

CLINICAL POLICY ADVISORY GROUP (CPAG)

Gamete Storage Policy

***Statement**

Derby and Derbyshire Integrated Care Board has agreed that Gamete Storage should be commissioned only when the eligibility criteria listed within the policy are met.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

***Statement of Intent**

The Gamete Storage policy is currently being reviewed at a regional and national level

1. Background

This policy relates to the preservation of gametes (oocytes and semen) and embryos, in post-pubertal patients, in advance of chemotherapy or radiotherapy treatment for cancer or conditions requiring male urological or female gynecological surgery that carries a high risk of infertility.

This policy was developed following a review of the NICE Clinical Guideline for Fertility, published in February 2013, NICE Quality Standards for Fertility Problems and takes account of the Equality Act 2010 including age discrimination legislation and the Human Rights Act 1998. The policy includes criteria which are outside of the recommendations laid out within the associated NICE Clinical Guidelines. The ICB Governing Bodies considered these recommendations in the context of their budget allocation for assisted reproduction services and the associated opportunity costs.

Adverse effects associated with a number of medical treatments can impact on fertility, either by direct injury or via systemically administered agents. In some cases, the individual's fertility will return after the treatment is completed but in other cases fertility never returns or is severely impaired. Technological advances mean that cryopreservation of semen, oocytes, embryos and ovarian/testicular tissue offers opportunities to preserve fertility prior to the start of treatment.

In line with the recommendation by the NICE Fertility Guideline, access to cryopreservation and storage associated with treatment induced infertility has been considered separately to assisted reproduction services and the general fertility pathway.

Cryopreservation is a technique that freezes an individual's eggs or sperm for use in future fertility treatment. Cryopreservation of sperm is a well-established technique used to maintain an individual's fertility. Cryopreservation of eggs is a newer technology, though has been widely used in relation to cancer treatment for a number of years.

2. Recommendation

Gamete cryopreservation will be commissioned in individuals undergoing medical or surgical treatment who may be at risk of permanent infertility as a result of their treatment. Gamete cryopreservation will not be commissioned for social reasons, or if gametes are being frozen for use by individuals other than the patient receiving treatment.

It should be noted that the policy does not address NHS funding for the future use of frozen gametes. Provision of gamete freezing and storage under the terms of this policy is made without prejudice to the future determination of funding of any subsequent fertility treatment.

The following are outside the scope of this policy:

- Cryopreservation of gametes and embryos in pre-pubertal patients.
- Cryopreservation of gametes and embryos and sperm requested for social reasons.

3. Criteria for Commissioning

Patients eligible for NHS-funded gamete cryopreservation should be about to commence treatment (funded on the NHS) that may cause permanent infertility as a result of their treatment. Conditions considered appropriate for gamete cryopreservation include but are not limited to:

- Malignancies or other autoimmune conditions requiring chemotherapy.
- Malignancies requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs.
- Conditions requiring male urological or female gynecological surgery.
- Conditions requiring specialist endocrinology services.
- Rare mitochondrial disorders.

The policy also includes retrieval and storage for transgender patient who are receiving treatment for gender dysphoria which may cause permanent infertility (hormone therapy, reconstructive surgery etc.).

Individuals should also meet the following criteria:

- The patient has no living children. This includes a child adopted by the patient. Continued storage will not be funded if the patient subsequently adopts a child or achieves a pregnancy leading to a live birth.
- Females of reproductive age up to 42 years old (stimulation treatment to take place prior to individual's 43rd birthday).
- Males of reproductive age up to 55 years old (sperm retrieval to take place prior to individual's 56th birthday).
- The impact of the treatment on the patient's fertility has been discussed between the patient and the treating clinician.
- The patient is able to make an informed choice and consent to undertake gamete harvesting and cryopreservation.
- The patient is aware that funding for gamete harvesting and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment.
- Registered with a GP in Derby & Derbyshire.

Women, who are preparing for medical treatment for cancer that is likely to make them infertile, should only be offered oocyte or embryo cryopreservation if they meet all of the following criteria:

- They are well enough to undergo ovarian stimulation and egg collection; **and**
- there is sufficient time available to harvest eggs before the start of their cancer treatment.

Women who are undergoing gynecological surgery should only be offered oocyte gamete or embryo cryopreservation. In circumstances, such as women whose uterus will be removed completely, necessitating surrogacy as the only means of future pregnancy (including patients on a transgender pathway), this should not limit their eligibility for gamete, oocyte or embryo cryopreservation. However, the future use of frozen oocytes, gametes or embryos will be in line with all relevant policies in place at the time, for example relating to surrogacy.

4. Cryopreservation Services Funded

Oocytes, sperm, and embryos will be stored for an initial period of 5 years, with an automatic renewal for a further 5 years, being authorised, for patients who continue to meet all other eligibility criteria.

- Sperm will normally be stored for a maximum period of 10 years, or until a man reaches the age of 56 years old, whichever is sooner.
- Eggs and embryos will normally be stored for a maximum period of 10 years, or until a woman reaches the age of 43 years old, whichever is sooner.

Storage of sperm beyond 10 years is not normally funded.

Patients who have undergone NHS funded cryopreservation but no longer meet eligibility criteria may choose to self-fund continued cryopreservation of stored material.

Embryo storage using donor sperm is not routinely commissioned.

5. Exclusion Criteria

Individuals will not be eligible for NHS-funded gamete cryopreservation if:

- Gametes are being frozen for non-medical or non-surgical reasons, for example for social reasons.
- They have previously been sterilised, even if sterilisation has been reversed.

Cryopreservation of ovarian or testicular tissue is still considered to be an experimental procedure and therefore funding of this is not included under this policy.

Surgical sperm retrieval (if required) is not covered by this policy. NHS England hold the commissioning responsibility for this.

The ICB will not fund any additional costs for the transportation of sperm, eggs or embryos if required.

6. Rationale for Recommendation

Cryopreservation of sperm is a well-established technique which has been used for over 40 years [1]. Cryopreservation of eggs has been developed more recently with the first live birth in the 1980s.

The National Institute for Health and Care Excellence (NICE) Guidance for fertility problems: assessment and treatment (CG156) recommend that people preparing to have treatment for cancer that is likely to result in fertility problems are given the option to preserve (freeze and store) their eggs, sperm or embryos for possible use in the future.

The Effects of Cancer Treatment on Reproductive Functions: Guidance on Management', published by the Royal College of Physicians, the Royal College of Radiologists and the Royal College of Obstetricians and Gynaecologists in 2007. The report recommends that sperm

banking should be universally available and funded for all males commencing treatment which has a risk of future infertility.

The Human Fertilisation and Embryology Authority has approved and regulates the storage of frozen sperm, oocytes and embryos. It sets out the mandatory requirements for legal storage of gametes and embryos. Storage can only be funded at appropriately licensed centres.

NHS England Guidance for "Formation of clinical commissioning policies for fertility preservation: Guidance for Clinical Commissioning Groups" issued in 2019 which states "all patient groups whose medical treatment may compromise fertility should be in the contemplation of a CCG when its clinical commissioning policy for fertility preservation is being developed or is under review. Given the legal duties identified above, CCGs must not determine which patient group might be offered fertility preservation services on a basis which discriminates against those patients because of a protected characteristic, including gender re-assignment."

7. Useful Resources

- NICE Clinical Guidance Fertility problems: assessment and treatment (CG156) published February 2013 : Last updated September 2017
<https://www.nice.org.uk/guidance/cg156/ifp/chapter/freezing-sperm-eggs-or-embryos-before-cancer-treatment>

8. References

- NHS England Guidance "Formation of clinical commissioning policies for fertility preservation: Guidance for Clinical Commissioning Groups" issued in 2019
[NHS-England-Guidance-for-CCGs-on-Fertility-Preservation.pdf \(gic.nhs.uk\)](#)

9. Appendices

Appendix 1 - Consultation

Consultee	Date
Clinical Policy Advisory Group (CPAG)	July 2019
Consultant in Public Health	June 2018 - ongoing
East Midlands Affiliated Commissioning Committee (EMACC)	June 2018 - ongoing
Clinical and Lay Commissioning Committee (CLCC)	August 2019
Clinical Policy Advisory Group (CPAG)	October 2019
Clinical and Lay Commissioning Committee (CLCC)	November 2019
Clinical Director & Consultant Gynaecologist and subspecialist in Reproductive Medicine, Nurture Fertility	December 2022
Consultant in Reproductive Medicine, STHFT	December 2022
Consultant Obstetrician & Gynaecologist, Clinical Director, O & G, CRHFT	December 2022
Director of Public Health, Derby City Council	December 2022
Chief Executive Officer, Derbyshire LGBT+	December 2022
Senior Public Equality and Diversity Manager, DDICB	December 2022
Consultant Gynaecologist, UHDBFT	December 2022
Clinical Policy Advisory Group (CPAG)	March 2023
Public Health Consultant	July 2023
Clinical Policy Advisory Group (CPAG)	July 2023

Appendix 2 - Document Update

Document Update	Date Updated
<u>Version 2.0</u> Updated policy	March 2023
<u>Version 2.1</u> <ul style="list-style-type: none"> Paragraph relating to women undergoing Gynecological surgery (section 3 – page 3) has been re-worded to address the inequality issue. Inclusion of Glossary to help explain the terminology used within the policy. 	July 2023

Appendix 3 - Glossary

Term	Meaning
Gamete Cryopreservation	The process of freezing cells or tissues and depositing them in liquid nitrogen at -196°C is called cryopreservation
Embryo	An embryo develops from a zygote, the single cell resulting from the fertilization of the female egg cell by the male sperm cell. In humans, it is called an embryo until about eight weeks after fertilisation (i.e., ten weeks after the last menstrual period [LMP] in most cases), from which point it is then called a foetus.
Gametes	Male or female reproductive cell that contains half the genetic material of that organism
Human Fertilisation and Embryology Authority (HFEA)	UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. (HFEA, 2009).
Infertility	Inability to become pregnant, maintain a pregnancy or carry a pregnancy to live birth
Invitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in the laboratory.
National Institute for Health & Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
Oocyte	Female gametocyte or germ cell involved in reproduction. It is an immature ovum, or egg cell produced in the ovary during female gametogenesis.
Sperm	Male reproductive cell, formed in the testicle. A sperm unites with an egg to form an embryo
Sterilisation	Surgery undertaken to make a person unable to produce offspring
Surgical Sperm Retrieval	Retrieval of sperm for fertilisation from the epididymis or testicles to assist conception for couples where the male partner suffers from azoospermia. The retrieved sperm is used immediately for fertilization or stored for future fertility treatment
Surrogacy	Practice whereby a woman (the surrogate mother) carries and give birth to a child for another person and (usually) that person's partner, who is not able to have children. In a surrogate pregnancy, eggs from the woman who will carry the baby or from an egg donor are fertilized with sperm from a sperm donor to make an embryo.