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## **Social' egg freezing and the UK's statutory storage time limits**

**Article (Accepted version)  
(Refereed)**

**Original citation:**

Jackson, Emily (2016) '*Social' egg freezing and the UK's statutory storage time limits*. [Journal of Medical Ethics](#) . ISSN 0306-6800

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Available in LSE Research Online: August 2016

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## **‘Social’ egg freezing and the UK’s statutory storage time limits**

Within the past few years, following the development of a new fast-freezing technique known as vitrification, fertility clinics have started to offer the option of egg freezing to women concerned about their declining fertility.<sup>1</sup> I am not concerned here with the pros and cons of egg freezing, or its wider social or ethical implications.<sup>2 3 4</sup> Rather, my focus is solely and narrowly upon the the UK’s statutory time limit for the storage of gametes, and its unintended, and perhaps even perverse consequences for elective or ‘social’ egg freezing.<sup>5</sup>

### **When to freeze eggs?**

A woman’s chance of conceiving naturally drops steadily during her thirties and rapidly after the age of 40. The risk of miscarriage also increases significantly.<sup>7</sup> Contrary to popular belief, IVF does not offer a solution to age-related fertility loss: it can bypass blocked fallopian tubes, but it cannot reverse egg degeneration.<sup>8</sup> The pregnancy rate per embryo transfer for women receiving IVF treatment using their own fresh eggs drops between the ages of 35 and 45 from 38.2 to 2.2 per cent.<sup>9</sup> If a woman freezes her eggs before her fertility starts to decline, IVF using her own frozen eggs will be more likely to work into her late thirties and forties.

Because egg freezing is in its infancy, reliable data are scarce. The American Society for Reproductive Medicine has calculated that, for women freezing their eggs in their mid-twenties to mid-thirties, there is a clinical pregnancy rate per thawed oocyte of between 4.5 and 12 per cent.<sup>10</sup> Although not identical, pregnancy rates for IVF using frozen oocytes are now broadly comparable with pregnancy rates using fresh oocytes,<sup>11</sup> so that a woman who froze her eggs at the age of 35 could benefit from an IVF success rate closer to 38 per cent than 2 per cent well into her forties.

The optimum time to freeze one’s eggs, from a clinical point of view, would be during a woman’s teens or twenties. But success rates are not the only consideration and other factors militate in favour of later freezing. One of these is that the younger a woman is when she freezes her eggs, the less likely she is ever to use them in treatment, because she will probably be able to conceive naturally, when she decides to start a family.<sup>12</sup> Egg freezing may be more likely to work if she returns to use her frozen eggs, but it is also more likely to have been a physically invasive waste of time and money. If a woman instead freezes her eggs in her late thirties, when her fertility is already in decline, the process may be more invasive and expensive, if more cycles are needed, and the pregnancy rate per frozen oocyte will be lower, but she is more likely to return to use her frozen eggs. As part of the informed consent process, a woman juggling these complex odds needs clear and frank information in order to help her to decide whether to freeze her eggs at a relatively early age, or to first ‘wait and see’ if she conceives naturally before her fertility starts to decline.

My focus in this article is on a second, legal reason why women would be ill-advised to freeze their eggs at the optimum clinical time, namely the existence of statutory time limits on the storage of gametes. For a range of reasons, these time limits work against good clinical practice in egg freezing: they make the process more invasive and expensive, and reduce the chance of a successful outcome. In addition, the latest version of the Regulations that permit extensions of the time limit in certain circumstances are, in relation to social egg freezing, more restrictive than the version they replaced. In addition to being contrary to good clinical practice, mandating the destruction of a woman’s eggs once the time limit has expired represents an interference with her to right to respect for her family life which is neither necessary nor proportionate. My claim will be that the statutory time limit, and the options for extension, are no longer fit for purpose.

## **Statutory time limits and extensions**

The Human Fertilisation and Embryology Act 1990 originally allowed gametes to be stored for up to 10 years, and embryos for five.<sup>13</sup> Regulations passed in 1991 permitted extensions to this 10 year time limit, where the gametes were for the person's own use and he or she was under the age of 45 when the gametes were provided, and his or her 'fertility since providing them has or is likely to become, in the written opinion of a registered medical practitioner, significantly impaired'.<sup>14</sup> Extensions could be granted only until the gamete provider reached the age of 55.<sup>15</sup>

When the 1990 Act was updated in 2008, the statutory storage time limits for gametes and embryos were brought into line with each other. Both gametes and embryos can lawfully be stored for up to 10 years.<sup>16</sup> The Regulations that permit extensions to these time limits were also updated, in 2009, 'in order to ensure that a wider group of people who suffer from premature infertility are able to extend storage', to include those who need to use donor gametes or a surrogate mother.<sup>17</sup> The wording of the Regulations was also amended. Instead of an upper age limit of 55, the 2009 Regulations introduced the option of successive 10-year storage periods where:

on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gamete or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.<sup>18</sup>

If these conditions are satisfied, the statutory storage period is extended for another 10 years from the date the written opinion was provided. Further 10-year extensions will require further written opinions, up to a maximum total storage period of 55 years.

The 55-year maximum storage period was introduced in part in order to correct an anomaly under the previous Regulations. The age limit of 55 was, in the Minister's words 'not sufficiently flexible to meet individual circumstances', because it 'meant that men who were prematurely infertile were prevented from extending storage beyond the age of 55, despite the fact that they were still prematurely infertile at that age'.<sup>19</sup> This new time limit also facilitated inter-generational donation, for example, between a mother and her infertile daughter. In both Houses of Parliament, the case was raised of a constituent of Andrew Stunell MP, a mother whose daughter suffered from Turner syndrome, a chromosomal disorder resulting in infertility, who wanted to be able to store her eggs in order to donate them to her daughter in the future.<sup>20</sup>

## **Statutory time limits and egg freezing**

None of these rules were drafted in order to accommodate the interests of women freezing their eggs as insurance against age-related fertility decline. Indeed, it could be argued that, for several reasons, they are positively contrary to those interests, and to good clinical practice.

First, if women have only 10 years within which to use their frozen eggs, there are good reasons to delay freezing in order to ensure that they can be used when they are most likely to be needed. A woman who freezes her eggs at the age of 30 is more likely than a 38-year-old egg freezer to be able to retrieve sufficient eggs for freezing in one or two cycles (15 is the recommended minimum number of eggs to freeze to give a realistic chance of pregnancy). The process is therefore likely to be cheaper and less invasive. Because her eggs are younger, an IVF cycle with embryos created from her frozen eggs is also more likely to result in a pregnancy and live birth. But the statutory storage limit will result in her eggs being destroyed or allowed to perish when she is 40 years old. A 30-year-old egg freezer will be unable to use her own frozen eggs at the age of 41 or 42, even though this is precisely the age when she is likely to benefit from having frozen her eggs. In contrast, a 38-year-old egg freezer is likely to have to undergo more invasive cycles, at greater expense in order to retrieve sufficient eggs to freeze, and the

chance of a successful pregnancy will be significantly lower. But she will have until the age of 48 to use her frozen eggs.

A 30-year-old egg freezer would not be eligible for a ten-year extension at the age of 40, unless she was facing premature infertility, perhaps as a result of early menopause. Women who experience the normal age-related decline in their fertility are not 'prematurely infertile', and are therefore ineligible for an extension to the 10-year storage period. This means that, after 10 years, clinics will be forced to dispose of the eggs of those women who are most likely to benefit from having their younger, frozen eggs in storage.

Second, if a woman froze her eggs at the age of 30, and experienced difficulty conceiving at the age of 41, after her own eggs had been destroyed, she might be advised to use donor eggs. This will cost significantly more, and may mean that an egg donor is exposed unnecessarily to the processes of hormonal stimulation and egg retrieval, which could have been avoided if the 30-year-old egg freezer had been permitted to use her own eggs after 11 years of storage. For women who froze their eggs in their twenties or early thirties, and who subsequently struggle to conceive naturally, the direct result of the 10-year statutory storage limit might be the wholly unnecessary use of donated eggs. This is overwhelmingly likely to be contrary to the woman's wishes, and against the best clinical interests of the donor.

Third, if eggs are nearing the end of their statutory storage period, it is possible to apply for Special Directions permitting their export to a country in which they could be used lawfully after the statutory storage period has expired in the UK. A 30-year-old egg freezer, nearing the age of 40 and concerned about her eggs' imminent destruction could then apply for Special Directions to export her eggs. Although no cases have yet arisen, it could be predicted that the HFEA would adopt the same approach as it has in relation to the export of sperm, and take into account the fact that the woman's right to respect for her private and family life (protected by Article 8 of the European Convention on Human Rights) is likely to be at stake, such that any interference must 'pursue a legitimate aim', 'fulfil a pressing social need', be 'necessary in a democratic society' and be 'proportionate and non-discriminatory'.<sup>22</sup> But even if export is possible, it is clinically unnecessary. It will make treatment more expensive and inconvenient, and in some countries the woman might be exposed to additional clinical risks, if, for example, two or more embryos are put back during her treatment cycle.

### **Why have time limits?**

In 1990, the risks of long-term storage were unknown, and so it made sense to have a time limit until evidence emerged of the safety and efficacy of long-term storage. It is now clear that time limits on storage are not required on safety grounds. Embryos and gametes can be used safely and effectively in treatment after being in storage for much longer than 10 years, and indeed, UK law permits gametes to be stored for as long as 55 years, in cases of premature infertility. Instead the principal reason for retaining time limits upon storage is to ensure that clinics are not obliged to store their ex-patients' embryos and gametes indefinitely. As Andrew Stunell MP explained in parliament, in response to his constituent's request to store her eggs for her daughter's use, he had received a letter from the Interim Chief Executive of the HFEA which had stated that '[t]he storage limit was originally set so that clinics would not be over-burdened by the number of samples in storage'.<sup>23</sup>

There is evidence that patients put off making decisions about the disposal or donation of their stored gametes and embryos, and that it is not uncommon for them to fail to reply to letters from clinics requesting decisions about disposal or continued storage. This is not because they do not care about what happens to their stored gametes; rather, as Guido Pennings explains, patients procrastinate or avoid communicating with their clinic as a result of their 'uncertainty, a desire to keep their options open and a desire to avoid irreversible statements and

a general uneasiness and unfamiliarity in thinking about these issues'.<sup>25</sup> A default statutory storage limit, with the possibility of rolling, time-limited extension periods, therefore enables clinics lawfully to dispose of gametes and embryos if patients fail to make decisions or become uncontactable.

A further background consideration, evident in some of the parliamentary debates over the Regulations, is concern about the prospect of post-menopausal or 'elderly' motherhood.<sup>28</sup> Whether or not it makes sense to restrict access to fertility treatments to people of 'reproductive age' is beyond the scope of this article. Although in theory egg freezing could enable women in their fifties, sixties and even seventies to bear children using their own frozen eggs, all of the evidence suggests that women who freeze their eggs are not seeking to become mothers in old age, rather they simply want to increase their chance of conception in their early to mid-forties.

Regardless of whether preventing post-menopausal motherhood is a legitimate statutory objective, or whether it represents justifiable or unjustifiable discrimination on the grounds of age, it is illogical to rely upon a 10-year storage limit in order to achieve this aim. A 10-year storage time limit would only work to prevent post-menopausal motherhood in women freezing their eggs after the age of 40, when they are, in any event, unlikely to have sufficient ovarian reserve for egg freezing to be a viable option. For women freezing their eggs in their twenties or early thirties, the 10-year time limit prevents them from using their own eggs during their normal reproductive lifespan. A more straightforward and effective way to prevent elderly women accessing IVF (if this is what the time limits are supposed to achieve) would be to place an age limit on access to treatment. And while there is no statutory age limit upon access to fertility treatment in the UK, in practice, most clinics set an upper age limit for female patients of 50 years of age.

## Human rights implications

It is axiomatic that the forced destruction of a person's stored gametes potentially interferes with their human rights, and, more specifically, with their Article 8 right to respect for their private and family life.<sup>i</sup> This right is not absolute, and so the state could justify any interference provided that it could be said to be, not only 'in accordance with the law', which the statutory time limits undoubtedly are, but also 'necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'. It is hard to see how permitting time-limited extensions to the storage of eggs in order to ensure that women can use their frozen eggs in their forties would pose a risk to the rights of others, or to 'public safety' or 'health and morals'.

If the reasons for the existence of a statutory storage time limit are, first, to prevent clinics from being burdened with the indefinite storage of gametes and, second, to prevent post-menopausal motherhood, there are clearly ways of achieving these aims without mandating the destruction of women's eggs after 10 years, unless she happens to be prematurely infertile. Rolling time-limited extensions to a 10-year storage limit achieve the first aim, and a simple age limit would achieve the second.

## Alternative approaches

If current UK law works against best clinical practice, such that, in addition to its human rights

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<sup>i</sup> Article 12, the right to marry and found a family, might also be at stake, but most cases involving restrictions upon the use of gametes have instead invoked Article 8.

implications, it makes egg freezing more invasive, risky, expensive and likely to fail, what alternative approaches might there be? Perhaps ironically, it could be argued that, despite predating the clinical use of vitrification by several decades, the recommendations in the 1984 Warnock Report and the 1991 Regulations would be a better fit with social egg freezing than the updated 2009 Regulations.

The 1984 Warnock Report was clear that a balance had to be struck between the need for flexibility to accommodate individuals' circumstances and the impracticality of indefinite storage:

we feel it is unreasonable to put an absolute limit on the length of time for which eggs or semen can be stored. On the other hand it would also be unreasonable and impractical to expect those responsible for storage to maintain all eggs and semen stored indefinitely.<sup>32</sup>

The Committee's proposed solution was:

a system of five yearly reviews. When the reviews are carried out, men and women who have stored semen or eggs can indicate whether they wish storage to continue or whether they have no further use for the gametes and wish them to be destroyed or donated.<sup>33</sup>

If the Warnock Report's recommendation had been implemented, social egg freezers would be able to benefit from extended storage, because they could request an extension at successive five year reviews.

The criteria for extended storage that were, in fact, enacted in 1991 were that the person was under the age of 45 when they provided their gametes and that their fertility was likely to become significantly impaired. In practice, this was interpreted to mean that their fertility was likely to become significantly *and prematurely* impaired. As the Department of Health's Impact Assessment for the 2009 Regulations explained: 'extension over 10 years was granted only to medical cases of premature infertility'.<sup>34</sup> However, the words used in the 1991 Regulations do not rule out an alternative interpretation that would facilitate extended storage for social egg freezers. Women over the age of 45 are unlikely to have sufficient ovarian reserve to make egg freezing a viable option, and so if a more liberal (and perhaps literal) interpretation was given to the wording in the 1991 Regulations, egg freezers under the age of 45 whose fertility is likely to become significantly impaired – i.e. all of them – would be able to benefit from 10-year extensions to the storage of their frozen eggs.

But while the approach adopted in 1991 is inadvertently a better fit with social egg freezing than the newer Regulations, perhaps it would be better to permit extended storage for reasons that specifically match the reasons why women might want to store their eggs for longer than 10 years. We could, perhaps borrow from the approach adopted in Victoria, Australia, where a 10-year storage time limit is supplemented by the possibility of appeal to a Patient Review Panel, which can grant extensions, for 10 years at a time, with the gamete provider's written consent, provided there are 'reasonable grounds' for doing so. Guidance sets out when the Panel will 'normally' consider there to be reasonable grounds for an extension, two of which are relevant here and would directly accommodate the needs of women who froze their eggs in their twenties or early thirties:

- the patients are not ready to use them in their own treatment due to their personal circumstances,
- the patients have not completed or are undecided about completing their assisted reproductive treatment or family.<sup>35</sup>

## Conclusion

Because social egg freezing is in its infancy, we do not know what practical impact the 10-year time limit will have upon women who have frozen their eggs. If a woman has three years of storage left, at what point should she give up on meeting a suitable partner and attempt IVF with

donor sperm, for example? It seems likely that women faced with the imminent destruction of their eggs will feel under pressure to use their eggs before time runs out for them, ironically perhaps creating a newly-ticking non-biological clock. Nor do we know if the statutory time limit is shaping women's decisions about when to freeze their eggs. For example, are women putting off freezing their eggs until their mid-thirties in order to ensure that their eggs will be usable until their mid-forties?<sup>36</sup> More research is needed into how the 10-year time limit shapes women's decisions about the freezing and subsequent use of their eggs.

The 2009 Regulations were not passed in order to accommodate the interests of women freezing their eggs as insurance against age-related fertility decline. Their impact upon this patient group is therefore inadvertent. Nevertheless, it is clear that, in relation to social egg freezing, the 2009 Regulations are a backward and regressive step which, contrary to the Minister's reassurance in parliament,<sup>37</sup> leave some women demonstrably worse off than they would have been under the previous Regulations. By mandating the destruction of a woman's eggs during her reproductive lifespan, unless she happens to be prematurely infertile, the rules are illogical and their effects perverse.

The current rules allow for extraordinarily long extensions of storage, for up to 55 years, at the same time as ruling out short extensions for women who suffer natural age-related fertility decline. Prematurely infertile men can therefore store their sperm well into old age, while a woman who freezes her eggs at the age of 30 will not be able to use her own eggs in treatment when she is 41. To paraphrase the President of the Family Division of the High Court in the context of time limits on applications for parental orders in cases of surrogacy, if we assume that parliament intended a sensible result, this cannot have been parliament's intention: 'It is the very antithesis of sensible; it is almost nonsensical.'<sup>38</sup>

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<sup>3</sup> Mertes H, Pennings G. Social egg freezing: for better, not for worse. *Reproductive biomedicine online*. 2011 Dec 31;23(7):824-9.

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<sup>8</sup> Daly I, Bewley S. Reproductive ageing and conflicting clocks: King Midas' touch. *Reproductive biomedicine online*. 2013 Dec 31;27(6):722-32.

<sup>9</sup> HFEA. *Fertility Treatment 2014: Trends and Figures*. 2016.

<sup>10</sup> The practice committees of the SART and ASRM. *Mature oocyte cryopreservation: a guideline*. 2013.

<sup>11</sup> Cil AP, Bang H, Oktay K. Age-specific probability of live birth with oocyte cryopreservation: an individual patient data meta-analysis. *Fertility and sterility*. 2013 Aug 31;100(2):492-9.

<sup>12</sup> Mesen TB, Mersereau JE, Kane JB, Steiner AZ. Optimal timing for elective egg freezing. *Fertility and sterility*. 2015 Jun 30;103(6):1551-6.

<sup>13</sup> Sections 14(4) and 14(5).

<sup>14</sup> Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 regulation 2(2).

<sup>15</sup> Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 schedule 1.

<sup>16</sup> Human Fertilisation and Embryology Act 1990, as amended, sections 14(3) and (4).

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- <sup>17</sup> Department of Health. Impact Assessment for the Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations. 2009
- <sup>18</sup> Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) 2009, regulation 4(3)(b).
- <sup>19</sup> Baroness Thornton HL Deb 21 Oct 2009 Column 767.
- <sup>20</sup> HC Deb 12 May 2008 Column 1145; Evan Harris HC Deb 5 June 2008 Column 139; Earl Howe, HL Deb 21 Oct 2009 column 764
- <sup>22</sup> HFEA. Special Directions Applications. <http://www.hfea.gov.uk/8818.html>. (visited June 2016).
- <sup>23</sup> HC Deb 12 May 2008 Column 1146.
- <sup>25</sup> Pennings G. What are the ownership rights for gametes and embryos? Advance directives and the disposition of cryopreserved gametes and embryos. *Human Reproduction*. 2000 May 1;15(5):979-86.
- <sup>28</sup> Earl Howe, HL Deb 21 Oct 2009 column 765.
- <sup>32</sup> Report of the Committee of Enquiry into Human Fertilisation and Embryology. 1984. para 10.7.
- <sup>33</sup> para 10.8.
- <sup>34</sup> Department of Health. Impact Assessment for the Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations. 2009.
- <sup>35</sup> The Patient Review Panel. Guidance Note No 3: Extensions of gamete and embryo storage. 2013.
- <sup>36</sup> Sarner M. I'm 29: should I freeze my eggs?. *The Guardian* 14 August 2015.
- <sup>37</sup> Baroness Thornton HL Deb 21 Oct 2009 Column 767.
- <sup>38</sup> Per Sir James Munby P in *Re X (A Child) (Surrogacy: Time limit)* [2014] EWHC 3135 (Fam).