

Gamete and embryo storage limits

Consultation response by the Progress Educational Trust 1 May 2020

Introduction

About the Progress Educational Trust

The **Progress Educational Trust (PET)** is a registered charity which advances public and professional understanding of science, law, ethics and policy in the fields of assisted reproduction, embryology and genomics.

PET's **vision** is to improve the choices for people affected by genetic conditions and infertility. PET's **mission** is to educate and debate the responsible application of reproductive and genetic science.

PET's experience in this field is substantial. The charity was founded in 1992, while its precursor organisation – the **Progress Campaign for Research into Human Reproduction** – was founded in 1985 to campaign on legal and ethical issues that had come before the UK Parliament.

About this consultation

PET welcomes the UK Government's consultation on gamete and embryo storage limits.

PET also welcomes the Government's related recent announcement of a temporary two-year extension to these storage limits, in order to help fertility patients during the current coronavirus pandemic.

This temporary extension not only helps fertility patients in the immediate term, but also usefully highlights broader issues that the Government should take on board in relation to its consultation.

Interest in gamete and embryo storage

PET has a longstanding interest in medical, legal, ethical, social and policy aspects of the cryopreservation and storage of gametes and embryos.

PET has held numerous public events discussing this area, with input from a wide range of experts as well as from patients and the wider public.

The most recent of these public events – '**Frozen Fertility: The Challenges of Storing Eggs, Sperm and Embryos**' – was held in Edinburgh on 8 January 2020, and was attended by 180 people.

A series of six films documenting this event is available to watch on PET's **YouTube** channel at <https://bit.ly/2SlogyI> and a written summary of the discussion is available to read in PET's flagship publication **BioNews** at www.bionews.org.uk/page_147510

Other public events on this subject that have been produced by PET in recent years include the following.

- **Beating the Biological Clock: Should You Freeze Your Eggs?**
Evening event in London, 21 October 2015 (180 attendees)
Summary available on BioNews at www.bionews.org.uk/page_95256

- **Can Women Put Motherhood on Ice?**
Evening event in Edinburgh, 15 June 2016 (80 attendees)
Summary available on BioNews at www.bionews.org.uk/page_95581
Podcast available on BioNews at www.bionews.org.uk/page_95598
- **Frozen Assets? Preserving Sperm, Eggs and Embryos**
Evening event in Edinburgh, 25 October 2016 (70 attendees)
Summary available on BioNews at www.bionews.org.uk/page_95760
- **Make Do or Amend: Should We Update UK Fertility and Embryo Law?**
One-day conference in London, 5 December 2018 (240 attendees)
Summary of relevant conference session available on BioNews at www.bionews.org.uk/page_140669
- **Trouble in Store? How Not to Break the Law when Storing Embryos and Gametes**
Evening event in London, 29 October 2019 (160 attendees)
Summary of relevant conference session available on BioNews at www.bionews.org.uk/page_145992

PET's #ExtendTheLimit campaign

In 2019, PET launched a campaign entitled **#ExtendTheLimit**, calling on the UK Government to extend the 10-year storage limit for eggs cryopreserved for non-medical reasons.

This campaign received widespread coverage across traditional and social media, both nationally and regionally. See, for example, the following article.

- **Frozen eggs storage 10-year limit 'should be changed'**
BBC News, 28 October 2019
www.bbc.co.uk/news/health-50182675

The campaign was originally launched with a petition on the UK Parliament's petitions website. This petition can still be viewed online at <https://tinyurl.com/extendthelimit>

The petition received more than **1,000** signatures within the space of a week, but was then forced to close – along with all other petitions on the UK Parliament's petitions website – due to a General Election being called.

PET relaunched the **#ExtendTheLimit** campaign in March 2020, with a new petition on the **Change.org** website at www.change.org/extendthelimit

The advent of the global coronavirus pandemic has prevented PET from promoting this petition as widely as it would have liked. Despite this, the petition has received more than **650** signatures at the time of writing.

10 key principles

Drawing upon its work on the cryopreservation and storage of gametes and embryos, PET has developed **10 key principles** which inform its responses to the Government's consultation questions.

These 10 principles take account of the views of diverse patients, professionals and policymakers, and are as follows.

1. The law and regulation that govern the cryopreservation and storage of gametes and embryos should be drastically simplified.
2. The same rules should apply to sperm, eggs and embryos.

Other reproductive bodily materials, such as gonadal tissue and gamete precursor cells, fall outside the scope of this consultation. But the Government should be mindful of the existence and use of these other materials, and should be clear and consistent in regulating their storage and use.

3. The same rules should apply to all patients – regardless of their reasons for storing gametes or embryos, and regardless of their sex or gender.
4. The distinction between storage for medical reasons and storage for non-medical reasons should be removed from law and regulation in this area. One patient group should not be characterised as more or less deserving than another.
5. 'Premature infertility' is a contentious and poorly defined concept. References to patients being or becoming '*prematurely infertile*' are therefore unsuitable for inclusion in law or regulation, and should be removed.
6. It is for clinicians to judge whether people requesting fertility treatment should be treated. A clinician's judgment on the matter is informed by their individual expertise and experience, by the expertise and experience of their colleagues and professional bodies, and by laws and regulations that apply to medicine in general (rather than fertility in particular).
7. In addition to the factors informing clinical judgment that are described above, established fertility law requires clinicians to take account of '*the welfare of any child who may be born as a result of the treatment*' before providing a woman with '*treatment services*'. Reform of fertility law in relation to gamete and embryo storage should not be used as a pretext to add further welfare considerations to this requirement, or to preempt the outcome of clinical judgments.
8. A patient's decision to freeze and store gametes or embryos, and a patient's decision to *use* stored gametes or embryos in order to try to achieve a pregnancy, are two very different junctures in the fertility treatment journey and should not be conflated. Clinicians make distinct judgments in relation to these two different junctures. A clinician cannot make a final judgment about whether to try to establish a pregnancy until a patient expresses a wish to *use* stored gametes or embryos.
9. If and when patients should experience difficulty choosing what should happen to their stored gametes or embryos, legal limits on storage periods are *not* an appropriate means of addressing this. Furthermore, whether and on what terms gamete or embryo storage is publicly funded – or should be – is a completely separate matter from whether fertility law should set temporal limits on storage.
10. Any changes made to the law in this area must apply retrospectively as well as prospectively. Transitional provisions should be made to accommodate people whose gametes or embryos are already in storage, particularly women who have stored their eggs for non-medical reasons.

Note on the numbering of consultation questions

Please note that in PET's responses below, consultation questions are numbered in the same way as in the Government's *consultation document*, and *not* in the same way as in the Government's online questionnaire (which employs different numbering).

1) Possible changes to the 1990 Act

1. Should the statutory storage period for cryopreserved 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?

Other.

Please specify.

The only limit that should be placed, on the otherwise indefinite storage of cryopreserved gametes or embryos, should be the patient's compliance with an active renewal process. Patients who wish to continue with storage should be obliged to reaffirm this wish periodically (PET proposes every 10 years) to the relevant clinic.

At present, a temporal statutory limit of 10 years is set out in the Human Fertilisation and Embryology Acts 1990 and 2008, with provision for this limit to be extended in circumstances specified in regulations. Regulations in turn specify that extension should be permitted for patients who are judged to be prematurely infertile, or likely to become so.

As explained in its response to **Q15** below, PET would like a renewal period of 10 years to remain in place. Superficially, this would resemble present arrangements. Beyond this superficial resemblance, however, PET would like to see – for reasons detailed in response to **Q4** below – a thoroughgoing change to the arrangements that currently govern gamete and embryo storage.

Instead of the current default statutory limit of 10 years with specified regulatory exceptions, PET proposes that there should be *no* time limit on gamete or embryo storage, *but* that there should be a renewal period which applies in all circumstances. This renewal period (which PET proposes should be 10 years) should not be conceived of as an exception *to* the rule concerning gamete or embryo storage, but rather should be conceived of *as* the rule.

In other words, the need for renewal is – in and of itself – a meaningful limit on what is otherwise potentially indefinite storage. No other limit is necessary in fertility law. (The question of whether or not the public funding of continued storage should be limited, and if so then how, is a separate area of policy.)

It is PET's view that *all* patients, regardless of whether or not they are judged to be (in)fertile, should be permitted to store gametes or embryos indefinitely – provided that they actively reaffirm their wish to continue doing so, after a specified renewal period (which PET proposes should be 10 years), according to a specified process.

PET does not have a firm view of where this reaffirmation process should be defined – whether in statute, in regulations, in guidance from the statutory regulator (the Human Fertilisation and Embryology Authority), or in some combination of these. What is important is that this process must be sufficiently well-defined to enable patients and clinics alike to operate with confidence.

Patients must be confident that, if they adhere to the specified reaffirmation process, then ongoing storage of their gametes or embryos is secure. Clinics must be confident that, if they adhere to the specified reaffirmation process – and if reaffirmation is *not* forthcoming from the patient – then they will eventually be permitted to destroy stored gametes or embryos (rather than being obliged to continue storing gametes or embryos in the absence of clarification from the patient).

Clinics should bear responsibility for providing a clear explanation of the specified reaffirmation process to patients. Furthermore, the Human Fertilisation and Embryology Authority should provide additional material explaining the specified reaffirmation process for the benefit of patients (this should be as a supplement to, rather than a substitute for, an explanation from clinics).

The reaffirmation process should involve clinics taking specified demonstrable steps to notify patients – a specified number of months before the renewal period lapses – that the deadline for renewal is approaching. If the patient does not contact the clinic expressing their wishes within a specified period of this notification being issued, then the clinic should take a series of specified demonstrable steps to try to elicit a response from the patient.

If, after these steps have been duly and demonstrably taken, a response from the patient is still not forthcoming, then the clinic should eventually – a specified number of months after the renewal period lapses, and/or a specified number of months after the requisite steps have been taken (whichever date falls latest) – be permitted to destroy the patients' gametes or embryos.

4. Why do you think that the limit should be increased?

The statutory limit on the duration for which cryopreserved gametes or embryos can be stored, and arrangements governing storage periods more broadly, evolved from historical circumstances that are not relevant to the present situation. These arrangements originated in a time when assisted conception was still novel, and when the cryopreservation of gametes or embryos was still largely experimental.

Since the laws governing gamete and embryo storage were drafted, the science of cryopreservation has changed drastically, as have society's attitudes towards fertility preservation and later motherhood. PET believes the law needs to be changed to reflect improvements in the reliability of freezing and thawing techniques, as well as changes in society which mean that many women now have children later in life.

A temporal statutory limit has no scientific basis, because gametes and embryos remain viable if cryopreserved for longer than 10 years (or indeed if cryopreserved for longer than 55 years). In the specific case of egg cryopreservation, the temporal statutory limit – and the fact that this limit can be extended only in circumstances of current or likely premature infertility – has discriminatory consequences for women, because female fertility declines far more steeply with age than does male fertility.

If a woman wishes to try to preserve her fertility, the best time for her to freeze her eggs is in her 20s. But under the current law, if a woman freezes her eggs when she is 28, she has to be ready to use them before she is 38. If she is *not* ready to use her eggs by the time she is 38, she has a limited number of options which are potentially debilitating, both emotionally and financially.

- She can see her eggs destroyed, and with them perhaps her best or only chance of becoming a biological mother.
- She can become a parent before she is ready to do so, either with a partner or as a single mother using sperm donation.
- She can try to fund the transfer of her eggs to a fertility clinic overseas, and then try to have fertility treatment abroad at a later date.

This is the quandary faced by a substantial number of women in the UK. In order to avoid this quandary, other women wait until their mid-to-late 30s – when their egg quality is declining – before freezing their eggs.

This alternative course of action can have equally adverse consequences, reducing the chances of successful fertility treatment and promoting poor clinical practice. A woman's age at the time of egg collection plays a vital role in the likelihood of a successful outcome from fertility treatment, as discussed in the following research.

- **Association between the number of eggs and live birth in IVF treatment: an analysis of 400,135 treatment cycles**
Sunkara, Rittenberg, Raine-Fenning *et al*, *Human Reproduction*, 2011
<https://doi.org/10.1093/humrep/der106>

- **Predicting the likelihood of live birth for elective oocyte cryopreservation: a counselling tool for physicians and patients**

Goldman, Racowsky, Farland *et al*, *Human Reproduction*, 2017

<https://doi.org/10.1093/humrep/dex008>

Furthermore, the younger a woman is at the time of egg collection, the fewer the eggs that need to be collected and the fewer the stimulation cycles that are necessary to collect these eggs. Freezing eggs later in life involves greater risks to women's health, combined with decreased chances of a successful outcome.

The Government's consultation document cites the latest data on fertility treatment trends and figures published by the Human Fertilisation and Embryology Authority, highlighting the fact that one-third of UK women freezing their eggs are under 35. However, the more significant fact is that two-thirds of UK women freezing their eggs are *over* 35.

This situation is encouraged by the current legislation. In addition to causing other problems discussed above, the 10-year limit on egg storage for non-medical reasons acts as a perverse incentive for women to freeze their eggs at a suboptimal time.

8. Should any conditions be applied to those seeking to freeze embryos or gametes beyond a certain limit?

No.

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

No.

II) 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.

The criterion currently used for storage extension – namely, that extension is only permitted if a patient '*is prematurely infertile or is likely to become prematurely infertile*' in the opinion of '*a registered medical practitioner*' – should be removed.

PET would like this criterion to be removed because it believes – as explained in response to **Q3** above – that *all* patients, regardless of whether and by whom they are or are not judged to be (in)fertile, should be permitted to store gametes or embryos indefinitely. An additional reason for removing this criterion is that 'premature infertility' is a contentious and poorly defined concept, and is therefore unsuitable for inclusion in law or regulation.

No new criteria should be introduced in relation to storage. The Human Fertilisation and Embryology Acts 1990 and 2008 already require fertility clinicians to take account of '*the welfare of any child who may be born as a result of the treatment*' before providing a woman with '*treatment services*'. The outcome of such judgments by fertility clinicians should not be preempted in criteria set out in legislation or regulation.

Furthermore, a fertility clinician cannot make a final judgment about whether to try to establish a pregnancy until a patient expresses a wish to *use* stored gametes or embryos. This judgment cannot be made at the time when a patient first freezes and stores gametes or embryos, because the patient's circumstances – whether in relation to 'welfare of the child' considerations, or in relation to age and health – can change substantially between initial storage and subsequent use.

PET is concerned that the Government has conflated cryopreservation with use in its consultation document. PET's concerns on this point are set out in greater detail in response to **Q21** below.

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

Yes.

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

No.

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?

There should be *no* absolute limit on the period of time for which a patient's gametes or embryos can be stored. Furthermore, premature infertility should *not* be a consideration in deciding the period of time for which a patient's gametes or embryos can be stored.

As explained in its response to **Q3** above, PET believes that the only limit that should be placed – on the otherwise indefinite storage of cryopreserved gametes or embryos – should be compliance with an active renewal process.

The need for renewal is, in and of itself, a meaningful limit on what is otherwise potentially indefinite storage. No other limit is necessary in fertility law. (The question of whether or not the public funding of continued storage should be limited, and if so then how, is a separate area of policy.)

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

No.

III) Other comments

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

PET notes that the structure of this consultation – with the first half of the consultation addressing the Human Fertilisation and Embryology Acts 1990 and 2008, and the second half of the consultation addressing the Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009 – assumes that the underlying function of and relationship between these Acts and these Regulations, as they relate to gamete and embryo storage, should remain unchanged.

PET disagrees with this assumption. As explained in its responses to **Q3** and **Q4** above, PET believes the arrangements that currently govern gamete and embryo storage evolved from historical circumstances that are not relevant to the present situation. The setting of a temporal statutory storage limit, with provision for this limit to be extended in circumstances specified in regulations, is no longer a logical approach. This area of law requires a more thoroughgoing change than this consultation perhaps allows for.

Furthermore, PET notes that the scope of this consultation is limited to gametes and embryos, excluding other reproductive bodily materials such as gonadal tissue and gamete precursor cells. This is reasonable, given that storage of these other materials is currently governed by other areas of law. But PET urges the Government to be mindful of the existence of these other reproductive materials, and to be mindful of the storage and use of such materials in novel contexts as technology advances.

The Government's consultation document refers to an earlier consultation on fertility law that was held in 2005, and respondents who noted that '*many patients had difficulty in making up their minds to finally dispose of their gametes and embryos*'. PET should like to take this opportunity to observe that many patients do *not* experience the difficulty referred to here, and would take exception to the implication that they struggle in this way.

A patient can make a legitimate decision to store gametes or embryos for a substantial period of time, without using them. If and when patients *do* experience difficulty choosing what should happen to their stored gametes or embryos, legal limits on storage are not an appropriate means of addressing this. Public engagement, education and good communication between the clinic and the patient are the best channels through which to address such difficulty in making decisions.

Whether and on what terms public funding is, or should be, available for continued gamete or embryo storage, is a completely separate matter from whether fertility law should set temporal limits on storage. Decisions about what storage it is reasonable for the state to fund can be made by the appropriate authorities in England and the devolved nations.

In its responses to consultation questions provided above, PET adheres to the limitations of the questionnaire via which responses to this consultation can be submitted online. However, having read all of the consultation questions in full, PET has concerns about some of the questions that it was not permitted to respond to online. PET should like to raise these concerns here, before moving on to some additional final considerations.

Respondents who answer 'Yes' to Q8 above, '*Should any conditions be applied to those seeking to freeze embryos or gametes beyond a certain limit?*' (to which PET responded 'No'), are then asked to answer Q9, '*What do you think these conditions should be?*'. Q9 adds in parentheses '*(For example, that the patient should be under a certain age or that they should undergo additional welfare checks as part of fertility treatment.)*'

PET believes that the examples given in parentheses here are inappropriate – certainly in relation to gamete storage, and arguably in relation to embryo storage as well. These examples involve considerations that become relevant at the time when patients seek to *use* their stored gametes (or embryos), but which may not be relevant at the time when gametes (or embryos) are initially frozen and stored. These are two very different junctures in a patient's fertility treatment journey, and should be dealt with separately.

The Human Fertilisation and Embryology Acts 1990 and 2008 require fertility clinicians to take account of '*the welfare of any child who may be born as a result of the treatment*' before providing a woman with '*treatment services*'. Such '*services*' arguably include the process whereby a woman's eggs are first collected and cryopreserved, but even if this is the case, it remains possible that the woman's circumstances will change substantially thereafter.

A fertility clinician cannot therefore make a final judgment about whether to try to establish a pregnancy, until a patient expresses a wish to *use* stored gametes (or embryos). This is also true of the patient's suitability for treatment on medical grounds such as their age and their overall state of health. The Government's wording in this consultation question unhelpfully conflates different aspects of fertility treatment that should be kept distinct.

Furthermore, PET struggles to understand what the Government has in mind when it discusses '*welfare checks*' in Q9, unless this is intended to refer specifically to the law's existing '*welfare of the child*' provisions. If this is the case, then it should be made clear.

If this is *not* the case, then PET believes the reference to '*welfare checks*' to be illegitimate. Reform of fertility law in relation to gamete and embryo storage should not be used as a pretext to add further welfare considerations to the law's existing '*welfare of the child*' provisions.

Respondents who answer '*Yes*' to **Q19** above, '*Should embryos, eggs and sperm each have their own storage limit?*', are asked to provide further detail. Respondents who answer '*No*' (as did PET) are not asked to elaborate. PET should like to say here that introducing different storage limits for these different reproductive bodily materials would add unnecessarily to the complexity of the law in this area, and would increase the potential for undue discrimination.

Granted, nature already discriminates between the sexes in relation to fertility. Female fertility declines far more steeply with age than does male fertility, and it eventually declines to zero (whereas male fertility often does not). Of course, it is also the case that females are the carriers of pregnancies. However, such natural inequalities cannot be helpfully compensated for via the imposition of different storage limits for eggs, sperm and embryos.

Moving on from the Government's consultation questions to wider considerations, PET should like to discuss the present coronavirus pandemic, and the fact that this pandemic has led to the mandatory suspension of all UK fertility treatment. Women with stored eggs who were approaching the 10-year limit when the pandemic began were already in a difficult quandary, for reasons given in PET's response to **Q4** above, and the suspension of fertility treatment will only have added to their difficulties and anxieties.

PET therefore welcomes the Government's recent announcement of a temporary two-year extension to gamete and embryo storage limits, as this will go some way towards alleviating the difficulties and anxieties of affected patients. The extension also underlines the fact that there is no scientific basis for present-day storage limits, because with present-day freezing and thawing techniques, gametes and embryos remain viable if cryopreserved for longer than 10 years (or indeed if cryopreserved for longer than 55 years).

The extension is welcome, but the broader point remains. *All* UK patients should be permitted to store gametes and embryos for more than 10 years, regardless of whether or not their reasons for doing so are medical, and regardless of whether fertility treatment resumes or whether it continues to be suspended.

The pandemic also has other ramifications for gamete and embryo storage. If and when the impact of coronavirus subsides, and fertility treatment is permitted to resume, there could well be a growth in demand for gamete and embryo freezing. Storage might be perceived as a form of insurance, in case coronavirus should return or in case the UK should experience a different pandemic with similarly far-reaching consequences.

Accompanying this possible increase in demand, there is likely to be greater uncertainty surrounding the fate of stored gametes and embryos. Not all private fertility clinics will survive the loss of income from the suspension of fertility treatment during the pandemic, and the logistics of transferring responsibility for storage and accompanying paperwork – if a clinic should close – are fraught with difficulty.

The same difficulty is faced by certain NHS fertility clinics, which were already facing challenging circumstances and possible closure when the pandemic began. See for example this article, in which the logistics of dealing with cryopreserved gametes and embryos – if an NHS clinic is forced to close – are described by one member of clinic staff as '*mind-boggling*'.

- **NHS's oldest IVF clinic at risk of closure amid increasing privatisations**
Guardian, 19 April 2020
[www.theguardian.com/society/2020/apr/19/
uks-oldest-ivf-clinic-at-risk-of-closure-amid-increasing-privatisations](http://www.theguardian.com/society/2020/apr/19/uks-oldest-ivf-clinic-at-risk-of-closure-amid-increasing-privatisations)

Such imminent challenges, concerning the storage of gametes and embryos, make it all the more imperative that the law governing this area is brought up-to-date and made fit for purpose.

Finally, any changes made to the law in this area must apply retrospectively as well as prospectively. Transitional provisions should be made to accommodate people whose gametes or embryos are already in storage, particularly women who have stored their eggs for non-medical reasons.