

This submission provides the formal response from the Human Fertilisation and Embryology Authority (HFEA) to the Department for Health and Social Care (DHSC) public consultation on gamete (egg, sperm) and embryo storage limits.

We are in favour of a change in legislation which increases the length of time patients can store their gametes and embryos which they intend to use in their own treatment or in their partner's treatment. The current 10-year statutory storage limit and 2009 Statutory Storage Period for Embryos and Gametes Regulations are too restrictive and negatively impact on a persons' reproductive choice.

It is important to have a framework in place that allows patients who need to store for longer than 10 years to be able to do so, particularly in cases where women are storing electively at a young age to preserve their fertility and need to store for longer than the current 10-year limit.

### **Our proposed approach**

We welcome the government's decision to review its existing legislation on storage limits. In doing so however we recognise the potential difficulties that any increase in storage limits could place on fertility clinics storing gametes and embryos. We know that some clinics already find it difficult to keep in touch with patients whose gametes or embryos are in storage, especially those who have been storing for an extended period. To try to address this, our submission proposes an approach that would balance the interests of those patients who would benefit from an increase in the storage periods with the practical concerns from a clinic perspective over keeping in touch with patients, and storage capacity issues. Our proposed approach would allow patients who are intending to store their gametes or embryos for use in their own treatment to be able to store for up to a maximum of 55 years so long as certain conditions are met. We propose that patients wishing to store for longer than 10 years would need to meet the following conditions:

- The patient (gamete provider) provides new written consent to storage every 10 years (up to a maximum of 55 years)
- The patient (gamete provider) confirms that they are storing because they are intending to use the gametes or embryos in their own treatment or in their partner's treatment (including surrogacy arrangements)
- The clinic has offered the patient counselling before they consent to every additional 10 years storage

The rationale for these conditions is detailed in our full response below. A possible mechanism by which it could be introduced is by having an initial 10-year statutory storage period and replacing the 2009 storage Regulations with new Regulations containing the new conditions proposed above. This would allow all patients who meet these conditions to be able to store their gametes and embryos for up to a maximum of 55 years.

### **Background information**

Although the majority of patients who store embryos are storing for use in subsequent cycles, and these patients do not generally store for very long, the reasons for people accessing fertility treatment have been changing over the years.

An increasing number of patients store their gametes and embryos for both medical and non-medical reasons, including a small but increasing number of women storing their eggs to use at a later stage.

#### **1. Egg and embryo storage**

\*Register data is accurate as of 21 April 2020. We work from a live database, so information is subject to change over time. Information on sperm storage is recorded only when used as part of treatment. Storage limits are also relevant to sperm storage, but not all sperm held by fertility clinics is held on the HFEA Register and is not reported here.

The HFEA has a statutory responsibility to keep a Register of information about donors, treatments and children born as a result of those treatments.\*

- The total number of cycles in which **embryos** were stored for a patient's own use increased by 26% (20710 to 26067) between 2015 and 2019
- The total number of cycles in which **eggs** were frozen for a patient's own use increased by 118% (1269 to 2761) between 2015 and 2019
- In 2019, just over one in three patients freezing eggs were under 35 (888 out of 2379, 37%). For these women especially, we believe that the 10-year storage limit is too restrictive. Only 12% (297 out of 2379) of patients were aged 40 or over.

## 2. **Methods of freezing and viability**

The developments in freezing techniques and especially the move from slow freezing towards vitrification means that eggs and embryos are more likely to maintain their quality when thawed and fertilised (even after an extended period in storage). These technological advancements have particularly had an impact on eggs, making egg freezing a more viable option for preserving a woman's fertility. Many eggs will have been storage for many years and technology and improvements have occurred more recently.

- Studies have shown that frozen eggs have the same developmental potential as fresh eggs<sup>1</sup>, and clinical pregnancy rates from embryos created from thawed eggs are equivalent to fresh IVF treatment<sup>2</sup>.
- In the UK in 2017, the birth rate per embryo transferred was comparable for frozen fresh embryos. For patients aged under 35, birth rate per embryo transfer was 27% per frozen embryo and 30% per fresh embryo. For patients aged 40 and over, birth rate per embryo transfer was 9% per frozen embryo and 5% per fresh embryo<sup>3</sup>.
- In 2017, fewer than 600 egg thaw cycles took place at fertility clinics across the UK. Approximately 19% of IVF treatments using a patient's own frozen eggs were successful in 2017. However, this is highly dependent on the patient's age at time of freezing and the freezing techniques used when the eggs were frozen.

## 3. **Compliance with the current law**

- As the fertility regulator we also provide advice and guidance to licensed clinics in the [HFEA Code of Practice](#) on how to comply with the current requirements of the Human Fertilisation and Embryology Act 1990 (as amended) and the 2009 storage Regulations. We monitor compliance through our compliance and inspection process, taking regulatory action against clinics who fail to comply where necessary.
- Through our inspection process and other engagement with clinics we can identify common areas of non-compliance where clinics fail to adequately comply with the legislation. We see that some clinics encounter problems with deciphering the 2009 Regulations and interpreting who meets the premature infertility criteria for extending storage, with clinics interpreting the regulations differently. We also see errors by clinics in incorrectly completing the required Medical Practitioner Statement (MPS) for extending storage. Where this happens, it results in gametes and embryos being stored unlawfully which is a serious non-compliance with regulatory implications for the clinics involved. Due to these clinic errors, often the only option for patients is to export their samples out of the country.

In reviewing the existing legislation the DHSC will need to consider how any change will affect gametes or embryos that are stored for purposes other than their own use, such as for donation purposes, either for someone else's treatment or for use in training or research. You should also consider the requirements for posthumous use and storage of gametes and embryos. Our response briefly touches on these points however further discussion of the impact of any change to the legislation is needed. Any legislative change would also need to consider transitional arrangements so that any changes could be implemented as smoothly as possible.

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## Consultation questions

### Possible changes to the 1990 Act

- 1. Should the statutory storage period for frozen embryos, eggs and sperm change from the current limit of 10 years?**
  - Yes
- 2. Do you think the limit should be increased or decreased?**
  - Increased
- 3. If you think the limit should be increased, what should the new limit be:**
  - 15 years
  - 20 years
  - material should be stored for the donor's lifetime
  - unlimited
  - **other – please specify**
    - We propose that all patients are allowed to store their gametes or embryos up to a maximum of 55 years as long as certain new conditions are met. The mechanism for this could be by introducing a new initial storage period of 10 years with the option to extend storage every 10 years up to a maximum of 55 years. The new conditions we propose are met before every 10 year extension is that the patient provides new written consent to storage, that the patient confirms that they are storing because they are intending to use the gametes or embryos in their own treatment or in their partner's treatment, and that the clinic has offered the patient counselling before they consent to every additional 10 years storage.
- 4. Why do you think that the limit should be increased?**

We support the argument that the current 10-year statutory storage limit and 2009 Regulations are too restrictive and negatively impacts on reproductive choice.

In the majority of cases patients may only need to store their gametes or embryos for up to 10 years, however we believe it is important to have a framework that allows patients who need to store for longer to be able to do so, in particular cases where women are storing at a young age to preserve their fertility for elective reasons and need to store for longer than the current 10 year limit. We suggest that these patients should be permitted to consent to extend storage through the same process as patients who are storing for medical reasons.

In our proposed framework, patients provide consent to store their gametes and embryos for a new standard 10-year storage period but then can provide additional consent every 10 years up to a maximum of 55 years, providing that certain conditions are met. This is expanded on in answer to question 9, however in summary these conditions would be that:

- The patient (gamete provider) provides new written consent to storage every 10 years (up to a maximum of 55 years)
- The patient (gamete provider) confirms that they are storing because they are intending to use the gametes or embryos in their own treatment or in their partner's treatment (including surrogacy arrangements)
- That the clinic has offered the patient counselling before they consent to every additional 10 years storage

These conditions could replace the conditions currently set out in the 2009 Regulations that only allow patients who might become or who are prematurely infertile to extend storage. The 1990 Act's 10-year statutory storage period could remain the same.

### **Reasons to support a 10-year standard storage period that can be extended up to 55 years**

While we are in favour of increasing the time patients can store their gametes and embryos, we also recognise the concerns some clinics have regarding storage capacity and the risk of losing touch with patients storing for long periods of time.

After asking the sector for their views, some storage clinics have told us that currently most patients (both male and female) consent to store for the maximum 10-year storage period. We also found that some clinics were reluctant to discard stored gametes and embryos until they reach the end of their consented storage period, even in cases when a patient had broken the terms of their contractual arrangement i.e. by losing contact or not paying their storage fees.

HFEA guidance provides for clinics to have contractual agreements with their patients regarding the practicalities of storage (e.g. an agreement to pay storage fees or store whilst funding is available) that is separate from a patient's consent to storage, and the standard terms and conditions should make it clear to patients that if they fail to make payment of storage costs or fail to maintain regular contact with the clinic that the clinic may remove their gametes or embryos from storage even if their consent period has not yet lapsed. From hearing from storage clinics around this point, we have found that almost all UK clinics claim to have contractual agreements with their patients, but only half stop storing a patient's gametes and embryos if the terms of their agreement are breached. The other half of clinics continue to store until the end of the statutory 10-year period regardless of whether or not storage has been paid for.

Clinics also encounter patients who are reluctant to allow their eggs or embryos (less so sperm) to perish, even if they are not planning to use them in their own treatment. This may be due to them not being able to make the difficult decision to discard their samples, or for religious reasons.

While a 10-year renewal of consent framework may not completely mitigate against this, a mechanism that requires patients to re-consent every 10 years would give a clinic the opportunity to keep in touch, to discuss with the patient the reasons for continued storage and to offer counselling. Feedback from the sector also revealed that the majority of clinics impose an upper age limit for patients they are willing to treat, which could provide a useful mechanism for discussing whether continued storage for a patient's own use is still a feasible option after a prolonged period of storage. This could also mitigate the risk of clinics treating older patients where it could pose a risk to either mother or child.

We favour proposing a maximum time limit of 55 years in order to provide clarity to clinics and patients and to avoid confusion, as well as to ensure consistency across the sector.

#### **5. If you think the limit should be decreased, what do you think the limit should be:**

- 8 years
- 5 years
- other – please specify

6. Why do you think that the limit should be decreased?
7. Why do you think that the limit should stay the same?
8. **Should any conditions be applied to those seeking to freeze embryos or gametes beyond a certain limit?**
  - Yes
9. **What do you think these conditions should be? (For example, that the patient should be under a certain age or that they should undergo additional welfare checks as part of fertility treatment.)**

As referred to in our answer to question 4, we support the position to increase the amount of time all patients can store their gametes or embryos, not only those who are prematurely infertile. It is our belief that the current conditions for extending storage which apply to only patients that are storing because they are at risk, or have become, prematurely infertile is too restrictive. We would support an approach that treats patients equally and that would allow all patients to extend storage if they are intending to use the gametes or embryos for their own treatment.

We know that there is a small but increasing number of patients storing their gametes and embryos for future use. The current rules do not adequately reflect the biological advantages of women being able to store eggs earlier and still use them at a time when they are ready to start a family. We are therefore suggesting a potential mechanism for allowing patients to store for longer, which is to introduce a new 10-year statutory storage period and to allow all patients to consent to extend storage in a series of 10-year increments up to a maximum of 55 years. If this approach is adopted the law would enable all patients to store for longer than 10 years, so long as they complied with certain new conditions. These could be set out in Regulations replacing the current 2009 storage Regulations.

These conditions could be that:

**a) written consent be provided by the gamete or embryo provider(s) before every extension**

Setting this condition will serve as a mechanism to check in with patients regularly, at every 10-year period. We suggest that new Regulations be introduced that replace the 2009 storage extension Regulations. If the Government were to consider this the HFEA could adapt its current extension of storage consent forms (ES and LGS forms) in line with any new Regulations that was introduced. Other forms (MT and WT) would also be updated.

**b) the stored gametes or embryos be intended for use in the patient's own treatment, or their partner's treatment (including for use in surrogacy arrangements which will lead to the gamete provider and partner becoming parents)**

Setting this condition will help ensure that patients are storing gametes and embryos that they do plan to use in their treatment, and less so for other reasons such as only storing because they do not want to make the difficult decision to discard.

**c) the patient be offered counselling by their clinic before every extension.**

Setting this condition will help patients who may be struggling to make the difficult decision to discard their gametes or embryos if they do not plan to use them. This will provide patients with an opportunity to discuss the reasons for continued storage, and implications of a possible future pregnancy.

We do not think that having restrictions in terms of age are necessary. As previously mentioned, the majority of fertility clinics in the UK impose their own upper age limits and are required to talk to patients about potential risks of treatment. They also have a right to refuse treatment if they think it will be unsafe for the mother.

If the Government adopted this approach, we would consider providing more guidance about counselling in situations where patients are reluctant to stop storing their gametes or embryos, and the importance of discussing why the patient wishes to continue storage. We would also strengthen the emotional support guidance we provide for patients, to help them review their options. General guidance about risk is already required in our Code of Practice. We would be happy to provide additional information about this if our approach is considered.

**10. Should embryos, eggs and sperm each have their own storage limit?**

- No

**11. If they should each have their own limit, what should that be? Please state the limit for each below:**

- embryos:
- eggs:
- sperm:

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## Possible changes to the 2009 storage regulations

**12. Do you think that the provisions in the regulations need updating?**

- Yes

**13. Do you think the criteria that permit storage extension for those who are prematurely infertile are still appropriate and should remain?**

- No

**14. Are there other additional criteria that might be appropriate to include? If so, please specify what these may be.**

As referred to answers above, a change in legislation is needed to increase the reproductive choices of fertility patients. Our proposed approach would potentially see new regulations introduced that replace the 2009 Regulations.

All patients should be able to store for longer up to a maximum of 55 years, if they are planning to use their samples for their own treatment or their partners treatment. If new regulations are introduced, we would like to see them expanded to allow all patients intending to use the gametes or embryos for their own treatment (regardless of whether they are prematurely infertile) to extend their storage. If the Department adopted this approach there would no longer be a need to provide an MPS in order to extend.

Below we outline the problems we have encountered with the existing 2009 Regulations and the arguments in favour of allowing all patients to store for longer under any new Regulations introduced by the government.

### Difficulties clinics face in applying the existing 2009 regulations

Our role as regulator is to ensure fertility clinics and research centres comply with the law. One way we check that samples are being stored according to consent and to the law is by carrying out audits during clinic inspections. Stored samples are chosen at random, and HFEA inspectors check the consents for those samples to ensure they are correct and lawful. We often identify non-compliances around storage consent, which means these are areas our inspectors are concerned about. These non-compliances often represent a breach in the legislation.

One increasingly common area of non-compliance is clinics wrongly interpreting the requirements of the Regulations, in particular around the MPS i.e. where the MPS is missing, or have been filled out

incorrectly, especially the date that it must be signed. There are also problems around the definition of premature infertility and who qualifies for storage extension. The definition of premature infertility can be interpreted in different ways which leads to variable practice and variable outcomes for patients.

### **Patients exporting gametes or embryos nearing the end of storage overseas**

We are also seeing a small but growing number of patients wishing to export their gametes or embryos because they are nearing the end of the 10-year storage period and are not ready to use them in treatment. Currently, if a patient wishes to store their gametes or embryos past 10 years but do not qualify as prematurely infertile, the only option is to export from a UK clinic to one outside the country. In order to do this, certain conditions must be satisfied as defined in [General Directions 0006](#) such as *'The remaining term of the relevant storage period for the gametes or embryos ... not less than 6 months from the date on which they are to be exported.'* If a request for export does not meet this requirement, there may still be grounds on which to allow an export to take place, and in such cases, an application for a Special Direction must be made. Such applications are considered by the HFEA's Statutory Approvals Committee (SAC) and this is a lengthy process.

In the past three years, failure to meet the condition around remaining term of the storage period represented 20% of all applications made relating to export. In 2019 this represented 36% of all applications relating to export.

SAC meets monthly, and each Special Direction application is assessed case-by-case on the basis of the particular details of the information that has been provided. There are currently worries within the committee about the amount of Special Direction applications that are being received, and there is potential for this to grow as more and more patients reach the 10-year limit for storage, and many clinics do not have an effective bring-forward system to catch these issues before it is too late to apply for General Directions to export. The application for Special Directions is a long, laborious process for the HFEA and for the clinics who have to submit an application justifying exactly why the export should take place. Export also involves potential costs for patients, which not all may be able to afford. If our recommendations are accepted and extension past 10 years is allowed for all patients regardless of premature infertility, exports due to surpassing this time limit will not be necessary, and patients will be able to continue treatment at home in the UK where we are better able to regulate.

After asking for feedback from the sector, almost all respondents told us that it would make it easier to comply with regulations if the statutory storage period were the same for every patient regardless of whether they are prematurely infertile or not.

### **Promoting the reproductive choice of patients**

The existing legislative provisions for extending storage beyond 10 years is based solely on the reasons for why they were stored (i.e. because the person is likely to become or is prematurely infertile). In the interests of equity and promoting reproductive choice we would support an approach that would allow storage extension for all patients.

As the DHSC notes in their consultation, women are at the peak of their fertility in their 20s, and the earlier a woman freezes her eggs, the better chance she has of achieving a healthy pregnancy when she is ready. HFEA figures correlate with this, and have shown that birth rates decrease with age; while the birth rate per embryo transferred is above 25% for women under 35, this decreases to 15% or lower for women over 40, and to less than 5% for women over 44<sup>3</sup>. However, freezing at the most optimal age means the 10-year storage limit will expire in the woman's 30s or early 40s, which may be too early for some people to start their families.

Data from the HFEA Register shows that in 2019, there were just under 1,000 cycles for patients under 35 freezing eggs for their own use, and this age-group represented the highest proportion (35%) of cycles using this treatment. The number of egg freezing cycles for this younger age group has more than doubled since 2015, when there were 470 cycles. The number of egg freezing cycles for women

aged 43 and over however has stayed relatively consistent, increasing from 70 to 80 cycles between 2015 and 2019. This tells us that as an increasing number of younger women choose to freeze their eggs, they may be more disadvantaged by the 10-year storage limit.

In our recent communication with storage clinics, we asked whether they thought women would freeze their eggs earlier if the statutory storage period was increased; almost all respondents said yes. We know that after 10 years of storage some patients are not ready to use their gametes or embryos, a situation we know UK fertility clinics have encountered numerous times. Half of the storage clinics we consulted said they had had to export or discard samples that had reached the 10-year limit for patients who would otherwise have chosen to extend.

When the Ethics Committee of ASRM found elective egg freezing to be ethically permissible in 2018<sup>4</sup>, their main argument was that this procedure enhanced reproductive autonomy and promoted social equality. The RCOG's recent Scientific Impact Paper<sup>5</sup> on elective egg freezing for non-medical reasons agreed that younger women are 'disadvantaged by the current legislated limit of 10 years' duration of storage' and that the current statutory storage limit has 'no biological or medical basis and is against the interests of women wishing to freeze eggs at a younger, more effective age'. The circumstances by which patient are freezing their gametes or embryos decides how long they can keep them in storage, which is not in line with treating everyone equality or with reproductive choice.

#### **Limited risk of women becoming pregnant at an older age**

While considering the arguments in favour or extending the time patients can store their gametes or embryos, we considered the potential risk that this may lead to an increase in the number of people becoming pregnant when they are older, with increased risk of complications for both mothers and babies. It is true that the risk of complications is higher in women over 35, with greater obstetric risks like pre-eclampsia and diabetes, and higher risk of multiple births, miscarriage or stillbirth. While there is no law in the UK which stipulates an upper age limit for women receiving fertility treatment, we know that many fertility clinics impose their own upper age limits for accessing treatment. From asking the sector, we know that almost all clinics have an upper age limit, which ranges between 45 and 55 years old. Most clinics have told us that their imposed limit was unlikely to change if the laws around storage changed. It is also important to consider that clinics can refuse treatment to patients if they feel this can be justified on a clinical basis, for instance due to concerns over a patient's age or health. The American Society for Reproductive Medicine (ASRM) released in 2016 an evidence based statement looking at an upper age limit where treatment would be considered appropriate, and concluded that this was 54 years<sup>6</sup>, which is in line with the upper age limit for clinics in the UK.

#### **15. Is the 10-year frequency of renewal still appropriate?**

- No (under the current Regulations)

#### **16. If not, what period of time do you think is more appropriate and why?**

We recommend adopting a 10-year renewal of consent up to a maximum of 55 years, which will serve as a mechanism to check in with patients regularly, at every 10-year period, to help clinics stay in touch with their patients regarding their intentions with their frozen gametes or embryos. This will also help address capacity issues in centres.

#### **17. Is the 55-year maximum storage limit still appropriate?**

- No (under the current Regulations)

#### **18. If not, what maximum period of time for those who may be prematurely infertile would be appropriate? For example, would the donor's lifetime be an appropriate limit?**



Our proposed approach as outlined above would include a 55-year maximum storage limit however it would apply to all patients who wish to extend storage, provided they meet the conditions detailed in Question 9.

**19. Should embryos, eggs and sperm each have their own storage limit?**

- No

20. If they should each have their own limit, what should that be? Please state the limit for each below.

- embryos:
- eggs:
- sperm

**21. Do you have any other comments on gamete and embryo storage limits not covered in these questions?**

**Storage of gametes and embryos for donation purposes**

We recommend that the Department carefully consider how any new rules on storage may affect gametes and embryos being stored for donation purposes for someone else's treatment. Currently under the 2009 Regulations donated gametes and embryos can only be stored for a maximum of 10 years, unless the gamete provider or the person who the gametes are being provided to, meet the criteria of being prematurely infertile, and the gamete provider has consented to storage beyond 10 years.

Data from the HFEA Register shows that in 2019, there were 7027 frozen eggs donated for treatment, compared to 3907 in 2015; this represents an 80% increase. There was also an increase of 44% in the number of frozen embryos donated during this period. The amount of fresh eggs and embryos donated however has stayed consistent. This tells us that frozen eggs and embryos are being increasingly donated for use in someone else's treatment.

While we are in favour of allowing extension of storage for gametes and embryos, there are potential implications for how longer storage periods could affect the supply of donor gametes and embryos, and how donor conceived people could be impacted if samples are stored for longer before being donated, meaning the provider would reach an older age as patients are able to donate their samples to others later in life. It is therefore important to consider how allowing extension beyond 10 years after donation could balance the potential positive implications of increasing availability, whilst trying to mitigate the potential negative impact on donor conceived people. In particular, that a longer storage period may mean that the donor is more likely to have passed away before the donor-conceived person has a chance to seek identifiable information about their donor, and the possibility of large age gaps between donor-conceived siblings.

For these reasons our initial suggestion is to consider the option of allowing all donated gametes and embryos to be stored for up to a maximum of 20 years from the time the gamete provider provides consent to donate their gametes or embryos. This would mean that the maximum possible age gap between donor-conceived siblings would be 20 years, and the maximum age a donor could reach before donated material is used would be limited. However there is still a risk, although small, that a donor could be very elderly or may have passed away by the time the donor conceived person has been able to access identifiable information once they have reached 18 years old. While this is our initial suggestion, we recommend engagement with relevant stakeholders, including the donor conceived community, to understand potential implications. We would be happy to be involved in any further discussions you may have on this.

Additionally the department should consider the impact of any changes on inter-generational donation, for instance in the case of a mother donating eggs to her daughter (perhaps due to infertility from

Turner syndrome). For this scenario a storage period of 20 years is unlikely to be long enough. Any new regulations should take this situation into account.

### **Storage of gamete and embryos for research and training purposes**

We recommend that the Department consider how any new rules on storage may affect gametes and embryos being donated for research and training purposes.

Currently, if gametes or embryos are donated for use in research or training, they must be used within the statutory storage period for the activities consented to. We have found that patients donate their samples for use in research or training towards the end of their statutory storage period, such that for some there is minimal time remaining for their use in research or training. Therefore, the samples are not used and are allowed to perish at the end of the statutory storage period without the gamete provider's consent being acted upon. There is also the potential for samples to be used in research which is hurried by an impending storage expiry, or for samples to not even be considered for research donation because their remaining time in storage is so limited.

We therefore suggest that if consent to donation to research or training is given within the last year of the statutory storage period (whether this has been extended beyond 10 years or not), regulations should make provisions for gamete providers to be able to consent to storage for an additional two years if they are, at the same time, consenting to the use of their gametes or embryos in research or training activities. This will allow stored gametes and embryos to leave the treatment pathway and be stored for up to two years beyond the statutory storage period, allowing them to be used in well planned research and training activities. It will be clear that once the patient has consented to their samples being used in research or training activities, the samples can no longer be used for treatment purposes.

### **Posthumous use and storage of gametes and embryos**

We recommend that the Department carefully consider how any new rules on storage will affect gametes and embryos being stored for posthumous use. Under the 2009 Regulations, a gamete provider can give consent to store their gametes or embryos created with their gametes for up to 55 years as long as they meet the premature infertility criteria. Before their first 10-year period has expired, a medical practitioner will need to certify in writing that the medical criteria for premature infertility have been met for storage to continue for more than 10 years. The storage period can then be extended by further 10-year periods (up to a maximum of 55 years) if it is shown that the criteria continue to be met. The 2009 Regulations do not require the gamete provider to provide consent at every 10-year period. This means that if the gamete provider dies or becomes mentally incapacitated storage can continue as long as the 2009 Regulations have been met. The gametes or embryos can then be used for their partner's treatment if they consented to posthumous use before they died.

If the department were to abolish the 2009 Regulations and adopt a system whereby all gamete providers were treated equally and were required to give consent every 10 years for storage to continue (for a maximum of 55 years) they would need to think about how this would effect patients who have gametes and embryos in storage who then die or become mentally incapacitated. These patients would not be able to renew their consent at the end of every 10-year period. For example, the department may wish to consider allowing gamete providers who wish to continue to store their gametes in the event of their death to consent to store for the maximum of 55 years without requiring them to renew their consent every 10 years. This would allow storage to continue for longer than 10 years, up to 55 years for use in their partners treatment after death (as long as they had also consented to posthumous use). We would suggest that the patient receiving the treatment would still be required to satisfy the conditions for extension; that they intend to use the gametes or embryos for their own treatment, and that they have been offered counselling.

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