Department of Health & Social Care

Changes to gamete (egg, sperm) and embryo storage limits

Government Response to public consultation

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Executive Summary

Background

Individuals across the UK are increasingly choosing to freeze their gametes (eggs and sperm) and embryos. There is a variety of reasons for this, including not being ready for a family but wanting to preserve fertility; cancer treatment that may affect fertility; or, less commonly, because they are planning to transition or undergo gender re-assignment surgery. The Human Fertilisation and Embryology Authority (HFEA) reported that in 2019 in the UK, 37% of women freezing their eggs were under the age of 35, 53% were 35-40, and 12% were over 40.

The Human Fertilisation and Embryology Act 1990, as amended in 2008 (the "HFE Act") governs the use and treatment of gametes and embryos. The HFE Act currently limits the storage of gametes and embryos to a maximum of ten years. Subsequent changes to the Act through the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (the "2009 Regulations") permitted an extension of the baseline storage limit for ten-year periods up to a maximum of 55 years for those who can demonstrate a medical need. More recently, in response to the disruption to fertility services during COVID-19, the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 (the "2020 Regulations"), were introduced, allowing for an additional two-year storage in addition to the maximum base limit of ten years for those with material in storage on 1 July 2020.

Cryopreservation techniques have improved significantly since the current statutory limits were set. Studies show that frozen eggs today have the same developmental potential as fresh eggs. Clinical pregnancy rates from embryos created from thawed eggs are equivalent to fresh IVF treatment. In 2017, the birth rate per embryo transfer was 27% per frozen embryo for women aged under 35 and 30% per fresh embryo. For women aged 40 and over, birth rate per embryo transfer was 9% per frozen embryo and 5% per fresh embryo.

The current storage limits often restrict women to two choices. To freeze their most viable eggs in their 20s and use them to have a family in their 30s even if they are not ready; or to freeze their far less viable eggs in their 30s to start a family in later life, which is when treatments have a lower chance of success. Some choose to continue storage abroad which is expensive and depending on the country, may lack regulatory controls.

Consultation

In view of the significant scientific innovation and societal changes in family formation since the law on storage limits was first set, the government launched a public consultation

on 11 February 2020, to seek views about changing the statutory storage limits for gametes and embryos. The consultation ran for 12 weeks and closed on 5 May 2020.

This document summarises the analysis of the responses received to the consultation and sets out the government's proposals to change the legislation.

Broadly, the responses to the consultation indicated:

- support to increase the statutory storage limits for gametes and embryos
- no consensus about how long any extension should be
- support for storage limits for eggs, sperm, and embryos to be the same for all, irrespective of medical need

Policy analysis and summary of conclusions

Having considered the range of responses to the consultation, the government applied four key tests when developing the new policy position. These were:

- ensuring equity for all patients
- facilitating greater reproductive choice
- reducing administrative burden to fertility clinics and the regulator
- ensuring public acceptability

Taking account of the many different perspectives and in view of the above policy tests, the government concluded that the option which best meets these tests is to offer 10-year renewable storage periods to everyone, to a maximum of 55 years, with some limited conditions.

This option is supported by key sector organisations and reflects the current approach for prematurely infertile patients. The new approach would apply to everyone, irrespective of medical need. In addition, it would facilitate reproductive choice for all patients who may have very different reasons for storing their material. For extremely young children storing their gametes (e.g. children undergoing cancer treatment), this limit would continue to enable them to use their gametes for the full term of their reproductive lives. An approach that applies to all will also simplify administration. Finally, 10 years renewable storage to a maximum of 55 years already has broad public acceptability through the operation of the 2009 Regulations.

The consultation responses highlighted the need for ongoing provisions for the clinically infertile. The government confirms that changes should not infringe on the current rights of

this patient group. The current 10-year renewable storage periods with a 55-year limit was seen by respondents as meeting the needs of this group.

The government's proposed policy changes reflect the commitment to encourage all types of family formation and to increase reproductive choice for all.

In summary, the government intends to change the law to increase the statutory storage limits for gametes and embryos for everyone regardless of medical need to 10-year renewable periods, with a maximum limit of 55 years. As part of this new settlement, there will be new requirements for statutory ten-year review periods and explicit written consent from the patient will be required to continue storage. This will ensure that people have a proper opportunity to consider their reproductive needs going forward and can take professional advice and counselling, if they wish to.

The proposed changes do have consequential implications for some particular storage classifications, including third party donations, known or family donations, posthumous use and research. We will undertake further consultation with key stakeholders to explore these areas further.

The government recognises the concern that this change in approach might lead to an increase in the age of some new parents, to the possible detriment of the pregnant mother and child. However, the government believes that the current regulatory safeguards are sufficient to prevent inappropriate treatment and the regulator, the Human Fertilisation and Embryology Authority (HFEA), will take particular care to oversee implementation of the new legislation.

The following sections set out the detailed results of the public consultation and the government Response.

The public consultation

The government ran a 12-week consultation from 11 February 2020 asking the public for their views about possible changes to the statutory storage limits for eggs, sperm, and embryos, set out in the Human Fertilisation and Embryology Act. The consultation closed on 5 May 2020.

The consultation sought views on:

- whether the current ten-year statutory storage limit for gametes and embryos should increase, decrease, or stay the same, and why
- what the new limit should be
- whether there should be additional conditions on those seeking to freeze gametes or embryos beyond a certain limit, and if so, what these should be
- whether eggs, sperm, and embryos should each have their own storage limit, and if so, what these should be
- whether there should be a different storage limit for those with a medical need; and if so, why and what the new limit should be

Response Summary

The consultation received 1,222 responses via the online survey and via email, including 17 from key sector organisations. Responses were analysed by Department of Health and Social Care policy officials with support from analysts.

Questions were optional to answer; some respondents only answered some of the questions. The majority of questions provided the respondent with the opportunity to give a justification for their answer or provide additional information in a free text box. All free text responses were grouped into discrete themes and were analysed.

Responses to questions have been summarised below. Where appropriate, consultation questions have been grouped to better illustrate the feedback received and decisions taken as a result.

Part 1: Changes to statutory limits

This section focuses on consultation questions 1-7, which asked whether there should be a change to the statutory storage limits and if so, what that change should be. Responses to Questions 3 and 5 have been summarised together in Table 1, page 10.

Question 1: Should the statutory storage period for frozen embryos, eggs, and sperm change from the current limit of ten years?

- Yes - 1023 (84%)
- No - 183 (15%)
- Not Answered - 16 (1%)

The consultation received 1206 responses to Question 1. The majority of responses, 1023 (84%), were supportive of change to the current statutory storage limit of ten years.

Question 2: Should storage limits increase, decrease or stay the same?

- Increase - 902 (74%)
- Decrease - 155 (13%)
- Stay the Same - 150 (12%)
- Not Answered - 15 (1%)

Question 2 asked about the type(s) of change that people would like to see to statutory storage limits. The consultation received 1206 responses to Question 2, with the majority, 902 (74%), wishing to see the limit increase from the current ten years. A further 155 respondents (13%) responded that they would like to see the limit decrease. 150 respondents (12%) were content with the current ten-year limit.

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

Free text feedback to questions 4, 6, and 7 is grouped together based on common themes below. These questions did not provide the respondents with pre-existing answers to choose from.

The consultation received 837 free-text responses to Question 4. Those in favour of increasing the ten-year storage limit (74% of the total respondents to the consultation) most frequently responded that the current limit is outdated, fails to take into consideration scientific and societal advances, and limits individual choice. About a tenth of respondents highlighted that since the introduction of the HFE Act, new freezing and storage techniques, including vitrification, have been introduced, which greatly enhance the viability of eggs, sperm, and embryo following cryopreservation.

About half of respondents to this question noted that an increase in storage limits would allow for more flexible family formation, balancing the interests of donors and children, would give individuals more autonomy over their reproductive choices and would have a particularly positive impact on women's reproductive rights.

Respondents also noted that the current fixed ten-year limit failed to consider individual circumstances, including time to recover from serious illness, and that it caused unnecessary distress and reduced the opportunities for donors to access their own gametes.

Many respondents highlighted that it was inconsistent and unfair that renewable storage periods of 10 years up to a 55-year maximum was allowed in cases of premature infertility, but only ten years in all other circumstances. Several respondents commented that destroying the embryos after ten years was wasteful.

Question 6: Why do you think that the limit should be decreased?

The consultation received 145 free-text responses to Question 6. About half of those in favour of decreasing the ten-year storage limit (13% of the total respondents to the consultation) expressed a particular concern in relation to embryo storage. The objections centred on the premise that embryos are human life and that life starts at conception, therefore embryos should be treated with respect and should not be stored or destroyed.

Respondents argued that embryos should be implanted into the mother's womb as soon as possible and that storage was not natural as it would put the life of an individual on hold. About a third of these respondents stated explicitly that their religion was a guiding influence in reaching this viewpoint.

About a tenth of respondents to the question noted that increasing the storage limits might encourage older pregnancies, which could have negative implications for both the parents and the child. Finally, some respondents suggested that a reduced limit would benefit the NHS and that instead of storing embryos, the option of adopting or fostering should be pursued.

Question 7: Why do you think that the limit should stay the same?

The consultation received 143 free-text responses to Question 7. About half of those in favour of the current limit staying in place (12% of the total respondents to the consultation) felt that ten years provided individuals with enough time to decide if they wanted to start a family. Many thought that ten years was sufficient to deal with serious illness and provided individuals with time to undergo fertility treatment, if this was required. Some respondents did agree that the ten-year limit could be increased in exceptional circumstances for medical reasons, as is the case now.

About a fifth of respondents raised concerns that an extension to the limit could be seen as encouraging people to start a family later in life and that the quality of gametes and embryos would deteriorate to the detriment of the pregnant mother and child. Respondents questioned whether there was enough scientific evidence to support an increase. Finally, a small proportion of respondents cited possible increased costs to the NHS, if storage limits were extended.

Questions 3 and 5: What should the limit be changed to?

As mentioned, the responses to Questions 3 and 5 have been combined to help better understand the range of views on a new storage limit. The consultation received 897 free-text responses to Question 3 asking whether the limit should be increased, and what the new limit should be. There were 154 free-text responses to Question 5 asking whether the limit should be decreased, and what the new limit should be.

Table 1 Breakdown of the responses to Questions 3 and 5.

Proposed new limits	Number of respondents supporting each option
0 years	23
1-2 years	72
3-9 years	54
15 years	55
20 years	240
30-35 years	26
50-55 years	16
Age 40-55	73
Age 60	<10
Menopause	<10

Donor's lifetime	276
Unlimited storage	139
Case by case basis	39
As short as possible	<10

Some responses could not be easily assigned into a category and are excluded from the table. Categories with fewer than 10 responses are depicted as <10 so that respondents are not identifiable.

A range of proposals was put forward about how much the current ten-year limit should be changed to. The most popular proposal, supported by about 26% of respondents, was that the limit should be extended to match the donor's lifetime. The second most popular view supported by 23% of respondents was the current limits should be extended to 20 years. Many respondents supported no limit in place.

If answers in support of extending the limit to match the donor's lifetime and to not have a limit are combined, they constitute 39% of responses.

Part 2: Additional conditions to be applied to those seeking to freeze embryos or gametes

This section focuses on consultation questions 8-9, which asked about additional conditions that might be applied to individuals seeking to freeze their gametes and embryos.

Question 8: Should there be conditions applied to people beyond a certain limit?

- Yes - 655 (54%)
- No - 547 (45%)
- Not Answered - 20 (2%)

The consultation received 1202 responses to Question 8. The majority - 655 (54%) - responded that they wished to see additional criteria applied to those seeking to freeze their gametes.

Question 9: What do you think these conditions should be?

The consultation received 395 free-text responses to Question 9. Respondents proposed several different conditions, with the most common being an upper age limit of the donor's 50th birthday to discourage older parents.

Additional conditions supported by respondents included:

- storage should be renewed periodically based on clinical assessment
- extension should only be provided to those with a clinical need, for example due to illness or premature infertility
- costs of extended storage should be met by the donors
- there should be regular contact between the clinic and the donor to provide renewed consent and confirm the need for ongoing storage
- the donor should undertake a physical and mental health assessment to confirm ongoing suitability for becoming a parent
- the latest scientific advice should be considered, including the condition and suitability of the gametes and embryos for use

Part 3: Different limits for eggs, sperm, and embryos

This section focuses on consultation questions 10-11, which asked whether eggs, sperm, and embryos should be treated the same or if different limits should be applied to each of them.

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

- Yes - 239 (19.5%)
- No - 582 (47.5%)
- Not Answered - 401 (33%)

The consultation received 821 responses to Question 10, with the majority - 582 (47.5%) - wishing to see the same limit applied to eggs, sperm, and embryos.

Question 11: If they should each have their own limit, what should that be?

The consultation received 200 free-text responses to Question 11, with a wide-range of views.

Table 2 Breakdown of the responses to Question 11.

Proposed new limits	Number of respondents supporting each option		
	Eggs	Sperm	Embryo
0-5 years	11	18	35
6-10 years	38	47	56
15-18 years	15	13	27
20-25 years	78	59	44
30-35 years	24	19	17
40-45 years	<10	<10	<10
50-55 years	25	31	17
60 -70 years	<10	<10	0
80+ years	<10	<10	<10

Categories with fewer than 10 responses are depicted as <10 so that respondents are not identifiable.

Part 4: Review of the 2009 Storage Regulations for the prematurely infertile

This section focuses on consultation questions 12-20, examining the suitability of the 2009 Regulations, which were intended to specifically address the needs of prematurely infertile patients.

The 2009 Storage Regulations allow for extensions to the statutory storage period of ten years, if the person storing the embryos or gametes can provide a written medical opinion that they are prematurely infertile or likely to become prematurely infertile. Extensions can be given for up to ten years at a time, up to a maximum storage limit of 55 years. In light of any changes to the statutory storage period, these regulations would need to be updated.

Questions 12- 20 asked for views about how the regulations may need to be updated considering potential changes to the primary legislation.

Question 12: Do you think that the provisions in the regulations need updating?

- Yes - 925 (76%)
- No - 272 (22%)
- Not Answered - 25 (2%)

The consultation received 1197 responses to Question 12, with the majority - 925 (76%) - in support of revising the 2009 Regulations.

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

- Yes - 718 (59%)
- No - 476 (39%)
- Not Answered - 28 (2%)

The consultation received 1194 responses Question 13, with just over half of respondents - 718 (59%) - agreeing that it is important to maintain the current provisions for the clinically infertile.

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

The consultation received 470 free-text responses to Question 14. Many of these contained similar answers to Question 6. The broad themes in the responses were:

- there were objections to any storage of embryos on ethical or religious grounds
- calls to allow donors to decide how long to keep their gametes/embryos in storage
- recommendations that the mother's age should be considered when it comes to using frozen gametes or embryos and that the restrictions should reflect natural fertility - for example, women should not be able to use frozen eggs or embryos past their early 50s
- arguments that in the interests of equality, the same restrictions should apply to the storage and use of sperm and eggs

Question 15: Is the ten-year frequency of renewal still appropriate?

- Yes - 600 (49%)
- No - 587 (48%)
- Not Answered - 35 (3%)

The consultation received 1187 responses to Question 15, with just under half of respondents - 600 (49%) - expressing a view that regular appraisals between the clinics and the patients should continue to take place at ten-year intervals, as is the case currently for the prematurely infertile.

Question 16: If not, what period of time do you think is more appropriate and why?

The consultation received 496 free-text responses to Question 16.

Table 3 Breakdown of the responses to Question 16.

Proposed renewal frequency	Number of respondents supporting each option
No limit	168

Up to one year	13
2-5 years	92
7-10 years	17
12-15 years	17
20-25 years	106
30-35 years	13
40-55 years	18
Age 50-60	14
Case by case basis	25

Some responses could not be easily assigned into a category, and these are excluded from the table.

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

- Yes - 704 (58%)
- No - 491 (40%)
- Not Answered - 27 (2%)

The consultation received 1195 responses to Question 17, with the majority - 704 (58%) - indicating that the current storage limit is still appropriate for those with a medical need.

Question 18: If not, what maximum period of time for those who may be prematurely infertile would be appropriate?

The consultation received 426 free-text responses to Question 18.

Table 4 Breakdown of the responses to Question 18.

No storage	26
1-5 years	17
10-15 years	<10
20-25 years	16
30-35 years	25

40-45 years	32
50-55 years	13
60-70 years	<10
Age 35	<10
Age 40-55	95
Age 60-65	<10
Donor's lifetime	105
Unlimited storage	61
Case by case basis	14

Some responses could not be easily assigned into a category, and these are excluded from the table. Categories with fewer than 10 responses are depicted as <10 so that respondents are not identifiable.

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

Questions 19 and 20 asked about different limits for eggs, sperm, and embryo, relating specifically to the prematurely infertile. The responses did not provide any additional information to what was already said in response to Questions 10 and 11.

Government Response

Government Response to Questions 1-7: changes to statutory limits

The consultation responses reflected a broad range of opinions, including from:

- individuals who were supportive of extending storage limits for gametes and embryos either because of being affected by infertility or because they had to defer starting a family for a later stage in their life
- healthcare workers in this field and their professional organisations, who supported those directly impacted by the current restrictions and held positive views on extending the current storage limits
- individuals whose views were strongly informed by their faith, who expressed concerns about the extension of storage limits and raised objections to the use of embryos outside the human body to create life

The government has considered all responses to the consultation and noted that the majority of respondents (74%) wished to see an increase to statutory storage limits, whilst recognising that there were a wide range of views about what the new limit should be.

When considering the consultation responses, the government applied four key tests to develop the new policy position. These were:

- ensuring equity for all patients
- facilitating greater reproductive choice
- reducing administrative burden to fertility clinics and the regulator
- ensuring public acceptability

The government concluded that the policy which best balances the four tests above is to offer everyone a new approach based on 10-year renewable storage periods up to a maximum of 55 years, regardless of medical need. This policy will provide equity to all fertility patients, irrespective of medical need, wishing to freeze their gametes or embryos. The proposed policy will also facilitate choice, through enabling individuals to store their gametes or embryos for longer and make an unpressured choice to start a family later in life, if that is their preference. The policy change will be particularly positive for women, who are impacted more by clinical infertility as well as earlier onset of age-related fertility decline and the negative psychological consequences. The proposed policy will over time

simplify the administrative tasks for the regulator, the Human Fertilisation and Embryology Authority, and for fertility clinics and has the support of key sector organisations.

The government therefore intends to bring in legislation to offer renewable 10-year storage periods to a maximum of 55 years for eggs, sperm, and embryos, for all, regardless of medical need.

We note that a frequently raised concern about the extension of storage limits was that it might encourage people to start a family later in life and that this would be to the detriment of the mother and child.

In the UK, the National Institute for Care Excellence (NICE) fertility guidance recommends an age range for fertility treatment of 23 to 42 years for NHS treatment, based on the clinical evidence of treatment effectiveness. Private providers do not apply a direct age cut-off for treatment but make an individual welfare assessment before proceeding. Fertility centres are under statutory obligation to take account of the welfare of any resulting or affected child. Clinics must also provide a suitable opportunity to receive proper counselling to all parties involved. Importantly, the HFE Act allows the regulator to remove the licences from clinics if they fail to comply to carry out these duties. Clinics will also consider the social circumstances of the patients and whether the mother is fit and healthy for pregnancy, alongside broader professional duties of care to their patients.

In introducing new legislation, the HFEA will update its Code of Practice, which sets out the standards required to be met by clinics and assessed through inspection. Through this process the HFEA will ensure that offers of fertility treatment will meet all the required high professional standards. The government's view is that these regulatory measures provide a strong and appropriate safeguard against unsuitable treatment that might endanger mother or child.

Government Response to Questions 8-9: additional conditions to be applied to those seeking to freeze embryos or gametes

The government recognises that any revised scheme would have administrative implications for the sector regulator, the HFEA, and fertility clinics. The HFEA recommended in their response, as did many individuals, that whatever the new extended limits, there should be a review, including additional counselling, between the patient and the clinic every ten years to ensure the stored material was still required and consent was renewed. They also suggested that if patients were not contactable or did not pay storage fees as agreed, clinics should have the power to dispose of material, once reasonable attempts at contact have been made. The government has considered these proposals in detail and agrees with that position.

Therefore, the government proposes that as part of the ten-year review, the person(s) storing: a) will need to confirm the material is intended for their own use; b) they need to confirm their consent to continue storage; and c) they will need to be offered counselling.

Specifying this in legislation will give weight to these requirements and ensure clinical and patient compliance.

Government Response to Questions 10-11: different limits for eggs, sperm, and embryos

The government noted that there was a marked drop-off in response to these questions, with only 821 respondents providing an answer as to whether there should be a different storage limit for eggs, sperm, and embryos. However, of those who responded, 582 favoured the same storage limit for gametes and embryos.

The government considered the responses and agrees that a maximum 55-year storage period should apply to eggs, sperm, and embryos equally.

Government Response to Questions 12-20: review of the 2009 Storage Regulations for the prematurely infertile

The government noted that there was general support for keeping the storage limit for the clinically infertile at 55 years and that a periodic review should be in place, with most respondents supporting a ten-year review period, as is the case now.

The government recognises that there is broad support for the maintenance of provisions for the clinically infertile and that changes to the legislation must not infringe on the current rights of this patient group. The views expressed in the consultation advocated for the current 55-year limit to remain in place.

In view of the responses and wider considerations, the government has decided to set aside the 2009 Storage Limits Regulations and update the statutory storage limits to an offer of 10 year renewable storage periods with a maximum of 55 years for all, regardless of medical need, as mentioned in response to Questions 1-7.

This will greatly simplify the administrative burden on clinics and will make clear to all individuals their rights when it comes to freezing their gametes and embryos.

Next Steps

Following consultation, the government will take steps to change the legislation to allow for 10-year renewable storage periods for frozen eggs, sperm, and embryos up to a maximum of 55 years, when parliamentary time allows.

We will undertake further focused consultation with key stakeholders on the consequential impact of the proposed new scheme for some particular storage classifications to inform future legislation.

The new approach will provide individuals with greater choice when it comes to family planning and will ensure that there is parity between those wanting to freeze their gametes or embryos for medical and for social reasons.

The government will work with the regulator, the Human Fertilisation and Embryology Authority, to ensure that, when the recommended changes are made, the changes are communicated to clinics and patients in an appropriate manner and regulatory oversight is provided for the safe implementation of the changes.

Conclusion

Family units and family formation in the UK are vastly different today than they were when the Human Fertilisation and Embryology Act (the "HFE Act") was introduced and last reviewed. In a modern society, individuals are starting their families later in life and are increasingly choosing to freeze their gametes (eggs and sperm) and embryos to preserve fertility. The reasons for this are diverse but can include not being ready or able to start a family, medical conditions that might lead to premature infertility, or undergoing gender re-assignment.

The HFE Act sets the statutory storage limits for gametes and embryos at ten years, with the possibility of extension up to 55 years for those who can demonstrate a clinical need. The government recognises that these current arrangements are increasingly disadvantageous towards women and unnecessarily restrictive of individual freedom of choice about when to start a family when science has progressed so much.

In February 2020, we ran a public consultation to seek views regarding changes to the current legislation. The consultation responses and our analysis of policy options have indicated that a change is now appropriate and a new approach of ten year renewable storage periods up to a maximum of 55 years for gametes and embryos and available to all, irrespective of medical need, should be introduced. The new renewable provisions will require ongoing written consent from the patient to continue storage and access to counselling. This will ensure that people have a proper opportunity to consider their reproductive needs going forward and can take professional advice, if they wish to.

The proposed policy change is intended to facilitate greater reproductive choice and will allow for less stressful family formation in a changing society. Importantly, it will provide equity for all, regardless of medical need, and will help reduce administrative burden for clinics and the regulator.

The government will legislate when Parliamentary time allows.

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