NHS
Coventry and Warwickshire
Integrated Care Board

NHS Funded Cryopreservation of Gametes and Embryos Policy

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
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Name of author and title:	Joint ICB Clinical Commissioning Policy Development Group
Name of reviewer and title:	Ali Cartwright
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

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1. Policy statement

1.1. This policy aims to provide criteria for access to and funding for cryopreservation of gametes (sperm and oocytes) and embryos for the people registered with a Coventry and Warwickshire GP practice.

1.2. The policy specifically relates to cryopreservation of gametes and embryos in patient groups who are at risk of infertility due to medical or surgical NHS funded treatment including patients with gender dysphoria or for patients at risk of premature ovarian insufficiency.

1.3. Patients will be offered one NHS funded treatment to recover and preserve gametes subject to the patient meeting the eligibility criteria

2. Introduction

2.1. Cryopreservation is the process of freezing and storing biological materials so that it can typically be used at a later date to conceive a pregnancy.

2.2. Infertility may be an unwanted side-effect of an NHS funded medical or surgical treatment; (this is described as iatrogenic infertility).

2.3. Infertility may be the result of premature ovarian insufficiency. This can occur for several reasons such as; due to congenital disorder, as a result of medical or surgical treatment or due to autoimmune conditions.

2.4. The following patient groups are covered in this policy:
   2.4.1. Patients who will be having medical or surgical treatment for cancer.
   2.4.2. Patients who will be having NHS funded medical or surgical treatment for other conditions and as a result infertility is potential risk.
   2.4.3. Patients who are at high risk of premature ovarian insufficiency (POI). Most common genetic cause of POI is Turner syndrome.

2.5. Cryopreservation is not available for any other patient group, i.e., for patients embarking on a private pathway of care likely to cause infertility or patients who wish to delay conception for non-medical reasons.

2.6. In cases where there is significant likelihood of a patient becoming infertile as result of NHS funded treatment, patients must meet eligibility criteria set out in this policy in order to access cryopreservation services.

2.7. All patients about to embark on a treatment within an NHS pathway of care that might cause infertility should be offered an opportunity to discuss their circumstances with a fertility specialist, regardless of potential eligibility for cryopreservation.

2.8. For patients who do not fall within the scope of this policy but where there is demonstratable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request (IFR) may be considered.

2.9. Approval for cryopreservation does not guarantee future funding of assisted conception treatment. For this the patient will be required to meet the criteria set out in the Assisted Conception Treatment policy at time of application.

2.10. This policy will ensure that all patients across registered with a Coventry and Warwickshire GP practice who require cryopreservation services are treated according to the ICBs' Commissioning Principles.

2.11. This policy applies to Coventry and Warwickshire ICB and the principle providers of these services, NHS and private providers, irrespective of where the patient is being treated.

3. Eligibility criteria for cryopreservation

3.1. The patient must be permanently registered with a Coventry and Warwickshire GP practice.

3.2. The patient, if female, must be of reproductive age.

3.3. The patient, if male, must have reached or else undergone adolescence.

3.4. The patient must meet one of the following clinical criteria:

3.4.1. The patient must be undergoing NHS funded medical or surgical treatment which is likely to lead to infertility.

3.4.2. Patient is at high risk of premature ovarian insufficiency. For the purposes of this policy, POI is defined as:

3.4.2.1. Amenorrhea of at least 12 months;

3.4.2.2. Hormonal profile in the menopausal range;

3.4.2.3. Under the age of 40.

3.5. In females preparing to undergo medical treatment for cancer that is likely to render them infertile, the following should be considered:

3.5.1. The patient is well enough to undergo ovarian stimulation and egg collection; AND

3.5.2. This will not worsen their condition; AND

3.5.3. Enough time is available before the start of their cancer treatment.

3.6. There must be written consent for treatment and gamete storage.

3.7. The provider of the service must ensure that the patient receives appropriate counselling.

3.8. NHS funded cryopreservation treatment will not be available if the infertility is the result of a sterilisation procedure.

3.9. The ICB does not routinely fund cryopreservation of ovarian and testicular tissues except in cases where gamete and embryo cryopreservation cannot be achieved.

3.10. The ICB does not fund cryopreservation for those who wish to delay conception for non -

medical reasons.

4. NHS funding for storage of gametes and embryos conditions

4.1. Cryopreservation for fertility for adults may be funded for up to 10 years.

4.2. If fertility is found to have returned, either through fertility testing or through conception and pregnancy, or the patient dies with no written consent regarding posthumous use, then continued storage will not be funded.

4.3. The patient is able to self-fund for a further period providing that the appropriate length of storage set out by human fertilisation and embryology authority regulations is not exceeded.

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

4.5. The preferred provider for services is the Centre of Reproductive Medicine, University Hospitals of Coventry and Warwickshire NHS Trust. However, other clinics will be considered upon application to the ICB.

5. Relevant National Guidelines and Facts

NICE Guidance CG 156 Fertility: Assessment and treatment for people with fertility problems
(February 2013, last updated September 2017)

The impact of the medical/surgical intervention on the patient's fertility should be discussed by the relevant medical/surgical team. When deciding to offer fertility preservation to people diagnosed with cancer, the following should be taken into account:

Diagnosis
Treatment plan
Expected outcome of subsequent fertility treatment
Prognosis of the cancer treatment
Viability of stored/post-thawed material

A lower age limit for cryopreservation fertility preservation will not be used. Patients must be informed that even though they may meet criteria for cryopreservation, it does not automatically mean they will meet criteria for using the stored material for assisted conception in an NHS setting.

Royal College of Physicians, Royal College of Radiologists and Royal College of Obstetricians and Gynecologists (2007) – Joint Guidance "The effects of cancer treatment on reproductive functions"

This guidance makes recommendations specifically around cancer diagnosis and treatment of induced infertility. It recommends the use of cryopreservation of material prior to commencing a treatment pathway that could potentially make a patient infertile.

Possible future effects of chemotherapy or radiotherapy on fertility should be discussed with all patients with reproductive potential. It should be recognised that the prospect of infertility can be psychologically and socially damaging for both men and women by that such an outcome can, to some extent, be mitigated by gamete and embryo storage. Gametes can only be stored and used in a centre licensed by the HFEA

Human Fertilisation and Embryology Authority (HFEA) Code of Practice

The HFEA is the UK's independent regulator overseeing use of gametes and embryos in fertility treatment. Its Code of Practice sets out both mandatory requirements and recommended guidance (incorporating an interpretation of mandatory guidance) for organisations involved in this area of health care.

British Fertility Society Policy and Practice Guideline: Fertility preservation for medical reasons in girls and women. January 2018.

The policy has made certain recommendations regarding cryopreservation. For instance, the risk of infertility, diminished ovarian reserve, and premature ovarian insufficiency should be assessed based on age, type and dose of chemotherapy.

Women/couples should be advised that embryo cryopreservation is an established technique, with success rates for the transfer of frozen-thawed embryos comparable to those for the transfer of fresh embryo. Furthermore, women/couples should be advised of the length of time their oocytes/embryos can be stored and that this limit is statutory.

NHS England
Gender Identity Dysphoria

NHS England commissions the gender identity dysphoria pathway. Cryopreservation is advised in the service specification of NHS England to be the responsibility of the patient's ICB and is not commissioned by NHS England.

Human embryo and fertility act 1990

Cryopreservation of gametes or embryos must meet the current legislative standards. The provider of the service must ensure that the patient receives appropriate counselling and provides full consent. Both partners must be aware of the legal position regarding embryos which have been cryopreserved, should one partner remove consent to their ongoing storage or use. The provider of the service should contact patients annually to confirm that they wish to continue storage. The patient will be responsible for ensuring the storage provider has up to date contact details. The provider must ensure that material is only stored where there is a valid consent in place.

References

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Cancer treatment and survivorship statistics, 2016. Kimberly D. Miller MPH Rebecca L. Siegel MPH Chun Chieh Lin PhD, MBA Angela B. Mariotto PhD Joan L. Kramer MD Julia H. Rowland PhD Kevin D. Stein PhD Rick Alteri MD Ahmedin Jemal DVM, PhD. First published: 02 June 2016 https://doi.org/10.3322/caac.21349

Appendix A – Definitions

Cryopreservation – Cryopreservation is a process where organelles, cells, tissues or any other biological constructs susceptible to damage caused by unregulated chemical kinetics are preserved by cooling to very low temperatures. At low enough temperatures, any enzymatic or chemical activity which might cause damage to the biological material in question is effectively halted. Cryopreservation methods seek to reach low temperatures without causing additional damage caused by the formation of ice crystals during freezing.

Gametes - A gamete is the male or female reproductive cell that contains half the genetic material of that organism. Human gametes are egg cells and sperm.

Oocytes - An oocyte is a female gametocyte or germ cell involved in reproduction. It is an immature ovum, or egg cell. An oocyte is produced in the ovary during female gametogenesis. The female germ cells produce a primordial germ cell (PGC), which then undergoes mitosis, forming oogonia. During oogenesis, the oogonia become primary oocytes.

Embryo - An embryo is a multicellular diploid eukaryote at its earliest stage of development . 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.

Infertility - Is the inability to become pregnant, maintain a pregnancy or carry a pregnancy to live birth.

Iatrogenic - Iatrogenesis or iatrogenic effect, a term with Greek origins meaning "brought forth by the healer", is any untoward consequence or complication of medical treatment or advice to a patient. Some iatrogenic effects are clearly defined and easily recognised, such as a complication following a surgical procedure.

Cytotoxic therapy - is a medicine which kills growing cells in our bodies. It is usually administered to kill cancer cells but can also be used for other medical conditions. These medicines can also kill healthy cells such as eggs or sperm, resulting in infertility

Exceptional clinical circumstances are the clinical circumstances pertaining to a particular patient, which can properly be described as exceptional when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e., similar patients). A patient with exceptional clinical circumstances will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

A **Similar Patient** is a patient who is likely to be experiencing the same or similar clinical circumstances as the requesting patient, and who could therefore reasonably be expected to benefit from the requested treatment to the same or a similar degree.

Individual funding request (IFR) is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment – on the basis of their clinical individuality.

Quality and Equality Impact Assessment

Scheme Title:	NHS funded Cryopreservation of gametes and embryos policy		
Project Lead:	Clive Campton, IFR Manager Kate Cogman, Contracts Manager	**Senior Responsible Officer:**	Matt Gilks, Director of Commissioning
		Quality Sign Off:	Mary Mansfield
Intended impact of scheme:	The Cryopreservation Commissioning policy supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.		
How will it be achieved:	The Governing Body adopts the policy.		

Name of person completing assessment:	**Clive Campton**
Position:	**IFR Manager**
Date of Assessment:	**August 2020**

Quality Review by:	**Mary Mansfield**
Position:	**Deputy Director of Nursing**

Date of Review:	September 2020

Stage 1a: High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			References from public health research support effectiveness				
	Patient experience	✓			Extent of policy will impact on patient experience				
	Patient safety			✓					
	Parity of esteem			✓					
	Safeguarding children or adults			✓					
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Policy will offer patients opportunity to preserve their fertility				
	Ensuring people have a positive experience of care			✓					
	Preventing people from dying prematurely			✓					

	Helping people recover from episodes of ill health or following injury			✓					
	Treating and caring for people in a safe environment and protecting them from avoidable harm			✓					
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors			✓					
	Access to the highest quality urgent and emergency care			✓					
	Convenient access for everyone			✓					
	Ensuring that citizens are fully included in all aspects of service design and change			✓					
	Patient Choice			✓					
	Patients are fully empowered in their own care			✓					
	Wider primary care, provided at scale			✓					
Access	Patient choice			✓					

Could the proposal impact positively or negatively on any of the following:									
	Access			✓					
	Integration			✓					
Compliance with NHS Constitution	Quality of care and environment			✓					
	Nationally approved treatment/drugs			✓					
	Respect, consent and confidentiality			✓					
	Informed choice and involvement			✓					
	Complain and redress			✓					

*Risk score definitions are provided in the next section.

Risk rating score definition

Likelihood	Impact
1 – Rare	1 – Negligible
2 – Unlikely	2 – Minor
3 – Moderate	3 – Moderate
4 – Likely	4 – Major
5 – Almost certain	5 – Catastrophic

	Likelihood				
Consequence	Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost Certain (5)
Catastrophic (5)	5	10	15	20	25
Major (4)	4	8	12	16	20
Moderate (3)	3	6	9	12	15
Minor (2)	2	4	6	8	10
Negligible (1)	X-1	2	3	4	5

How will a successful implementation of quality indicators be measured?

Quality Outcome	Measured By
Positive Health gain	Gathering information on successful outcomes and patient experience
Enhancing quality of life	Information from clinics on patient feedback

Stage 1b: Equality Questions

The Public Sector Equality Duty requires us to **eliminate** discrimination, **advance** equality of opportunity and **foster** good relations with protected groups. Consider how this policy / service will achieve these aims.

Other partners/stakeholders involved in scheme:	N/A
Who will be affected by this piece of work?	ICB registered patients

PROTECTED GROUP	Is there likely to be a differential impact? (Please tick one)			Evidence/Comments for answers. Where available please share any baseline data and research on the population that this piece of work will affect. Include any consultations with service users that have been carried out.
	YES	NO	UNKNOWN	
Gender		✓		The impact of this policy has been discussed at length by the Coventry and Warwickshire Joint Policy Development group and all protected characteristics and Human Rights values given due regard and only patient demographic issues that could impact on individual risk and/or clinical effectiveness were taken into account when reaching a decision. The evidence used to inform this policy consists of: Advice and guidance from the Department of Health, current relevant regional policies and guidance, NHS England commissioning policies. In summary, any negative impact on equality is unlikely and the policy is concordant with current advice and guidance from NICE, Department of Health and NHS England.
Race		✓		As above
Disability (including mental impairment, learning diff)		✓		As above
Religion/belief		✓		As above
Sexual orientation		✓		As above
Age	✓			As above
Social deprivation		✓		As above

Carers		✓		As above
Human rights		✓		As above
Pregnancy and Maternity		✓		As above

Stage 1c: Post Implementation Review

Use the template below to record outcomes of reviews – if more than one is required cut and paste the box below:

Quality Impact	**Has there been a differential impact?** (Please tick one)			**Evidence/Comments for answers**	**Mitigations**
	YES	**NO**	**UNKNOWN**		