Department of Health & Social Care

Regulatory Triage Assessment

For Increasing Gamete & Embryo Storage Limits to a Maximum of 55 Years for All

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Contents

Regulatory Triage Assessment (RTA)

Title of proposal	Increasing Gamete & Embryo Storage Limits to a Maximum of 55 Years for All
Expected date of implementation	As soon as possible.
Origin (Domestic/International etc.)	Domestic
Date	May 2021
Lead Policy Contact	Csenge Gal
Lead Analytical Contact	Stephanie DeMiranda
Reason for Triage Assessment	Negligible cost implications.
Is the policy in scope of OI3O?	N/A

Policy Proposal Summary

Individuals across the UK are increasingly choosing to freeze and store their gametes (eggs and sperm) and embryos.

The legislation governing the use and treatment of gametes and embryos, including their storage, is the Human Fertilisation and Embryology Act 1990, as amended in 2008 (the "HFE Act"). The HFE Act limits the storage of gametes and embryos to a maximum of 10 years.

The government recognises that current storage limits restrict women's reproductive choices, and therefore launched a public consultation to seek views about changing the statutory storage limits for gametes and embryos on 11 February 2020. The consultation ran for 12 weeks and closed on 5 May 2020.

As a result of the consultation, the proposed policy change is to increase the statutory storage limits for gametes and embryos, from the current 10 years to 10-year renewable storage periods up to a maximum of 55 years, regardless of medical need. There will be requirements for statutory 10-year review periods and explicit written consent from the patient to continue storage.

The relevant clauses of the HFE Act would be amended through primary legislation.

How many businesses are likely to be affected?

In 2019/2020 there were 106 licensed clinics across the UK, which provide fertility treatment. In addition, there are 16 licensed facilities, which undertake research involving

human embryos, and 14 licensed facilities which provide storage only. Two-thirds of clinics are standalone, with the rest owned by 10 private clinic groups.

Of the 106 clinics that provide fertility treatment, 62 (58%) are private and 44 (42%) are NHS, treating a mix of NHS and private patients.

Most of the licensed clinics offering fertility treatments, 91, are based in England, of which 30 (28%) are based in London. There are 4 licensed clinics offering treatment in Northern Ireland, 7 in Scotland and 4 in Wales[i].

What are the main impacts for business? Are these impacts direct or indirect?

This RTA provides a proportionate analysis of the potential costs to business if the statutory storage limits for gametes and embryos were increased from the current 10 years to 10-year renewable periods up to a maximum of 55 years.

A number of simplifying assumptions were made to carry out the analysis. As a general rule, where there is uncertainty the analysis assumes a greater impact on business than might be considered most likely; this analysis may thus be read as a reasonable worst-case scenario (RWCS) analysis of the potential impact on business.

In particular, the top end of the range of costs identified assumes that all patients that can take advantage of the proposed increase will do so, even though a number will likely opt instead to utilise their frozen gametes or embryos, or dispose of them, before the storage limit of the maximum 55 years is approached.

Two costs are identified as having a direct impact on businesses:

- familiarisation costs with the measure (which is estimated on a per-business basis)
- additional communication costs (the cost of contacting all patients, estimated on a per-patient basis)

Other costs were identified but were considered indirect, negligible, or net zero, and were not analysed further, such as:

- If patients choose to continue storage of gametes and embryos that would otherwise breach storage limits (and be disposed of), there may be additional costs associated with the storage. However, in most cases these costs will be fully passed on to patients, and so are not included in the estimated impact on business. The Human Fertilisation and Embryology Authority (HFEA) estimate cost of annual storage to be around £300 per year[ii]. This cost is considered both indirect and net zero.

- It is likely that additional storage space will be needed by clinics and storage facilities, if demand keeps rising. Data from the HFEA shows that there is already an increase in people choosing to freeze their gametes and embryos and this demand is likely to continue to grow. In 2013 there were 871 embryo storage cycles, had increased to 7,031 by 2018, an increase of 707%, albeit from a low starting point. Similarly, egg storage cycles have increased from 596 in 2013, to 1,933 in 2018, which is an increase of 240%. Data on sperm storage is not readily collected by the HFEA in the same way and so it is not available[iii]. As freezing techniques have improved, a typical patient today will have a single, fresh embryo transferred in their first cycle. Any additional embryos created will be stored for use in subsequent frozen embryo transfers. In 2013, there were 13,420 IVF cycles using frozen embryos, which had increased by 93% to 25,889 in 2018.

- The below costs are presented for context only. As with the current storage costs, any additional storage costs are expected to be passed on in full to patients and are considered net zero. A small proportion of patients who are undergoing cancer treatment or gender reassignment are eligible for gamete or embryo storage on the NHS. The proposed policy changes will not affect these patients, nor will it increase the numbers eligible for NHS funding.

    - A standard storage unit (a ‘dewar’) holds a maximum of 280 cryopreserved patient samples, and costs around £1,500[iv].

    - Storage dewars require liquid nitrogen: although there would not be an additional cost of storing more samples in current dewar capacity, any additional dewar capacity purchased would see an associated increase in liquid nitrogen costs.

    - The HFEA require an audit to be conducted on cryopreserved samples every 2 years. If more samples are in storage, this may increase the time taken by scientific staff to complete the audit. However, in the short to medium term, the expected volume of additional storage is not considered likely to have a material impact on these costs. These costs are also considered indirect. Furthermore, the HFEA estimate that if the regulations are simplified and clinics are not having to make decisions about whether someone is “prematurely infertile” or not, then this might reduce errors and inconsistencies around the paperwork for storage and thus could actually reduce the inspection time required.

Quantification of the (direct) costs and benefits to business outlined above

Total **direct costs faced by businesses are estimated at £818k -£1.64m**, comprising £28k-£56k of familiarisation costs, and £790k -£1.58m communication and implementation costs.

Familiarisation costs

Businesses will need to reflect on the new measure, engage and train staff to ensure the new regulations are understood and implemented correctly.

Familiarisation costs are estimated at £28k-£56k
(£460-£920 per business for c100 entities = £46k -£92k, ~60% of which are private.)

These costs are considered to impact at the legal entity level – with clinic groups able to spread costs across several clinics. There will likely be some costs within each clinic (of reading, as opposed to writing guidance), but these are considered immaterial and are not explicitly analysed as part of this proportionate assessment, but implicitly reflected by the upper estimate.

Estimation of cost per business

The low estimate of £460 per business is based on six hours of a Band 9 Medical Consultant's time including a 22% uplift to account for on-costs[v]. The upper estimate (£920) doubles this estimate to take account of: difficult cases; high-cost area supplements; any support from other staff not captured in the initial estimate; and the costs of communicating guidance to staff (which are difficult to estimate, and judged disproportionately detailed analysis).

As above, a subset of clinics with historic storage consent problems may need to take additional legal advice; however, the marginal cost is not considered significant.

Estimation of number of businesses

Of the total 136 licensed facilities in the UK in 2019/2020, 113 have storage facilities, and of these 44 are part of ten private clinic groups and 69 are stand alone; thus, there are 79 separate businesses (69 standalone plus 10 groups) currently considered to face these costs[vi].

Communication and implementation costs

All patients with material in storage will have to be informed by clinics of the change in law. Based on the estimates there are between 11,000-20,000 individuals with gametes or embryos in storage. The lower estimate is based on there being a similar number of eggs and sperm stored, whilst the higher estimate doubles the number of embryos and eggs in storage to take into account stored sperm too.

Gamete and embryo storage require explicit written consent. The proposed policy to increase storage up to a maximum of 55 years with review periods every 10 years will require additional consent to be obtained, as part of each review period. In the longer term, there will be administrative actions (and costs) in clarifying with patients whether they wish to utilise the additional storage time offered by the proposed increase to the statutory storage limits and obtaining consent. In the short term, only those will have to renew

consent who are coming up to the 10-year mark at the time when the policy is implemented.

Communication and implementation costs are estimated at £790k -£1.58m. £158-£316 per patient, for ~5,000 patients).

Estimation of cost per patient

A cost of £158-£316 per patient is estimated. The lower estimate comprises three hours of a Band 8a Embryologist spent writing to patients and billing (two hours) and correcting storage expiry dates on IT systems (one hour), plus two hours of a Band 5 Administrator providing support to both of those activities. The salaries have been uplifted by 22% to account for on-costs.

The upper estimate doubles this to take account of; difficult cases; high-cost area supplements; any support from other staff not captured in the initial estimate; and the cost of any follow-up letters during the review periods, if letters are unacknowledged by patients.

Estimation of number of patients

Between April 2019 and March 2020, the number of patients coming up to the end of their storage period for eggs or embryos was 2,375. The number of patients storing sperm is not known as there is relatively poor data for this, but for the purposes of this analysis we doubled this figure to 4,750 to take this into account. Based on this, in the immediate term about 5,000 patients would have to be contacted to obtain consent to extend storage of their gametes or embryos. In reality, not all patients who are eligible to extend the storage of their gametes or embryos will choose to do so, many patients will decide to discard samples at the 10 year review period in any case, having completed their families or no longer wanting to consider future treatment.

References

[i] Human Fertilisation and Embryology Authority report “State of the fertility sector 2019/2020” State of the fertility sector 2019/2020 | Human Fertilisation and Embryology Authority (hfea.gov.uk)
[ii] Human Fertilisation and Embryology Authority estimate. Egg freezing | Human Fertilisation and Embryology Authority (hfea.gov.uk)
[iii] Human Fertilisation and Embryology Authority report “Fertility treatment 2018: trends and figures” Fertility treatment 2018: trends and figures | Human Fertilisation and Embryology Authority (hfea.gov.uk)
[iv] Human Fertilisation and Embryology Authority estimate
[v] Salaries taken from https://www.healthcareers.nhs.uk/working-health/working-nhs/nhs-pay-and-benefits/agenda-change-pay-rates, holiday entitlements taken from https://www.nhsemployers.org/-/media/Employers/Documents/Pay-and-reward/AfC-Handbook-Version-2.pdf?la=en&hash=71CEB30BF3286D25E65F4F0B649994F79867FAF0 and hours from https://www.nhsemployers.org/tchandbook/part-3-terms-and-conditions-of-service/section-10-hours-of-the-working-week#:~:text=10.1%20The%20standard%20hours%20of,be%20counted%20as%20working%20time
[vi] Human Fertilisation and Embryology Authority report “State of the fertility sector 2019/2020” State of the fertility sector 2019/2020 | Human Fertilisation and Embryology Authority (hfea.gov.uk)

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