Regulatory reform: consent

Introduction

1. The Human Fertilisation and Embryology Act 1990 (as amended) (the Act) sets out the conditions that govern the administration of patient consent.
2. Informed consent is one of the most important principles in healthcare and is a fundamental feature of the Act. Clinic staff are responsible under the Act for obtaining properly informed consent from their patients. The Act requires that consent given by patients is written and is fully informed before they store or use their eggs, sperm or embryos. Before clinics ask their patients to give consent, they must give them enough information to enable patients to understand the nature, purpose and implications of their treatment or donation, offer a suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking, and provide information about the procedure for varying or withdrawing any consent given, and about the implications of doing so. There must be a record of this information and counselling provision as well as a record of consent.
3. The consent requirements of the Act are far more detailed and stringent than for any other types of human tissue, however, and the administrative arrangements for the taking of consent are complex which can in itself lead to errors, and professional approaches to informing patient consent have changed since the 1990s. There are good grounds for considering whether and if so how, elements of the consent regime should be changed in a modernised Act.
4. This paper sets out a range of options for reform. Some of these proposals might be termed 'administrative' – e.g., how legal parentage is administered, electronic consent, and whether there ought to be an explicit statutory reference to the idea that there should be a limit on the number of families that can be created from a single donor. These relate to areas on which a policy consensus is already generally established, or which do not raise new issues of principle. Other proposals – e.g., variations in consent after embryos have been created, posthumous consent, the donation of embryos for research – relate to areas where there is a greater range of views and/or raise issues of principle.
5. The remainder of this paper considers each issue in turn, beginning with 'administrative' issues before moving on to issues of 'principle'. Each section begins with a short summary of the current situation, followed by an identification of the issues where the Act is showing its age and concluding with options for change. The aim is to provoke debate on the merits of those options, which are summarised in the discussion section at the end of the paper in Annex A.

1. Administrative issue: legal parenthood

The current situation

6. Some prescriptive specifics of the Act's requirements on the administration of consent around legal parenthood mean that errors and anomalies may require court orders to remedy them. In other scenarios, the specifics of the Act are unclear or absent. The HFEA has found practical ways to make the law work, but these remain open to legal challenge.

Note: The current legislation (deriving originally from the EUTCD), does not acknowledge or accommodate the option of two women being 'treated together' i.e., where a female partner provides her eggs for the treatment of her female partner. This disparity has resulted in partners being screened and

recorded as ‘donors’. This is being actively discussed with DHSC and we expect there to be a resolution via a separate legal route. We do not propose to cover this issue further here, therefore.

Issues

7. There are a wide range of issues with the current consent regime. The examples set out below are not exhaustive.

   a) **where a civil/married partner of a woman receiving donor sperm/donor embryos treatment does not agree to the treatment this is not a guaranteed route out of legal parenthood**. The Act presumes the civil/married partner will be the parent unless it is shown that he or she did not consent to the donor treatment, so completing the ‘stating lack of consent’ form that HFEA offers, may not be enough to demonstrate this.

   b) **where a man donates embryos (rather than sperm) for the treatment of a single woman the sperm provider could potentially be considered the legal father**. Closing this loophole in the Act would allow embryo donors to be more certain on their legal status, which may result in an increase in the number of donated embryos available for treatment to single women. This includes where a man wishes to become a known donor to his single ex-partner, of their embryos (originally created jointly with their gametes for treatment use together as a couple). For some single women, embryos they have previously created with a (now) ex-partner will be their only chance at genetic parenthood. Others may simply want the opportunity to use embryos that they have already created, with their ex-partner being a known donor.

   c) **The requirements for clinics to store parenthood consent forms for 30 years is not long enough to allow future queries or disputes about parenthood to be resolved easily**. Clinics are also not always set up for long term record keeping over decades ahead, especially if they close or change ownership.

   d) **It is not possible under the Act to change parenthood consent after treatment has taken place, which has caused issues for patients**. Before treatment takes place, consent must be in place from both the woman being treated and the intended father/second parent (if they are not married/in a civil partnership) in order for them to be the legal parent. However, if there is a mistake on the consent form, or if it isn’t signed, currently it must go to court to resolve.

Options for change

8. The Act could be updated to allow more certainty of who the legal parents will be from the outset, or increase clarity for patients, and perhaps would reduce the need for the courts to get involved.

   a) **Where a civil/married partner of a woman receiving donor sperm/donor embryos treatment does not agree to the treatment this is not a guaranteed route out of legal parenthood.** In such cases amending the HFE Act could allow him or her a clearer route out of parenthood. Possible options could be**: 1)** if the intention is to allow for courts to settle parenthood depending on the circumstances of each case, the Act should retain the provision that the married partner will

automatically be the legal parent, but update this to state that in a dispute, statements of lack of consent may be taken into account by the court. **2)** If the Act is updated to allow married/civil partners to opt out of parenthood when donor sperm/embryo are used, the legislation could also be further amended to allow for the person receiving treatment to give consent to someone other than her married/civil partner, being the legal parent (e.g., to allow for coparenting).

b) **where a man donates embryos (rather than sperm) for the treatment of a single woman the sperm provider could potentially be considered the legal father.** The Act should be amended to explicitly prevent male embryo donors from being the legal father to children conceived by single women receiving treatment with donor embryos. Including for men wishing to become a known donor to their single ex-partner, of embryos originally created jointly with their gametes for use together. Remedy could be to add 'or embryos created from his sperm' to the existing provision.

c) **The requirements for clinics to store parenthood consent forms for 30 years is not long enough to allow future queries or disputes about parenthood to be resolved easily** The Act could be amended to require legal parenthood consent forms to be stored for longer than 30 years. If data is to be stored longer term, a long-term repository for parenthood consent information outside of the relevant clinic might be appropriate, but that raises questions about what type of repository would be needed, and how it would be funded.

d) It is not possible under the Act to change parenthood consent after treatment has taken place, which has caused issues for patients The Act could be updated to allow corrections in consent to legal parenthood to be made after treatment has taken place (e.g. lack of, or missing, legal parenthood consent forms, and/or the clinic not identifying errors that could raise doubt over the validity of the consent). This could be either through clinics or via birth registration.

2. Administrative issue: electronic consent

The current situation

9. The Act (Schedule 3) requires 'effective and written consent', reflecting paper-based record systems. However, technology has moved on and many licensed centres now use electronic methods and systems for capturing and recording consent. The HFEA's Code of Practice has recognised this shift and provides guidance on the use of electronic systems for consent.

Issues

10. **The need for (hand)written signed consent from the gamete provider is unnecessarily restrictive and may lead to errors** – it may act as a brake to the adoption of electronic methods of administrating consent. These can reduce human error and be more convenient for patients. The Act's requirement for written signed consent from gamete providers has been a contributory factor in a number of court cases, especially in respect of posthumous use. And despite Code of Practice guidance, licensed clinics often have questions/concerns for the HFEA about whether their electronic systems for recording consent are compliant with the legislation.

Options for change

11. **The need for (hand)written signed consent from the gamete provider is unnecessarily restrictive and may lead to errors** - clarifying (and preferably simplifying) requirements around the administration and recording of consent would make it easier and possibly less costly for patients/donors to give consent and for clinics to obtain it. It ought to reduce cases where patients need to seek legal advice and/or go to court. Options include: **1)** an explicit reference in the Act to make it clear that consent in relation to gametes and embryos can also be considered as effective if given electronically (and that a pen and paper signature is not necessary), or **2)** the Act could be amended to be less prescriptive, giving the HFEA freedom to decide on the appropriate consent administration regime.

3. Administrative issue: Consent for storage and use of testicular and ovarian tissue

The current situation

12. There is overlap between the HFE Act and Human Tissue Act regarding the consent (and regulation in general) for storage and use of testicular and ovarian tissue.

Issues

13. **The legislation is unclear regarding the consent needed for storage and use of testicular and ovarian tissue which contains eggs or sperm, or their precursor cells.** A joint statement/memorandum of understanding is in place with the Human Tissue Authority to enable this to take place.

Options for change

14. **The legislation is unclear regarding the consent needed for storage and use of testicular and ovarian tissue which contains eggs or sperm, or their precursor cells.** The HFE act could be amended to give clarity on whether consent is required under the HTA or HFEA regime, or both. Clarity on the consent requirements for storing and using testicular and ovarian tissue would ensure clinics obtain the right consent, under the right regime, and that it is stored and used appropriately. It would reduce legal reliance on the HFEA and HTA's working memorandum of understanding agreeing their responsibilities/licensing in this area.

4. Administrative issue: family limit

The current situation

15. There is currently no statutory requirement limiting the number of families a donor can consent to being created. Following a review in 2005, the HFEA introduced a policy limit of ten families which is set out in guidance. That same guidance also defines a 'family' as being: "The woman to be treated and any person together with whom she is proposing to receive treatment, and any legal child of that woman or of any person with whom she is proposing to receive treatment, at the time at which treatment is to take place". There have been various issues regarding breaches of this limit and definition of a 'family'.

Issues

16. The lack of any statutory limit or definition of the family for this purpose means that clinic observance is weaker than it ought to be – while there is no 'right' number of families, there is widespread agreement

that it is appropriate to place some sort of limits on the number of families a donor can create. The question therefore is about the most effective and proportionate means to achieve this end. Guidance on this issue has not been as effective as we would have hoped. While part of the explanation lies with the practical issues faced by different clinics around information-sharing about their use of gametes from the same donor, which would make it easier to avoid breaches of the ten-family limit; part of it relates to the status of guidance itself and the current definition of the family.

Options for change

17. The lack of any statutory limit or definition of the family for this purpose means that clinic observance is weaker than it ought to be - it might be helpful to reflect the idea of a family limit in legislation, and to define what constitutes a family for this purpose, and to outline the associated consent expectations. Were this idea to have support, we would not recommend explicitly stating that it should be a ten-family limit in law. Doing so would make it harder to change as the evidence of the dangers of consanguinity or the psychological impact of family size changes. With such definitions in place, clinics may take more care not to breach the limit and the HFEA would have more power to penalise those clinics that do so. A key principle for defining a 'family' within any statutory limit, should be supporting the ability for there to be a genetic link between siblings and half siblings. The Act could also make it explicit that in order for a potential child to be classed as a sibling/half sibling of an existing child (defined as being within the same family for this purpose), the child and the potential child would also need to share at least one legal parent.

5. Administrative issue: payment arrangements coupled with consent

The current situation

18. There have been cases of licensed centres restricting storage consent to tie in with agreed private payment or NHS funding arrangements

Issues

19. **Restricting storage consent to tie in with agreed private payment or NHS funding arrangements is suboptimal for patients.** It increases the risk of centres either storing illegally, if consent has elapsed, or disposing of the gametes or embryos when the patient has not been in touch to renew/extend the paid or funded consent period. Also, the coupling of payment/funding arrangements with consent may make it harder for patients to move their gametes/embryos to a different centre.

Options for change

20. **Restricting storage consent to tie in with agreed private payment or NHS funding arrangements is suboptimal for patients.** Clarity should be given in the legislation that consent should be independent of practical/payment arrangements and that centres must not themselves seek to limit storage consent to reflect payment or funding arrangements.

6. Principle: posthumous consent

The current situation

21. The current provisions of the Act give rise to a number of problematic scenarios in respect of posthumous use. First, the Act allows gametes to be stored without specifying a use, which has led to legal cases where the patient has then died, and the partner is unable to use the gametes because no consent to use was given. Second, the Act does not allow an individual to consent on behalf of another person after they have died. Third, where donor sperm is used, in order for a deceased partner to be considered the parent, an embryo must have been created before their death.

Issues

22. **How to create greater flexibility without overriding the centrality of patient autonomy –** patient consent is one of the cornerstones of the Act. The ability to separately consent to storage and to use does create more complexity both for clinics and patients, but it does not present a problem for most patients most of the time. For the minority who store gametes for reasons of fertility preservation separate consent to storage and to use often makes sense, e.g., for young cancer patients who do not know whether they wish to use their gametes later. However, for some patients introducing greater flexibility in the Act around existing patient consent to posthumous use of gametes and embryos would enable them a chance to complete their families if their partner has died.

Options for change

23. **How to create greater flexibility without overriding the centrality of patient autonomy** – there are several options depending on the scenarios to be addressed; the Act could be amended:
    - to combine consent to storage and to use - i.e., to require the patient to specify a use for their gametes at the time of storage; (this would need to be freely variable at any time, and to include a mechanism for patients who are not in a position to have a view about future use)
    - introduce a 'power of attorney' (POA) type option to allow for posthumous consent to use decided by a nominated person with POA consented to by the patient when living. This could assist an individual to be able to consent on behalf of another person e.g., when a woman wants to use her partner's sperm after he has died.
      However, mitigation would need to be found to the risk that POA consents given at the time of consent to storage and/or use, which may be consented to years in advance of use, could be outdated by the time the patient has died (eg where the patient changed partners but did not update their POA consent before they died). In other scenarios aside from the issue about specifying use, including where the patient acquires a lack of capacity to make the relevant decisions, the POA would need to be carefully considered to still allow for patient autonomy and mitigate a potentially increased risk of coercion (e.g., the terminally ill being coerced by their partners)
    - in the scenario that an embryo (using donor sperm) is transferred to the woman after the death of the male spouse, civil partner or intended parent who did not provide sperm, Act to be updated to allow the deceased spouse, partner or intended parent to be the legal parent after their death. Currently the deceased partner can't be considered the parent under the Act in this situation.

7. Principle: Clarity on consent requirements for procurement/harvesting of gametes and partner treatment with sperm (IUI)

The current situation

24. Currently there is no requirement in the HFE Act to obtain written effective consent from a person before using their gametes for their own/their partner's treatment.

Issues

25. **Consent before using a person's own gametes for their own/their partner's treatment.** In posthumous situations, lack of consent to procurement can mean that for example, if a man was in the process of undergoing treatment with a partner (and has already consented to use of his sperm for treatment in e.g. IUI) it's unclear whether the legislation allows for sperm to be harvested after his death and then used IUI or for any other types of treatment, such as IVF. Or if a man dies/become mentally incapacitated whilst in the process of undergoing IVF and has signed the IVF consent forms, for use of his gametes/embryos created in treatment, it is unclear whether it is possible to harvest his sperm without him having given consent to harvesting.

Options for change

26. **Consent before using a person's own gametes for their own/their partner's treatment.** Clarity is needed in the Act on consent requirements for procurement/harvesting of gametes and partner treatment with sperm (IUI). Consider explicitly consolidating all types of consent relevant to harvesting/procuring, storing and using gametes under an amended HFE Act (also taking into account what consent is required under EUTCD).

8. Principle: consent to research

The current situation

27. People who decide that they no longer need their embryos for their own treatment might be given the option to donate them to research, to training, or for the use other patients for their treatment. If these choices are not right for them, or are not available to them, they might decide to end continued storage and to allow their embryos to perish. HFEA surveys show that many patients who decide that they no longer need their embryos for their own treatment would be interested in donating embryos to research, because they would like to potentially help others. The Act currently requires consent to the use of embryos in research to be for 'use for the purposes of any project of research' and does not explicitly permit research embryo banking. The Code of Practice therefore requires consent for donation to be given to 'a specified research project'. Not every clinic offering treatment has links to an active research project, however. Scientists in the UK are clear that a reliable, timely supply of donated embryos would enable them to do more research, which in turn could bring new understanding that may help fertility patients.

Issues

28. **How to ensure that it is easier for patients to consent to their embryos being used in research** - patients wishing to contribute embryos to research use, if their own clinic is not recruiting to a research project, have to find another research project to take embryos. This may not always be possible logistically, financially or because their embryos are unsuitable for a given project. Researchers note that the restriction of donation of embryos to specified projects only, may prevent embryos being available for different projects who could use them. It also poses practical barriers to researchers starting new projects when the supply of suitable donated embryos may be hard to predict in advance. Embryos consented to be donated to specific research projects can be wasted if something changes and the project can no longer use them.

Options for change

29. **How to ensure that it is easier for patients to consent to their embryos being used in research** – amend the Act to explicitly allow patients to give a broad consent to use of embryos for the purpose of research if they wanted to, rather than only allowing donor consent to be specific to an individual research project. This would allow donated embryos to be consented to be stored under a research biobank arrangement, awaiting the biobank's decision to permit their future use in research by a suitable project when needed. Embryos would then only be used in research in line with the donating patients' consent given to the biobank, and with the benefit of continued oversight of the biobank's governance. The HFEA would regulate both the biobank storing the embryos and (as currently) each research project using donated embryos. Scientists could gather more knowledge in advance of which bio-banked donated embryos may be available, which could help them when setting up new research projects.

Annex A

Table for discussion

The Advisory Group are invited to discuss the issues identified and potential options for change as set out above. In summary:

1: Administrative issues: Legal Parenthood	**Issue:** a) The current legislation does not acknowledge or accommodate the option of two women being 'treated together' i.e. where a female partner provides her eggs for the treatment of her female partner. **Options for change:** *The HFE Act could remove the requirement for same-sex female partners being screened as donors as though they were not already in a physical relationship with each other. In terms of legal parenthood and consent, the Act could also allow the partner providing eggs to be classed as a partner or another, new, category. Consideration would also need to be given to ensuring only appropriate patient screening/testing requirements are made by the Act*
	Issue: b) where a civil/married partner of a woman receiving donor sperm/donor embryos treatment does not agree to the treatment, they can state their lack of consent but currently this is not a guaranteed route out of legal parenthood. **Options for change:** ***1)*** *Status quo - HFE Act should retain the provision that the married partner will automatically be the legal parent, but update to state that statements of lack of consent may be taken into account in any dispute.* ***2)*** *If HFE Act is updated to allow married/civil partners to opt out of parenthood when donor sperm/embryo are used, then DHSC could also propose further amending the legislation to allow for the person receiving treatment, to give consent to someone other than her married/civil partner being the legal parent (e.g., to allow for coparenting).*
	Issue: c) where a man donates embryos (rather than sperm) for the treatment of a single woman. If challenged

	the sperm provider could potentially be considered the legal father. **Options for change:** *Amendment to explicitly prevent male embryo donors from being the legal father to children conceived by single women receiving treatment with donor embryos, including where the embryos were originally created with a partner for use together, but where he now wishes to become a known donor and his (ex) partner is willing to accept this. Remedy could be to add 'or embryos created from his sperm' to the existing provision.*
	Issue: d) The requirements for clinics to store parenthood consent forms for 30 years is not long enough **Options for change:** *We recommend that the Act is amended to require legal parenthood consent forms to be stored for longer than 30 years. We also suggest government considers requiring a long-term repository for parenthood consent information that is not in the relevant clinic (eg, storage by the HFEA, General Register Office, etc).*
	Issue: e) is not possible under the Act to change parenthood consent after treatment has taken place- if there is a mistake on the consent form, or if it isn't signed, currently it needs to go to court to agree. **Options for change:** *The HFE Act to provide a more proportionate system for allowing corrections to be made to parenthood consent after treatment has taken place, either through clinics or via birth registration.*
2: Administrative issue: Electronic consent	**Issue:** The need for (hand)written signed consent from the gamete provider is unnecessarily restrictive and may lead to errors • **Options for change** *Options include: **1)** an explicit reference in the Act to make it clear that consent in relation to gametes and embryos can also be considered as effective if given electronically (and that a pen and paper signature is not necessary), or **2)** the Act could be amended to be less prescriptive, giving*

	the HFEA freedom to decide on the appropriate consent administration regime.
3: Administrative issue: Consent for storage and use of testicular and ovarian tissue	**Issue:** The legislation is unclear regarding the consent needed for storage and use of testicular and ovarian tissue which contains eggs or sperm, or their precursor cells. • **Options for change** *The HFE act could be amended to give clarity on whether consent is required under the HTA or HFEA regime, or both.*
4: Administrative issue: Family limits	**Issue:** The lack of any statutory limit or definition of the family for this purpose means that clinic observance is weaker than it ought to be • **Options for change** *to reflect the idea of a family limit in legislation, and to define what constitutes a family for this purpose, and to outline the associated consent expectations.*
5: Administrative issue: Payment arrangements coupled with consent	**Issue:** Restricting storage consent to tie in with agreed private payment or NHS funding arrangements is suboptimal for patients. • **Options for change** *Clarity should be given in the legislation that consent should be independent of practical/payment arrangements*
6: Principle: Posthumous consent	**Issue:** How to create greater flexibility without overriding the centrality of patient autonomy • **Options for change** *there are several options:* • *to combine consent to storage and to use - i.e., to require the patient to specify a use for their gametes at the time of storage;* • *introduce a 'power of attorney' (POA) type option to allow for posthumous consent to use decided by a nominated person with POA consented to by the patient when living.*

	• *to allow the deceased spouse, partner or intended parent to be the legal parent after their death, in the scenario that an embryo (using donor sperm) is transferred to the woman after the death of the male spouse, civil partner or intended parent who did not provide sperm.*
7: Principle: Clarity on consent requirements for procurement/harvesting of gametes and partner treatment with sperm (IUI)	**Issue:** No requirement for consent before using a person's own gametes for their own/their partner's treatment • **Options for change** *Clarity is needed in the Act on consent requirements for procurement/harvesting of gametes and partner treatment with sperm (IUI). Consider explicitly consolidating all types of consent relevant to harvesting/procuring, storing and using gametes under an amended HFE Act*
8: Principle: Consent to research	**Issue:** How to ensure that it is easier for patients to consent to their embryos being used in research • **Options for change** *amend the Act to explicitly allow patients to give a broad consent to use of embryos for the purpose of research if they wanted to, rather than only allowing donor consent to be specific to an individual research project.*