

Summary: Intervention & Options

Department /Agency:
Department of Health

Title:
Impact Assessment for the HFE (Statutory Storage
Period for Embryos and Gametes) Regulations.

Stage: FINAL

Version: FINAL

Date: June 2009

Related Publications: Consultation report on regulations to implement the HFE Act 2008 – Part 1 The HFE (Statutory Storage Period for Embryos and Gametes) Regulations

Available to view or download at:

<http://www.dh.gov.uk>

Contact for enquiries: Stephanie Croker

Telephone: 020 7972 3054

What is the problem under consideration? Why is government intervention necessary?

Sperm and eggs (gametes), or embryos can be stored (frozen) for later treatment if they are not used immediately. Under the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") gametes can be stored for up to ten years and embryos for up to five. Regulations enable these storage periods to be extended until the person who will use them is 55 years of age, if certain criteria relating to infertility are met.

The current regulations need to be updated to reflect the changes made to the statutory limits and the definitions by the Human Fertilisation and Embryology Act 2008 ("the 2008 Act"), and to allow for more people to extend.

What are the policy objectives and the intended effects?

In updating the current regulations, the Government intends to ensure that a wider group of people who suffer from premature infertility are able to extend storage to include, for example, situations where people require surrogates or are using gametes or embryos from a donor. We propose introducing successive ten year extended storage periods until a maximum storage period of 55 years for that embryo or gamete is reached, rather than having an age-related limit.

What policy options have been considered? Please justify any preferred option.

1. Update the regulations to significantly widen the criteria for extension of storage, to allow many more people to extend storage; including those who are not prematurely infertile.
2. Update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years. This is the preferred option; it provides for more situations, whilst maintaining effective regulation.
3. Update the regulations to take account of the changes made by the 2008 Act, but make no additional changes to the criteria in the current regulations.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The regulations have been subject to a three month public consultation, January 2009 to March 2009. Post-implementation monitoring by the HFEA will be ongoing.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the Responsible Minister:



Date:

25.6.09

Summary: Analysis & Evidence

Policy Option: 2

Description: Update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years.

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'. The costing is based on the assumption that an extra 900 people take up this opportunity each year (including those storing donor gametes/embryos or who require a surrogate), with average storage costs of £200 pa. The net present cost for the decade starting 2010 is £9.6m.
	One-off (Transition)	Yrs	
	£ 0		
	Average Annual Cost (excluding one-off)		
	£ 1.15m		Total Cost (PV) £9.6m
Other key non-monetised costs by 'main affected groups' There will be a temporary and minimal increase in administrative burdens as clinics operate between two sets of regulations during the transitional period. The HFEA is to produce new guidance, which has been accounted for as part of the changes to the Code of Practice needed to implement the 2008 Act.			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups'. Storage is an optional cost for patients, but for those with gametes or embryos in storage, the benefits are unquantifiable in monetary terms and in their view, exceed any costs that they have to pay.
	One-off	Yrs	
	£ N/A		
	Average Annual Benefit (excluding one-off)		
	£ 1.15m		Total Benefit (PV) £ >9.6m
Other key non-monetised benefits by 'main affected groups' Other benefits include; clearer set of regulations applying to both gametes and embryos for purposes of extension due to infertility, and more people able to extend storage. The rolling extension period will encourage patients and clinics to improve how they maintain contact over the extended storage period (paragraph 21).			

Key Assumptions/Sensitivities/Risks The costs above are based on the assumption that 50% more people will extend storage than do currently (900 people). This estimate includes those storing donated gametes and/or require surrogacy. (Paragraphs 53-56). The net present cost assumes that 75% of those who extend storage will have stopped storing a decade later.

Price Base Year N/A	Time Period Years N/A	Net Benefit Range (NPV) £ N/A	NET BENEFIT (NPV Best estimate) £ Unknown, but positive.
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What is the geographic coverage of the policy/option?		UK		
On what date will the policy be implemented?		October 2009		
Which organisation(s) will enforce the policy?		HFEA		
What is the total annual cost of enforcement for these organisations?		£N/A		
Does enforcement comply with Hampton principles?		Yes		
Will implementation go beyond minimum EU requirements?		Yes		
What is the value of the proposed offsetting measure per year?		£N/A		
What is the value of changes in greenhouse gas emissions?		£ N/A		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium N/A	Large N/A
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of	£ 0	Decrease of	£ 0
Net Impact		£ 0	

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

Introduction

1. Gametes and embryos can be stored for a period of 10 and 5 years respectively under the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"). This period can be extended in circumstances set out in regulations. Section 14(5) of the 1990 Act, sets out the regulation-making power for extending or shortening the storage period for gametes, embryos and human admixed embryos.
2. The current regulations are the Human Fertilisation and Embryology (Statutory Storage for Embryos) Regulations ("the 1996 Regulations") and the Human Fertilisation and Embryology (Statutory Storage) Regulations 1991 ("the 1991 Regulations")¹.
3. The 2008 Act changes the statutory storage period for embryos to ten years, bringing it into line with the statutory storage period for gametes. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ("the Storage Regulations"), made under Section 14(5) as amended by the 2008 Act² will replace the 1991 and the 1996 Regulations.
4. The Storage Regulations will set out the new statutory storage period for gametes and embryos, and the criteria for extension.
5. The Storage Regulations are subject to the negative procedure.
6. The Impact Assessment for the Human Fertilisation and Embryology Bill can be found on the Department of Health's website – http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211³

Reason for intervention

7. The 1991 and 1996 Regulations need to be updated to reflect changes made by the 2008 Act, which apply a 10 year storage period for embryos *and* gametes. The Department also wishes to take the opportunity to update the 1991 and 1996 Regulations to address situations raised during debates on the Human Fertilisation and Embryology Bill⁴. For example, proposals were made that the extensions of storage periods should be permitted in more cases including surrogacy or the storage of donated gametes, to introduce more flexibility. In order to respond to these concerns the Department wishes to widen the provision of extended storage (subject to the infertility criteria being met) to benefit those people storing donor gametes or embryos, and those who wish to use a surrogate.

Background

The 1991 and the 1996 Regulations.

8. Under the 1991 Regulations the storage period for gametes can be extended if:
 - the gamete provider was aged under 45 when the gametes were provided
 - the gametes are for their own use, and
 - a medical practitioner certifies in writing that their fertility since providing the gametes has or is likely to become significantly impaired.

¹ S.I. 1991/1540. and S.I. 1996/375

² The Department of Health has produced an illustrative version of the 1990 Act, as amended by the 2008 Act. Section 14(5), as amended, can be viewed on the Department's website - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205

³ Accessed 10 June 2009.

⁴ 12 May 2008; Hansard columns 1145-1147 and 5 June 2008; Hansard columns 137-142

The number of years the storage period can be extended by is set by reference to the gamete provider's age – with an absolute limit on storage once they reach 55 years of age.

9. Under the 1996 Regulations the storage period for embryos can be extended if:
- the people whose gametes were used to create the embryo consent to extended storage
 - the woman to be treated is aged under 50 years when the embryos are first stored (and she is not intending to act as a surrogate), and
 - two medical practitioners have certified in writing that the gamete providers, or the woman being treated if she is not a gamete provider is or is likely to become prematurely and completely infertile.

Again the extension periods are set by reference to the age of the gamete providers or woman being treated with an absolute limit on storage once they reach 55 years of age.

10. In addition, under the 1996 Regulations provision is made to enable a shorter extension period of ten years for cases where the gamete provider or woman being treated has or is likely to develop significantly impaired fertility or where embryos have been tested to avoid passing on an inherited medical condition. Again there is a cap on storage once the woman being treated reaches 55 years of age.

Policy Objectives

11. The circumstances in which storage of gametes and embryos can be extended will be set out in one single set of Storage Regulations to replace the two sets that are currently in place. As the 2008 Act amended the 1990 Act to provide a ten year statutory storage period for embryos, to mirror that for gametes, it was also felt appropriate for the extension of both storage periods to be subject to the same criteria. The Government recognises that a human embryo has a special status, but extension relates to the patient's circumstances rather than to what is being stored.

Infertility criteria

12. In the 1991 and the 1996 Regulations, the infertility test for extension beyond ten years is worded differently. In the 1991 Regulations the test for extension is "significantly impaired" fertility and in the 1996 Regulations, the test for extension beyond 10 years is "prematurely and completely infertile." Although the test in the 1996 Regulations is worded more stringently than in the 1991 Regulations, in practice they were interpreted similarly, in that extension over ten years was granted only to medical cases of premature infertility. Under the Storage Regulations we propose a test of "premature infertility", which we would expect to be interpreted in a similar way to the current tests. We chose the wording "prematurely infertile" because during consultation, some clinicians stated that 'significantly infertile' or "completely infertile" was unclear from a medical perspective. Although the term infertility is used generally to describe those people who require medical assistance to achieve a pregnancy, strictly speaking, from a medical perspective, it means people who are unable to have children at all. In this context, to be completely infertile or significantly infertile does not make sense. Deciding who meets the criteria of "premature infertility" will remain a clinical decision, allowing a registered medical practitioner to take into account the individual circumstances, alongside guidance provided by the HFEA.

Who should benefit from the extended storage provision?

13. It was felt that the scope of the 1991 and 1996 Regulations should be extended and that extended storage should be allowed not only for the gamete providers or woman being treated, but also for those who used donated embryos or gametes. Additionally, extension should be allowed where a couple require a surrogate, for example, in cases where a woman might store her eggs or embryos prior to having a hysterectomy, and so would need a surrogate in order to use them. The Storage Regulations provide that extension of storage of gametes or embryos could be permitted if the person for whom the gametes or embryos

were being stored (“the person to be treated”) is or is likely to become prematurely infertile and the appropriate consents were in place.

The storage limit

14. On reflection, the Department of Health considered that it was no longer appropriate for the storage periods to be set by reference to the age of the people who will be treated. No such age limit is specified under the provisions of the 1990 Act itself, and it meant that there were people who were disadvantaged; particularly men who wished to use their stored sperm in treatment and who were arguably still “prematurely infertile” at 56. Prior to consultation, the draft Storage Regulations proposed that the 55 year age limit would be replaced by a time limit of a maximum of 55 years, irrespective of the age at which the person first put the gametes/embryos in storage.
15. As a result of consultation on the draft Storage Regulations (see paragraphs below), the Government propose to replace the age limit in the 1991 and 1996 Regulations with a rolling extension. The Storage Regulations enable the storage period to be extended at any point within the initial ten year period for a further ten years if the gamete provider, person to be treated or person to whom the embryo or gamete has been allocated is or is likely to become prematurely infertile. The storage period may then be extended for subsequent ten year periods, until a maximum storage period of 55 years is reached, provided that the premature infertility criteria is demonstrated at any time within each ten year period.

The transitional provisions

16. The Storage Regulations also make 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 Storage Regulations are met.
17. Any embryos in storage that are subject to the original storage period on 1 October 2009 (five years or less) will automatically benefit from the statutory storage period of 10 years from the date they were first placed in storage. In practice the gamete providers will have to consent to how long the embryo can actually be stored for. In addition if the conditions set out in the Storage Regulations are met then the storage period for those embryos will be the rolling extension period as described under the Storage Regulations.
18. People who have already extended storage of their embryos under the 1996 Regulations will be able to benefit from the rolling storage period as described under the Storage Regulations if they meet the conditions set out in the Storage Regulations. If not, the storage period will remain the period set out in the 1996 Regulations.
19. People who have gametes in storage (either under the ten year period or who have extended under the 1991 Regulations) will be able to benefit from the rolling storage period if they meet the conditions set out in the Storage Regulations. If they do not then the storage period will remain the period set out in the 1991 Regulations, or ten years as applicable.

Consultation

20. We undertook a widespread public consultation on the draft Storage Regulations over three months from January to March 2009. This consultation allowed different groups of people to respond to the proposed policy. A consultation report was published on the Department of Health Website in May 2009.⁵
21. Many organisations supported the proposal that the same criteria for extension should apply irrespective of whether gametes or embryos were being stored. There was also support for the proposal to retain the principle of allowing extension for exceptional circumstances, but to allow extension where donated gametes, or a surrogate were required. Many responses

⁵ Available online at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098882

from individuals, religious and public interest groups raised ethical concerns; in particular, there was unease about not having an age limit. Consultation responses from clinicians and professionals described potential difficulties with the regulations in practice. These included difficulties associated with keeping in touch with patients throughout a long storage period. The rolling extension policy (paragraph 15) goes some way to address both the ethical concerns about removing the age limit, and the practical concerns about any administration burden on clinics during a long storage period. The rolling extension, however, still allows flexibility for clinicians to take into account the circumstances of the person in question.

22. Prior to consultation, the draft Storage Regulations included a provision to enable extended storage of embryos in cases where an embryo has been tested to avoid an inherited medical condition. In such cases, the draft Storage Regulations provided that embryos could be stored for 55 years providing the necessary consents were in place. This built upon the provision in the 1996 Regulations, which enable extended storage in cases where the embryos have been tested to avoid passing on a genetic medical condition where there is a risk that one of the gamete providers might carry an inheritable medical condition. The Department of Health in consultation with stakeholders have been unable to envisage any circumstances in which it would be necessary or appropriate to store these embryos for longer than ten years, it is also inconsistent with the general criteria for extension. This provision has therefore been removed from the Storage Regulations.
23. Following consultation, the Government proposed the following changes to the draft Storage Regulations consulted upon:
- that storage of embryos and gametes can be extended beyond 10 years where someone is (or is likely to become) prematurely infertile (but not automatically following embryo testing)
 - that the overall time limit of 55 years is replaced with a rolling extension of successive ten year periods up to a maximum of 55 years.

These changes have been incorporated into the discussion of the preferred option (2) in this Impact Assessment.

Links to other policy areas and strategies/ programmes of work

24. These regulations were one of four sets of regulations on which the Department of Health consulted upon in order to implement the 2008 Act. The other three sets of regulations related to the HFEA procedure for revocation, variation or refusal of a licence, the procedure for appealing against an HFEA licensing decision, and regulations relating to the procedure for the disclosure of identifying information for research purposes. The consultation reports relating to the response to the other three sets of regulations are available online.⁶

Policy Options

25. In reviewing the Storage Regulations, three potential options were identified:
- Option 1 – update the regulations to significantly widen the criteria for extension of storage, to allow many more people to extend storage including those who are not prematurely infertile.
 - Option 2 – update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years. This is the preferred option; it provides for more situations, whilst maintaining effective regulation.
 - Option 3 – update the regulations to take account of the changes made by the 2008 Act, but make no additional changes to the criteria in the current regulations

⁶ http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098882

Option 1 – update the regulations to significantly widen the criteria for extension of storage, to allow many more people to extend storage including those who are not prematurely infertile.

26. This would be beyond the scope of the regulatory power and against the intentions of Parliament when passing the legislation.

Preferred Option 2 – Update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years.

27. This option would broaden the provision for extending storage, allowing for more people with premature infertility to extend. For example, those storing donated gametes or embryos and those who wish to use a surrogate, but limits this to people who are prematurely infertile or who are likely to become prematurely infertile.

28. This option provides for people who, for clinical reasons, may need to store their embryos or gametes for longer and ensures equality in terms of age or gender; allowing, for example, 56 year old men to have treatment using their stored gametes if they satisfy the medical requirements.

29. The premature infertility criteria will need to be met before storage is extended for a further ten-year period. This test will prevent people from storing gametes or embryos after the average natural childbearing age.

30. In addition, under the provisions of the 1990 Act (as amended by the 2008 Act) there is a licence condition that requires clinics to consider the “welfare of the child” before providing treatment, including that child’s need for supportive parenting. The detail of this consideration is for the HFEA to determine, however, it means that parents who might be considered to be “prematurely infertile” at the point that extension is granted, would be assessed still further before having any treatment with their stored gametes or embryos within that extended storage period.

Option 3 - Update the regulations to take into account the changes made by the 2008 Act, but make no additional changes to the criteria in the current regulations.

31. The regulations would be updated to take into account the statutory changes made by the 2008 Act. However, this option means retaining the current regulatory provisions and structures. Therefore the situations identified in Parliament (such as the mother who donated gametes for her daughter who had Turner’s syndrome – paragraph 39) that contributed to the Government’s decision to review the law in this area, would not be addressed.

32. Retaining a maximum age limit of 55 as above could disadvantage some individuals, particularly men who at 56 might wish to have children using stored gametes and who, arguably, are not yet “prematurely infertile”.

33. There have been several cases where men, who have been treated for cancer and stored sperm but have started their family late, have not been able to continue to store their sperm after the age of 55 despite the fact that they had not yet completed their family.

Sectors and groups affected

34. According to the HFEA, there are currently 93 centres licensed to store gametes or embryos. Licensed centres, clinical staff, their patients, and, to a lesser extent, donors, will be directly or indirectly affected by the proposed measure.

35. The legislation will extend to the United Kingdom. The regulator will also have powers to assist any other public authority in the UK.

Benefits and risks

Option 1: update the regulations to significantly widening the criteria for extension of storage, to allow many more people to extend storage including those who are not prematurely infertile.

36. A very wide exception would be likely to go beyond the scope of the power and would be contrary to the intentions of Parliament who, when passing the legislation, put in place the statutory storage period and a regulation-making power to allow for exceptions.

Preferred Option 2 – Update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years.

37. The provisions allow for a wider range of individuals, suffering from premature infertility, (such as those with donor gametes or embryos allocated to them), to extend storage. The cost of storing gametes or embryos is voluntary, and those who take up the opportunity do so because in their view, the benefits exceed the costs that they have to pay.
38. A non age-related maximum storage limit of 55 years would mean that, for example, men who were prematurely infertile could store gametes or embryos, thereby preserving the opportunity for them to father children for a length of time equivalent to those fertile men who do not need to store. For example, allowing for a man who put gametes in storage before cancer treatment, after which he became prematurely infertile, to start a family when he was in his 50's.
39. The Storage Regulations would also allow individuals who had gametes allocated to them by a donor to be allowed to extend the storage period for those gametes or embryos, with the donor's consent. This would include the case raised in Parliament of the young girl with Turner's syndrome, whose mother had wished to put her own eggs in storage for her daughter's use⁷. The 1991 Regulations would only have allowed the eggs to be stored for ten years, and not extended as they were not intended for use by the gamete provider. The Storage Regulations will permit extended storage in this example, as the daughter would use the gametes, she would be the "person to be treated", who would meet the requirements of the Storage Regulations.
40. Under the 1996 and 1991 Regulations, two registered medical practitioners are required to certify that the gamete provider or woman to be treated is, or will become prematurely infertile in order to extend. Under the Storage Regulations, we propose that only one registered medical practitioner's opinion is needed, reducing the regulatory burden.
41. Maintaining the principle, that extension should only be for medical infertility, and maintaining an overall storage limit reduces the risk of overstretched clinical capacity, whilst the rolling extension will help clinics manage the storage period more effectively.
42. The extended storage limit has been changed from a sliding scale up to an age related 55 years, to a system of rolling extension up to a maximum time-period of 55 years. This would reduce the risk that some people would be prevented from storing gametes or embryos past their 55th birthday despite the fact that they were prematurely infertile.
43. The rolling extension means that if they fulfil the criteria for extension, patients can extend storage in successive ten-year periods, until a maximum time limit of 55 years. At some point during each ten year extension, patients must still fulfil the original criteria, i.e. that they are, or are at risk of becoming prematurely infertile in order to get a further ten years. The rolling extension will mean that fewer and fewer patients are continuing to store at the close of each ten year period; we have estimated that 75% of patients who extend storage will have stopped storing a decade later.
44. This rolling extension was supported in order to both help clinicians to manage their administrative burdens, and in response to ethical concerns that the 55 year time period could allow people to have children long after the average natural childbearing age. The risk

⁷ 5 June 2008; Hansard column 140

that a longer storage period will allow older people to have babies is low, as the patients will be assessed against the criteria for extension (“premature infertility”) every ten years. All patients are assessed by the clinic who will also consider the ‘welfare of the child’ before treatment.

45. The Storage Regulations also make transitional provision to enable embryos or gametes which are already in storage on 1 October 2009 to benefit from the new extended storage periods. 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 will benefit from the new extended storage periods, if consent is in place and the conditions under the Storage Regulations are met. For those who do not fulfil the criteria as set out in the Storage Regulations, the storage period will be as agreed under the 1991 or 1996 Regulations, or will be ten years from the date the gamete or embryo was first placed in storage (the new statutory storage period inserted by the 2008 Act).
46. There would be minimal transitional burdens on both the HFEA and the clinics. This is because transitional provisions will allow patients whose embryos or gametes are stored when the Storage Regulations come into force to be able to benefit from the new provisions if they fulfil the criteria for extending storage and the relevant consents are in place. For those who do not fulfil the new criteria, the storage period will be either ten years from the date the embryo or gamete was first placed into storage or the period determined under the current 1991 or 1996 Regulations. This means that clinics may have gametes and embryos with storage periods as described according to the 1991 Regulations, or the 1996 Regulations, as well as other gametes and embryos which are being stored under the new system. We drew attention to this transitional burden in the impact assessment, which was published as part of the consultation on these Storage Regulations, and discussed the transitional burdens in consultation meetings with clinical representatives.

Option 3 - Update the regulations to take into account the changes made by the 2008 Act, but make no additional changes to the criteria in the current regulations.

47. In maintaining the *status quo* in terms of the upper age limit for extension, and the requirements to extend, this option has the short-term advantage of temporary avoidance of costs and uncertainty/or disruption associated with change.

Costs

48. Some of the changes that will be introduced by the Storage Regulations are unquantifiable in monetary terms or in terms of direct effects.
49. There will be voluntary costs as more people take advantage of the opportunity to extend storage of gametes and embryos; however, private clinics currently charge for storage so costs would largely be recouped and even some NHS clinics charge for freezing embryos.

Option 1: Significantly widening the criteria for extension of storage, to allow many more people to extend storage including those who are not prematurely infertile.

50. This option could be beyond the scope of the regulatory power and against the intentions of Parliament when passing the legislation.

Preferred Option 2 – Update the regulations to widen the provision to include those storing donor gametes/embryos and/or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years.

51. There will be minimal costs associated with updating the Storage Regulations, as updating HFEA guidance is part of a larger project to update the Code of Practice, which has already been accounted for under the Impact Assessment for the 2008 Act as a whole.
52. Storage is an optional cost for patients, but for those with gametes or embryos in storage the benefits are unquantifiable in monetary terms and exceed any costs that they have to pay.

53. There is limited available data about the number of patients with gametes and embryos in storage and how many extend. However, a rough estimate of future impact can be gained from the facts and figures provided by the HFEA in 2006. In 2006 there were 34,855⁸ patients receiving treatment (this includes those having treatment with fresh and stored cycles). This is used in this assessment as a proxy figure for those with gametes/embryos in storage. Applications to extend storage are estimated at a maximum of 5% of the total figure of people storing gametes and embryos in a normal year (approximately 1,800 patients).
54. Under the Storage Regulations, the number of people who would be allowed to extend storage will increase because the provision has been widened to include people storing donated gametes/embryos and those who require a surrogacy arrangement. We have based our calculations for the costings on the assumption that 900 people will take up the opportunity to extend storage each year, which would increase the number of people extending by 50% - from 1,800, to 2,700 patients. This is still a small percentage of the total number of people who store, although it is an increase in the number of people extending storage. Of those who extend storage, about 75% are assumed to have stopped storing by a decade later.
55. The assumption that 900 people will benefit from this opportunity has been calculated by using proxy figures of the number of people intending to use stored gametes or embryos with a surrogate, the number of survivors of childhood cancer who might store donated gametes, and the number of girls born in the UK with Turner's Syndrome each year.
56. The costs relating to extended storage are optional costs. More people will be provided with the opportunity to extend storage, estimated at 900 people per year storing at £200 per annum. The result is a net present cost of £9.6m, assuming a 50% increase in the number of people who store.
57. The Storage Regulations may increase a minimal regulatory burden during the transitional period as clinics have to operate under different sets of regulations in some cases. The rolling extension will necessitate that clinics contact patients who have gametes and/or embryos in extended storage more regularly, however, the regulatory impact is likely to be low, as in the consultation period we were advised that fewer people extending for long periods would balance the burden of the additional assessment every 10 years. Infertility can be diagnosed at any point during the ten years, including at the outset and by one, rather than two registered medical practitioners (as under the 1991 or 1996 Regulations).

Option 3: Update the regulations to take into account the changes made by the 2008 Act, but make no additional changes to the current regulations.

58. Costs (not including the current costs of regulation *per se*) associated with this option are difficult to quantify. They include opportunity costs for those who share the exceptional circumstances raised by those with clinical expertise, and in parliamentary debates, (such as where a mother who wishes to donate eggs to a daughter who suffers from infertility due to Turner's Syndrome) that the Storage Regulations aim to address.

⁸ This figure was provided by the *HFEA Facts & Figures 2006; Fertility Problems and Treatment* (October 2008) available online at <http://www.hfea.gov.uk/en/1215.html#additional> accessed November 27 2009.

Summary costs and benefits for preferred option

Option	Total benefit per annum	Total cost per annum
<p>Update the Storage Regulations to widen the provision to include those storing donor gametes/ embryos and/ or those who require a surrogate. Provide a rolling extension for a maximum limit of 55 years.</p>	<p>Clearer set of regulations applying to both gametes and embryos for purposes of extension due to infertility.</p> <p>Storage is an optional cost for patients, but for those with gametes or embryos in storage the benefits are unquantifiable in monetary terms and exceed any costs that they have to pay.</p> <p>Transitional provisions will allow people under the current system to benefit from extended storage period where conditions are met.</p>	<p>More people will be allowed to extend storage. The costing for this is based on the assumption of an extra 900 people taking up this opportunity each year, with average storage costs of £200 pa.</p> <p>Fewer people extending for long periods would balance the burden of the additional assessment introduced by the rolling extension.</p> <p>Costs include minimal burdens in the transitional period as some clinics may have to operate between two sets of regulations, but these will only be temporary.</p>

Equality issues

59. There can be strong religious beliefs associated with the development and use of reproductive technologies. However, storage of gametes or embryos is something that individuals may choose to do, and the benefits of the updated Storage Regulations will apply to everybody regardless of religion or belief. (This is discussed further under the annexed Equality Impact Assessment, paragraphs 34-39).
60. The Government believes that the provisions in the Storage Regulations are unlikely to have any adverse impact on equality, including with regard to race, disability, age, gender, sexual orientation and human rights.
61. Updating the Storage Regulations will have a positive effect promoting equality of opportunity and eliminating unjustifiable discrimination in terms of age and gender.
62. A full Equality Impact Assessment is at Annex A.

Enforcement, sanctions and monitoring

63. Existing law in this area is enforced through a range of sanctions including criminal penalties as well as measures attached to licensing. The remit of the HFEA has inspection and monitoring functions.

Implementation and delivery plan

64. The 1990 Act provides that the Storage Regulations are subject to the negative procedure, so they will be laid in Parliament but are not required to be debated.
65. The Storage Regulations will come into force on 1 October 2009.

Post-implementation review

66. The HFEA has specific functions to monitor developments in their field of interest and, including to advise Ministers as required. Post-implementation review of the Storage Regulations will be ongoing. The effectiveness of the HFEA will be monitored primarily through the usual procedures for oversight of arm's length bodies, including clearance and monitoring of business plans and annual accountability reviews.

Summary and conclusion

67. The Government believes that the 1991 and 1996 Regulations need to be updated to reflect the changes made to statutory limits and definitions made by the 2008 Act, and also to update the provisions for extension as a result of cases highlighted to the Department of Health.
68. In updating the current regulations, the Government intends to ensure that a wider group of people who suffer from premature infertility are able to extend storage, for example, in situations where people require surrogates or are using embryos or gametes from a donor. We propose introducing successive ten year extended storage periods, subject to the medical criteria being met until a maximum storage period of 55 years for that embryo or gamete is reached, rather than having an age-related limit. The Government aims to ensure that regulation remains effective, and continues to secure public confidence.
69. Option 2 will meet the Government's stated objectives and provide a legislative framework that is fit for purpose into the future.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	No
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	Yes
Race Equality	Yes	Yes
Disability Equality	Yes	Yes
Gender Equality	Yes	Yes
Human Rights	Yes	No
Rural Proofing	No	Yes

Annexes

Equality impact assessment

Purpose and intended effect

1. The Department intends to re-make the Storage Regulations for gametes and embryos⁹ to ensure that they remain fit for purpose in light of the situations raised in Parliament and by clinicians and patients to the Department of Health.
2. The Human Fertilisation and Embryology Authority (HFEA) is a statutory licensing body whose remit involves licensing and inspection, producing a Code of Practice for licence holders, and providing advice to Ministers as required. The HFEA is also a “competent authority” responsible for overseeing the requirements of the European Union Tissue and Cells Directive¹⁰ on setting standards of quality and safety for the storage of human tissues and cells, with regards to human gametes and embryos.
3. The three equality strands where there are existing statutory duties on public bodies to have due regard to promoting equality/eliminating unlawful discrimination are race, disability and gender equality. The Department of Health has opted, in addition, to have a policy of promoting equality/eliminating unjustified discrimination in relation to religion and belief, sexual orientation and age.
4. Outlined below are the main proposals that will be reflected in the new Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations, (“the Storage Regulations”) and an assessment of the impact.

Initial scoping assessment and action plan for the regulations

Summary of the purpose and aim of the proposed policy

5. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 (“the 1996 Regulations”) and the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 (“the 1991 Regulations”), need to be updated to reflect the changes to statutory limits and definitions made by the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”), and address concerns highlighted to the Department of Health, that the conditions for extension are too restrictive.
6. Under the 1990 Act as amended by the 2008 Act the statutory storage period for gametes and embryos is ten years. Regulations may provide that in certain circumstances a longer or shorter storage period may be substituted for the ten year period.
7. The Storage Regulations enable the storage period to be extended at any point within the initial ten year period for a further ten years if the gamete provider, person to be treated, or person to whom the embryo or gametes has been allocated, is or is likely to become prematurely infertile. The storage period may then be extended for subsequent ten year periods, until a maximum storage period of 55 years is reached, provided that the premature infertility criteria is demonstrated at any time within each ten year period.

⁹The 1991 Regulations (S.I. 1996/375) and the 1991 Regulations (S.I.1991/1540).

¹⁰ 2004/23/EC as implemented by The Human Fertilisation and Embryology (Quality and Safety) Regulations (S.I. 2007/1522) and The Human Tissue (Quality and Safety for Human Application) Regulations (S.I. 2007/1523)

Assessment

Race

8. The proposed policy is not likely to impact differently on people on grounds of their race. The reasons for this are that race is not a consideration that alters a decision to extend storage or not. The policy has a positive impact helping those with clinical need. It may be the case that one ethnic group is more likely to suffer premature infertility than another. If this turned out to be the case, the policy would impact positively on people on grounds of their race if that correlated with clinical need.
9. We have considered whether there are opportunities to promote equality of opportunity that could be taken if the proposed policy were adjusted. Equality of opportunity is available to all, but there are not specific opportunities to promote equality of opportunity.
10. The proposed policy is thought likely to help to eliminate unjustifiable discrimination. The reason for this is that the legislation could not be used as a basis on which to discriminate.
11. The proposed policy is not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.
12. The proposed policy is likely to promote good relations between people of different groups. The reason for this is that all people will be treated equally.

Disability

13. The proposed policy is not likely to impact differently on people on grounds of disability. The reasons for this are that disability is not a consideration that alters a decision to extend storage or not. It may be that people with different disabilities will require different levels of attention throughout fertility treatment.
14. We have considered whether there are opportunities to promote equality of opportunity that could be taken if the proposed policy were adjusted. Equality of opportunity is available to all; people with disabilities where their disability may affect their level of fertility may benefit from the Storage Regulations, but there are not specific opportunities to promote equality of opportunity.
15. The proposed policy is thought likely to help to eliminate unjustifiable discrimination. The reason for this is that the legislation could not be used as a basis on which to discriminate.
16. The proposed policy is not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.
17. The proposed policy is likely to promote good relations between people of different groups. The reason for this is that it all people will be treated equally.

Gender or Transgender

18. The proposed policy is not likely to impact differently on people on grounds of their gender. The reasons for this are that everybody has the same access to extension of storage. The provisions on storage are couched in gender-neutral terms. Both a woman or a man who is, in the opinion of a registered medical practitioner, prematurely infertile, would both be able to extend storage of gametes or embryos allocated to them, irrespective of who will be treated with the gamete or embryo.
19. We have considered whether there are opportunities to promote equality of opportunity that could be taken if the proposed policy were adjusted. The answer is no, because we considered the current legislation very carefully in terms of how it impacted upon people dependent on their gender, and their age and we revised the storage limits appropriately.
20. In updating the Storage Regulations, we preferred a non age-related time for extension, because the current maximum age limit for embryos and gametes in storage up to 55 years and we thought that this might impact differently in terms of gender. There are instances of

men and women having children over the age of 55 naturally, but whilst this was unusual for women, and associated with certain health risks, it is neither so risky nor so unusual for men. We did not want to have different policies dependent on gender, so decided to replace the age limit with a rolling extension subject to a maximum time limit for storage of 55 years.

21. Concerns were raised in consultation that a 55 year time limit might mean that older people were storing gametes or embryos. However, these concerns are addressed by the rolling extension. The rolling extension would mean that there may come a time when a man or woman no longer qualified for extension, as it would be difficult to argue that a woman in her 60s was still "prematurely" infertile. However, the rolling extension allows scope for clinical discretion, which may take into account gender in relation to 'premature infertility'. Furthermore, there is a licence condition that requires clinics to consider the welfare of the child¹¹ before providing treatment, including that child's needs for supportive parenting. The detail of this consideration is for the HFEA to determine, however, it means that older parents who might be considered to be "prematurely infertile" at the point that extension is granted, would be assessed still further before having any *treatment* with their stored gametes or embryos.
22. As most people use stored gametes or embryos in less than ten years, the impact of the preferred policy is thought likely to be low as currently only 5% of those storing need to extend storage, and although we estimate that this will increase, it is still very low as a proportion of the total number.
23. The proposed policy is thought likely to help to eliminate unjustifiable discrimination. The reasons for this is as above, namely we are creating a non age-related time period for extended storage.
24. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.
25. The proposed policy is thought likely to promote good relations between people of different groups. The reasons for this are as above, paragraph 20, the Storage Regulations improve relationships between people of different groups in terms of gender.

Age

26. The proposed policy is thought not likely to impact differently on people on grounds of their age. The reasons for this are as described in paragraphs 20 and 21; we are choosing a maximum storage period for embryos and gametes of 55 years. The maximum period will no longer be age-related, but for successive ten year periods. Under the 1991 and 1995 Regulations storage is limited to when the person who will be treated reaches 55 years of age.
27. In reviewing the age limit, we took into account legal considerations. There is currently no domestic anti-age discrimination that would specifically apply to the regulations. However, a challenge to the upper age limit (of 55 years) in the regulations could be brought under Article 8 (right to respect for private and family life) in conjunction with Article 14 (prohibition of discrimination) of the European Convention for Human Rights. There would only be a breach of the right if any interference was unjustified.
28. We took the view that an age limit could be justified in terms of the risks to the health of an older mother, and in terms of considering the welfare of any resulting child. Women who give birth over 56 years of age show higher risks of complications. Yet drawing lines in medicine is always somewhat arbitrary, some older mothers may suffer no complications during pregnancy, and be able to support their children well into adulthood and the opposite also applies, younger mothers may suffer complications and be unable to support their children. The age limit also impacts in terms of gender, as suggested above, as men father children without risks to their own health after 55.

¹¹ Section 13(5) of the 1990 Act

29. The differential impact between conditions under the current system, compared to the Storage Regulations, is thought likely to be positive. The reasons for this can be demonstrated by considering the following scenario. If a man has treatment for cancer at age 30, at which age he puts gametes into storage because of future infertility, these would reach the end of the initial storage period when he was 40. Under the 1991 Regulations, he would have only 25 years of storage until he reached the age 55. However, under the Storage Regulations he could extend them for a further 10 years by rolling extension until a maximum limit of 55 years. The criteria for extension under the Storage Regulations would take age into account, but allow for flexibility depending on the circumstance of the patient. The Storage Regulations would allow the man in the above scenario to have treatment using his stored gametes after the age of 55, when he might still be considered to be "prematurely infertile".
30. The impact of the proposed policy on people in terms of age is thought likely to be low. The reasons for this are that extension past the initial 10 years is already an exceptional case. Therefore, although most people are able to use their embryos/gametes in the initial ten year period, cases like the above scenario would be rare, but would be provided for under the proposed legislation. Couples with gametes and embryos in storage under the 1991 and 1996 Regulations would be able to take advantage of the benefits of extension under the Storage Regulations if they fulfil the criteria for extension.
31. The proposed policy is thought likely to help to eliminate unjustifiable discrimination. The reasons for this are as described in the above scenario.
32. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.
33. The proposed policy is thought likely to promote good relations between people of different groups. The reasons for this are as above.

Religion or Belief

34. The proposed policy is unlikely to impact differently on people on grounds of their religion or belief, however it may be considered differently by people on grounds of their religion or belief.
35. We accept that the provisions of the 1990 Act raise issues of conscience. Of these issues of conscience, religion or belief may play an influential role. Although everybody, regardless of religion or belief, would have the same access to treatment services, storage and extension of storage, there may be issues of conscience raised in relation to the Storage Regulations. Some respondents to the consultation felt that although the Storage Regulations would not directly have an impact upon them, they would impact upon the society of which they were a part. Responses covered a spectrum of religions and beliefs, with responses from different Catholic groups, Protestant and Islamic groups. Some people were against the storage of gametes and embryos *per se*, some felt the initial ten-year limit was sufficient without extension, and some believed there should be no storage limit at all so to allow indefinite storage.
36. Responses to the consultation confirmed that many issues of conscience were raised by the Storage Regulations. However, that there should be a statutory storage period for gametes and embryos and extension subject to certain circumstances as specified in regulations has been agreed in both Houses of Parliament. Therefore, we consider that, on balance, the benefits of the proposed policy for all people regardless of religion or belief, outweigh any concerns about the policy in relation to different views which may have been influenced by religion or belief.
37. The proposed policy is thought not likely to help to eliminate unjustifiable discrimination. The reason is that issues of unjustifiable discrimination are not applicable.
38. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.

39. The proposed policy is thought not likely to promote good relations between people of different groups. The reason is that this consideration is not applicable to this policy.

Sexual Orientation

40. The proposed policy is thought not likely to impact differently on people on grounds of their sexual orientation. The policy does not differentiate between heterosexual and same sex couples – the issue is whether they are prematurely infertile. The prevalence of the Lesbian, Gay and Bisexual population is estimated to be 6% which is the figure estimated by Treasury Actuaries.

41. We have considered whether there are opportunities to promote equality of opportunity that could be taken if the proposed policy were adjusted. We have concluded that the answer is no, because we have taken pains to make sure that there are equalities of opportunity in terms of sexual orientation are promoted in the proposed policy.

42. The criteria to extend storage refers to premature infertility. We would consider this to mean cases of complete medical infertility such as someone who has had treatment for cancer that has left them infertile, or someone who is unable to produce eggs. These clinical reasons would apply to heterosexual or same sex couples. If someone is in a same sex relationship, or is single, this would not in itself make them eligible to have extended storage.

43. The Government considers that, on balance, the policy would not discriminate on grounds of sexual orientation. The reasons for this are that storage can be extended as long if there is a clinical need and the criteria for extension are fulfilled, regardless of sexual orientation.

44. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.

45. The proposed policy is thought likely to promote good relations between people of different groups. The reasons for this are as above.

Small Firms Impact Test

46. Many licensed clinics (which are predominantly private sector based) and research centres can be considered to be small firms (with under 50 staff). The changes made by the Storage Regulations should have a minimal affect on clinics. Storage is voluntary, and clinics will recoup costs as most patients will pay for most or all of their storage, and in some exceptional cases storage may be funded by the NHS.

47. All licensed clinics received a hard copy of the consultation document and were encouraged to respond to the consultation. The Department also met with the HFEA Licensed Centres Panel to discuss the impact of the Storage Regulations on clinics. To minimise the impact of the requirements on firms employing up to 20 people, the approach taken is to amend the Storage Regulations in light of the consultation, so that there is a rolling extension up to a maximum of 55 years. One of the intentions behind this rolling extension is to reduce the administrative burdens as fewer people will be extending for long periods. The rolling extension might also encourage clinics and patients to maintain closer contact whilst storing over a long period.

Legal Aid

48. The proposals will clarify the current law allowing for more people to extend storage and, bringing it up to date with current technology and attitudes. That the proposals have taken into account age and gender equality considerations should reduce the potential of legal challenge.

Health Impact Assessment

49. The storage limit for extension under the updated Storage Regulations would potentially allow people to store gametes and embryos after they were 55 years old. However, concerns that this would mean that older men and women could be having children with

risks for older expectant mothers and an impact upon the health services can be allayed by the safeguard of the rolling extension. The "premature infertility" test would prevent a further extension of the storage period if the patient would no longer be considered to be *prematurely* infertile, and therefore there would be little risk that the removal of the age limit from the regulations would impact upon the health services in terms of risks, for example, for older expectant mothers. Furthermore, all clinics have a duty to consider the welfare of the child before providing treatment as outlined in the HFEA Code of Practice. Therefore, the proposals do not have a significant impact on human health, lifestyle or demand on NHS services, and therefore do not have any health impact relevant to this assessment.

