PET
Fertility • Genomics • Clarity

Modernising the Regulation of Fertility Treatment and Research Involving Human Embryos

Consultation response by PET
14 April 2023

Patient safety and promoting good practice

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

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree ✓
- Unsure
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree ✓
- Unsure
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree ✓
- Unsure
- Prefer not to answer

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

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

20. If you would like to comment further on issues related to patient protection and how the HFEA regulates, please tell us more.

This section of the HFEA's consultation focuses on issues of compliance and HFEA-imposed sanctions, noting that *'the fertility sector in the UK has changed significantly since the HFEA was set up'*. However, nowhere does the consultation document mention that breach of the HFE Act is a crime, with corresponding *criminal* sanctions.

Nor does the consultation document offer a view on whether this arrangement remains appropriate, and if so then why. This is an unfortunate omission, because it is vital context for all that follows.

We responded *'Unsure'* to **Q12** – *'To what extent do you agree or disagree that the HFEA should have greater freedom to vary its inspection regime?'* – because much would depend on how this latitude was introduced and used by the HFEA.

We agree that greater flexibility in this area would be beneficial for compliant (and therefore low-risk) clinics, and could also incentivise an improvement in the performance of other clinics (as they strive to reduce the frequency of inspections). The proposal to remove the licence renewal *'cliff edge'*, granting ongoing licences *'subject to periodic and risk-based inspection'*, is likewise welcome.

However, the converse situation then arises, and poses difficulties. If clinics have a vexed relationship with the HFEA for any reason (for example if they have previously been critical of the HFEA, or have brought legal proceedings against the HFEA) then those clinics might perceive a greater frequency or intensity of inspection as a form of persecution. A more flexible system would therefore need to incorporate a clear and transparent process, to demonstrate how inspection decisions have been reached by the HFEA.

Meanwhile, we are disappointed that the consultation document discusses issues of inspection and licensing solely in relation to *treatment* centres. This is characteristic of the consultation as a whole, which gives the impression that research is an afterthought for the HFEA. Without human embryo research in the UK, there would be no IVF for fertility clinics to offer. Researchers, too, would benefit from greater flexibility in the regularity and form of HFEA inspections.

We responded *'Unsure'* to **Q13** – *'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?'* – because we would like to see other options explored, in addition to the options proposed by the HFEA.

It is worth considering whether the current situation, where responsibility lies with a single Person Responsible (PR), diminishes leadership accountability for the multiple disciplines in the fertility sector. Another consideration is the interplay between the licence holder and the PR roles, and whether sharing more responsibility with the licence holder could be a solution.

The consultation document observes that the requirement for a single PR *'is increasingly out of step where licensed clinics are part of a larger commercial group'*. A counter-argument is that having an individual as the locus of responsibility serves as an important check on the consequences of the private fertility sector consolidating into a small number of larger groups, and that dispersing the responsibilities of the PR among deputies may be all too convenient.

In any case, PET would like to see options other than the possibility of deputy PRs explored by the HFEA, in conversation with relevant professional bodies – in particular, the **British Fertility Society** and the **Association of Reproductive and Clinical Scientists**.

We responded *'Strongly disagree'* to **Q14** – *'To what extent do you agree or disagree that the HFEA should have a broader, more effective range of powers to tackle non-compliance?'* – because the HFEA has not made a persuasive case that this is required or justified.

According to the data accompanying HFEA's latest *State of the Fertility Sector* report, **231** non-compliances were identified during HFEA inspections in 2021/2022 (**9** *'critical'*, **115** *'major'* and **107** *'other'*). The HFEA says of these figures that *'only 4% of non-compliances were critical, highlighting the high quality of care provided by clinics in the UK'*.

Is the implication of the consultation document that the HFEA would have liked to impose appropriately calibrated sanctions in the 9 instances of *'critical'* non-compliance, but was unable to do so because of the *'very high bar for any regulatory action'*? Or is the implication that the less severely non-compliant clinics should have received correspondingly minor sanctions, despite providing a *'high quality of care'*? It is unclear. No examples (not even hypothetical examples) are offered.

We responded *'Unsure'* to **Q15** – *'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?'* – because the HFEA has not made a persuasive case that this is required or justified.

The consultation document notes that *'the CQC can fine a service provider when it fails to provide safe care or provides treatment that results in avoidable harm to a service user or exposes them to a significant risk of exposure to harm'*. It is not explained why the HFEA needs powers to do this, if it can already be done by the Care Quality Commission.

The consultation document claims that financial penalties *'would ensure that a clinic would need to improve their standard of care whilst minimally impacting existing patients'*. But such penalties do not guarantee that the *'standard of care'* will improve quickly, if at all. What is the evidence that fines would serve as a deterrent?

In the increasingly consolidated private sector, fines can be more easily written off by larger groups (which can absorb fines levied against one of their subsidiary clinics), while the cost of fines is ultimately liable to be passed on to patients (through increased prices). In the public sector, fines amount to moving public money from one part of the system (the NHS) to another (the Treasury).

The consultation document claims that unlike financial penalties, licence suspension *'could possibly require the clinic to close which would significantly impact patients and their treatment'*.

PET does not wish to see patient care disrupted, but if the *'standard of care'* at a particular clinic falls below the required standard, then should that clinic really be permitted to continue providing treatment?

The consultation document suggests that the HFEA would like to use financial penalties not just *'to address serious non-compliance'*, but also *'to shape clinic behaviour'*. This is overreach. It is not the place of the HFEA *'to shape clinic behaviour'*, and the regulator is liable to face legal challenge if it uses sanctions to pursue such an objective.

We responded *'Strongly disagree'* to **Q16** – *'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?'* – because this misconstrues the purpose of the HFE Act and of the HFEA.

The consultation document notes that *'The Act is silent on patient care'*, and a recurring theme in recent HFEA communications is that the word *'patient'* does not appear in the Act (aside from two fleeting references in the context of disclosure of information) – the implication being that this is some sort of failing of the legislation. But the omission is hardly surprising, when one considers that the Act does not regulate patients. Rather, it regulates the uses of human gametes and embryos.

Clinic staff – including doctors, embryologists, nurses and counsellors – all have their own professional guidelines and standards to adhere to when it comes to patient safety, as well as laws and regulations that govern healthcare in general. The introduction of the HFEA's policy on single embryo transfer, which had a significant impact on patient care (the HFEA itself regards this policy as highly successful), did not rely on any new *'explicit duty'* being enshrined in law.

The HFEA's current inspection reports describe *'four areas covering all the activities of a licensed centre'*, namely:

1. *The protection of the patient, and children born following treatment at this centre.*
2. *The experience of patients at this centre.*
3. *The protection of gametes (sperm and eggs) and embryos at this centre.*
4. *How this centre looks after important information.*

Given the centrality of patients to the first two items in this list, it seems clear that clinics are already inspected against criteria of *'patient care and protection'*. What would the proposed change to the legislation add to this?

According to the HFEA's latest *State of the Fertility Sector* report, **76** patient complaints were made to the HFEA in 2021/2022 (a decrease from **88** the previous year). In the words of this report: *'Around 60,000 patients undergo treatment, storage, and/or donation cycles per year. About 0.1% of these patients submit complaints to the HFEA annually.'* We fail to see the case for a new *'explicit duty on the HFEA and clinics to act to promote patient care and protection'*.

We responded *'Strongly disagree'* to **Q17** – *'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?'* – because no explanation is offered of how this would be pursued, or what it would entail.

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The HFE Act is structured largely around regulating what can be done – and by whom – to or with gametes or embryos outside the human body. Such regulation is achieved largely via a system of licences. If the HFEA wishes to propose a thoroughgoing revision of the Act (perhaps in tandem with a review of other legislation), so that this area is regulated on an altogether different basis, then we welcome the ambition but we would like to see the proposal.

The consultation document refers to *'wellness clinics'*, which highlights the need for precision. The category of *'wellness'* goes well beyond healthcare, to encompass areas that are regulated (if at all) on a very different basis. *'Related fertility services'*, as referred to in **Q17**, might include the following.

- Financial products designed to help self-funding patients pay for treatment (including products such as 'no baby, no fee').
- Vitamin and mineral supplements targeted at men and women trying to conceive.
- Acupuncture and reflexology.
- Chinese herbal medicine.
- Fertility coaching.
- Fertility astrology.
- Womb massage.
- Fertility testing services.
- Conception cups.
- Apps to deliver personalised fertility treatment recommendations.
- Fertility monitors and sensors.

While PET would welcome measures to clean up or clamp down on some of these services, it is far from clear how this might be achieved. Nor is it clear that the HFE Act and the HFEA are the best way of achieving it.

The term *'related fertility services'* could also be taken to encompass medical treatment that takes place in general gynaecology or urology clinic and is not licensed by the HFEA (such as fibroid removal prior to commencing fertility treatment, or a repair to a varicocele). We assume that this is not the HFEA's intention, but care must be taken with such terminology.

We responded *'Unsure'* to **Q18** – *'To what extent do you agree or disagree that the current appeals process should be changed?'* – because we are still formulating our view on this question.

We responded *'Unsure'* to **Q19** – *'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?'* – because no examples are given of what rules the HFEA has been unable to introduce in the past, or should like to introduce in the future.

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It is also clear from the consultation document that the HFEA is seeking to limit clinics' opportunity to raise a challenge to new standard licence conditions, so that perhaps only one clinic can object. This is inequitable, and PET opposes this. Furthermore, this likely to put the HFEA's powers in conflict with the Regulators' Code at https://www.gov.uk/government/publications/regulators-code and how regulators should engage with those whom they regulate.

Finally, is the HFEA seeking additional powers to regulate the provision of 'add-on' treatments?

In the consultation document, it is asserted that treatment add-ons are not adequately covered in the HFE Act. The point is made that *'The recent Women's Health Strategy notes that changes to the HFEA's regulatory powers may be needed to cover fertility treatment add-ons, where we have no power to exercise control over such treatments even when they have not been proven to be effective'*.

But the HFEA gives no clue in this consultation of how it would like the law to be changed. Instead, the respondent is left second guessing which (if any) of the questions in the consultation might relate to add-ons. PET has a longstanding interest in the use of add-ons, and would have welcomed the opportunity to comment on the HFEA's plans in this regard.

Access to donor information

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree ✓
- Unsure
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree ✓
- Unsure
- Prefer not to answer

24. If you would like to comment further on issues related to access to donor information, please tell us more.

We responded *'Strongly disagree'* to **Q21** – *'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?'* – because we do not think there is a sufficiently strong case for making this a legal requirement.

The HFEA's *Code of Practice* already requires clinics to inform donors and recipients of the possibility that a donor-conceived child might discover the donor's identity, before the child reaches the age of 18. Writing this requirement into legislation is therefore unnecessary, and will not add to the likelihood of people appreciating the ramifications of this possibility.

It is also ill-advised to specify a particular technology via which identity might be discovered. To pick up on a theme that arises later in this consultation, such specificity does not make for 'futureproof' legislation. Direct-to-consumer genetic testing was not on the radar when the HFE Act was originally passed in 1990, and it had only just hit the market when the HFE Act was updated in 2008. Perhaps in future, AI-enabled facial analysis and facial recognition (to pick one example) will offer a new means of identifying likely genetic relatives online.

We responded *'Unsure'* to **Q22** – *'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?'* – because we think this *'double track'* option (as it has been referred to by the HFEA elsewhere) is misguided, and liable to cause more problems than it solves.

The rationale for the proposal seems to be the fact that donors, donor-conceived people and donor-conceived genetic siblings can now potentially identify one another – deliberately or accidentally – without needing to engage with or obtain information from the HFEA. PET does not think this situation, in and of itself, justifies any change to the law. The HFEA can still continue to hold information about donor conception, and can still provide this information as appropriate when asked.

The consultation document observes that some parents of donor-conceived children *'will actively seek out information in their child's early years because they want their child to have contact with the donor during childhood'*. The appetite among parents to do this is not known, and no attempt to quantify the numbers involved is provided in the consultation document. Our knowledge of the impact on donor-conceived children, if parents do this, is similarly scant.

If people wish to have a donor who is identifiable from the outset, then they already have the option of using a 'known' donor. Additionally, there is nothing in the HFE Act or related legislation that

precludes some other arrangement, in which a donor waives their entitlement to (temporary) anonymity. If donors, recipients, clinics or the HFEA (whether separately or in concert) wished to experiment with new models along these lines, this would not require legislative permission.

On the contrary, specifying such an alternative model would – again – not make for 'futureproof' legislation. We do not yet know which model of donation might work best, in an era of direct-to-consumer genetic testing and the first 'opening the register' cohort about to reach the age of 18 (doubtless bringing new challenges and considerations, not all of which will have been foreseen).

Furthermore, the *'double track'* option is in effect a two-tier system for donor-conceived children, and could itself become a source of resentment or dissatisfaction among such children. Inevitably, there will be some children who know their donor and wish they didn't (it is one thing for a child to know that they are donor-conceived, it is quite another for them to know the donor in question) and there will also be some children who don't know their donor and wish they did.

Granted, both scenarios can occur already. But it is probably unwise to entrench and systematise the distinction in law, in the way the HFEA proposes. Any proposed change to the law in this (already vexed) area should be approached cautiously, and should involve thoroughgoing engagement with advocacy groups focusing on donor conception issues (while keeping in mind that there can be a wide disparity of views among donors, recipients and donor-conceived people) and also with academics who have specialised in this area.

We responded *'Strongly disagree'* to **Q23** – *'To what extent do you agree or disagree that the Act should require all donors and recipients to have implications counselling before starting treatment?'* – because we do not think there is a need for any new requirements in the Act along these lines, and also because the HFEA has badly conflated different aspects of counselling in its consultation.

The language around counselling is often confused. This leads to misunderstandings and mismatched expectations of what counselling entails, and who is best placed to deliver or facilitate it. It is disappointing to see the HFEA perpetuate this confusion in its consultation.

In relation to **Q23**, the consultation document refers to *'donors and recipients'* having *'access to information about the implications of their decision before starting treatment'*, and says *'the principle of properly informed consent requires all donors and recipients to have access to information about the implications of their decision'*.

Yet rather than making access to or provision of information about the implications of donation mandatory, **Q23** instead proposes making *'implications counselling'* mandatory.

This is unhelpful. There are differences between:

- **Information counselling**

  This involves the provision of medical information. Under UK regulation, such counselling must be provided in order for a fertility patient's consent to be valid. This sort of counselling would usually be provided by a member of the medical team.

- **Therapeutic counselling**

  This involves helping a person deal with (current, future or potential) challenges, decisions, difficulties, distress or emotions. Under UK regulation, such counselling is *not* required in order for consent to be valid (indeed, it is an important principle that

such counselling is voluntary). The content and outcome of such counselling is usually confidential.

- **Implications counselling**

  This involves the provision or clarification of information about the implications of treatment or donation, and also involves exploring these implications. This has fallen into a grey area. Who is qualified to deliver such counselling? Is such counselling necessary, in order for consent to be valid? Does it, or can it, include a therapeutic element?

The mandatory provision of information does not need to be written into the HFE Act, as it is already a requirement for consent to be valid. By contrast, therapeutic counselling must always be a voluntary decision, otherwise it ceases to be therapeutic.

If the HFEA is minded to recommend that informing patients and donors about the implications of donor conception should be mandatory, then it must take care to clarify that it is only the provision of *information* about implications that is mandatory.

If the HFEA is concerned that therapeutic counselling is not being offered appropriately, then perhaps this could be monitored via the HFEA's PRISM system, by requiring clinics to record the offer and the uptake of therapeutic counselling.

Consent

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 agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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?

- Strongly agree ✓
- Agree
- Disagree
- Strongly disagree
- Unsure
- Prefer not to answer

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 agree ✓
- Agree
- Disagree
- Strongly disagree
- Unsure
- Prefer not to answer

28. If you would like to comment further on issues related to consent, please tell us more.

Below, we set out our thoughts on **Q25**, **Q26** and **Q27** of this consultation, and on related material in the consultation document. However, we would like to begin by saying that the issue raised by **Q27** – consent to the use of embryos or gametes in research – is of particular importance, and raises much wider issues.

Under the present regime, scandalously large numbers of unused human embryos go to waste in the UK – often without patients ever being given the option to donate embryos to research, and sometimes in direct contravention of their wishes. This waste of a precious resource is a tragedy.

In our discussions with people working in the fertility sector and in human embryo research, we have heard accounts of patients wishing to donate unused embryos, who have taken it upon themselves to track down and contact relevant researchers – only to discover that they are unable to donate their embryos, for legal or practical reasons. We are failing such patients.

Every fertility patient in the UK needs to be presented with the option of donating embryos or gametes to research, at appropriate junctures during their treatment journey. This should include giving patients the option of donating to research in general – ideally, to a **UK national embryo research bank** – rather than to a specific research project. This should also include the option of donating gametes for use in creating embryos specifically for research.

At present, enabling fertility patients to donate embryos to research is so prohibitively cumbersome and expensive, it is hardly surprising that only a minority of UK clinics opt to do so – they are disincentivised. Furthermore, under present licensing arrangements, embryos consented for use in research are having to be moved from treatment centres to research centres immediately upon completion of the relevant paperwork – an impractical situation.

Much of the current burden and expense is unnecessary, and should be removed (we give specific examples in our comments on **Q27** below). But the HFEA should go further. **There should be a general obligation for fertility clinics to make human embryos available for research purposes.**

This should be justified in terms of meeting a **public interest**. In our answer to **Q31** in the next section of this consultation, we propose a corresponding integration of the concept of the public interest into the *'principal purposes'* for which embryo research is permitted in the HFE Act.

Moreover, when a patient donates unused embryos for use in research, they should be able to have confidence that these embryos *will* be used in research. At present, the default is for research

embryos to be mandatorily discarded if there is a change to the rules or a problem with paperwork, or if a research project is discontinued. This is an egregious violation of patient wishes.

Moving on to the multiple choice questions in this section of the consultation, we responded *'Unsure'* to **Q25** – *'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?'* – because although we are indeed of the view that aspects of the current consent regime can and should be simplified, we do not think an *'opt out'* model is sufficient to achieve this.

The *'opt out'* model is described merely as an *'example'* in **Q25**, but it is the only approach to simplification presented in the relevant part of the consultation document. This suggests that an *'Agree'* or *'Strongly agree'* response to **Q25** will be interpreted as an endorsement, which is unfortunate. This also indicates a lack of ambition on the part of the HFEA, in terms of rethinking the way consent might be addressed.

The consent required from fertility patients by the current HFE Act – and, perhaps more so, by the HFEA's *interpretation* of this Act – is overly prescriptive (duplicating requirements from other areas of legislation and regulation), and is also overly specific (resulting in a proliferation of different consent forms that have accumulated piecemeal over the years). All of this can and should be radically simplified. There may be specific instances where an *'opt out'* option is part of the solution, but a far more thoroughgoing review of consent is needed.

The heading of one of the relevant sections of the consultation document, *'Consent to treatment and legal parenthood'*, highlights one of the major difficulties. The current HFE Act does not make a sufficiently clear distinction between two aspects of assisted conception – treatment and legal parenthood – that are being consented to, and that are not in actuality coextensive.

IVF is a process of mixing the gametes of certain consenting parties, in the hope of creating viable embryos that might then be used to establish a pregnancy. Parenthood is a legal status that will be held by certain consenting parties *if* a pregnancy is established and *if* it results in a live birth. The way that these two aspects of assisted conception are adjoined in the HFE Act, and the way this is then promulgated through the consent regime, creates opportunities for ambiguity and for differing interpretations and expectations (some of which result in legal disputes).

Making the relevant consent forms more intricate and diverse compounds these problems, rather than resolving them. Completing a multitude of complex forms inevitably becomes a rote exercise without accompanying comprehension, while practitioners default to requiring as many forms as possible to be completed by the patient, as a precaution against future legal problems. The situation is self-perpetuating. Someone must take the initiative and cut the Gordian knot.

These problems have been thoughtfully considered by a number of UK-based legal scholars in recent years, including a former Deputy Chair of the HFEA (Professor Emily Jackson) who knows whereof she speaks. PET understands that the **British Fertility Society** is also exploring potential solutions to some of the legislative difficulties regarding consent. PET would encourage the HFEA to engage with these discussions, and to be innovative in its recommendations to Government regarding consent in the HFE Act.

We responded *'Strongly agree'* to **Q26** – *'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?'* – because the special status of medical secrecy that applies to assisted conception has long since ceased to be justifiable.

At present, the only professionals who are entitled to access patient-specific fertility treatment information are staff at the relevant fertility clinic and staff at the HFEA (plus, in certain circumstances, the Registrar General or a court). Except in a medical emergency, this information cannot be disclosed to anyone else – not even the patient's GP – unless the patient has given specific consent for disclosure.

This situation is almost unique in UK law. The only comparable restrictions on disclosure concern sexually transmitted infections and gender reassignment. By contrast, information concerning termination of pregnancy – an area which involves as much sensitivity and need for confidentiality as assisted conception, if not more so – is not subject to such restrictions.

Partitioning fertility treatment records from a patient's other medical records leads to problems. Separate sets of notes need to be kept, even within the same medical facility (for example if a fertility clinic is embedded in an NHS Trust). This is not good medical practice, in terms of either safety or efficiency. It can also lead to confusion – on the part of patients and health professionals alike – as to what information has been disclosed, or can be disclosed, and to whom.

Fertility professionals aspire to offer – and increasingly, are *expected* to offer – a seamless service, from GP referral through investigation to appropriate treatment. The mandatory secrecy of fertility treatment makes such a service difficult, if not impossible, to achieve. Furthermore, in a context where health services are increasingly expected to be paperless, the partitioning of fertility patient notes involves contorted and onerous uses of IT.

The status of medical secrecy is a holdover from the early years of IVF, and relates to sensitivities that are no longer relevant now that assisted conception is mainstream. Maintaining the status quo would suggest that there is still a stigma associated with infertility, and that fertility treatment is a taboo subject which should be hidden *even* from medical professionals (who are bound by patient confidentiality).

None of this is to deny the importance of recording, handling and storing patient information in secure and diligent ways. Rather, it is to say that fertility treatment information should be subject to the same standards as – and, where appropriate, should be integrable with – other forms of patient information.

There is strong patient as well as professional support for this change. At a public event entitled '**Does Fertility Treatment Still Need to Be a Medical Secret?**', held by PET in Edinburgh in 2019, the panel speakers and the audience were of the unanimous view that the answer to the question posed in the event title was 'no'. These panel speakers included Gwenda Burns – then Chief Executive of **Fertility Network UK** – who said that removing the status of medical secrecy would benefit patients, by helping them to access the treatment and support they need for their physical and/or mental health.

We responded *'Strongly agree'* to **Q27** – *'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?'* – because we would very much like generic consent to become an option (in fact, the default option) for donating embryos (or gametes) for use in research. We would also like to see a UK national embryo research bank established.

The current system fails patients and fails embryo research. Many practical impediments currently militate against the donation of embryos for research, making donation difficult even in instances where the patient is eager to donate and the relevant clinic is keen to support research. How many

more unused embryos might be donated to research projects, if the option to donate existed at every clinic, and if all patients were made aware of this option?

We have some insight into this, thanks to the patient survey that was conducted by the HFEA in April/May 2017 (as part of its 2016-2018 *'Improving embryo research'* project, the results of this survey were discussed at an Authority meeting in June 2017). The 188 respondents to the survey are not necessarily generalisable to the wider population, but it is striking that **58%** of them said they would prefer to donate embryos than allow them to perish, while only **6%** said that they would prefer their embryos to be discarded.

In our own work on improving conversations about unused embryos, we have learned that most patients who donate embryos to research wish for closure. Their fertility treatment may not have had the outcome they wished for, and even if their treatment was successful, their decision that they will never use embryos remaining in storage may be a difficult (or at least significant) moment for them.

Patients in this situation do not wish to enter into an open-ended arrangement where they agree to be contacted, at an unspecified point in future (perhaps years later), to give additional consent. They simply wish to be able to make a donation to 'science'. This is what we lack at present, and what a system of generic consent – and ultimately, a UK national embryo research bank – would achieve.

There are several useful precedents and resources that could be drawn upon in creating such a resource, and in thinking about appropriate consent processes. The **Health Research Authority** provides helpful guidance on consent at https://www.hra-decisiontools.org.uk/consent/ while the **Human Developmental Biology Resource** – which collects embryonic/fetal tissue, donated by women undergoing termination of pregnancy – has more than 20 years' experience of taking consent in a sensitive context.

The bank would be regulated by the HFEA (unless the responsibilities of regulators were partitioned differently under future legislation, a possibility we discuss at the end of our answer to **Q31** below). For this reason, the bank would have to be managed entirely independently of the HFEA.

Even an interim 'virtual' embryo bank, rather than a centralised bricks-and-mortar facility, could help to address a major problem with the current system – the span of time that can separate donation of embryos or gametes from the launch a research project. At present, many embryos are mandatorily discarded for the simple reason that the donor could not be reached.

An additional important step would be to incorporate (the option of) consent to donating future embryos to research, into the standard process of taking consent from gamete donors. An increasing proportion of embryos donated to research were created using donor gametes (due in part to an increase in assisted conception being used by same-sex couples and single people), but contacting the relevant donors in order to obtain the requisite consent is even more difficult than contacting patients.

This is a particular tragedy, because gamete donors (having been screened) are even more likely to be healthy and fertile than a patient in a heterosexual couple. Embryos created with donor gametes are therefore likely to be of particularly high quality from a research perspective, and it is all the more unfortunate that under present arrangements, these are being discarded.

Consider the example of **Bourn Hall Clinic**. Dr Kay Elder, Senior Research Scientist at Bourn Hall, explained at the 2023 PET event '**Your Chance for Change: Shaping the UK's Fertility and Embryo Law**' that she has had to discard many embryos donated by patients to research because – despite painstaking efforts – she could not contact the donors from whose gametes the embryos were (often a decade or more previously) originally created. On the very few occasions when she has succeeded in contacting the donor, and has explained the sort of consent she is seeking, the donor (and/or the donor's current family) has sometimes reacted with distress.

Dr Elder explained that **143** embryos donated by patients at Bourn Hall for use in research, that were created with donor gametes, are currently due to be mandatorily discarded. Many more have had to be discarded for similar reasons in previous years. This is a tragic waste.

Furthermore, even Bourn Hall – which has a strong commitment to enabling the donation of embryos for research – can only enable embryo donation at its clinic near Cambridge. Bourn Hall is unable to accept the donation of embryos from patients at its own satellite clinics in Norwich, Peterborough, Wickford, King's Lynn and Colchester, even though it would very much like to accept such donations, because the regulatory requirements involved in moving embryos from one location to another are so complex as to be prohibitive. This situation must change.

The HFEA's consultation document says that *'patients should continue to be allowed to donate their embryos directly to specific research projects only if that is their preference'*. While patient choice is important, PET considers this to be the wrong approach. It replicates current problems, such as the mandatory discard of embryos if the research project is discontinued before the embryos are used.

Finally, in addition to enabling donation of embryos or gametes to research, it is also important to give patients the option of **donating embryos or gametes for use in training** (without which embryologists and others would not be able to acquire necessary expertise and experience) and also to **enable research into – or involving – clinical embryology itself**. The latter type of research falls into a grey area, in the categories of the current HFE Act.

Scientific developments

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 agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

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 agree
- Agree
- Disagree
- Strongly disagree
- Unsure ✓
- Prefer not to answer

31. If you would like to comment further on issues related to scientific developments and how the HFEA regulates these, please tell us more.

Scientific research is vital to assisted conception, and is too often deprioritised or overlooked in discussion of related law and policy. IVF, and also preimplantation genetic testing (PGT) and related innovations, owe their very existence – and much of their subsequent refinement – to pioneering human embryo research that took place in the UK. There are many other areas of reproductive and developmental science, and science more generally, where the study of human embryos is extremely useful.

This HFEA consultation, and its supporting documentation, lack the ambition that is required if the UK is to build upon its global reputation for research and innovation in relation to human embryos. PET sympathises with the HFEA's nervousness about far-reaching legislative change, but the opportunity for such change is so rarely available that when it arises, a full range of possibilities should be considered and consulted upon. This is all the more important, when Parliament may take several years to consider such changes, during which time science will continue to advance.

As discussed in our answer to **Q28** above, at present UK fertility clinics are perversely *disincentivised* from enabling embryo research, without which the treatments offered by these clinics would not exist. This situation must be reversed. **There should be a general obligation for fertility clinics to make human embryos available for research purposes.** This would fulfil the wishes of fertility patients who want to donate embryos and know that they are benefiting research.

Unwarranted impediments to research involving human embryos and gametes must be removed. For example, the current requirement to report the movement of every single research embryo to the HFEA is prohibitively cumbersome and expensive for research centres. More generally, the rules that govern the use of gametes and embryos in research should be simplified.

The *'principal purposes'* for which embryo research is permitted, in **Schedule 2** of the HFE Act, should be revisited. Five such *'principal purposes'* were set out in the original Act in 1990, and the list was expanded to eight in 2008. This list should be revised again, to consider permitting embryo research for purposes (such as development of diagnostic tests, and development of methods for *avoiding* rather than treating disease) that are not straightforwardly accommodated by the current list. Moreover, emphasis should be placed on the **public interest** throughout the *'principal purposes'*, affirming the fact that the interests of the public are well served when human biology, disease, development and reproduction are better understood.

The current HFE Act requires research *'to be necessary or desirable for'* one (or more) of the *'principal purposes'*, before it can be licensed by the HFEA. The criterion *'necessary'* should be

removed from the HFE Act, leaving only the criterion *'desirable'*. When the HFEA assesses the merits of a licence application in relation to the *'principal purposes'*, this assessment is best described as a judgment of the *desirability* of the research. The necessity of research is a far more subjective matter, and not one that a licensing body is best placed to judge.

Moving on to consider the multiple choice questions in this section of the consultation, we responded *'Unsure'* to **Q29** – *'To what extent do you agree or disagree that the Act should explicitly give the HFEA greater discretion to support innovation in treatment?'* – because the question seems to conflate several issues that we would like to see disentangled.

The question could be interpreted as alluding to several things, including:

- **Fertility treatment add-ons** (these are referred to explicitly in the first section of the consultation document, but not in this fourth section).
- Different ways of **assessing and selecting embryos** prior to transfer (these might overlap with fertility treatment add-ons).
- **Radically novel assisted conception techniques**, that would not at present be legally permissible in treatment (these are discussed explicitly in the consultation document in relation to **Q30**, but **Q29** could equally be interpreted as alluding to such techniques).

We will address each of these in turn. If these were *not* the scenarios that the HFEA had in mind when posing this question, then it would have been helpful if illustrative examples had been provided. (Perhaps the HFEA did not wish to give the impression that it was endorsing particular new techniques. If so, a case study of an older example might have been used.)

We should also like to note that while the distinction between treatment and research is very important – in the HFE Act, and more generally – there is an ambiguity in the Act regarding whether a treatment licence is sufficient to permit research into, or involving, clinical embryology itself. This should be clarified in any future legislation.

In relation to **fertility treatment add-ons**, the difficulty is that the HFE Act is structured largely around regulating what can be done – and by whom – to or with gametes or embryos outside the human body. Either this continues to be the case (in which case some fertility treatment add-ons will inevitably fall outside this scope), or a more thoroughgoing revision of the Act must be argued for. *'Greater discretion to support innovation in treatment'* – as referred to in the question – is not a clear way of seeking to discourage the use of dubious add-ons (or conversely, of seeking to support any add-ons that might prove to be effective).

In relation to different ways of **assessing and selecting embryos** prior to transfer, and particularly methods that involve genetic or genomic tests, **PGT-M** and **PGT-SR** have long been established as effective for certain specific purposes. Far more contentious are **PGT-A** and **PGT-P**.

It is a stretch to refer to **PGT-A** as an *'innovation'*, given that its use was first approved by the HFEA in 2001 (granted, new ways of assessing embryo aneuploidy without the need for a biopsy have recently been proposed). More than two decades on, the assumption that it is beneficial to the patient to prefer (apparently) euploid embryos over aneuploid embryos – when both aneuploidy and mosaicism have been shown to occur naturally in early embryos, without persisting or leading to problems – seems increasingly to be an old assumption in search of ever-changing new justifications. This is one technique to which the HFEA could usefully bring a more critical eye.

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The HFEA should also address the mixed messages about PGT-A that are given by its website. PGT-A is given a 'red' traffic light at https://www.hfea.gov.uk/treatments/treatment-add-ons/pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ to indicate that it is not supported by evidence. At the same time, the *'Fine tune your search'* feature for search results in the *'Choose a Fertility Clinic'* tool at https://www.hfea.gov.uk/choose-a-clinic/clinic-search/ promotes *'PGS'* (an alternative term for PGT-A), by suggesting that users of the website might wish to use the availability of PGS (under the heading *'Screening services'*) as a criterion for selecting clinics. PET first brought this issue to the HFEA's attention in early 2020, and has raised it several times since.

As for **PGT-P**, a growing number of professional bodies – including the **European Society of Human Genetics**, the **American College of Medical Genetics** and the **International Society of Psychiatric Genetics** – have recently issued statements condemning the use of this approach. The problems with PGT-P are numerous, but many of them come down to profound differences between polygenic scores and more traditional forms of genetic or genomic data. These differences mean that polygenic scores cannot meaningfully inform a selection from a limited number of available embryos. This deficit is probably intrinsic to polygenic scores themselves (when considered in a reproductive context), rather than being rectifiable via future refinement of the technique.

Radically novel assisted conception techniques – for example, involving *in vitro* gametogenesis and/or genome editing – would be most deserving of the description *'innovation in treatment'*. We discuss such possibilities below, in relation to **Q30**.

The *'sandbox'* approaches discussed in the consultation document in relation to **Q29** might be a helpful and legitimate way for the HFEA to assess certain innovations in future, allowing for the tentative and closely supervised introduction of such innovations. But this would not obviate the need for transparent discussion of any wider issues raised by the innovation in question.

We responded *'Unsure'* to **Q30** in this consultation – *'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?'* – because the question is too general for us to express a firm view. Our response would depend on the specific *'amendments and extensions'* proposed, and we also think it is important to disentangle considerations particular to research from considerations particular to treatment.

The consultation document states that *'this survey is not the place to resolve whether the current restrictions should change'*, but does not explain why this consultation *'is not the place'* to discuss such changes. The document suggests that instead of making such changes, *'the Act should be futureproofed'*. Futureproofing the HFE Act is a laudable ambition (who would wish to pass legislation that cannot withstand future developments?), but in some instances, the best way to achieve this ambition is indeed to propose immediate changes to the Act.

One example given in the consultation document – **extending the current 14-day limit on human embryo research** – is a case in point. We shall discuss this first, as it is a restriction specific to research, and then we shall proceed to consider parts of the consultation document that bring in treatment considerations.

The time to consider amending the Act to extend the 14-day limit is not, as the consultation suggests, at some indefinite point in the future via a regulation-making power. The time is now.

There is no longer a compelling case for mandatory discard of precious embryos that have been donated to research, once they reach the 14-day stage and there is so much still to be learned

from them. Instances when (non-living) human embryos from the 14-28 day period become available for research – as with the recent Oxford-led study at https://doi.org/10.1038/s41586-021-04158-y – are invaluable but vanishingly rare, and therefore insufficient.

Embryo culture beyond 14 days is the only way researchers can acquire understanding of aspects of early development and organ formation, and hence the only way we can begin to address aspects of disease and pregnancy loss. Extended embryo culture is also the only way to properly validate alternative embryo models (we discuss such embryo models further below), thereby establishing the contexts in and purposes for which such models are useful, while also clarifying the contexts in and purposes for which use of human embryos proper remains essential.

The HFEA's consultation document refers to the fact that human embryo culture cannot at present continue beyond the appearance of the primitive streak. This, too, is a problem. Whereas the 14-day limit counts days in a way that can at least be agreed upon objectively, the primitive streak restriction inevitably involves subjective considerations, because the appearance of this feature is not instantaneous but rather is a process (with both morphological and molecular aspects).

The HFEA's current Code of Practice requires research centres to record *'the procedure that will be used to ensure that embryos do not develop after 14 days or the primitive streak'* before a project begins, but there is a lack of clear precedent regarding what would constitute an observation of the appearance of the primitive streak. With longer periods of embryo culture becoming technically feasible, and with technologies (including genome editing) that could potentially affect the rate of development of research embryos, it is increasingly possible that the primitive streak might (begin to) appear in a laboratory-cultured embryo – even with a 14-day limit in place.

The primitive streak restriction should therefore be removed entirely from the HFE Act.

Some will object that research projects involving extended embryo culture, within the present limits, are rare and therefore are a low priority for law reform. But this is a self-fulfilling outlook. The 14-day limit and the associated primitive streak restriction have a chilling effect, creating a fear of inadvertently crossing a line and creating a vague sense – among researchers, institutions and funders – that such research is somehow intrinsically dubious or risky.

It is time for this to change. The UK should aspire to be at the forefront of embryo research on multiple fronts, including creating new legal and scientific possibilities for extended embryo culture.

Moving on from the 14-day limit, we are concerned that the consultation document risks confusing research and treatment considerations, when it states that *'scientific advances are creating new categories of cells... which are outside the regulatory categories of the Act'*. The examples given are ***in vitro* gametogenesis** (**IVG**) and **stem-cell-based embryo models** (**SCBEMs**). But these technologies are very different, and should be kept separate when thinking about the HFE Act.

IVG could be a candidate technology for use in fertility treatment, if current research efforts prove successful. Broadly speaking there are three scenarios that might be envisaged, with differing implications.

1. Gametes are both created and taken to maturity *in vitro*, and are then used in IVF to create an embryo. The definition of *'permitted'* gametes and embryos in the current HFE Act would not permit this embryo to be transferred.

2. Gametes (or their precursors) are created *in vitro* and transplanted to a patient, and gametes are subsequently collected from this patient and used in IVF. The definition of *'permitted'* gametes and embryos in the current HFE Act *might* not permit the resulting embryo to be transferred (there is a potential ambiguity here).

3. Gametes (or their precursors) are created *in vitro* and transplanted to a patient, and this patient then conceives naturally. This scenario falls completely outside the scope of the current HFE Act.

There may also be asymmetry between IVG for male and female gametes. It may transpire that scenario 1 above is optimal for male gametes while scenario 2 above is optimal for female gametes, or vice versa. In that situation, multiple regulators and regimes could become implicated. (We will refrain from speculating on further complications, if it ever becomes feasible to obtain female games from biological males or male games from biological females.)

How would the scenarios above be dealt with, if it were considered desirable to permit – or to facilitate the later permitting of – the use of IVG in treatment? Scenarios 1 and 2 would require reconsideration of the concept of *'permitted'* gametes and embryos. This is a recurring theme in our response to this consultation, and is discussed further below. Meanwhile, Scenario 3 may require the HFEA to reconcile itself to the fact that this is a matter outside its remit.

On this theme, we note that there has already been confusion – from sources including the HFEA – over whether transplanting or grafting a patient's previously preserved gonadal tissue back into the patient, as a way of restoring lost or compromised fertility, constitutes use of gametes in a manner governed by the HFE Act.

Any change to the HFE Act should seek to dispel uncertainty on this question, and particular attention should be paid to the distinction between male and female gonadal tissue (the likelihood of the tissue containing gametes is different in each case). It would be preferable if gonadal tissue were considered outside the scope of HFE Act, and were regarded in the same manner as other autologously transplanted tissue – that is, regulated by the Human Tissue Authority but *not* by the HFEA.

SCBEMs are very different from IVG, and are *not* a likely candidate technology for direct use in treatment. The one scenario in which these two things would overlap is if SCBEMs were ever used as part of a *method* of IVG – a specific situation that would have to addressed if it ever arose, but that does not justify conflating these two otherwise distinct areas preemptively.

Unlike IVG, SCBEMs – which are a useful addition to (but not a straightforward replacement for) human embryos in the research context – are likely to remain confined to laboratory use for the foreseeable future. Inasmuch as clarity is needed regarding the legal status of SCBEMs, it would be of greatest benefit to clarify that SCBEMs are – and should remain – *outside* the scope of the HFE Act and therefore outside the remit of the HFEA.

This is not to deny that questions and challenges are posed by advances in research involving SCBEMs – rather, it is to argue that these questions and challenges are best dealt with elsewhere. We are pleased that the **Governance of Stem-Cell-Based Embryo Models** (**G-SCBEM**) project – coordinated by **Cambridge Reproduction**, with input from PET – is currently addressing this very issue, developing a recommended governance framework for UK research involving SCBEMs. Such a framework will help to meet the need for greater clarity.

Moving on from IVG and SCBEMs, the consultation document discusses *'the regulation making power written into the HFE Act in 2008 that required positive approval of the resulting statutory instrument of the Mitochondrial Regulations of 2015'*. This precedent is instructive, because while there is much to recommend those Regulations – including the fact that they limit the purpose for which mitochondrial donation may be used – it is unfortunate that the Regulations also specify and restrict the mitochondrial donation techniques that are legally permissible.

This is an inappropriate level of scientific detail to have specified at the statutory level. It is reasonable that approval be sought from Parliament if there is a proposal to use mitochondrial donation for a new purpose (for example, as a novel fertility treatment technique rather than as a means of avoiding the transmission of mitochondrial disease). But it is *not* reasonable that approval must be sought from Parliament to use a particular mitochondrial donation technique, should it transpire to be safer or more efficacious than techniques developed previously.

(On a related theme, there may be a case for permitting the use of certain genome editing tools in assisted conception, for purposes *other* than conventional genome editing. One such use could be to remove unwanted 'carried over' mitochondrial DNA from a mitochondrial donation embryo.)

A better and more futureproof approach – not just for mitochondrial donation, but for any reproductive technology addressed by the HFE Act and by related legislation – would be to **legislate for *the purpose for which reproductive technology may used*, and not for the *method via which that purpose may be achieved***. This would have the additional benefit of making the legislation flexible in relation to new and emerging scientific concepts, that may not fit easily into established legal categories.

The consultation document refers to the fact that *'the Act does not permit interventions in the nuclear DNA of gametes or embryos for use in reproduction'*, and then goes on to discuss genome editing (it should be noted that this restriction is also relevant to IVG). We welcome consideration by the HFEA of how such innovative approaches might be permitted in future, should they be shown to be safe and efficacious. Again, this will necessitate **reconsidering the concept of *'permitted'* gametes and embryos**, that was introduced into the HFE Act in 2008.

One option is simply to redefine a *'permitted'* gamete or embryo, but there is a risk that the relevant definition will become unworkably convoluted and insufficiently futureproof. Another option – notwithstanding the fact that the concept of the *'permitted'* gamete or embryo has served a useful purpose since 2008 – might be to devise an entirely different way of distinguishing between reproductive materials that may be legally used in treatment, and reproductive materials that may only be legally used in research.

Finally, while it is understandable that the HFEA might wish to propose an expansion of its powers when making recommendations for law reform to Government, we would urge the HFEA not to assume that it must *always* be the regulator – going forward – of the use of reproductive materials in research. **Different regulatory arrangements could be considered**, especially if the **Human Tissue Act** were reviewed at the same time as the HFE Act.