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| <b>Leicester City, East Leicestershire and Rutland &amp; West Leicestershire Collaborative Commissioning Policy</b><br><b>Gamete/Embryo cryopreservation</b> |   |
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# Leicester City, East Leicestershire and Rutland & West Leicestershire Collaborative Commissioning Policy

## Gamete/Embryo cryopreservation

### Policy Statement

**Equality statement** Clinical Commissioning Groups (CCGs) in the Leicester, Leicestershire and Rutland (LLR) are committed to ensuring equality of access and non-discrimination, irrespective of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

In carrying out its functions, the CCGs must have due regard to the different needs of different protected equality groups in their area. This applies to all the activities for which they are responsible, including policy development, review and implementation

Due Regard. The CCG commitment to equality means that this policy has been screened in relation to paying due regard to the Public Sector Equality Duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment, victimisation; advance equality of opportunity and foster good relations

**Background** Gamete/embryo cryopreservation is a technique that can be used to preserve the fertility of individuals through the freezing of sperm, eggs or embryos.

**Statement** Gamete/embryo 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.

Provision of gamete preservation under the terms of this policy is made without prejudice to the future determination of any subsequent fertility treatment.

**Surrogacy** The NHS in LLR will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement because:

(a) this treatment is not considered by the NHS in LLR to be a priority for NHS investment,

(b)The NHS in LLR is unlikely to be in a position to be able to

reach an assessment as to whether the parties have concluded a lawful surrogacy arrangement, and

(c) The NHS in LLR is concerned that the funding of such treatment raises substantial risks that NHS bodies and doctors providing care connected to surrogacy arrangements would be exposed to unknown medico-legal risks.

Surrogacy, or any assisted conceptions involving surrogacy do not form part of this policy.

**Training**

There are no known training issues.

**Dissemination**

To all CCGs and relevant trusts

**Leicester City, East Leicestershire and Rutland & West Leicestershire Collaborative Commissioning Policy**

**Gamete/Embryo cryopreservation**

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## 1. Introduction

This policy sets out the criteria for access to NHS-funded gamete cryopreservation services for patients who are the responsibility of Clinical Commissioning Groups (CCGs) in Leicester, Leicestershire and Rutland (LLR). It covers the provision of gamete cryopreservation and storage for individuals undergoing certain medical and surgical treatments who may be at risk of permanent infertility as a result of their treatment.

## 2. Definition(s)

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.

## 3. Aim and Objectives

The aim of the policy is to identify those individuals who will be eligible to receive NHS-funded cryopreservation of their gametes.

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.

## 4. Criteria for commissioning

Patients eligible for NHS-funded gamete cryopreservation should be about to commence treatment that may cause permanent infertility as a result of their treatment. Conditions considered appropriate for gamete cryopreservation are:

- malignancies requiring chemotherapy
- malignancies requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs
- conditions requiring male urological or female gynaecological surgery
- other autoimmune conditions requiring the use of Chemotherapy (eg:- Rheumatoid arthritis)

Women who are preparing for medical treatment for cancer that is likely to make them infertile, should only be offered oocyte 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 gynaecological surgery should only be offered oocyte cryopreservation if, following surgery, pregnancy would still be viable.

Individuals should also meet the following criteria:

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|------------------------|--|
| Age                    | <ul style="list-style-type: none"><li>Females of reproductive age up to 42 years old (stimulation treatment to take place prior to individual's 43<sup>rd</sup> birthday)</li><li>There is no age limit for male. .Surgical sperm retrieval (SSR) can be performed in exceptional circumstances for male patients.</li></ul> |
| Registered GP          | Registered with a GP in Leicester Leicestershire and Rutland   |
| Previous sterilisation | Individuals who have previously been sterilised will not be eligible for cryopreservation  |
| Consent                | Written consent to treatment and gamete storage will be required   |

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#### *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
- their infertility is as a result of a congenital disorder

Future use of frozen gametes will be in line with all relevant policies in place at the time.

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.

#### *Links with fertility treatment policies*

Meeting the criteria for NHS-funded gamete cryopreservation does not automatically entitle individuals to subsequently receive NHS-funded assisted conception treatment. In order to receive subsequent NHS funding an individual will be required to meet the eligibility criteria outlined in policies in place at the time relating to assisted conception and IVF/ICSI, or the prevailing relevant policy of a successor organisation at that time

## **5. Patient pathway**

Treatment will only be funded at centres licensed by the Human Fertilisation and Embryology Authority.

Access into services for gamete cryopreservation will be by consultant referral. The consultant responsible for the care resulting in infertility will be required to provide the following information for all individuals referred for gamete cryopreservation:

- name
- date of birth

- address
- GP
- details of the underlying condition
- confirmation that the treatment carries with it a significant risk of permanent infertility
- for female cancers, confirmation that the use of stimulation drugs as part of the egg retrieval process will not be detrimental to the patient

In order for commissioners to monitor uptake of gamete/embryo cryopreservation as a result of this policy, referrals should be submitted to the relevant CCG for notification.

Treatment provided will be the most appropriate for their individual clinical circumstances and will include:

- confirmation that the individual meets the inclusion criteria for gamete cryopreservation as detailed in this policy, and does not meet any of the exclusion criteria
- screening, as a minimum, for HIV, hepatitis B and hepatitis C prior to treatment. People found to test positive for one or more of these should be offered specialist advice and counselling and appropriate clinical management
- written consent for cryopreservation of individual's gametes/embryos
- provision of medication for stimulation of gamete/embryo production, as required
- harvesting of gametes/embryos
- gamete/embryo freezing

The NHS will fund the storage of eggs/embryos for a maximum period of 10 years, Sperm will be stored for a maximum period of 10 years. Individual patients can choose to continue the storage of their gametes/embryos beyond this period but this must be paid for privately.

On the death of the patient NHS funding for gamete/embryo storage will cease. However, if it is lawful to do so and there is a legally binding document is signed by the patient allowing the use of frozen sperm or eggs after death, NHS funding of gamete/embryo cryopreservation will continue for up to a total of 10 years.

## 6. Evidence Base

Cryopreservation of sperm is a well-established technique. Cryopreservation of eggs is a much newer technology, although is demonstrating improved results at a fast pace. In 2009 the HFEA reported that approximately 900 babies had been born worldwide following egg freezing, with 5 live births in the UK, but with many thousands of eggs having been stored in the UK.<sup>1</sup> It should be noted that due to the relatively novel nature of oocyte cryopreservation, only a relatively small proportion of the oocytes that have been frozen have subsequently been used in fertility attempts.

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<sup>1</sup> Human Fertilisation and Embryology Authority (2009) [www.hfea.gov.uk/46.html](http://www.hfea.gov.uk/46.html)

In addition, the risks of oocyte cryopreservation will not be quantified until a much greater number of babies have been born using these techniques.

#### *NICE guidelines*

The NICE clinical guidance 11 *Fertility: assessment and treatment for people with fertility problems*<sup>2</sup> recommends that men and adolescent boys preparing for medical treatment that is likely to make them infertile should be offered semen cryostorage because the effectiveness of this procedure has been established.

The guidelines recommend that women preparing for medical treatment that is likely to make them infertile should be offered oocyte or embryo cryostorage as appropriate if they are well enough to undergo ovarian stimulation and egg collection, if this will not worsen their condition and sufficient time is available. The guidelines also state that women should also be informed that oocyte cryostorage has very limited success. However, it should be noted that the clinical guidelines were published eight years ago, when oocyte cryopreservation techniques were not as developed.

Individuals with cancer who wish to preserve their fertility are a specific group considered within the NICE guidance, and the following recommendations are made:

- when discussing cryopreservation with people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow the procedures recommended by the Royal Colleges of Physicians, Obstetricians and Gynaecologists and Radiologists
- at diagnosis, the impact of the cancer and its treatment on future fertility should be discussed between the person diagnosed with cancer and their cancer team
- for cancer-related fertility preservation, do not apply the eligibility criteria used for conventional infertility treatment
- there should be no fixed lower age limit for cryopreservation for fertility preservation in people diagnosed with cancer
- when deciding to offer fertility preservation to people diagnosed with cancer, take the following factors into account: diagnosis, treatment plan, expected outcome of subsequent fertility treatment, prognosis of the cancer treatment, viability of the stored/post-thawed material
- when using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocytes
- offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment that is likely to make them infertile
- use freezing in liquid nitrogen vapour as the preferred cryopreservation technique for sperm
- offer oocyte or embryo cryopreservation to women of reproductive age (including adolescent age) who are preparing for medical treatment for

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<sup>2</sup> NICE (2004) *Clinical guidance 11: Fertility: assessment and treatment for people with fertility problems*

cancer that is likely to make them infertile if: they are well enough to undergo ovarian stimulation and egg collection **and** this will not worsen their condition **and** enough time is available before the start of their cancer treatment

- in cryopreservation of oocytes and embryos, use vitrification instead of controlled-rate freezing if the necessary equipment and expertise is available
- store cryopreserved material for an initial period of 10 years
- do not continue to store cryopreserved sperm, beyond 10 years, for a man whose normal fertility has restored by the time he is discharged from oncology follow-up

The updated NICE guidance is due to be published October 2012.

#### *British Fertility Society*

The British Fertility Society published guidelines for oocyte cryopreservation in 2009.<sup>3</sup> The guidance highlights that there is strong evidence for use of oocyte cryopreservation, and that oocyte survival rates may be higher using vitrification techniques compared to slow-freezing. However the guidance also report that the long-term safety and efficiency of vitrification remain to be confirmed.

#### *Other evidence*

The Royal College of Physicians, the Royal College of Radiologists and the Royal College of Obstetricians and Gynaecologists published a guidance report on the effects on reproductive functions in individuals undergoing cancer treatment in 2007.<sup>4</sup> The report recommends that sperm banking should be universally available and funded to all males commencing treatment which has a risk of future infertility. The report considered that egg storage was still developmental, but it should be noted that the report was published a number of years ago when oocyte cryopreservation techniques were not as advanced.

A recent systematic review included five randomised controlled trials of oocyte preservation, undertaken between 2005 and 2009.<sup>5</sup> Oocyte survival rates following cryopreservation ranged from 65-97% and clinical pregnancy rates using vitrification freezing techniques ranged from 38-65%. The meta-analysis reported no significant difference in ongoing or clinical pregnancy rates between vitrified and fresh oocytes and significantly higher oocyte survival and fertilisation rates using vitrified oocytes compared to slow-frozen oocytes. The authors concluded that vitrification is an efficient method to preserve oocytes, but due to the small number of studies included further clinical trials with larger samples sizes are required to strengthen the conclusion.

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<sup>3</sup> Cutting, R. et al (2009) Human oocyte preservation: Evidence for practice *Human Fertility* 12(3): 125-136

<sup>4</sup> Royal College of Physicians, The Royal College of Radiologists and the Royal College of Obstetricians and Gynaecologists (2007) *The effects of cancer treatment on reproductive functions: Guidance on management*

<sup>5</sup> Cobo, A. and Diaz, C. (2011) Clinical application of oocyte vitrification: a systematic review and meta-analysis of randomised controlled trials *Fertility and Sterility* 96(2):277-285

## 7. Financial considerations

The treatment costs for egg retrieval and freezing are approximately £2,700 per patient. The treatment costs for sperm freezing are approximately £300 per patient per year. If surgical sperm retrieval is required then this would cost an additional £850 per patient.

Using the potential demand estimates provided in Table 1, the estimated costs for each CCG are provided in Table 2. It should be noted however, that the recent number of Individual Funding Requests received by each CCG is considerable less than the demand estimates.

It should also be noted that implementing this gamete cryopreservation policy may increase the number of individuals requesting NHS-funded assisted conception treatment, however these costs have not been considered within this policy. It should also be noted that provision of NHS-funded treatment under this policy does not automatically entitle individuals to receive NHS-funded assisted conception treatment.

Individual CCGs will be required to determine their funding mechanism for this policy.

*Table 2: Estimated costs of gamete cryopreservation, by previous PCT*

| Locality   | Estimated costs (£) |
|--|---------------------|
| Derbyshire County and Derby City PCT Cluster                     | 87,900              |
| Leicestershire County and Rutland and Leicester City PCT Cluster | 95,100              |
| Lincolnshire PCT Cluster   | 69,600              |
| Northamptonshire and Milton Keynes PCT Cluster                   | 87,900              |
| Nottinghamshire County and Nottingham City PCT Cluster           | 91,500              |
| Total  | 432,000             |

## 8. Date of Review

The levels of demand should be reviewed after 12 months to determine better estimates of future demand for gamete cryopreservation services under this policy.