human embryos' Consultation document, 28 February 2023 (henceforth 'Consultation document'), p. 22.
[8] *Ibid*., p. 8.
[9] *Ibid*.
[10] *Ibid*., p. 12.
[11] *Ibid*., p. 21, *emphasis* added.

In the first place, the continued use of the phrase 'patient' safety obscures the fact that fertility treatment involves specific risks to the safety of *women*. This perpetuates the problem of making the risks to women invisible.[12]

In the second place, the phrase 'patient safety' is ambiguous as it is not clear who counts as a 'patient'. The phrase 'a patient or a donor'[13] in the consultation document seems to imply that women who donate eggs, whether for treatment or research, whether as a donor mother or egg donor for mitochondrial disease,[14] are not 'patients'. These women seem therefore to be excluded from those 'at the heart of a revised law'.[15] Furthermore, if the safety of egg donors is neglected in this way, how much more is the danger of exploitation of surrogate mothers, especially those from, or in, low income countries. These proposals do little to address the ongoing harms that the fertility industry does to women who are paid for their eggs or for the use of their wombs.

In the third place it is not clear whether the child conceived by IVF is a 'patient' whose safety should be 'at the heart of a revised law'. The consultation discusses the rights of donor-conceived offspring but there is no mention of the interests of the children conceived by IVF but not by donor. Nor does the consultation address the interest of donor-conceived children other than in relation to information about donation. There is no explicit reference to the physical safety of these children.

Lastly, it is important to acknowledge ethical concerns other than the safety of the treatment. This is very evident in the use of human embryos in research and the potential use of genome editing in reproduction. There are important concerns that need to be acknowledged in relation to the commodification of the human embryo and in relation to wider society. The acknowledgement of the safety of women (including donors and surrogate mothers), and safety of children should be included alongside other principles rather than being made the exclusive 'over-arching focus'.

The remit of the HFEA

The HFEA is a quango, an arms-length body appointed by, but independent of, Government. It is a regulator, like the Human Tissue Authority or the General Medical Council. The principle function of the HFEA is to implement the Act by means of the issuing and reviewing of licences for treatment or research that involves the use of human gametes and embryos. As it regulates these activities it is also within the remit of the HFEA to collect and collate information about the current state of clinical practice and scientific knowledge of these activities. The Act specifies that the HFEA should 'keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters'.[16] It is no part of the remit of the HFEA to act as a campaign organisation or a lobby group, whether for its own interests or for others. It exists to regulate the law, not to change it.

For the HFEA to lobby for specific changes to legislation threatens to undermine trust in the regulator as implementer of the law. It is also an abuse of its status for, as a body, it is neither elected nor

[12] See, for example, D. Dickenson 'The lady vanishes: What's missing in the stem cell debate'. *J Bioeth Inq* 2006; 3: 43–54.
[13] *Op. cit.*, Consultation document, p. 1.
[14] On this proposed technique see S. Barber and P. Border, 'Mitochondrial donation'. Commons Library Standard Note Published 29 January 2015, Standard notes SN06833.
[15] *Op. cit.*, Consultation document, p. 8.
[16] Human Fertilisation and Embryology Act 1990 (as amended by the HFE Act 2008) 8 (1) a.

representative of wider society. The HFEA is known to have selected its members according to their views on ethics. On 18 October 2002, Suzi Leather, then chair of the HFEA, gave evidence to the U.S. President's Council on Bioethics in Washington D.C. She was questioned by Professor Gilbert Meilaender as to whether there were members of the HFEA who were opposed to embryo research.

> *Ms Leather replied: 'Your question (is) about should we have people who are opposed to it'.*
>
> *Prof Meilaender: 'The question is, do you?'*
>
> *Ms Leather: 'No, we don't. This does come up as an issue, and I think that the Government has felt in a sense of what would be the purpose of having somebody there. It is not as if we are not continually reminded that there are many people who hold very firm views against what we do.*
>
> *And I believe that those views should be respected, but they are outwith the moral consensus in the UK at the moment, and I don't think we need them continually on the committee saying that I am opposed to all of this… because I think that would stop the decision-making that we have to do'.*[17]

The HFEA criticised for acting outside its remit

Also in 2002 Ruth Deech, outgoing chair of the HFEA, was asked whether the UK Parliament intended, when it set up the HFEA, that 'fundamental decisions that make basic changes in humanity should be decided by the HFEA'.[18] The example given was the genetic selection of 'saviour siblings'. She replied, 'The fact that the HFEA took that decision protects Members of Parliament from direct involvement in that sort of thing'. However, the House of Commons Select Committee on Science and Technology was not impressed by the claim that Parliament needed 'protecting' from having to make complex ethical decisions.

In a later report, the Committee was also highly critical of the HFEA for 'campaigning, corporately, for changes in legislation'[19] and expressed concern that '… the HFEA has crossed the boundary from regulation to advocacy'. In the view of the Committee, 'by promoting gamete donation in its corporate publications it has acted outside its statutory remit and crossed a boundary that risks compromising public trust'.

The current consultation as advocacy

There are several indications that the present consultation has also crossed the boundary from information gathering into advocacy.

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[17] Cited by Memorandum from 'Comment on Reproductive Ethics', House of Commons Science and Technology Committee. Fifth Report of Session 2004- 05. *Human Reproductive Technologies and the Law*. London: HMSO, 2005: Vol. II (HC 7-II), Appendix 21, para 10.

[18] Minutes of Evidence taken before the Science and Technology Committee, Wednesday 24 April 2002, para 5. https://publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/2042402.htm

[19] House of Commons Science and Technology Committee. Fifth Report of Session 2004- 05, 2005: Vol. 1, para. 216.

To begin with, while the consultation document states that, 'The government asked the HFEA to make recommendations for change'[20], there is clear evidence that this process was initiated not by the Government but by the HFEA itself. The possibility of revising the Act was not included in the manifesto of the present government, nor in any white paper, nor in any public announcement by the Department of Health and Social Care or the Secretary of State. While the Government has agreed that the HFEA could make recommendations for a change in the law, it was the HFEA that lobbied for the opportunity to do this, both privately to government and publicly to the media.

As early as September 2020, in relation to marking the anniversary of the establishment of the HFEA, the Director of Strategy and Corporate Affairs argued that: 'A key issue for the HFEA is to mark what needs *to change in the HFE Act* to bring it in line to where we are in 2021 as well as looking to 'future-proof' it'.[21]

The minutes of a HFEA meeting in September 2021 state that, 'A formal in-person event for the 30th anniversary of the HFEA would not be held during 2021 because of the impact of Covid, but we would continue with our guest blogs on potential changes to legislation and the Chair would have two opportunities to *set out the case for reform of the HFE Act* later this year'.[22]

In a speech in December 2021, Julia Chain, the new chair of the HFEA stated that, '*We need a modernised law* and during my tenure as Chair, this will be one of my main priorities… My aim is to reach an outline agreement with the Department for Health and Social Care by the end of this year on what needs to change'.[23]

In a paper for the HFEA meeting of February 2022 it states, 'Throughout 2021, *we developed an argument* that elements of *the HFE Act were now in need of modernisation* to keep pace with changes in the fertility market, in science and medical technology, and in social and cultural mores. We focused on three themes: patient protection, scientific development and issues such as consent and data sharing. *The then minister, Lord Bethell, agreed* that modernisation was needed and the HFEA should work with DHSC towards an agreed way forward. To this end, we are aiming to present the DHSC with a set of proposals by the end of 2022'.[24]

Similarly, in May 2022, in an interview with Peter Thompson, the chief executive of the HFEA, the Guardian reported that '*The HFEA is seeking far-reaching changes* to the 1990 Human Fertilisation and

[20] *Op. cit*., Consultation document, p. 1.
[21] C. Ettinghausen 'Marking 30 years of the HFEA – Planning for 2021' Paper for the Authority meeting, 16 September 2020 (*emphasis* added): https://www.hfea.gov.uk/media/3196/16-september-2020-authority-papers.pdf
[22] HFEA, Minutes of Authority meeting, 23 September 2021, 5.9 (*emphasis* added): https://www.hfea.gov.uk/media/xtbhwkq1/2021-09-23-minutes-of-authority-meeting.pdf
[23] HFEA, 'The HFEA 30 years on - what needs to change? Speech by Julia Chain, HFEA Chair, at Progress Educational Trust conference' Press Release (*emphasis* added): https://www.hfea.gov.uk/about-us/news-and-press-releases/2021-news-and-press-releases/the-role-of-the-regulator-uk-perspectives/ This paragraph was repeated *verbatim* in a speech to the conference 'Fertility 2022': https://www.hfea.gov.uk/about-us/news-and-press-releases/2022-news-and-press-releases/fertility-2022-julia-chain-chair-of-the-hfea/
[24] C. Ettinghausen, 'Modernising fertility regulation: a plan for legislative change', Paper for the Authority meeting, 09 February 2022 (*emphasis* added): https://www.hfea.gov.uk/media/zrddkglw/9-february-2022-authority-papers.pdf

Embryology Act that governs the fertility sector and, after a consultation, is planning to propose draft legislation by the end of the year'.[25]

Indeed, even the press release for the current consultation is entitled 'Fertility law needs modernising, *says UK regulator*'.[26] It is the regulator who is saying this, not the Government. There is no mention in the press release, nor in the speeches, interviews or blogs of the chair of the HFEA, that the government first asked for this. It is clear that this was an argument 'developed' by the HFEA, a case 'set out' by the HFEA, and the minister later 'agreed' to ask for recommendations. The criticisms levelled by the House of Commons Select Committee in 2002 are equally applicable here. The HFEA is conducting a 'campaign, corporately for change in legislation'. It is acting beyond its remit. Rather than the regulator implementing the will of Parliament, the regulator is aiming to produce draft legislation for Parliament to implement. The tail is wagging the dog.

The current consultation as directive

After careful examination of a previous public consultation conducted by the HFEA, the Canadian bioethicist Françoise Baylis, concluded that the HFEA 'had a clear policy preference … [and] it sought to communicate this preference to those who were consulted. Indeed, in many respects, the HFEA consultation process can be seen as an exercise in strategic public relations'.

In this case, the policy preferences are even clearer. The HFEA has already concluded that 'far-reaching changes' are needed and, with the help of 'an expert advisory group' has already identified what these changes are. The consultation does not ask the question of whether the law needs to be revised. This is taken for granted. People are asked only to express the extent of their agreement or disagreement with recommendations that the HFEA has formulated. In each case, arguments are set out for the HFEA recommendation but no counter arguments are supplied so that people could weigh the arguments and evidence, nor are people invited or encouraged to think outside these predetermined choices. It may be that some recommendations might be modified in the light of feedback but the overall frame clearly directs people to the HFEA's preferred answers.

In the view of the Anscombe Bioethics Centre, the HFEA has not made a persuasive case for a far reaching change to the law. The fact that the HFE Act is 30 years old is not itself a reason for change, most of the proposed changes would be deleterious, and the modest positive proposals could be achieved without a major revision of the Act.

The position of the Anscombe Bioethics Centre is that the HFE Act is an unjust law that provides very little protection to women and less to human persons at the embryonic stage, but the kind of reform envisaged by the HFEA would not address these concerns and would carry the risk of further adverse changes even beyond those set out in the present consultations. It would also be a distraction from more urgent concerns of Government in relation to the state of healthcare in the United Kingdom.

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[25] H. Devlin, 'UK fertility watchdog could recommend scrapping donor anonymity law', *Guardian*, 20 May 2022 (*emphasis* added).

[26] HFEA, 'Fertility law needs modernising, says UK regulator', Press Release, 28 February 2023 (*emphasis* added): https://www.hfea.gov.uk/about-us/news-and-press-releases/2023-news-and-press-releases/fertility-law-needs-modernising-says-uk-regulator/

The discouragement of participation by wider society

The consultation is framed to discourage, as far as possible, participation from wider society. In the press release, it is stated that 'Professional sector experts as well as patients themselves, are being urged to respond'.[27] This invitation to '[f]ertility experts, patient and sector organisations and patients themselves'[28] is reiterated at the end of the statement.

At no point in the press release are members of the public included among those who are urged or invited to respond. Indeed, from the press release it is not clear whether the consultation is even *open* to members of the public. It is only if someone begins the consultation, despite not being specifically invited to do so, that he or she will find that it can be completed by 'an interested member of the public'.[29] The length of the consultation and the short time period provided (only 6 weeks, not the 'at least 12 weeks' recommended[30] for public consultation on complex or controversial matters) also serve to discourage all but the most committed.

It is seemingly without irony that the last recommendation is for 'strict case-by-case oversight of any research *past 14 days* where justified, and *after extensive public engagement*'.[31] Given the complete lack of wider public engagement in the formulating of these recommendations, the narrow and highly directive character of the questions, and the lack of invitation to members of the public to respond, it is difficult to give credence to this commitment to 'extensive public engagement'. The character of the present consultation is rather a demonstration of how little the HFEA values the opinions of the wider public in relation to the generation of human life.

[27] *Ibid*.
[28] *Ibid*.
[29] *Op. cit*., Consultation document, p. 2, question 2.
[30] HM Government Code of Practice on Consultation 2008, page 4. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf This document has been superseded by others but these do not alter the fundamental criteria.
[31] *Op. cit*., Consultation document, p. 26, *emphasis* added.

Anscombe Bioethics Centre Responses to the consultation question

12. To what extent do you agree or disagree that the HFEA should have greater freedom to vary its inspection regime?

Disagree

The HFEA has discretion to make site visits more frequently than two years, the proposal allows for site visits less frequently than this. Much can happen in two years and the current requirement lessens the scope for the HFEA to become too close to the commercial enterprises it regulates or to neglect its duty of oversight. This proposal weakens oversight for no obvious advantage to patients but only convenience to the regulator and to certain commercial interests.

13. To what extent do you agree or disagree that there should be more flexibility in the appointment of clinic leaders, for example introducing the option of a deputy PR, and broadening the criteria for the qualifications and experience required to be a PR?

Disagree

Accountability requires there be a person who is responsible. The sharing of such responsibilities dilutes this so that, for example, it may not be clear the PR or deputy PR is responsible. The lowering of qualifications and other requirements to be PR enlarges the pool of people available for the role but at the cost of reducing standards. This does not seem a positive step.

14. To what extent do you agree or disagree that the HFEA should have a broader, more effective range of powers to tackle non-compliance?

Prefer not to answer

As with other recommendations this is simply a plea for more powers for the regulator. However, without a clearer sense of what is proposed and how these powers would be used, it is not possible to evaluate this proposal.

15. To what extent do you agree or disagree that the HFEA should have a broader range of powers to impose financial penalties across the sector?

Disagree

For the HFEA to impose fines within a sector that is mainly commercial would carry the risk that such fines could become a significant source of income. This would then alter the way in which fines were used and the character of the inspection regime. It is also difficult for these to be levied in a way that is equitable between small and large organisations.

16. To what extent do you agree or disagree that there should be an explicit duty on the HFEA and clinics to act to promote patient care and protection?

Prefer not to answer

This question discloses the lack of concern for the welfare and safety of women in the past thirty years of regulation by the HFEA and to that extent is to be welcomed. However, it is not possible to agree with the statement as it is framed in the consultation, i.e. as the one 'over-arching focus' of a revised law. This would exclude other important concerns such as the status of the human embryo, the interests of children born through IVF and the maintenance of public trust. Safety is an important and indeed neglected issue, but cannot be the exclusive focus. Furthermore, as argued above, in relation to 'patient care and protection' there is an ambiguity about who is included as a 'patient' and whether this covers the egg-donors, surrogate mothers and children conceived by IVF. If these are excluded then the change would fail to protect the most vulnerable and might even make their situation worse.

17. To what extent do you agree or disagree that the HFEA should have a broader range of powers to tackle related fertility services not taking place in licensed clinics?

Disagree

There may be some treatments occurring in parallel with IVF that it is reasonable for the HFEA to regulate. However, the danger of this proposal is that fertility treatments which are ethical and do not involve use of gametes or human embryos would come into the ambit of the HFEA. This would include treatments to tackle the causes of infertility such as endometriosis as well as ways to optimise the chance of conceiving naturally, for example through NaPro technology. This proposal could thus lead to ethical alternatives to IVF being over-regulated and stifled by a body that has very close links with the commercial fertility industry and thus to IVF provision. Furthermore, as the consultation document acknowledges, other major developments, such as online sperm donation could not effectively be managed through expansion of the regulatory regime. What is needed in these cases is legal prohibition of such online arrangements.

18. To what extent do you agree or disagree that the current appeals process should be changed?

Prefer not to answer

Without clarity about the new appeals procedure it is not possible to evaluate its potential risks and potential benefits.

19. To what extent do you agree or disagree that there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions?

Prefer not to answer

Another plea for more powers for the HFEA. Again, without clarity about the proposed rules it is not possible to evaluate its potential risks and potential benefits.

21. To what extent do you agree or disagree that clinics should be required by law to inform donors and recipients of potential donor identification through DNA testing websites?

Agree

This currently seems necessary if consent is to be adequately informed. It is not clear that making this an overt statutory duty is necessary but it might remind people of a duty that is already implicit.

22. To what extent do you agree or disagree that the Act should be amended to provide parental and donor choice to opt for anonymity until age 18 or identifiable information after the birth of a child?

Disagree

The current law is problematic both because children may wish to know about their origins earlier than 18 and because of the possibility of finding out via online DNA tests. It is also problematic in that children may not be told that they are donor conceived. However, the proposal seems confused in making anonymity a 'choice' and gives insufficient weight to the views of the mature minor. It does nothing to address the issue of children not being told that they are donor conceived.

23. To what extent do you agree or disagree that the Act should require all donors and recipients to have implications counselling before starting treatment?

Agree

This currently seems necessary if consent is to be adequately informed. It is not clear that making this an overt statutory duty is necessary but it might remind people of a duty that is already implicit.

25. To what extent do you agree or disagree that the current consent regime could be simplified (for example to an 'opt out' model) in ways that continue to provide protection to patients?

Strongly disagree

The consent process is complex because the reality is complex and failure to acknowledge this complexity leads to consent that is not informed. To simplify is to lie. The question also presupposes that the only reason consent is sought is for 'protection' rather than, for example, the clinician treating the patient with respect and the patient taking responsibility for the decision. Paternalism can offer protection to patients but it does not respect them as decision-makers.

26. To what extent do you agree or disagree that the sharing of fertility patient data in a non-fertility medical setting should be brought in line with the current regulations for the sharing of other patient/medical data between healthcare providers?

Agree

As fertility treatment involves serious health risks, especially to women, even when performed by qualified professionals, it is clearly of benefit to patients for healthcare professionals to have access to records. As with other forms of data sharing, a patient might refuse to have a particular record shared, even among healthcare professionals, but the system should be set up to facilitate sharing. Nevertheless, this is a minor change and the kind of amendment that can be included in a future Bill on healthcare or on data protection. It does not require a far-reaching review of the Act.

27. To what extent do you agree or disagree that consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking?

Strongly disagree

Given the radical proposals later in this consultation, to enable legislation on reproductive genome editing and on experimentation on human embryos (or foetuses) without time limit, the generic consent, even if given, would not be informed consent. Some people would also object to selling embryos to commercial entities or selling data from research, or use of embryos for non-medical purposes, all of which are dangers with tissue or embryo banking. Furthermore, the use of the human embryo on the basis of broad generic consent further commodifies the embryo, making it a chattel to be used in the future for purposes as yet to be specified.

29. To what extent do you agree or disagree that the Act should explicitly give the HFEA greater discretion to support innovation in treatment?

Strongly disagree

Another plea for more powers. The proposal is to give the HFEA discretion to licence experimental treatments without evidence that it is 'necessary or beneficial'. This may facilitate innovation but at the cost of reducing legal and ethical standards. This not only has safety implications for the person undergoing treatment but also reduces the threshold for use of human embryos and may have implications for other third parties such as egg donors. When the HFE Act was passed, the requirement that all treatment and research licensed under the Act be 'necessary or beneficial' was presented as a key safeguard and an alternative to robust prohibition. The removal of this requirement would facilitate more actions that were unethical and actions that were more unethical.

30. To what extent do you agree or disagree that changes should be made to the Act to allow Regulations to be made (by secondary legislation or statutory instruments) to enable future amendments and extensions?

Strongly disagree

The most extreme proposal is left until last. This proposal is for activities that are highly controversial, indeed illegal in most countries and, in the case of genome editing, subject to an international moratorium, be approved in principle subject to the passing of later regulations.

This mechanism lowers the practical and political threshold to change by taking the decision in two or more parts. The example of 'three-parent'[32] IVF ('mitochondrial regulations') makes this clear. When the primary legislation was passed in 2008, the section on mitochondrial regulations received almost no scrutiny. This was in part because the debate focused on human-nonhuman admixed embryos and on parenthood but also in part because the provision for regulations would return to the House of Commons at a later date. This appeared to reduce the risks in passing the legislation as it would have another hurdle to overcome before the regulations came into effect. However, when the regulations came to be debated by the House, in 2015, the debate was broken-backed, limited, and superficial as the proposals were presented as having already been agreed in principle.

This experience provides a playbook for attempts to legalise the most controversial of procedures, up to and including heritable genome editing and experimenting of embryos without any fixed time limit. It could include experimenting of human or admixed foetuses up to viability if the technical challenges of ectogenesis could be overcome.

Use of secondary legislation makes it easier for the law to be changed in future with much less scrutiny. For this very reason, this mechanism is not appropriate for ethical questions of a fundamental kind which merit the highest level of political and public scrutiny. If someone wishes to argue for gestating human-primate foetuses to viability in artificial wombs, for example, then they should make the case for this by primary legislation and not seek to avoid debate by the sleight of hand of secondary legislation.

Behind this proposal for 'future-proofing' seems to be the assumption that every imaginable kind of research or treatment that is scientifically possible will eventually be accepted by society and permitted under licence. However, this attitude is morally corrupting as it encourages the acceptance of practices which are not currently justifiable on the basis that they might become so in the future. Rather than consider possibilities in the future, when they arise as concrete proposals and their implications can be properly evaluated and debated, we are invited to sign an ethical 'blank cheque' and embrace what Archbishop Habgood came to recognise as an 'unending research programme, further and further removed from its original moral justification'.[33]

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[32] On the terminology of 'three parent' see D.A. Jones, 'The other woman: Evaluating the language of "three parent" embryos' *Clinical Ethics* 2015, Vol. 10(4): 97–106.
[33] Quoted in T Banchoff, *Embryo Politics: Ethics and Policy in Atlantic Democracies*, Ithaca NY: Cornell University Press, 2011, p. 151.

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