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Consultation: *Gamete (egg, sperm) and embryo storage limits*

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribes are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB is very grateful to the UK Department of Health and Social Care for this opportunity to respond to the consultation on ***Gamete (egg, sperm) and embryo storage limits***. It welcomes its intention to promote public consultation, understanding and discussion on this topic.

Initial Remarks:

Depending on the circumstances of each person undergoing fertility treatment, gametes (eggs or sperm) or embryos that are not used immediately to have a child may be frozen for future use.

In addition, people are increasingly choosing to deliberately freeze and store their gametes. This may be because:

- they are not ready to have a family but want to preserve their fertility so that they can start a family later in life;
- they are having cancer treatment that may affect their fertility and wish to protect and preserve their future fertility;
- they may be planning on transitioning or having gender reassignment surgery but intend to start a family later.

The *Human Fertilisation and Embryology Act 1990* (the *1990 Act*), as amended by the *Human Fertilisation and Embryology Act 2008* (the *2008 Act*), sets the storage period for embryos and gametes stored for fertility treatment at a maximum of 10 years.

More specifically, the *Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009* (the *2009 Storage Regulations*) enables the storage period to be extended at any point within the initial 10-year period for a further 10 years if the gamete provider, person to be treated, or person to whom the embryo or gamete has been allocated is prematurely infertile or is likely to become prematurely infertile, for example individuals whose ovarian function has been destroyed through chemotherapy or radiotherapy.

The storage period may then be extended for subsequent 10-year periods, until a maximum storage period of 55 years is reached, provided that the premature infertility criteria are demonstrated at any time within each 10-year period. This must be confirmed in writing by a registered medical practitioner.

The government has received representations from Parliamentarians and other interested parties about the current provisions of the *1990 Act* concerning the time limit for storage of eggs, sperm and embryos and

whether they remain fit for purpose. In response, the government has agreed to undertake a public consultation to test public views about possible changes to the legislation. The following consultation, therefore, asks whether the government should make changes to the length of storage for eggs, sperm and embryos stored for fertility treatment.

Background to the consultation

History of the current legislation

Warnock Report

The recommendations in the 1984 report of the *Committee of Enquiry into Human Fertilisation and Embryology*, Chaired by Baroness Mary Warnock (commonly known as the “Warnock Report”), formed the basis of the *Human Fertilisation & Embryology Bill* that subsequently became the *Human Fertilisation & Embryology Act 1990*.

At the time, the committee felt it unreasonable to set an absolute length of time that eggs and sperm could be stored but also recognised it would be unreasonable and impractical to expect those responsible for storage to maintain all eggs and sperm stored indefinitely. Thus, the committee recommended automatic 5-yearly reviews. Where a couple were storing embryos for their own future use, the committee recommended there should be a definite time limit for storage because the risk of the use of frozen embryos was unknown and because of the legal and ethical complications that might arise over disposal of the embryos where the couple died, divorced or otherwise separated.

As a result, the committee recommended that storage should be reviewed at 5 years, with a maximum storage period of 10 years.

During passage of the *Human Fertilisation & Embryology Bill*, there was no substantial debate of Clause 14 (Condition of Storage Licences), which set the 10-year maximum statutory maximum storage limit for gametes. The bill was passed and became the *Human Fertilisation & Embryology Act 1990*.

Thus, under the *1990 Act*, the maximum statutory storage periods for embryos and gametes were set at 5 or 10 years respectively. In addition, the *Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991* (the *1991 Regulations*) and the *Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996*, (the *1996 Regulations*) made provision about the circumstances in which these periods could be extended.

Review of the 1990 Act, the Human Fertilisation & Embryology Act 2008

A public consultation took place in August 2005 as part of the review of the *1990 Act*, seeking views on whether the legislation should continue to set statutory maximum storage limits and, if so, how long these should be.

Where responses were received concerning the statutory maximum storage limit, there were a wide range of views and no consensus emerged. Respondents recommended a range of storage periods between 9 months and 20 years or a limit in line with “normal childbearing age”.

A number of responses suggested flexible periods, to take account of developments in knowledge and the individual circumstances of the gamete provider or decided by the doctor and patients at the time of storage. Concern was expressed that extending limits would result in the creation of larger storage banks without necessarily helping patients to reach a decision on storage. Other responses noted that while many patients had difficulty in making up their minds to finally dispose of their gametes and embryos, that would remain the case whatever the storage limit.

Following the consultation, a white paper was published in December 2006 containing policy proposals to update the *1990 Act*. The paper stated that the government remained convinced of the need for some limits on the periods for which gametes and embryos may be stored and believed that having clarity in the law (which may be adjusted from time to time) remained appropriate.

The government accepted that there was a case, given the greater experience of embryo storage, for extending the statutory storage period for embryos. Therefore, the government proposed to extend the statutory storage period for embryos from 5 to 10 years, bringing embryos into line with the storage periods for gametes.

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009

The *2008 Act* amended the *1990 Act* to provide that both embryos and gametes can be stored for up to 10 years. But the *Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009* (the *2009 Storage Regulations*) replaced the 1991 and 1996 Regulations to make provision about when the storage period for both embryos and gametes can be extended beyond 10 years in certain circumstances.

Whether a patient meets the criteria for extension is a clinical decision, allowing a registered medical practitioner to consider the individual circumstances, alongside guidance provided by the UK regulator for the fertility sector, the **Human Fertilisation and Embryology Authority** (HFEA).

The 1991 and 1996 Regulations set the storage periods by reference to the age of the person who will be treated, which should not exceed 55 years of age. Such an age limit is not a requirement under the *1990 Act* itself, and it meant that some people, men in particular, could not use stored gametes over the age of 55 despite the fact that they were arguably still prematurely infertile.

However, the *2009 Storage Regulations* replaced the age limit with a time limit. This change meant that the storage period for both embryos and gametes could be extended at any point within the initial 10-year storage period for a further 10 years if the premature infertility test is met.

The storage period may then be extended for subsequent 10-year periods, until a maximum storage period of 55 years is reached, provided that the prematurely infertile criteria are demonstrated at any time within each 10-year period.

The *2009 Storage Regulations* also made transitional provision to enable any embryos or gametes stored subject to the storage limits in the *1990 Act*, prior to amendment by the *2008 Act*, or to the periods under the 1991 or the 1996 Regulations, to benefit from the new storage periods, if consent is in place and the conditions under the *2009 Storage Regulations* are met.

HFEA fertility trends and figures

The HFEA publishes information on trends and figures in fertility treatment in the UK. The latest report was published in May 2019 which indicates:

- while both egg freezing and egg thawing treatment cycles have been increasing in numbers since they started being recorded in 2010, egg freezing has experienced a much steeper incline in use.
- there were 1,462 egg freezing cycles in 2017 (410 in 2012), while there were 581 egg thaw cycles in 2017 (159 in 2012).
- there were 479 egg freeze cycles for patients under 35, making up the highest proportion (33%) of people using this treatment. However, they were closely followed by the 35–37 age group at 426 cycles (29%).
- the highest proportion of people using frozen eggs are aged 44 and over (206 cycles, 35.5%).
- birth rates decrease with age when fresh or frozen eggs are used. While birth rate per embryo transfer 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.

If eggs are frozen below the age of 35, the chances of success will be higher than the natural conception rate as the woman gets older. Despite this, the most common age that women freeze their own eggs for treatment is 38, with some women freezing their own eggs into their 40s, when the likelihood of a future pregnancy from using these eggs is very slim.

Case for change

The government has received representations from Parliamentarians and other interested parties about the current provisions of the *1990 Act* concerning the storage of eggs, sperm and embryos and whether they remain fit for purpose.

The government has also considered whether the existing legislative provisions remain compatible with human rights legislation and believes that the scheme treats all equally, regardless of their circumstances.

However, the government is persuaded that there is a case to consider a change to the legislative framework. There have been significant improvements in freezing technologies since the last review of the legislation which make the storage of eggs for longer than 10 years possible, while maintaining sufficient egg quality to allow eggs to be thawed and fertilised even after an extended period in storage.

There are also important arguments to consider about reproductive choice for women and how the current legislation may affect that. Eggs frozen in a woman's 20s are at their peak of fertility meaning that, in general, the earlier a woman freezes her eggs, the better chance she has of achieving a healthy pregnancy. If frozen at this optimal age, a 10-year storage limit means that storage will expire in the woman's 30s, which may be too early for some people in the family-making decision cycle.

The woman will then have the option to thaw the eggs and create embryos using sperm from their partner or a donor, which can then either be used immediately or be frozen for a further 10 years. Otherwise, the woman will have to allow their eggs to perish. However, if a medical practitioner certifies that the woman is prematurely infertile, they can store their eggs for up to 55 years.

In response to these issues, the government is running this UK-wide consultation to test public views about possible changes to the legislation.

Possible policy options

One policy option would be to retain the current provisions set out in the legislation without making any changes. This option will maintain the current storage limit of 10 years for eggs, sperm and embryos, and the provision to allow storage for up to 55 years in cases of premature infertility.

Alternatively, the current legislation could be changed to alter the storage limit for eggs, sperm and embryos. Possible changes to the legislation are set out below.

Possible changes to the 1990 Act

One issue to consider is the impact of a 10-year limit on the storage of eggs in particular. It has been suggested that this limit may no longer be appropriate for women in view of improvements to egg freezing efficacy and the fact that eggs are more fertile if frozen at a younger age.

One policy option to address this issue could be to increase the statutory storage period for eggs, sperm and embryos beyond 10 years.

This may, however, have the effect of increasing the number of people becoming pregnant when they are older, with increased risk of complications for both mothers and babies.

Consideration should be given to the impact of prolonged storage on children born using gametes or embryos stored under these circumstances. This ought to include consideration of safety and quality issues related to prolonged storage, for example increased genetic problems or degeneration.

Another issue to consider would be that of the additional demand for storage facilities if the statutory storage period is increased. Patients are often reluctant to allow their eggs or embryos (less so sperm) to be allowed to perish, even if they are minded not to use them in their own treatment or donate them to others. With a longer storage limit they could remain in storage for significantly longer and possibly indefinitely.

Long-term storage carries the risk that clinics will lose contact with the patients (with the resulting non-payment of storage fees). Clinics cannot destroy gametes or embryos before the maximum storage limit is reached if contact is lost, unless they have written agreement to this from the gamete or embryo providers.

Patients are not obliged to agree to any local arrangement that their gametes or embryos can be disposed of if they do not maintain contact with the storage centre or pay the storage fee, with the result that the material stays in storage until the statutory limit is reached, with the storing establishment, including those in the NHS, meeting the continuing costs of that storage.

Another policy option could be to reduce the storage limit to fewer than 10 years to address the concerns related to increased maternal age risk and storage burden issues.

Possible changes to the 2009 storage regulations

The 2009 storage regulations allow for extensions to the statutory storage period of 10 years, if the person storing the embryos or gametes can provide a written medical opinion that he/she is prematurely infertile or likely to become prematurely infertile.

Extensions can be given for up to 10 years at a time up to a maximum storage limit of 55 years.

The 55-year maximum period recognises the potential fertility needs of adults who were infertile at birth or rendered infertile while still young children, for example after receiving treatment for childhood cancer. This allows gametes collected from the young patient or donated for their use as adults by a close family member to be held in storage until the child reaches adulthood and wishes to have a family of their own.

Private fertility clinics usually have an upper age limit for women needing fertility treatment of between 50 and 55. In the UK, menopause generally occurs between the ages of 45 and 55, with the average age being 51.

What will happen next?

Following the outcome of this consultation, the government will consider the responses and will issue a formal response that will be published online. Ministers will consider whether any changes should be made to the current legislation and, if so, what these changes should be.

Response to the Questions

Preliminary note from the SCHB

The SCHB regrets many of the articles adopted in both the Human Fertilisation and Embryology Act of 1990 and of 2008. More specifically, it regrets the very existence of stored human embryos which will eventually be destroyed - a problem which should be addressed as a matter of urgency. Moreover, the HFEA should publish the total number of embryos presently being stored in the UK and what eventually happens to them. Otherwise, the respondents to this consultation cannot be seen as being informed in preparing their replies.

The SCHB notes that patients should be asked to reflect about the destiny of their potential leftover embryos before they are created. This is in agreement with Dr Richard Kennedy, past secretary of the British Fertility Society and consultant gynaecologist at the Centre for Reproductive Medicine in Coventry, who indicated that “*it would be helpful to raise the issue of ‘what will you do with these embryos?’ before they are created.*”¹

¹ Sarah-Kate Templeton, Spare embryos ‘should be donated to infertile couples’, The Sunday Herald, 21 September 2003: <http://www.sundayherald.com/36912>

The SCHB is also surprised that the Government seems to consider that the alternative to implantation is to leave the embryo to perish when other solutions such as embryo adoption can be examined.

Concerning the creation of human embryos *in vitro*, the SCHB notes that in other countries, such as in Germany, it is considered unethical to create human embryos *in vitro* if they are not immediately implanted into the mother. This happens in order to avoid the difficult problem, which exists in the UK, of having an ever-increasing stock (more than 100,000) of frozen, unwanted and supernumerary embryos generally destined for destruction.

The SCHB recognises that even though an unacceptable large number of stored embryos does unfortunately exist in the UK, it would be preferable for these embryos to be given for adoption instead of being destroyed. The adoption of embryos, in a similar way as the adoption of children, is a very positive solution to an already existing difficult situation.

The SCHB would thus like to encourage the adoption by infertile couples of supernumerary embryos.²

The SCHB is of the view that an embryo belongs to both parties whose gametes were used to create this embryo. Both parties are therefore responsible for the embryo.

Possible changes to the 1990 Act

Note: Replies will not be given to all questions

Question 1

Should the statutory storage period for frozen embryos, eggs and sperm change from the current limit of 10 years?

Yes or no.

The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.

It also believes that couples should be appropriately counselled concerning the use and destiny of their prospective embryos before they are created.

Question 2

Do you think the limit should be increased or decreased?

- increased – please answer Questions 3 and 4
- decreased – please answer Question 5 and 6
- stay the same – please answer question 7

Question 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

Question 4

Why do you think that the limit should be increased?

² This should take account of the risk of incest if many embryos are adopted in a common location.

Question 5

If you think the limit should be decreased, what do you think the limit should be:

- 8 years
- 5 years
- other – please specify

Question 6

Why do you think that the limit should be decreased?

Question 7

Why do you think the limit should stay the same?

Question 8

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

Yes or no.

The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.

If you answered yes, please answer question 9.

Question 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.)

Question 10

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

Yes or no.

The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.

If you answered yes, please answer question 11.

Question 11

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

- embryos: **The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.**
- eggs:
- sperm:

Possible changes to the 2009 storage regulations

The 2009 storage regulations allow for extensions to the statutory storage period of 10 years, if the person storing the embryos or gametes can provide a written medical opinion that he/she is prematurely infertile or likely to become prematurely infertile.

Extensions can be given for up to 10 years at a time, up to a maximum storage limit of 55 years.

In the light of any changes to the statutory storage period, the regulations may need to be updated.

Question 12

Do you think that the provisions in the regulations need updating?

Yes or no.

Question 13

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

Yes or no.

Question 14

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

Question 15

Is the 10-year frequency of renewal still appropriate?

Yes or no.

If you answered no, please answer question 16.

Question 16

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

Question 17

Is the 55-year maximum storage limit still appropriate?

Yes or no.

The SCHB believes that consideration should be given to the impact of prolonged storage of gametes or embryos on the resulting children born from their use. This ought to include consideration of biological safety and quality issues related to prolonged storage, such as increased genetic problems or degeneration, but also on the ability of very old parents to appropriately look after their children.

If you answered no, please answer question 18.

Question 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?

Question 19

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

Yes or no.

The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.

If you answered yes, please answer question 20.

Question 20

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

- embryos: **The SCHB regrets the very existence of stored human embryos which will eventually be destroyed and believes that this problem should be addressed as a matter of urgency.**

- eggs:
- sperm:

Question 21

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

The UK Department of Health's report indicated that: "*The government has received representations from Parliamentarians and other interested parties about the current provisions of the 1990 Act*". However, the SCHB believes that it is inappropriate for such an official consultation to be initiated without giving any evidence of the number and identity of the Parliamentarians and other interested parties seeking to change the *1990 Act*. It is indeed necessary in a democratic system for openness and clarity to exist explaining how these representations eventually became an official consultation. How can the general public know whether these representations are not just the result of a very small number of fertility industry lobbyists or other individuals with a specific agenda?