

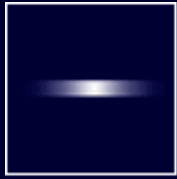
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# HFEA Annual Conference Storage Consent Workshop

Catherine Callaghan QC  
Blackstone Chambers



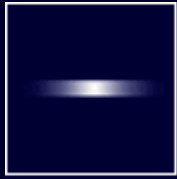


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# Why is it important to get storage consent right?

- All clinics store gametes/embryos
- Adverse consequences for PR/clinics if requirements are breached – breach of licence conditions, criminal offence
- Adverse consequences for patients – disposal of gametes/embryos which are stored without consent

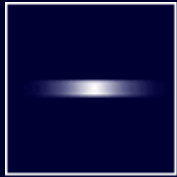


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# Overview

1. Consent to Storage
2. Payment arrangements
3. Maximum storage period and extension of storage period
4. Extending storage for gametes/embryos stored after 1 October 2009
5. Extending storage for gametes/embryos stored before 1 October 2009

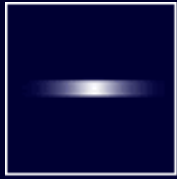


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## Consent to Storage

- Storage requires written and informed consent of gamete provider
- Gametes/embryos must not be kept in storage unless they are stored in accordance with the gamete provider's consent
- i.e. there must be effective consent to storage and storage in accordance with consent at all times (no gap in consent)

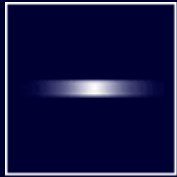


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# Payment arrangements

- Clinics are entitled to charge storage fees, and to remove gametes/embryos from storage if payment or funding ceases
- BUT payment arrangements should be kept separate from a patient's consent to storage
- i.e. patients should be free to choose how long to give consent to storage for (within bounds of the law)

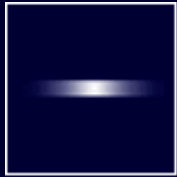


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# Maximum Storage Period and Extension of Storage Period

- Maximum storage period under Act is 10 years (statutory storage period)
- Regulations can extend statutory storage period in limited circumstances (premature infertility)
- 2009 Regulations determine whether storage can be extended in all cases

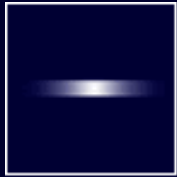


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# Extending Storage for Gametes stored after 1 October 2009

- Regulation 3 (embryos) and Regulation 4 (gametes)
- Gametes can be stored for up to 55 years if conditions are met
- Two conditions:
  - (1) Gamete provider gives written consent to gametes being stored for treatment purposes for longer than 10 years
  - (2) On any day within “relevant period”, a registered medical practitioner gives a written opinion that the gamete provider, or person to be treated, is or is likely to become prematurely infertile
- “Relevant period” means 10 years from the date that gametes were first placed in storage, or 10 years since the most recent medical opinion



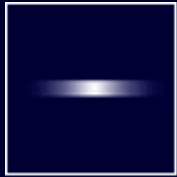
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# Extending Storage for Gametes stored before 1 October 2009

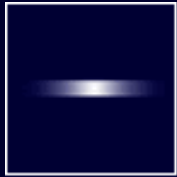
- Regulations 5 & 6 (embryos) and Regulations 7 & 8 (gametes)
- The maximum storage period will depend on whether the conditions for extended storage had already been triggered under the 1991/1996 Regulations by 1 October 2009
- For gametes, the conditions for extended storage under 1991 Regs:
  - (1) Medical opinion from registered medical practitioner that gamete provider's fertility since providing them has or is likely to become significantly impaired
  - (2) Gamete provider aged under 45 when gametes provided
  - (3) Gamete provider only consents to use in own treatment or with partner





# Extending Storage for Gametes stored before 1 October 2009

- If those conditions are met by 1 October 2009, then Regulation 8 applies.
  - Regulation 8: the maximum storage period is either the period ending 10 years after the most recent medical opinion up to a maximum of 55 years (where written consent of gamete provider to storage > 10 years and medical opinion on premature infertility within relevant period) or it is the extended storage period under the 1991 Regs (i.e. storage up to the age of 55)
- If those conditions are not met by 1 October 2009, then Regulation 7 applies.
  - Regulation 7: the maximum storage period is only 10 years unless gamete provider has consented to storage in excess of 10 years and there is a medical opinion on premature infertility provided within the relevant period.
- If your patient wants to extend storage beyond 10 years, make sure they have provided written consent to such storage and that medical opinions on premature infertility are obtained within each 10-year period.



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# Case Study

Patient X was born on 1 October 1980. In early 2009, when she was 28 years old, Patient X was diagnosed with leukaemia and was advised to undergo a course of chemotherapy. Patient X decided to preserve her eggs in the hope that she would be able to have children with a future partner. On 12 March 2009, Patient X completed HFEA WS Form (consent to the storage of eggs), consenting to storage of her eggs for a period of 10 years and consenting to her eggs being used in treatment with any future partner. Her eggs were cryopreserved and stored on the same day.

The clinic's 'bring-forward' system is defective and it has just discovered that the statutory storage period for Patient X's eggs expired in March 2019. Solicitors for the patient and her husband (whom she recently married) have written to the clinic, disputing that it is entitled to dispose of the eggs, and asserting that Patient X is entitled to continue to store her eggs for use in future treatment. The solicitors enclosed a letter from Patient X dated 10 May 2019 stating that she consents to storage of her eggs for longer than 10 years, and another letter dated 15 May 2019 from a consultant gynaecologist who stated:

*"I am writing with regards to an application for extension of storage of this lady's eggs, cryopreserved on 12 March 2009, when she was 28 years of age. As per the Regulations which applied at the time, as she is currently 38 years of age, her fertility potential using her own eggs is now significantly impaired, as compared with when she was 28 years of age. I look forward to a positive response regarding continued storage of these eggs."*