# Policy for Commissioning
# Cryopreservation for Patients due to Commence Medical or Surgical Treatment Likely to Permanently Affect their Fertility

**August 2019**

| | |
|---|---|
| Version: | 1.0 |
| Policy Number: | CL022/08/22 |
| Date ratified: | 29 August 2019 |
| Name of originator/author: | Lead Medical Advisor & Head of Individual Funding Requests & Complaints |
| Name of Sponsor: | Chief Nurse |
| Name of responsible committee | Quality Assurance Committee |
| Date issued: | September 2019 |
| Review date: | August 2022 |
| Target audience: | All staff working within or on behalf of NHS Sheffield CCG |

**To ensure you have the most current version of this policy please access via the NHS Sheffield CCG Intranet Site by following the link below:**

**http://www.intranet.sheffieldccg.nhs.uk/policies-procedure-forms-templates.htm**

**Policy Audit Tool**

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

**Please give status of Policy: New**

| | | |
|---|---|---|
| **1.** | **Details of Policy** | |
| 1.1 | Policy Number: | CL022/08/22 |
| 1.2 | Title of Policy: | Policy for commissioning cryopreservation for patients due to commence medical or surgical treatment likely to permanently affect their fertility |
| 1.3 | Sponsor | Chief Nurse |
| 1.4 | Author: | Lead Medical Advisor & Head of Individual Funding Requests & Complaints |
| 1.5 | Lead Committee | Quality Assurance Committee |
| 1.5 | Reason for policy: | Commissioning best practice |
| 1.6 | Who does the policy affect? | All patients who are about to undergo a medically necessary procedure or intervention which may permanently impair their future fertility |
| 1.7 | Are the National Guidelines/Codes of Practices etc issued? | Yes |
| 1.8 | Has an Equality Impact Assessment been carried out? | Yes |
| **2.** | **Information Collation** | |
| 2.1 | Where was Policy information obtained from? | National best practice |
| **3.** | **Policy Management** | |
| 3.1 | Is there a requirement for a new or revised management structure for the implementation of the Policy? | No |
| 3.2 | If YES attach a copy to this form. | |
| 3.3 | If NO explain why. | Can be operated under existing structures |
| **4.** | **Consultation Process** | |
| 4.1 | Was there external/internal consultation? | Yes |
| 4.2 | List groups/persons involved | IFR Request Panel and lead clinical experts |
| 4.3 | Have external/internal comments been included? | Yes |
| 4.4 | If external/internal comments have not been included, state why. | |
| **5.** | **Implementation** | |
| 5.1 | How and to whom will the policy be distributed? | Staff will be made aware of all new policies via the Weekly Bulletin. Policies will be available on the intranet. |
| 5.2 | If there are implementation requirements such as training please detail. | No |
| 5.3 | What is the cost of implementation and how will this be funded | N/A |
| **6.** | **Monitoring** | |
| 6.2 | How will this be monitored | Individual Funding Request Manager |
| 6.3 | Frequency of Monitoring | Ongoing as requests are made to the CCG |

**Version Control**

| VERSION CONTROL | | | | |
|---|---|---|---|---|
| **Version** | **Date** | **Author** | **Status** | **Comment** |
| 1.0 | August 2019 | Dr Clare Freeman and Allison Ball | New | Developed to be inclusive of all patient groups |

**Contents**

## 1. Introduction

Cryopreservation is the process of freezing and storing sperm, oocytes and embryos so that they can potentially be used at a future date, typically in an attempt to achieve a pregnancy.

This policy sets out the commissioning position on the provision of cryopreservation for a patient about to undergo a medically necessary procedure or intervention which may permanently impair their future fertility, for example chemotherapy, radiotherapy or gender dysphoria treatment.

This policy follows the available national clinical guidelines [1, 2, 3, 4] including those published by NICE (CG156 Fertility problems: assessment and management) and as such the usual local eligibility criteria for fertility treatment will not all apply at the time of gamete harvesting and cryopreservation.

Approval of cryopreservation does NOT guarantee future funding of assisted conception or fertility treatment. Should the patient wish to pursue NHS funded fertility treatment, the local eligibility criteria will apply at that point.

## 2. Scope

This policy applies to all patients who are about to undergo a medically necessary procedure or intervention which may permanently impair their future fertility.

## 3. Definitions

Cryopreservation: the process of freezing a patient's eggs, sperm or embryos in order to preserve their fertility

Fertility: the ability to conceive children

Gamete harvesting: the collection of a patient's eggs or sperm prior to cryopreservation.

Exceptionality: a patient may be considered exceptional to the general standard Policy if both the following apply:

- He/she is different to the general population of patients who would normally be refused the healthcare intervention, and;
- There are good grounds to believe that the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

## 4. Commissioning Criteria

Cryopreservation will be routinely commissioned according to the following criteria:

- The patient is due to commence a medical or surgical treatment likely to permanently affect their fertility;

- The impact of the treatment on the patient's fertility has been discussed with the patient by the treating clinician;

- The patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of sperm, oocytes or embryos;

- The patient is aware that funding for gamete harvesting and cryopreservation does NOT guarantee future funding of assisted conception or fertility treatment.

If a patient does not meet the commissioning criteria but the responsible clinician can provide evidence of exceptionality then a case should be made to the Individual Funding Request Panel.

### 4.1 Cryopreservation in females

The CCG will fund one cycle of egg retrieval, with or without fertilisation. If fewer than ten eggs are retrieved then one further cycle can be offered.

Ovarian tissue storage is currently considered to be experimental and will not be funded.

### 4.2 Cryopreservation in males

Accepted good practice is to collect and store at least two semen samples over a period of one week before any treatment likely to permanently affect fertility. The CCG will commission a maximum of three semen samples.

Testicular tissue storage is currently considered to be experimental and will not be funded.

Testicular sperm retrieval is considered to be specialised and is therefore commissioned by NHS England.

### 4.3 Duration of storage

The legal duration of storage is governed by statutory Human Fertilisation and Embryology Authority (HFEA) legislation and regulations:

- The CCG will routinely fund storage of gametes or embryos for an initial 10 year period.

- If storage is desired for longer than 10 years then an application for exceptional funding should be made to the Individual Funding Request Panel and each request will be considered on its own merit and in line with HFEA legislation.

(Note that statutory storage periods for gametes and embryos permit patients to store for a maximum of 10 years, and regulations for extending storage periods up to a maximum of 55 years.)

## 5. Monitoring effectiveness

Adherence to this policy will be monitored by the Individual Funding Request Panel.

## 6. Review

This document may be reviewed at any time at the request of either staff side or management, but will automatically be reviewed after three years or when a change in legislation dictates.

## 7. Links to other documents

Access to Infertility Treatment Policy (Yorkshire and Humber Policy)
Confidentiality Code of Conduct and Data Protection Policy
Individual Funding Request Policy
Information Security Policy

## 8. Mental Capacity Act

Having considered the MCA compliance statement, the MCA is not applicable to this policy.

## 9. Equality & Diversity Statement

NHS Sheffield CCG aims to design and implement services, policies and measures that meet the diverse needs of our service population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the Human Rights Act 1998 and promotes equal opportunities for all. This document has been assessed to ensure that no-one receives less favourable treatment on grounds of their gender, sexual orientation, marital status, race, religion, age, ethnic origin, nationality, or disability. Members of staff, volunteers or members of the public may request assistance with this policy if they have particular needs. If the person requesting has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

NHS Sheffield CCG embraces the six staff pledges in the NHS Constitution. This policy is consistent with these pledges.

## 10. References

1 NICE. Fertility problems: assessment and treatment (CG156) Sept 2017
Available from : https://www.nice.org.uk/guidance/cg156
Specifically : https://www.nice.org.uk/guidance/cg156/chapter/Recommendations#people-with-cancer-who-wish-to-preserve-fertility

2 RCoP, RCoR & RCOG. The effects of cancer treatment on reproductive functions: Guidance on management. November 2007
Available from :
https://www.rcr.ac.uk/system/files/publication/field_publication_files/Cancer_fertility_effects_Jan08.pdf

3 Human Fertilisation and Embryology Authority (UK Government Independent Regulator)
Available from : https://www.hfea.gov.uk/

4 Human Tissue Authority (The Regulator for Human Tissue and Organs)
Available from : https://www.hta.gov.uk/

**Appendix 1 NHS Sheffield CCG Equality Impact Assessment 2019**

**Equality Impact Assessment**

| | | |
|---|---|---|
| **Title of policy or service:** | Policy for commissioning cryopreservation for patients due to commence medical or surgical treatment likely to permanently affect their fertility | |
| **Name and role of officer/s completing the assessment:** | Allison Ball, Head of Individual Funding Requests & Complaints | |
| **Date of assessment:** | July 2019 | |
| **Type of EIA completed:** | **Initial EIA 'Screening'** ***x*** ***or*** **'Full' EIA process** ☐ | *(select one option - see page 4 for guidance)* |

| **1. Outline** | |
|---|---|
| **Give a brief summary of your policy or service**<br>• Aims<br>• Objectives<br>• Links to other policies, including partners, national or regional | This policy sets out the criteria by which the CCG commissions cryopreservation for patients due to commence medical or surgical treatment which may permanently affect their fertility.<br><br>This policy links to :<br>Access to Infertility Treatment Policy (Yorkshire and Humber Policy)<br>Confidentiality Code of Conduct and Data Protection Policy<br>Individual Funding Request Policy<br>Information Security Policy |

**Identifying impact:**

- **Positive Impact:** will actively promote or improve equality of opportunity;
- **Neutral Impact:** where there are no notable consequences for any group

- **Negative Impact:** negative or adverse impact causes disadvantage or exclusion. If such an impact is identified, the EIA should ensure, that as far as possible, it is justified, eliminated, minimised or counter balanced by other measures. This may result in a 'full' EIA process.

**2. Gathering of Information**
This is the core of the analysis; what information do you have that might *impact on protected groups, with consideration of the General Equality Duty*.

| **(Please complete each area)** | **What key impact have you identified?** | | | **For impact identified (either positive an or negative) give details below:** | |
|---|---|---|---|---|---|
| | **Positive Impact** | **Neutral impact** | **Negative impact** | **How does this impact and what action, if any, do you need to take to address these issues?** | **What difference will this make?** |
| **Human rights** | X | ☐ | ☐ | Positive impact for patients undergoing gender reassignment. | Will enable patients to be offered cryopreservation as part of their gender reassignment pathway. |
| **Age** | ☐ | X | ☐ | | |
| **Carers** | ☐ | X | ☐ | | |
| **Disability** | ☐ | X | ☐ | | |
| **Sex** | ☐ | X | ☐ | | |
| **Race** | ☐ | X | ☐ | | |
| **Religion or belief** | ☐ | X | ☐ | | |
| **Sexual orientation** | ☐ | X | ☐ | | |
| **Gender reassignment** | X | ☐ | ☐ | Positive impact for patients undergoing gender reassignment. | Will enable patients to be offered cryopreservation as part of their gender reassignment pathway. |
| **Pregnancy and maternity** | ☐ | X | ☐ | | |
| **Marriage and civil partnership** (only eliminating discrimination) | ☐ | X | ☐ | | |
| **Other relevant** | ☐ | X | ☐ | | |

| | | | | | |
|---|---|---|---|---|---|
| **groups** | | | | | |
| **HR Policies only: Part or Fixed term staff** | ☐ | ☐ | ☐ | | |

***IMPORTANT NOTE:*** *If any of the above results in '**negative'** impact, a 'full' EIA which covers a more in depth analysis on areas/groups impacted must be considered and may need to be carried out.*

Having detailed the actions you need to take, please transfer them onto the action plan below.

| **3. Action plan** | | | | |
|---|---|---|---|---|
| **Issues/impact identified** | **Actions required** | **How will you measure impact/progress** | **Timescale** | **Officer responsible** |
| | | | | |
| | | | | |
| | | | | |

| **4. Monitoring, Review and Publication** | | | | |
|---|---|---|---|---|
| **When will the proposal be reviewed and by whom?** | **Lead / Reviewing Officer:** | **Allison Ball** | **Date of next Review:** | **August 2022** |

## Appendix 2 Clinical Policies and Guidelines Appraisal Instrument

| | Yes | No | N/A | Comments |
|---|---|---|---|---|
| **Rationale** | | | | |
| 1. Is the rationale for the clinical policy/guideline clearly defined? | Yes | | | |
| **Policy/Guideline Development Group** | | | | |
| 2. Is the group responsible for policy / guideline development clearly identified? | Yes | | | |
| 3. Is there a clear description of the individuals involved in the policy / guideline development? | Yes | | | |
| 4. Does the group represent all key disciplines? | Yes | | | |
| **Context and Content** | | | | |
| 5. Are the reasons for developing the policy / guidelines clearly stated? | Yes | | | |
| 6. Are the objectives clearly identified? | Yes | | | |
| 7. Is there a clear description or the patients/staff/groups to which this policy / guideline applies? | Yes | | | |
| 8. Are there any circumstances in which exceptions might be made in using this policy / guideline? If so are the circumstances of this exception clearly documented? | | No | | |
| **Clarity** | | | | |
| 9. Does the policy / guideline describe the condition/process to be treated/detected/prevented? | Yes | | | |
| 10. Are the possible management options clearly stated? | Yes | | | |
| 11. Are the recommendations clearly stated? | Yes | | | |
| 12. Are the health benefits/potential harms and risks/costs of utilising the policy / guideline clearly identified? | Yes | | | |
| 13. Are there implications for services if implemented? | Yes | | | |
| **Identification and interpretation of Evidence** | | | | |
| 14. Are the sources of information used to devise the policy or guideline clearly described? E.G. National Guidelines/Codes of Practice | Yes | | | |
| 15. If so are they adequate? | Yes | | | |
| 16. Is there a satisfactory description of the method used to interpret and assess the strength of evidence and formulate appropriate recommendations? | Yes | | | |

| | Yes | No | N/A | Comments |
|---|---|---|---|---|
| 17. Is there an indication of how the views of interested parties were taken into account? | | No | | |
| **Rigour of Development** | | | | |
| 18. Was the policy / guideline independently reviewed prior to publication/issue? | | No | | N/A – based on best practice |
| 19. Was the policy / guideline piloted and if so has this been effectively evaluated? | | No | | Evaluation of the policy will be ongoing as requests are made |
| **Application** | | | | |
| 20. Are the staff that should receive this policy / guideline clearly identified? | Yes | | | |
| 21. Are there any staff awareness raising/training sessions required as a result of the new/revised policy / guideline? If yes, have training and development leads been informed of this? | | No | | |
| 22. Are methods of dissemination and implementation of the policy / guideline clearly identified? | Yes | | | |
| **Updating** | | | | |
| 23. Has a date for reviewing or updating the policy / guideline been agreed? | Yes | | | |
| 24. Has an individual/group responsible for this process been clearly identified? | Yes | | | |
| **Monitoring** | | | | |
| 25. Does the policy/guideline define measurable outcomes that can be monitored? | Yes | | | |
| 26. Has a process for monitoring and evaluating the effectiveness of the policy/guideline been agreed including, testing awareness and obtaining evidence of policy/procedures being put in place? | Yes | | | IFR Panel |