Modernising the regulation of fertility treatment and research involving human embryos

Summary

The HFEA is reviewing the law on fertility treatment regulation and embryo research to prioritise recommendations for change.

The consultation closes at 5pm April 14th 2023

Consultation description

The UK is a world leader in the regulation of fertility treatment and research involving human embryos. The Human Fertilisation and Embryology Act (the Act) first became law in 1990. In the 30 years since, there have been significant changes in the fertility sector including those accessing treatment, clinic ownership structure, the size of the sector, and services offered. The majority of fertility patients now pay for their own treatment, which can raise difficult questions about what treatments to have. Many UK regulators have a wider and more effective range of powers to improve compliance and protect patients and consumers than those available to the HFEA.

The proposals in this survey focus on the key changes that the HFEA believes should be made to the current law. The government has asked the HFEA to make recommendations for change, but any updates to the Act are decisions for government and parliament.

Your participation

This anonymous survey will help the HFEA collect views on some of the key issues that we are considering.

The survey is split into four areas where we think modernisation is most needed.

- **Patient safety and promoting good practice**
- **Access to donation information**
- **Consent**
- **Scientific developments**

In each area we provide a short summary of the **current situation**, then set out the issues with the Act, and describe our **proposals for change**. You will then be asked to agree or disagree with the proposal(s) and there will be free text boxes available for you to add more if you wish to or to comment on other issues.

Please note that you do not have to answer every question - you can give us your views on all four areas or just the ones you choose.

How we will use your survey responses

Completing this survey will not affect your treatment, your research, or your clinic. If you use the free text boxes provided in the survey, please do not include any information that could identify you if you are responding as an individual in a personal capacity (for example, as a patient or a donor). We will try to remove any identifying information that you give us. We may use any information, comments, or views you give in the survey in our report, or in other reports that we make. These documents are likely to be published online.

For this consultation, we may include responses received from organisations or individuals in our report. This may include the name of the organisation associated with the response and we will ask for an organisational email address to verify the response.

The personal information you supply will be processed in accordance with the provisions of the General Data Protection Regulation and the Data Protection Act 2018.

Please send your completed form to: enquiriesteam@hfea.gov.uk

Personal information

To complete this consultation, you must be aged 18 or over.

1. In what capacity are you responding to this consultation (please select only **ONE** option):

☐An individual sharing my personal views and experiences → Go to question 2

☐An individual sharing my professional views → Go to question 7

☐An individual sharing both my personal and professional views (i.e. you work in the fertility sector but have also been a patient or partner of a patient) → Go to question 2

☐On behalf of an organisation → Go to question 11

2. Please select the single option that is **MOST** relevant to your personal reason/interest for completing this consultation:

☐I am currently having, or have had fertility treatment, or I am the partner of someone who is having, or has had fertility treatment → Go to question 3a

☐I am a donor → Go to question 4a

☐I am a donor conceived person → Go to question 5

☐I am the parent of a donor conceived person → Go to question 6

☐I am an interested member of the public → Go to question 7

☐Other, please specify:

	→ Go to question 7

3a) Please select the option that best describe your fertility treatment experience (please select only **ONE** option):

☐I am a currently having, or have had fertility treatment

☐I am the partner of someone who is having, or has had fertility treatment

☐I am/was a surrogate

☐I am an intended parent (for example, through surrogacy)

☐Other, please specify:

3b) What is/was your legal marital or registered civil partnership during your most recent fertility treatment? (please select only **ONE** option)

☐Single, never partnered, married or in a registered in a civil partnership → Go to question 3d

☐Currently not partnered, married or in a registered in a civil partnership → Go to question 3d

☐Partnered but not married or in a registered civil partnership → Go to question 3c

☐Married or in a registered civil partnership → Go to question 3c

☐Separated, but still legally married or legally in a registered civil partnership → Go to question 3d

☐Divorced or formerly in a registered civil partnership which is now legally dissolved → Go to question 3d

☐Widowed or the surviving partner from registered civil partnership → Go to question 3d

☐Prefer not to say → Go to question 3d

3c) Who is or was your partnership, legal marriage or registered civil partnership to **WHILE** you were experiencing fertility treatment? (please select only **ONE** option)

☐Someone of the opposite sex

☐Someone of the same sex

☐Other

☐Prefer not to say

3d) Where did you have treatment? (please select only ONE option)

☐I had treatment in the UK

☐I went abroad for treatment

☐I had treatment both in the UK and abroad

☐Prefer not to say

3e) Have you used donor sperm/eggs/embryos in any of your treatment cycles? (please select only **ONE** option)

☐Yes → Go to question 3f

☐No → Go to question 7

☐Prefer not to say → Go to question 7

3f) If you have had treatment with donor sperm/eggs/embryos; which of the following is applicable? (you can select more than one option)

☐I have used donor sperm

☐I have used donor eggs

☐I have used donor embryos

3g) If you have had treatment with donor sperm/eggs/embryos, please tell us when you had treatment with donor eggs/sperm/embryos (you can select more than one option):

☐Before 1991

☐Between 1991 and 2005

☐Since 2005

☐Prefer not to say

→ Please go to question 7

4a) Please tell us about your donation (you can select more than one option):

☐I am an egg donor in the UK

☐I am a sperm donor (I am/was registered with and donating to a UK clinic or sperm bank)

☐I am an embryo donor in the UK

☐Other, please specify:

☐Prefer not to say

4b) Please tell us when you donated your eggs/sperm/embryos (you can select more than one option):

☐Before 1991

☐Between 1991 and 2005

☐Since 2005

☐Prefer not to say

→ **Please go to question 7**

5. Have you accessed, or would you access identifiable information about your donor (for example information that includes their name)? (please select only **ONE** option)

☐Yes, I have already accessed identifiable information via the HFEA

☐Yes, I have already accessed identifiable information via other websites/organisations please specify:

☐Yes, I intend to at another time via the HFEA

☐Yes, I intend to at another time via other websites/organisations

☐No, I do not want to access identifiable information

☐No, I am unable to access identifiable information

☐Other, please specify:

☐Prefer not to say

→ **Please go to question 7**

6. Have you accessed, or would you access identifiable information about your child's donor? (please select only **ONE** option)

☐Yes, I have already accessed information via the HFEA

☐Yes, I have already accessed information via other websites/organisations please specify:

☐Yes, I will at some point in the future via the HFEA

☐Yes, I will at some point in the future via other websites/organisations

☐No, I do not want to access identifiable information

☐No, I am unable to access identifiable information

☐Other, please specify:

☐Prefer not to say

→ **Please go to question 7**

7. Please tell us your age (please write this in number form, e.g. 31):

8. Which region of the UK do you live? (please select only **ONE** option)

☐England

☐Scotland

☐Wales

☐Northern Ireland

☐I don't live in the UK, please specify where you live:

☐Prefer not to say

9.What is your sex? (please select only **ONE** option)

☐Female

☐Male

☐Prefer to self-describe:

10.What is your ethnic group? (please select only **ONE** option)
☐Asian or Asian British (Indian, Pakistani, Bangladeshi, Chinese, or any other Asian background)

☐Black, Black British, Caribbean or African (or any other Black, Black British, Caribbean or African background)

☐Mixed or Multiple ethnic groups (White and Black Caribbean, White and Black African, White and Asian, or any other Mixed or Multiple Background)

☐White (English, Welsh, Scottish, Northern Irish, British, Irish, Gypsy or Irish Traveller, Roma, or any other White background)

☐Other ethnic group, please specify:

11. If you are responding on behalf as an individual sharing professional views, or an individual sharing professional and personal views, or on behalf of an organisation please complete the following:

What is the name of your organisation?

Please provide your personal or organisational email address, optional:

If you provide an email address, this may be used to verify the response is from the organisation named above, before it is included in the report. The email address will not be shared with anyone outside of the HFEA.

Which of the following best describes your organisation? (please select only **ONE** option)

☐A professional or clinical group or organisation

☐A research group or organisation

☐Academic group or organisation

☐A group, organisation, or charity representing patients or others

☐Other, please specify:

Patient safety and promoting good practice

The case for change

Patients should be assured that the treatment they are offered is safe, evidence-based and of a high standard. To provide this assurance, the HFEA wants to put patients at the heart of a revised law.

Fertility treatment is unique in modern healthcare - there is no comparable area of healthcare where a potential new life is created in a laboratory. But many of the regulatory issues we face are common to healthcare more generally - the **Cumberlege report** on women who suffered avoidable harm from private and NHS healthcare, described a system that did not adequately recognise that patients are its sole purpose. Like all healthcare regulators, the HFEA needs to put patient safety at the heart of its regulatory actions.

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.

The regulatory challenges of today are increasingly out of step with our powers. We want a new regulatory scheme that encourages a positive culture of best practice wherever possible, but with effective sanctions where necessary.

The fertility sector in the UK has changed significantly since the HFEA was set up. Today fertility treatment is provided predominantly through self-funding by patients, although this varies across the nations and regions of the UK. A majority of clinics are privately owned, many as part of large groups with external finance. Elements of fertility care and associated treatments are increasingly offered online or outside of our regulation.

Better patient care through risk-based inspection and licensing

Modern regulatory thinking is not just about taking action to tackle poor performance, it is also concerned with incentivising compliance. All regulatory regimes impose duties on the regulated entity. The Regulators' Code expects that the HFEA, like all regulators, carries out its activities in a way that supports clinics to comply and improve.

Good regulatory practice should be focused on the outcomes we wish to see, like patient safety. A one size fits all approach to regulatory activity is therefore often not appropriate, but there is currently little scope within the Act to approach licensing and inspections in a more targeted way.

Current situation

The law currently allows the HFEA to issue treatment and storage licences for up to five years after which the clinic needs to apply to renew its licence if it is to continue to offer licensed activities. The HFEA typically issues licences for a maximum of four years because the Act also requires us to inspect the licensed premises at least once every two years.

Issues

The law is inflexible and is out of step with modern risk-based regulation

The requirement to inspect premises at least every two years means there is no scope to exempt clinics from an inspection even when they are fully compliant. A more risk-based inspection cycle would vary the frequency of inspection according to risk and allow the HFEA to devote more of its resources to those clinics which need most support. Greater flexibility would also allow the HFEA to vary the proportion of the inspection which is conducted on-site and the proportion which is undertaken remotely.

This is not about moving away from on-site inspections; the evidence suggests that inspection can be a vital tool in ensuring that standards are met and provides an opportunity to speak to patients and clinic staff. But a robust inspection regime draws on a variety of evidence whether from performance data, documents or direct observation. At present, we are required to visit the clinic at regular intervals regardless of its level of compliance. A more flexible approach would also be more closely aligned with the Regulators' Code principle that regulators should base their regulatory activities on a proportionate approach to risk.

The requirement to renew a licence creates unnecessary uncertainty

Even if the HFEA were to have greater flexibility over when and how it inspected, this would not remove the necessity of a periodic licence renewal. In many other regulated sectors, including much of healthcare, providers are awarded ongoing licences provided they meet the required standards.

Proposals for change

The HFEA should have greater freedom to decide the regularity and form of inspections

This could be done via periodic licences (whether five years as now, or longer) or a more radical option granting all, or the most compliant, clinics an ongoing licence, subject to periodic and risk-based inspection. This would take away the artificial 'cliff edge' of a licence renewal. We would expect that the clinic will continue to meet the required standards unless their performance shows otherwise. Where the standards of care have fallen to unsafe levels, the HFEA should retain the power to shorten, suspend or revoke a licence.

12. To what extent do you agree or disagree that the HFEA should have greater freedom to vary its inspection regime? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Better supporting clinic leaders to deliver high quality care

Good regulation should aim to support those who provide services as well as challenge them to improve. Reform of the Act could enable the HFEA to assess and support those who lead fertility clinics even better.

Current situation

The regulatory focus of the Act largely falls on one individual: the 'Person Responsible' (PR). This individual is accountable for the conduct of all activities in the clinic. The PR in a clinic setting is required to have certain qualifications and experience, which limit the range of potentially suitable people who could be a PR. Given the importance of the PR's role, the HFEA runs an entry programme to support new PRs and provide continuous learning, which requires all PRs to understand the legal requirements of the role.

Under the Act, licences are granted to 'Licence Holders' (LH, who may or may not be the same person as the PR). The LH can be a corporate entity - such as health trust, a private business, or an individual.

Issues

The responsibilities of the PR are significant

There is no provision for the role to be shared, or for there to be deputy PRs. This is increasingly out of step where licensed clinics are part of a larger commercial group. The possibility to share the responsibilities of the PR would help to support flexible working and encourage a greater diversity of PRs.

Proposals for change

The possibility of appointing Deputy PRs and PRs with a broader range of qualifications or experience

Although much will depend on the circumstances and size of the clinic, the appointment of a deputy PR (or deputies) might provide a more sustainable and flexible model, especially where clinics are part of a wider commercial group structure. Additionally, broadening the criteria of qualifications and experience required to be a PR would improve the range of people suitable for the role.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Better regulatory tools to tackle poor patient care

When standards fall too far regulators must take robust proportionate action, but the current law means the HFEA cannot easily do this.

Many of the regulatory tools in the Act have been overtaken by developments in the fertility sector and more modern regulatory approaches. The Act has much to say about the protection of the embryo but has no similar focus on the patient. 'Treatment add-ons' are not adequately covered. The Act also assumes that treatment services only take place in licensed premises but now different types of fertility services are offered in non-licensed clinics or online.

Current situation

The HFEA has a limited range of powers and sanctions to respond to non-compliances. The HFEA can suspend a clinic's licence with immediate effect, take away the licence, or change the licence to impose additional conditions – for example, we could require a clinic to temporarily stop donor treatment if we had concerns about that aspect of the clinic's service, but it could continue to provide other treatments.

Issues

The range and order of regulatory sanctions make proportionate action difficult

At present, the HFEA must show that the requirements for taking away a licence are being met (the most serious sanction we have) before we look at what alternative action can be taken. This is a very high bar for any regulatory action, with the result that poor quality services might continue for longer than they should, increasing the risks to patients. Earlier, more targeted, regulatory action would better protect the patient and mean that the complete closure of a clinic, which is rarely in the patient's interest, is less likely.

The range of regulatory sanctions available to the HFEA are limited

Good regulation should try to achieve the greatest impact with the most proportionate sanction. For example, it would often be more proportionate to impose a financial penalty, which the HFEA is unable to do at present, rather than to remove or suspend a licence. The former would ensure that a clinic would need to improve their standard of care whilst minimally impacting existing patients, whereas the latter could possibly require the clinic to close which would significantly impact patients and their treatment. The regulator's power to impose financial penalties would also act as an important and effective deterrent for poor compliance across the sector.

The Act is silent on patient care

In recent years healthcare regulation has moved to put the needs and interests of patients at the centre. The absence of any specific statutory reference to patients in the Act is therefore out of step and can make it harder for the HFEA to take proportionate action where patient safety is at risk.

More fertility services are being offered that fall outside the remit of the Act

Some activities marketed as fertility treatments, but not covered by the Act, take place outside of HFEA licensed clinics. Some of these services might be in 'wellness' clinics, or they might be offered by introduction services advertised online. From the perspective of the patient going through fertility treatment it is all part of their treatment journey and the HFEA should have powers in these areas.

Additionally, there has also been a growth in private arrangements, including online sperm donation where the risks to a woman's health can be serious. However, it is difficult to see how any regulatory regime could effectively tackle such arrangements.

Proposals for change

The HFEA should have a broader and more proportionate range of powers

A range of escalating enforcement options would allow for a more effective response to the seriousness of the non-compliance.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The HFEA should have the power to impose financial penalties

In an increasingly commercial fertility sector, the power to levy a financial penalty could be a useful and proportionate tool to shape clinic behaviour, or to address serious non-compliance, and to incentivise compliance across the sector. In comparison 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. As when other UK regulators impose fines, any monies collected through such financial penalties by the HFEA would be passed to HM Treasury.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The Act should be revised to include an over-arching focus on patient care

Patient care should be an explicitly stated principle of the Act, with a requirement that HFEA decision-making and compliance by licensed clinics should have reference to it.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The Act should be revised to accommodate developments in the provision of related fertility services

By bringing all related services, whether offered in physical premises or online, within a broad definition of regulated fertility services to recognise the changing nature of wider fertility treatment.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Making licensing decisions more efficient

Licensing should provide clear, rigorous and speedy judgements for the licensed entity and allow the regulator to move quickly to tackle new challenges to the benefit of clinics and patients.

Current situation

The Act sets out how the HFEA must make licensing decisions and set clinic licence conditions. This covers updates to Standard Licence Conditions applicable to all clinics, or conditions imposed on an individual clinic because of a non-compliance. Sector-wide updates usually relate to major external changes (e.g. changes to the law). Occasionally they reflect a key change in HFEA policy.

The law also specifies how the HFEA should handle appeals from clinics against licensing decisions. Such decisions are, rightly, subject to a statutory right of challenge by clinics. In practice these challenges are rare.

In most cases the Act sets out a two-stage appeal process: a ‘representation hearing’ (a reconsideration of the proposed decision from a Licence Committee, followed by a second stage ‘appeal hearing’, involving a reconsideration of the case by an external and independent Appeals Committee.

If a clinic appeals against a licensing decision, the decision cannot take effect until this two-stage process has been completed, or the clinic accepts the proposed decision. This can take many months and creates uncertainty for the clinic and patients. The same rules and rights of appeal apply whether the proposed licensing decision is specific to only one clinic's licence, or if it results from a legal or policy change and is being proposed to apply to all UK clinics' licences.

Issues

The mandatory two-stage process to challenge licensing decisions is slow, costly and out of step with other regulators' practice

Challenges are rare, but the Act requires a protracted, overly legalistic and costly resolution process. At each stage the process can effectively resemble a court case. Other regulators can offer a more proportionate, quicker, less quasi-judicial procedure at the first step of a challenge by clinics.

The Act gives the HFEA insufficient ability to set and change standard licence conditions

Licence conditions offer a vital way to set standards in clinics, but the process required to introduce revised conditions applicable to all clinics is slow and unwieldy. This limits the HFEA's scope to use licence conditions in an agile way to respond to fast developing safety concerns or impose best regulatory practice. Even when HFEA licence conditions are applied to all clinics the option to raise a challenge is open to each individual clinic.

Proposals for change

The Act should be amended to allow the HFEA to determine and set a more proportionate appeals process

The aim would be to ensure that clinics' ability to challenge regulatory decisions remains transparent and fair, but that the process is quicker and cost effective for both the HFEA and clinics.

18. To what extent do you agree or disagree that the current appeals process should be changed? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The HFEA should have the ability to make rules governing how standard licence conditions are made and revised

The aim would be to ensure that technical changes can be introduced quickly and without incurring the risk of multiple challenges.

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? (please select only **ONE** option)

☐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.

Access to donor information

The case for change

The sharing of information around donor conception raises sensitive, challenging and complex questions.

When the Act was first introduced there was a general presumption that donation should be anonymous. Over time attitudes have changed, but the law does not fully reflect those changes. The current professional advice is that children benefit from learning from a young age that they have been conceived using donor gametes.

The issue of accessing donor information and identifying donors, has become more urgent with the growing popularity of easily accessible, relatively affordable direct-to-consumer DNA testing and matching services which have revolutionised our ability to find our genetic relatives. Mainstream media and social media have shone a light on how these services can provide information to those who previously had no way of finding out their full genetic origins.

Our proposals seek to provide patients and donors with options that recognise this changed situation.

Donor Anonymity

Currently donors remain anonymous until any children resulting from their donation are adults. At that point people conceived from donations made post-April 2005 and who are over 18 years old, can request identifying information about their donor from the HFEA via the **Opening the Register** service, based on verified data held on our Register.

Current situation

This information can include the donor's full name, date of birth, and most recent address. Donors are also able to find out from the HFEA the number, sex and year of birth of any children born.

Adults who were donor-conceived prior to 2005 are not routinely able to access identifiable donor information via the HFEA. Adults conceived between 1 August 1991 and 31 March 2005 can request only non-identifying details about their donor from the HFEA. However, donors who donated during this period can opt to remove their anonymity via the HFEA, if they wish, which allows donor-conceived adults the opportunity to access their donor's identifying details.

Adults who were donor-conceived after 1 August 1991 can also choose to share their contact details with any adult full or half genetic siblings they may have, by joining the **Donor Sibling Link** (DSL) voluntary contact service run by the HFEA.

Issues

The availability of direct-to-consumer DNA testing and matching websites and social media challenges assumptions about anonymity and the release of information about donors

The Act designates the HFEA Register as the central repository for verified donor information and as the single access point to it. However, the easy availability and increased use of direct-to-consumer DNA testing and matching websites and the availability of identifiable personal information on social media and the wider internet, have combined to allow many donors and donor-conceived people to be identified to each other, whether directly or by inference, outside of any information from the HFEA.

Third parties can also find out information about genetic relatedness between other people via these routes - whether this information is sought intentionally or is discovered unexpectedly. For example, someone may find out that they are donor conceived because of a genetically-related family member using a DNA testing website. Additionally, some groups offer DNA testing and matching between donor-conceived siblings who would like to make contact with each other, without trying to identify the donor.

The parental response to the possibility of commercial websites helping to reveal identities will vary

Some parents of donor-conceived children are pleased that identifiable donor information is now more easily discoverable earlier and through channels other than the HFEA. They will actively seek out information in their child's early years because they want their child to have contact with the donor during childhood. They may also, or alternatively, seek out their child's donor-conceived siblings who share the same donor in early childhood, so that social relationships can be made. Other parents may value the 18 years in which the donor(s) are not identifiable to their child and use the time to prepare their child to decide for themselves what information they might want to access in future. And other parents may never inform their child that they are donor-conceived. Donors will also have a range of responses regarding when donor-conceived individuals and their parents should receive this information.

Donation raises questions about parental choice and informed decision making

The decision to use donated gametes can have significant implications for the donor(s), the parent(s) and the donor-conceived individual(s). The decision might impact on existing and new personal relationships and family dynamics. Making sure that prospective parents have access to the right information on the use of donor gametes within their treatment is an important element of the treatment pathway to ensure that they can come to a properly informed decision. Patients may therefore benefit from discussing the implications of using donor gametes before treatment.

Proposals for change

In thinking about the future of access to donor information the following assumptions remain important:

- That the HFEA should continue to collect data about children born from a donor
- That consent is properly obtained, and donors and recipients are fully informed about the potential challenges to anonymity from DNA testing and matching services
- That parents should continue to decide when or if to tell their child about their donor-conceived status
- That patients should continue to be encouraged by clinics to be open with their children about how they were conceived

Clinics should be required by law to inform donors and recipients of the potential for donor identity to be discovered through DNA testing websites

As part of the consent process, clinics would be legally required to inform donors and recipients about the possibility that any children born from donation could discover their donor's identity before they are 18. This would change what is currently HFEA guidance into a legal requirement.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The Act should be amended to provide parental and donor choice to opt for anonymity until age 18 (as now) or identifiable information on request after the birth of a child

Under this scenario donors (when they donate) must decide whether they wish to remain within the existing legal framework (where anonymity is protected under the Act until the donor conceived individual becomes an adult), or whether they wish to be identifiable to parents by request via the HFEA. If a decision to opt for anonymity until 18 had been made, then the donor conceived adult would gain

information access rights from the age of 18. Parents would need to decide at the point of treatment whether they would like to choose a donor who is identifiable before or after their future child turns 18.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

The Act should require all donors and recipients to have access to information about the implications of their decision before starting treatment

The complexity of donation and the potential impact that it can have over a lifetime on wider personal relationships makes it unusual among medical treatments. Counselling must at its heart be a voluntary decision, but there is a good case that the principle of properly informed consent requires all donors and recipients to have access to information about the implications of their decision to use donor gametes before starting treatment.

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? (please select only **ONE** option)

☐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.

Consent

The case for change

Informed consent is one of the most important principles in healthcare. It is central to fertility treatment and clinic staff are required by law to obtain properly informed written consent from their patients before they store or use their sperm, eggs, or embryos.

The law relating to consent in fertility treatment is complex, particularly in cases involving donation or surrogacy. Consent to fertility treatment involves more than one person, and needs patients to consider potentially challenging scenarios, including making decisions about what might happen in the future to their gametes and any embryos in the event of their death (or mental incapacity). The conversation between clinic and patient is therefore crucial in ensuring consent is appropriately informed.

When consent is taken well the current rules provide certainty for all involved. But those rules are complex and both clinics and patients report difficulties with obtaining properly informed consent. In some cases, poorly taken fertility consents have had to be resolved by the courts which can be upsetting, time consuming and expensive.

This survey is an opportunity to consider whether there are ways of streamlining consent without giving rise to greater costs to the patient or compromising on certainty for all involved in treatment.

It is also an opportunity to seek views on ways in which fertility patient data can better be shared among medical professionals to ensure safer care and to improve the provision of embryos for research.

Consent to treatment and legal parenthood

Establishing the true wishes of the people involved in fertility treatment is vital and when consent is properly taken the current system provides certainty for all participants, not just at the time of treatment but also in the years that follow.

For many patients, the range of consents they need to give by law is relatively straightforward, but consent can be a particularly complex process where donation or surrogacy is involved. The requirements of the law can also be inflexible, particularly when circumstances change for patients for example, in the posthumous use of gametes.

Current situation

Like all medical treatment, fertility treatment requires the consent of the participants. The Act requires informed consent for a range of issues and scenarios: what sort of treatment to have, whether gametes are to be stored and for how long, whether donated sperm, eggs or embryos are involved, whether a surrogate will carry the child, who will be the legal parent if donor gametes are used and the person seeking treatment is not married or in a civil partnership, what might happen in the event of death, or if one of the parties changes their mind. Those consents are captured in the clinic on HFEA consent forms that patients, partners (if relevant) and donors are required to complete.

Issues

The complexity of consent

Consent to legal parenthood can be particularly complex and mistakes have given rise to cases having to be resolved by a court. Consent to legal parenthood currently takes place in a fertility clinic as part of the necessary discussion of treatment options. Some have argued that this element of the consent regime might be better dealt with by changes to family law rather than as part of the HFE Act. But patients will still need advice to reach a properly informed decision and if that is no longer provided at the clinic, it will inevitably involve more time and expense for the patient.

Some have suggested that the fact that a couple wish to use fertility treatment to have a child is evidence of each person's wish to become a legal parent of any resulting child from the treatment. However, experience from clinics suggests that this cannot always be taken for granted and there will always have to be a direct conversation with individuals to establish and record their agreement.

Proposals for change

Simplifying the consent discussion

The present system requires each participant to actively 'opt-in' to consent to each element of treatment or scenario. A different way to approach consent might be to follow a variant of the 'opt-out' approach which has been successfully adopted in some other areas of medicine. This could involve a consent regime built around a small number of common relationships. People would then be asked whether they wished to adopt this consent package or to actively 'opt-out' to make bespoke choices.

However attractive such a model might be, there is a risk that the potential variations in the circumstances of patients (such as a relationship breakdown, or death) might mean that consent could in some circumstances lack the degree of protection offered by the current consent regime.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Consent to disclosure

In modern medical practice, a patient's medical data is shared among all the professionals that need to know this information.

Current situation

The Act requires that fertility patients' treatment details are kept confidential from their other medical treatment data. This contrasts with most other areas of wider medical practice, where relevant patient

information is often shared for the purposes of individual care without seeking the patient's express consent. Data sharing of this kind for specified purposes can enable improvements in the individual's care and speed up diagnoses.

Issues

Disclosure of information under the Act

The treatment of fertility-related information under the Act creates an obstacle to sharing fertility treatment details within other clinical settings and makes joined-up patient care more difficult. This can have a directly negative effect on patient care. At present, obtaining consent from each patient can be complex, and may cause a delay when urgent treatment might be necessary.

One example is with Ovarian Hyperstimulation Syndrome (OHSS). OHSS is a potentially serious side effect which some patients develop in reaction to the drug treatment necessary for IVF. Due to the gravity of OHSS, the HFEA requires licensed clinics to report all 'severe' and 'critical' cases of OHSS to us. The confidentiality provisions of the Act mean that fertility clinics may not know about all such cases. They must rely on building relationships and data sharing agreements with their local hospitals to get a clear picture of the number of OHSS cases amongst their patients. This is inadequate as not all patients with OHSS will attend a local hospital that has a data sharing agreement with their clinic.

More generally, if health professionals are unable to find out about a patient's fertility treatment, access their medical notes or contact their GP, patients may not receive the right ongoing care or follow-up support for their fertility treatment outcome.

Proposals for change

Making it easier to share fertility treatment details within other clinical settings

The Act should be updated to require automatic record-sharing between clinics and the NHS central records systems, to support more joined-up and safer patient care at hospitals and within primary care. Comparable provision would also need to be made for record-sharing with private providers where fertility patients are receiving other medical treatment. Emphasis would need to placed on the fact that the sharing of medical data would only take place within regulated medical care in line with the rules that govern the sharing of other medical data.

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? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Consent to research

Patients who do not use all their embryos for their own treatment have the option to donate them to specific research projects. Donated embryos are crucial to enable scientists to do research, including the development of new treatments that may help fertility patients.

Current situation

The Act currently requires consent to the use of embryos in research to be donated to specific named projects. This makes it difficult to use research embryos efficiently through initiatives like research embryo banking.

Issues

Ensuring that there are enough suitable embryos available for research

Some patients will not want to donate embryos that they do not use in treatment to research. Others may place a lot of importance on being able to do so. Because the current system means any embryos donated have to be suited to the needs of the specific project(s) that their clinic has links to, not all embryos will be suitable, or, some clinics may not have links to any projects for embryo donation.

There is also considerable variation in embryo donation consent rates at clinics, which suggests that while some clinics may be actively promoting research projects to patients, others may not be discussing the option of research donation with patients fully. This may be in part because not every clinic has links to an actively recruiting research project, or to any research project. Overall, these factors can mean that licensed and ethically-approved research projects may lack access to a timely supply of suitable embryos, and that patients who would like to donate their embryos to research are not always able to do so.

Proposals for change

A generic consent to research option should be introduced

Allowing for broader generic consent to research would enable patients to donate to a research bank to store embryos, whether or not their clinic is currently linked to any research projects itself. The research embryo bank could then allocate the stored embryos to a suitable research project(s) when needed, in line with the patients' consent given to the research embryo bank. This could improve the timely supply of available embryos for research projects and allow more patients who wish to do so to support research. It would make it easier for patients whose clinics do not have links with research projects to donate their embryos to research if they wish to do so.

Some patients will welcome the opportunity to donate embryos to any research project. Others would only want to donate to a project that resonates with them personally. Patients should continue to be allowed to donate their embryos directly to specific research projects only if that is their preference.

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? (please select only **ONE** option)

☐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.

Scientific developments

The case for change

The Act has provided a robust but flexible framework that has helped to generate public trust in a sometimes-contested area of scientific and clinical work. Regulation has in turn created conditions where innovation can more easily flourish.

However, demand for new treatments continues. Patients' expectations of treatment possibilities have risen, partly due to the increase in self-funded treatment and the internet enabling wider access to information.

The link between fertility treatments and advances in genetics and genomics offers hope for families affected by serious genetic conditions. In future these may present prospective parents with new reproductive options.

Research in these areas continues at pace and is now (in places) pushing against, or going beyond, the boundaries of what would be legally permitted in the UK. That alone does not mean that the Act should be changed to accommodate such new scientific developments, but it does suggest that the Act should be future proofed so that it is better able to respond and adapt to innovation.

How regulation can best support innovation

Changes in the practice of the regulation of new technologies could support the earlier introduction of innovation in the fertility sector.

Current situation

Regulating emerging techniques or technologies, or new uses of established techniques or technologies, requires a balance to be struck between what is written in law and what is subject to regulatory discretion. At present, the law is ambiguous as to the circumstances in which the HFEA is able to approve new processes for use in a clinic, especially where more clinical evidence may be required to establish their efficacy.

Issues

The authorisation of licences for novel processes for use in treatment risks making the barrier to entry too high

Currently, the HFEA must assess whether a novel process is "necessary or desirable" prior to authorisation for use in treatment. But as with any new development, the scientific data alone cannot be conclusive without clinical evidence. Where clinical evidence is not yet available (for example, from trials in other jurisdictions), it can be hard for the HFEA to determine whether a process will achieve the stated aims in practice such as to make it 'desirable'. It would benefit patients if the law explicitly provided for the HFEA to pilot novel processes for a trial period, with appropriate controls and conditions available to the HFEA, if the initial promise is not demonstrated in practice.

Proposals for change

That the Act better encourages innovation

One way of enabling this approach is through the use of trials or regulatory **'sandboxes'**, which are a flexible approach to regulation increasingly used by regulators to encourage innovation while minimising risks. **Sandboxes** have been described as 'controlled experiments in which new products, services, or ways of doing things can be placed into a real-world environment'. Sandboxes allow regulators to place conditions on those conducting a newly approved process (or a process which is being assessed for approval), to ensure that it is only used in a limited, specific, monitored setting. Sandboxes build in review points to examine risk, allowing for regulatory intervention if a new process is not shown to be sufficiently safe and effective in practice. The sandbox rules usually involve working within what are effectively research principles, but as determined by the regulator, rather than being formally regulated as research.

An express statutory power to establish regulatory sandboxes, with a lower evidential threshold than is currently required for the full approval of a novel process, could provide the HFEA with greater flexibility to authorise relevant licensed centres to pilot innovative processes. This would be subject to effective safeguards, including specific restrictions, monitoring and reporting requirements, post-authorisation controls and, where appropriate, express mechanisms to swiftly amend, suspend or revoke the relevant authorisation.

Sandboxes would not be appropriate for all innovations, for example those presenting unacceptable safety risks to patients.

29. To what extent do you agree or disagree that the Act should explicitly give the HFEA greater discretion to support innovation in treatment? (please select only **ONE** option)

☐Strongly agree

☐Agree

☐Disagree

☐Strongly disagree

☐Unsure

☐Prefer not to answer

Improving the HFEA's ability to handle rapidly changing developments in science

The Act sets out several significant limitations on scientific research and possible future assisted reproductive technologies. At present, the entire Act would need to be re-opened to enable certain research or new treatment and it may be possible to design a new model that is more flexible but better maintains the social consensus over time.

Current situation

The restrictions in the Act reflect the social consensus when it was written. Over 30 years on, there may be a case for re-examining elements of that consensus, or recasting the Act so that it is better able to adapt to scientific developments over time.

Issues

The regulation of certain scientific advances in the Act means that our rules can be slow to adapt, to the detriment of patients

At present the entire Act needs to be re-opened to accommodate some developments in research or clinical practice. The pressure on parliamentary time inevitably means that such change happens rarely, which can restrict the development of novel research and new clinical techniques for use in assisted reproduction. The greater use of **secondary legislation** in these areas could combine parliamentary oversight with greater flexibility. The aim would be an adaptable regulatory mechanism that could command public support while allowing treatment and research advances to be considered in a more timely way.

Scientific advances are creating new 'categories' of cells such as in vitro-derived gametes, embryo-like entities, and stem-cell based embryo models which are outside the regulatory categories of the Act

The Act currently specifies that research involving gametes and embryos is regulated by the HFEA. However, these new categories of cells, despite their biological similarity to in vivo-derived gametes or embryos, are not currently regulated by the Act. These entities are becoming increasingly similar to bona fide human gametes and embryos, and research on these could offer significant benefits. It may be necessary to consider whether the Act needs to be revised to include these entities, or whether these biological cells should fall under the remit of other regulators. Without a flexible regime, the potential

future use of any such developments for patient benefit could be limited, even when the advances in the field establish that their use is ethical and safe.

The Act places limits on the use of human or admixed embryos in research which are now being challenged by scientific developments

At present the Act limits the use of human or admixed embryos in research to 14 days or the appearance of a primitive streak (if earlier). It is now increasingly possible for researchers to keep embryos alive beyond 14 days. If this were permitted in the UK for research purposes, it would lead to improved understanding of early embryo development and the possibility of new or improved treatments. There is a window of very early pregnancy between 14 – 28 days of embryo development which is not currently well understood by any existing permissible route. Increasing the 14-day rule would allow scientists a valuable insight into embryonic development and the study of disease processes, such as miscarriage and the development of congenital abnormalities. Extending this limit has been proposed by some international organisations. For example, the International Society for Stem Cell Research recently proposed **guidelines** to remove the 14-day limit on embryo research, and replace this with strict case-by-case oversight of any research past 14 days where justified, and after extensive public engagement.

In order to ensure that such a change could be dealt with in a timely, and flexible, manner a new mechanism could be put into law to allow for parliamentary consideration of the 14-day rule in the future, outside of reopening the HFE Act. This could be similar to 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**.

The Act does not permit interventions in the nuclear DNA of gametes or embryos for use in reproduction

At present there are significant safety, efficacy, and ethical issues raised by the application of nuclear germline genome editing in treatment. However, in future these issues might be resolved and the technique could have the potential to be offered in treatment to avoid passing on heritable conditions in certain defined circumstances. Amending the Act to specify a principle that in limited instances germline genome editing techniques could be used, subject to further parliamentary approval of regulations setting out principles for what such acceptable uses might be, would be one way forward.

Proposals for change

That the Act is 'future proofed'

This survey is not the place to resolve whether the current restrictions should change, but whether, given the pace of scientific development in the field, the Act should be 'future proofed' so that it could become more accommodating of potential new developments that offer patient benefit. Any change in the regulation of these advances would require wider public debate prior to parliamentary amendment.

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? (please select only **ONE** option)

☐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.

Thank you for your contribution to this HFEA consultation. We will be publishing our recommendations to government later this year and further information will be on our website and social media.

If you feel you might need some support after thinking about the topics in this survey, information on support is available on the HFEA website, or via your clinic if you are currently having treatment.