NHS Dorset

NHS Dorset Clinical Policy

Fertility – Assisted Conception

Local Evidence Based Intervention Policy

Preface

"The aim of the Evidence-Based Interventions programme is to prevent avoidable harm to patients, to avoid unnecessary operations, and to free up clinical time by only offering interventions on the NHS that are evidence-based and appropriate."

This policy is a local evidence-based policy that employs criteria-based access.

All managers and staff (at all levels) are responsible for ensuring that they are viewing and working to the current version of this procedural document. If this document is printed in hard copy or saved to another location, it must be checked that the version number in use matches with that of the live version on the NHS Dorset intranet.

All NHS Dorset procedural documents are published on the staff intranet and communication is circulated to all staff when new procedural documents or changes to existing procedural documents are released. Managers are encouraged to use team briefings to aid staff awareness of new and updated procedural documents.

All staff are responsible for implementing procedural documents as part of their normal responsibilities, and are responsible for ensuring they maintain an up to date awareness of procedural documents.

A	Summary Points

- Policy relates to treatment of Fertility – Assisted Conception in a secondary care setting.
- Provided case meets with the access criteria then prior approval is not required.

B	Associated Documents

- Policy for individual patient treatment, NHS Dorset
- Making sense of Evidence Based Interventions, NHS Dorset

C	Document Details
Procedural Document Number	25
Author	Hannah Nettle
Job Title	Principle Programme Lead
Directorate	Operations
Recommending committee or group	Clinical Commissioning Committee
Approving committee or group	Clinical Commissioning Committee
Date of recommendation (version 1)	17th March 2021
Date of approval (version 1)	17th March 2021
Version	6.4
Sponsor	Dr Karen Kirkham
Recommendation date	***Currently under review***
Approval date	***Currently under review***
Review frequency	3 Yearly
Review date	***Currently under review***

D	Consultation Process		
Version No	Review Date	Author and Job Title	Level of consultation

E	Version Control		
Date of Issue	Version No	Nature of Change	Approval Committee /Group
3.1	Jan 2011		
3.2	Feb 2011		
6	Jan 2015	Update to reflect NICE Guidelines and Equality Act	Chris Parsons
6.1	Sept 2015	Amended to e.g. (for example) from i.e. (that is) to clarify Cryostorage is accessible when potential infertility results from medical or clinical treatment.	Hannah Nettle
6.2	August 2017	Include a section, page 11, on Immigration Health Surcharge; Removal of assisted conception services (charges to Overseas Visitors)	Hannah Nettle
6.3	December 2017	Amendments; pathway for recurrent miscarriage & people with absolute cause of infertility do not have to demonstrate trying for 2 years; to reduce self-funded DI from 12 to 6 to demonstrate infertility for female same sex & add criteria for male same sex couples; both people of the couple have to be registered with a Dorset GP. Offer 6 cycles of IUI in this group, abandoned cycle of treatment & add in access to 1 more attempt for failed fertilisation, delays in treatment; amend oocyte and embryo cryostorage criteria; decisions for pre-implantation genetic diagnosis	Hannah Nettle

F	Supporting Documents/ Evidenced Based References	
Evidence	Hyperlink	Date
• Policy for individual patient treatment, NHS Dorset	Policy-for-Individual-Patient-Treatment.pdf (nhsdorset.nhs.uk)	June 2019
• Making sense of Local Access Based Protocols, NHS Dorset	Making-Sense-of-Evidence-Based-Interventions.pdf (nhsdorset.nhs.uk)	October 2020
• Management of Planned Care Policy, NHS Dorset	Management-of-Planned-Care-Access-Policy.pdf (nhsdorset.nhs.uk)	June 2019

G	Distribution List		
NHS Dorset Internal Intranet	NHS Dorset Internet Website	Communications Bulletin	External Stakeholders
✓	✓	✓	✓

Preface

Fertility - Assisted Conception

Evidence Based intervention Policy (EBI)

1.0 RELEVANT TO

1.1 All staff and Members within NHS Dorset ICB and all relevant referring and receiving clinicians

1.2 All providers of commissioned services to Dorset patients

2.0 INTRODUCTION

2.1 Care and treatment are commissioned by NHS Dorset ICB on behalf of the entire population. A key principle of our commissioning plans is that the value of NHS services locally can be improved by ensuring that we commission evidence-based services that meet healthcare needs. This means supplying interventions when there is a high probability of benefit and a low probability of harm whilst ensuring they are performed in the right place and at the right time.

2.2 This comes with a responsibility for managing an overall budget and therefore it is important that all commissioning decisions are based on need and are planned in a systematic and straightforward way that will ensure effective financial control. The overall responsibility is to ensure that commissioning decisions ensure equity in the overall use of healthcare resources for the entire population.

2.3 Commissioners need to balance the requirement to supply treatments for individuals against this need to improve value by commissioning services for populations. This means that there continues to be a focus on reducing or stopping procedures of limited or lower clinical value.

3.0 SCOPE

3.1 It should be noted that this document is only applicable to NHS Dorset patients. For all other patients, the providers will need to refer to the patient's respective commissioners' web pages to decide their access protocols and threshold criteria.

3.2 This document should be read in conjunction with the Policy for Individual Patient Treatment that supplies more detail on:

•The underlying principles.

•The decision-making framework.

•Specific circumstances relating to potential individual requests; and

•The appeal processes.

4.0 PURPOSE

4.1 This document lists the criteria to be considered when referring or assessing a referral for Fertility – Assisted Conception for an NHS Dorset Patient.

5.0 DEFINITIONS

5.1 Any definitions related to this Evidence Based Intervention are included as a Glossary at Appendix A.

6.0 ROLES AND RESPONSIBILITIES

6.1 It should be noted that it is the responsibility of the clinician referring or sending notification to ensure that all information is completed on the request forms sent to NHS Dorset.

6.2 All clinical staff involved with referrals for Fertility – Assisted Conception have a responsibility to ensure they follow the access criteria stated.

7.0 ACCESS CRITERIA

7.1 All couples will be expected to have gone through the primary and secondary care pathways as defined in the Fertility- Assisted Conception Criteria based protocol.

7.2 It is anticipated that some patients who are not eligible for treatment because they do not fulfil these criteria may, by virtue of their personal circumstances, be considered an exceptional case for NHS funding. If this is thought to be applicable, the patients' GP or Hospital Consultant may contact the Individual Patient Treatment Panel for consideration of exceptional circumstances.

8.0 NATIONAL HEALTH SERVICE REGULATIONS

IMMIGRATION HEALTH SURCHARGE UPDATE:

8.1 Immigration health surcharge; removal of assisted conception services Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, assisted conception services will no longer be included in the scope of services available for free for those who pay the immigration health surcharge. Further information can be found in the Explanatory Memorandum for these regulations.

9.0 BACKGROUND

9.1 In the general population (which includes people with fertility problems), it is estimated that 80% of women would conceive within one year of regular unprotected sexual intercourse. This rises cumulatively to 90% after two years.

9.2 Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. It is estimated that infertility affects one in seven couples in the UK. It appears that there has been no major change in the prevalence of fertility problems but that more people now seek help for such problems than did so previously.

9.3 NHS Dorset Governing Body considered the available evidence, existing guidelines, local clinical and public opinion in developing this criteria-based protocol.

10.0 TYPES OF FERTILITY TREATMENT

10.1 There are three main types of fertility treatment:

- Medical treatment (such as use of drugs for ovulation induction) which is not covered by this criteria-based protocol; Page 5 of 25
- Surgical treatment (for example, laparoscopy for ablation of endometriosis) which is not covered by this criteria-based protocol; and
- Assisted conception treatments, which are the subject of this criteria-based protocol.

11.0 WHAT ASSISTED CONCEPTION SERVICES ARE SUPPORTED

11.1 The following assisted conception technologies and techniques are supported in Dorset:

- Intrauterine Insemination (IUI)
- In-Vitro Fertilisation (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Surgical Sperm Recovery

11.2 The following fertility preservation techniques are supported in Dorset, in certain circumstances:

- Semen Cryostorage;
- Oocyte Cryostorage;
- Embryo Cryostorage.

11.3 The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. Treatment will only be supported at clinics holding the relevant HFEA license.

12.0 FERTILITY INVESTIGATION

12.1 Couples referred to gynaecology services for investigation of infertility do not need to meet the access criteria for assisted conception treatments detailed in this criteria-based protocol. The clinical definition of infertility is the failure to conceive after 1 year of regular unprotected intercourse and patients should not generally be referred before this time, with exception due to clinical need as specified in the referral.

12.2 Referral for investigation of infertility can be made even where there has not been regular unprotected intercourse for this time (1 year) or where the women is over the age of 36 or where there is:

- Known clinical cause or history of predisposing factors affecting fertility, for example, prior treatment for cancer.

12.3 Patients who are covered by the early investigation criteria listed above may be referred to gynaecology services at the discretion of the referring and receiving clinician. This will be a referral for investigations only and there will be a need for the couple to meet the access criteria for onward referral for assisted conception.

12.4 Following full investigation and if the couple meets the access criteria they can be offered a referral for assisted conception treatments.

12.5 If couples wish to defer treatment after referral, they may defer for up to 3 months; as long as this does not take the woman above the age of 42 years.

13.0 GENERAL ACCESS CRITERIA FOR ASSISTED CONCEPTION SERVICES

13.1 Couples must fulfil all the eligibility criteria for referral for IUI, IVF or ICSI.

Couples who do not meet these criteria should not be made to assisted conception services. If referrals are made in error the services will not accept these referrals nor commence assisted conception treatments. Clinicians wishing to seek exceptionality on behalf of the couple would have to seek funding via the evidence based interventions policy for commissioning treatments for individual patients. Our expectation is that people seeking assisted conception services will only be referred to a specialist after appropriate medical and surgical treatment within general gynaecology-fertility services.	
Partners: both must be:	

Preferably at the same GP practice	Both partners of the couple should preferably be registered to the same practice in NHS Dorset. If both partners of the couple decide to not register with the same GP practice, then one GP practice must agree to take the lead in coordinating the referral process for assisted conception. This is to ensure that relevant investigations and treatments run concurrently, and to avoid any duplication of investigations. If partners of the couple decide to not register with the same GP practice, then written consent from one partner will need to be given to the main lead GP (coordinating the referral process). This will provide authority for the lead GP to contact the GP where the other partner is registered, to discuss if the partner meets the access criteria.
Age – women: no lower age limit	There is no lower age limit for women however they must meet all other referral criteria. Women need to be referred before their 42nd birthday to ensure adequate time for treatment before reaching the cut-off age of 42 years for completion of treatment cycle
BMI 19 to 30 Kg/m2 female for 6 months prior to a referral	Body Mass Index within the range 19 to under 30 kg/m2 (this means that a BMI of 30 is outside the criteria). General Practitioners should advise patients regarding weight loss support if they meet all other criteria. Assisted conception treatments will only be provided when BMI is within the range stipulated and has been maintained within 19 to under 30 kg/m2 for the previous 6 months
BMI under 30 Kg/m2 for male for 6 months prior to a referral	Body Mass Index under 30 kg/m2 General Practitioners should advise patients regarding weight loss support if they meet all other criteria. Assisted conception treatments will only be provided when BMI is under 30 kg/m2 and has been maintained under this level for the previous 6 months.
Welfare of the child	The welfare of any resulting children is paramount. In order to take into account the welfare of the child, the clinician should consider factors which are likely to cause serious physical, psychological or medical harm either to the child to be born or any existing children of the family. This is a requirement of the licensing body, Human Fertilisation and Embryology Authority (HFEA)
Family Structure	Having living children from a previous relationship (including adopted children and offspring) does not negate eligibility. At least one of the partners must have no living children (this includes biological and legally adopted children and offspring) and there must be no living children from the current partnership to be eligible. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the welfare of the child.
Non-smokers for 6 months prior to a referral	Both partners must be non-smokers for 6 months prior to a referral. Non-smoking status for both partners will be tested with a carbon monoxide breath test prior to commencement of any treatment. General Practitioners should refer any smokers who meet all other criteria, to a smoking cessation programme to support their efforts in stopping smoking. Previous smokers must be non-smoking for 6 months prior to being put forward for assisted conception treatment and register below 5 on the Carbon Monoxide test.

Having regular unprotected intercourse for the 2 years prior to referral.	Couples must have been having regular unprotected intercourse for a 2-year period, documented by GP prior to referral for assisted conception, unless exception criteria apply. Couples who conceive naturally and who subsequently miscarry recurrently will be investigated. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for NHS gynaecological investigations and treatments if appropriate. If there is a requirement for assisted conception following NHS gynaecological investigations and treatments, then the referring clinician will need to outline in an individual request the rationale for the patient by passing the two-year trying period. The couple should meet all other areas of the policy access criteria. Couples who are already referred/about to start IVF/ICSI treatment and then conceive naturally but miscarry, can continue with IVF/ICSI after a period of 6 months trying, providing there is no further natural conception. Patients who are diagnosed with a cause of absolute infertility which precludes any possibility of natural conception and who meet all the other eligibility criteria will have immediate access to NHS funded assisted conception services, including IVF/ICSI.
Evidencing infertility in female same sex couples	Female same sex couples access to assisted conception is the same as it is for heterosexual couples i.e. one partner in the relationship is infertile and all other criteria are met. Same sex couples will need to evidence infertility. Proven infertility will be defined as: • One partner has explained infertility i.e. blocked tubes or anovulation (which is not corrected by oral ovulation induction agents); or • A woman of reproductive age who is using donor insemination to conceive should be offered further clinical assessment and investigation if she has not conceived after 6 cycles of donor insemination treatment within up to 2 years (and in the cases where 6 cycles of self-funded donor insemination need to be completed over the 2 year period this will be considered/assessed on a case to case basis), in the absence of any known cause of infertility. Donor insemination and intrauterine insemination in this situation would not be funded by the NHS. For female same sex couples who have not conceived after 6 cycles of donor insemination consider 6 cycles of unstimulated intrauterine insemination as an NHS funded treatment option for female same sex couples. In the case of women in which only one partner has proven infertility, clinicians should discuss the possibility of the other partner becoming pregnant before proceeding to interventions involving the partner with proven infertility. Same sex couples should have access to professional experts in reproductive medicine to obtain advice on the options available
Evidencing infertility in male same sex couples	Male same sex couples will be referred for infertility investigation if no pregnancy results following six cycles of donor insemination for which the man's donated sperm has been used. NHS Dorset will not fund donor insemination and intrauterine insemination in this situation.
Previous treatment history	A maximum of 1 NHS funded cycle will be supported by NHS Dorset
Reversal of sterilisation	Any patient that has undergone either a vasectomy or female sterilisation, or a reversal of these procedures, is ineligible for access to assisted conception services.

13.2 Preservation Treatments

People of reproductive age are eligible for preservation treatment prior to treatment that may affect their fertility e.g. cancer. This includes single people	
GP registration status	Both partners of the couple should preferably be registered to the same practice in NHS Dorset. If both partners decide not register with the same GP practice, then

	one GP practice must agree to take the lead in coordinating the referral process for assisted conception

13.3 Exclusions for fertility – assisted conception treatments and semen cryopreservation only: (either partner)

All couples need to meet the eligibility criteria set out in section 13, but couples will be excluded if either partner has:	Under a vasectomy or female sterilisation procedure or a reversal of either Conceived naturally and is currently being investigated for recurrent miscarriage. Referral can take place after investigations are completed and all other access criteria are fulfilled.

14.0 ASSISTED CONCEPTION SERVICES SUPPORTED IN DORSET

14.1 Patients should be reviewed against access criteria at each stage of treatment

Definitions	Clinical Indications	Comments
IUI	Consider intrauterine insemination as a treatment option in the following groups as an alternative to vaginal intercourse:	Offer up to 6 cycles of unstimulated Intrauterine insemination. (If it is clinically appropriate this may be stimulated intrauterine insemination) as a treatment option in the following groups as an alternative to vaginal intercourse: • People who are unable to or would find it very difficult to have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner of donor sperm. • People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) • People in same-sex relationships. • For people who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation,tubal patency and semen-analysis,offer a further 6 cycles of unstimulated intrauterine insemination before IVF is considered. • For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse: Do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstancesinclude, for example, when people have social, cultural or religious objectionsto IVF) advise them to try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered
IVF		IVF may be considered when: • In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), couples should be offered 1 full cycle of IVF, with or without ICSI. • In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled: o they have never previously had IVF treatment

		o there is no evidence of low ovarian reserve o there has been a discussion of the additional implications of IVF and pregnancy at this age
ICSI	severe deficits in semen quality obstructive azoospermia non-obstructive azoospermia failure of spermatogenesis failed or very poor fertilization	ICSI may be selected over IVF if the quality of sperm is found on the day to be poor (for unknown reasons). ICSI will generally not be offered for unexplained fertility problems as there is no evidence to suggest that ICSI improves pregnancy rates above those achieved with IVF

15.0 DONATED SPERM AND EGGS (OCCYTES) SUPPORTED IN DORSET

15.1 Patients should be reviewed against access criteria at each stage of treatment

Where gametes are used in combination with assisted conception (IVF/ICSI) the number of cycles will be in line with the cycles detailed below.

Definitions	Clinical Indications	Comments
SPERM	• genetic disorders affecting sperm • following chemotherapy or radiotherapy • obstructive azoospermia • non-obstructive azoospermia • infectious disease in the male partner (such as HIV) • severe rhesus iso-immunisation • severe deficits in semen quality in couples who do not wish to undergo ICSI	Donor sperm is supported for couples who meet the access criteria. Donor sperm may be considered to be used for same sex female couple where there are established medical reasons for infertility in one partner. Donor selection will take no longer than six months. Couples where donor selection has not been possible will be removed from the waiting list.
OOCYTE (eggs)	• premature ovarian failure • gonadal dysgenesis including turner syndrome Bilateral oophorectomy • ovarian failure following chemotherapy or radiotherapy • oocyte donation should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring • for patients in which the use of donor oocytes is clinically indicated • Certain cases of IVF treatment failure	Donor oocytes may be considered by a clinician, but the couple must meet the referral criteria. Women with markedly diminished ovarian function should be counselled on their low chances of conception using their own gametes, even with assisted reproduction. Donor selection will take no longer than six months. Couples where donor selection has not been possible will be removed from the waiting list.

16.0 IVF/ICSI TREATMENT DEFINITIONS OF A CYCLE

16.1 The HFEA and NICE both consider that a fresh assisted conception treatment cycle starts:

- on the commencement of ovarian stimulation
- or, if no drugs are used, when an attempt is made to collect eggs.

A full cycle of IVF/ICSI may produce several embryos suitable for transfer; those which are not transferred may be stored for future use. The HFEA considers that a frozen treatment cycle starts when a cryopreserved embryo is removed from storage in order to be thawed and then transferred.

Number of Cycles Offered

16.2 One full cycle will be provided to couples. A full cycle is defined in this criteria-based protocol as 1 fresh and 1 frozen implantation of embryos. A frozen cycle will only be available if there are embryos generated from the fresh cycle suitable for freezing.

16.3 Single embryo transfers will be undertaken where deemed clinically appropriate. Couples will not be able to choose not to have single embryo transfers when it is deemed clinically appropriate.

16.4 There should be a minimum of a 3-month interval between a fresh and frozen cycle, measured from the date the service is notified that the fresh cycle has been unsuccessful. Patients can proceed to treatment ahead of the 3-month interval if is deemed clinically and emotionally appropriate by the service.

16.5 For the purposes of this criteria-based protocol, the commencement of IVF/ICSI cycle is defined as commencement of ovarian stimulation, or if no drugs are used, when an attempt is made to collect eggs. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. One frozen cycle will follow a fresh cycle if deemed clinically appropriate.

16.6 Exception applies to above 16.5; when couples abandon ovarian stimulation and egg collection for clinical reasons couples are entitled to one further attempt (cycle) of IVF/ICSI as below 16.7 and 16.8.

16.7 In the case of funding for 1 more attempt when patients abandon a cycle due to being at risk of ovarian hyper stimulation syndrome the service should ensure it is deemed clinically appropriate for the patient to undergo treatment and it will not cause harm to the patient.

16.8 In the case of funding for 1 more attempt due to under ovarian stimulation response, the service should ensure it is clinically appropriate, e.g. a change in dose would be very likely to achieve stimulation or offer the option of IVF with donor eggs.

16.9 Exception applies to above 16.5 when couples have failed fertilization and do not create embryo/s they are eligible for 1 more attempt (cycle) of IVF or ICSI where failed fertilization has resulted from first attempt at IVF or ICSI cycle. This cycle of treatment can be with or without donor sperm if this is clinically recommended for success and the patient wishes to access donor sperm.

16.10 Once treatment has commenced couples are able to delay treatment between the fresh cycle and frozen cycle up to 12 months – up to the 1-year period that the stored embryo is funded by the NHS. Delays outside of this period will need to be agreed by the patient's GP and NHS Dorset. N.B agreed delays in treatment over the 12-month period must be discussed with the service and a provisional date re-booked with a clear communication plan agreed between couples and the service to discuss resuming treatment.

17.0 FERTILITY PRESERVATION TECHNIQUES SUPPORTED IN DORSET

Definition	Clinical Indication and Criteria	Criteria and Comments
Storage		
Family Structure		Having children already does not negate eligibility
Semen Cryostorage	Potentially impaired fertility as a course of treatment, e.g. malignancy of genital tract, systemic malignancies.	Where a man requires medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm production, such treatment includes radiotherapy or chemotherapy for malignant disease. Keeping in storage, if agreed. Where a man requires ongoing medical treatment that, whilst on treatment, causes harmful effects on sperm production, impotence or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option. Storage; initial period of ten (10) years. The man must not be older than 50. Anything outside of this will be considered via Individual Patient Treatment (IPT).
In the case of transgender/gender dysphoria, fertility preservation will include the freezing and storage of sperm.		
In the event a patient dies, storage can continue as above with the fertility centre managing ongoing storage decisions based on patient consent and wishes (as per HFEA regulations) and with any living partner and/or family.		
Oocyte Cryostorage or Embryo Cryostorage without simultaneous assisted	Potential treatment likely to impair fertility e.g. malignancy Funding for fertility preservation will be offered to individuals who have a disease or a medical condition	Women have access to oocyte/egg cryostorage. Couples will have the option to discuss access to oocyte/egg or embryo cryostorage, however clinical judgement will be applied to determine which option is most appropriate. Women should be offered cryostorage if they are well enough to undergo ovarian stimulation and egg collection, provided that this will not worsen their condition and that sufficient time is available.

conception treatment	which requires urgent medically necessary treatment that has a significant likelihood of making them infertile and those whose medical treatment (such as radiotherapy or chemotherapy) may compromise fertility. In addition, NHS Dorset will give consideration to those conditions which fall into a 'defined disease group' such as Mayer-Rokitansky-KusterHauser syndrome. Each case is assessed on an individual basis.	Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development. Criteria for cryopreservation: 1. Patients must have commenced puberty. 2. Female patient must not be older than 40 (Would enable some women to still meet assisted conception policy and completing treatment by age 43) . 3. Fertility preservation for the following patient(s) is not commissioned and will not be funded where the patient wishes to undergo female sterilisation and wishes to preserve fertility, or the patient wishes to delay conception. 4. The length of egg/embryo storage period funded by the NHS is up to 10 years. Requests for NHS funded storage beyond 10 years will be considered by individual treatment request and must not exceed appropriate HFEA regulations on length of storage. 5. At the time of fertility preservation treatment, patients do not need to demonstrate they comply with the below criteria as NHS Dorset recognises this would be unfair and delaying treatment until a patient could comply would be dangerous: a. of a non-smoker b. a BMI between >19 6. After preservation treatment if patients wish to access the NHS funded assisted conception treatment then couples would be expected to meet all aspects of the fertility assisted conception access criteria.
Embryo Cryostorage after NHS funded assisted conception	Suitable embryo's that are not transferred in IVF/ICSI cycle	Storage funding will be funded for a period of one (1) year.
Ongoing Storage	Self-funding following cessation of NHS funding	Once the period of NHS funding ceases, patients can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.
Post-storage Treatment		Commencement of cryostorage does not entitle people to assisted conception treatments. There is the potential for individuals to meet the access criteria for cryostorage and not to meet the criteria for infertility treatments at a later date. Further funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage

18. OTHER RELATED TECHNOLOGIES

Pre-Implantation Genetic Diagnosis

18.1 Pre-implantation genetic diagnosis (PGD) involves genetically testing an embryo in a laboratory prior to implantation and is usually used by patients with a known pre-disposition to a specific genetic disorder. PGD is an established technique that is becoming more widely used in this country under license from the HFEA for the diagnosis of genetic and chromosomal abnormalities for couples with a high risk of having an affected offspring:

- it is an additional step in an IVF treatment cycle and will involve removal of a cell from an embryo which is then tested for the faulty gene that causes the condition in the family. Those embryos which do not contain the faulty gene can then be implanted as appropriate.

18.2 PGD is currently HFEA licensed for a small number of centres, and a specific set of conditions. NICE has not considered PGD and specifically excluded the consideration from the production of the full guideline.

18.3 There are alternatives to PGD, including adoption, not having a child, using donor sperm or eggs, or prenatal diagnosis. Any patients who are considering PGD should be counselled on the options available to them.

18.4 Decisions regarding PGD treatments are made by NHS England. These decisions will be made within the framework of NHS England's Clinical Commissioning Policy for Preimplantation Genetic Diagnosis and, where appropriate, Commissioning Policy for Individual Funding Requests.

NHS England's Commissioning policies can be found here:
https://www.england.nhs.uk/wp-content/uploads/2013/04/e01-p-a.pdf
https://www.england.nhs.uk/wp-content/uploads/2017/11/comm-policy-indivdual-funding-requests.pdf

Surrogacy

18.5 Surrogacy is when a woman carries a baby for someone who is unable to conceive or carry a child themselves, with the intention of handing the baby over to the intended parents of parent (IP). The IP are couples or individuals who cannot have a child themselves and who are considering surrogacy as a way to become a parent. This includes heterosexual or same-sex couples in a marriage, civil partnership or living together / co-habiting, or individuals regardless of their relationship status.

There are two different types of surrogacy arrangements:

- Straight surrogacy (known as 'traditional surrogacy') – this is when the surrogate provides her own eggs to achieve the pregnancy and therefore has a genetic link to the child. The intended father, in either a heterosexual or male same sex relationship, or an individual including donor sperm via a fertility clinic), provides a sperm sample for conception through either self-insemination at home or artificial insemination with the help of a fertility clinic.

- Host surrogacy - (also known as 'gestational surrogacy') is when the surrogate does not provide her own egg to achieve the pregnancy. The embryos are created in vitro

and transferred into the uterus of the surrogate using eggs of the intended mother fertilised with sperm of the intended father or donor; or eggs of a donor fertilised with 19 sperm of the intended father, where the intended mother cannot use her own eggs, or the IPs are the same-sex male couple.

18.6 Surrogacy is governed by the Surrogacy Arrangements Act 1985 and the Human Fertilisation and Embryology Act 2008. It is a complicated area and raises a number of ethical and legal issues, including:

Ethical issues:

- The risk of conflict between the surrogate mother's wishes and intended parents in relation to the best interests of the child.
- Rejection of the child in cases of multiple pregnancy, disability or birth trauma by both surrogate and intended parents.
- Surrogate mother changing her mind during pregnancy or after child has been handed over to intended parents.
- Long term psychological effects on all those involved in the surrogacy arrangement.
- Conflict arising in relation to decision making during the pregnancy and aspects of care.
- Risk of morbidity and mortality to either the child or the surrogate mother.

Legal issues:

- Commercial surrogacy arrangements remain illegal in the UK, but reasonable expenses can be paid for altruistic surrogacy.
- Some non-profit organisations can lawfully assist potential surrogates and intended parents to navigate their surrogacy.
- There are differing and complicated legal frameworks when surrogate mother and intended parents are foreign nationals.
- Surrogacy agreements are not legally enforceable.
- Surrogate mother has legal rights over the foetus and is regarded as the legal mother.
- A parental order (PO) is required to transfer parentage and associated parental responsibility for decision making in treatment settings. The timing of a PO can result in different periods to navigate if the child requires treatment.

- NHS bodies are unlikely to be in a position to properly assess whether the parties have concluded a lawful surrogacy arrangement.

- Human Fertilisation and Embryology Act 2008 acknowledges that surrogacy involves complicated legal issues, and therefore all involved are advised to obtain legal advice prior to making any decisions.

  As a result of the ethical and legal issues involved in this complex area which presents unique challenges for both surrogate mother, child and intended parents, NHS Dorset will not fund treatment which relates specifically to commissioning fertility treatments directly associated with surrogacy arrangements, or fund any payments to the surrogate mother (to cover expenses, legal costs, treatments abroad or transport costs). In addition, there is no clear guidance for Commissioning bodies nationally. This matter will remain under periodic review, in accordance with best practice regarding policy monitoring, to ensure any changes within UK law, or national guidance or central policy regarding surrogacy arrangements, are noted for impact on the current funding position.

GIFT and ZIFT

18.7 There is insufficient evidence to recommend the use of gamete intra-fallopian transfer (GIFT) or zygote intra-fallopian transfer (ZIFT) in preference to IVF in couples with unexplained fertility problems or male factor fertility problems. GIFT and ZIFT are not supported.

Assisted Hatching

18.8 Assisted hatching is not supported because it has not been shown to improve pregnancy rates.

Cervical Mucus Testing

18.9 The routine use of postcoital testing of cervical mucus in the investigation of fertility problems is not recommended because it has no predictive value on pregnancy rate.

Reproductive Immunology

18.10 With the exception of aPL testing among women with recurrent miscarriage, there is little evidence to support any particular test or immunomodulatory treatment in the investigation and treatment of couples with reproductive failure. With the exception of aPL testing, Reproductive Immunology is not supported.

Varicocele Surgery

18.11 Varicocele surgery is not supported as there is no published evidence to support improvement in pregnancy rates.

19.0 CASES FOR INDIVIDUAL CONSIDERATION

19.1 Should a patient not meet the criteria detailed within this protocol, the Policy for Individual Patient Treatments (which is available on the NHS Dorset website or upon request), recognises that there will be occasions when patients who are not considered for funding may have good clinical reasons for being treated as exceptions. In such cases the requesting clinician must supply further information to support the case for being considered as an exception.

19.2 The fact that treatment is likely to be effective for a patient is not, a basis for exceptional circumstances. For funding to be agreed there must be some unusual or unique clinical factor in respect of the patient that suggests that they are:

- significantly different to the general population of patients with the condition; and
- they are likely to gain significantly more benefits from the intervention than might be expected for the average patient with the condition

19.3 In these circumstances, please refer to the Individual Patient Treatment Team at the address below:
Second Floor West
Vespasian House
Barrack Road
Dorchester
DT1 1TG
Telephone no: 01305 213505
Email: individual.requests@nhsdorset.nhs.uk

20.0 TRAINING

20.1 Training needs have been considered and there are no identified training requirements.

21.0 CONSULTATION

21.1 See schedule D

22.0 RECOMMENDATION AND APPROVAL PROCESS

22.1 See schedule C

23.0 COMMUNICATION/DISSEMINATION

23.1 See schedule G

23.2 Following approval at the proper Clinical Commissioning Committee each Policy will be uploaded to NHS Dorset's Intranet, Internet and added to the next GP Bulletin.

24.0 IMPLEMENTATION

24.1 A communication will be sent to all providers to launch this new EBI Policy.

25.0 MONITORING COMPLIANCE AND EFFECTIVENESS OF THE DOCUMENT

25.1 The effectiveness of this document will be checked via feedback from the Individual Patient Treatment Panel, referrers, and other members of NHS Dorset. An annual review of the feedback will be undertaken to see if minor modifications are needed to ensure clarity.

25.2 Information which supports a change to the relevant evidence-based protocol cannot be considered as part of the consideration of an individual request. Such information should be considered at the next review of the protocol. Clinicians should therefore be clear as to whether the information they are supplying is in support of a change to access criteria, and NHS Dorset will endeavour to ensure this is brought to the attention of the relevant team when the protocol is due for review.

26.0 DOCUMENT REVIEW FREQUENCY AND VERSION CONTROL

26.1 This document is reviewed every three years to take account of any changes in national guidance and to inform the contracting process.

Necessary modifications to improve clarity will result in the subsidiary part of the version number being incremented, i.e., Version 7.1 followed by versions 7.2 and 7.3 before being replaced following the next bi-yearly review by Version 8.

These updates will be clearly communicated via the channels shown in schedule G.

Definitions / Glossary of Terms

Embryo Cryostorage
Embryo cryopreservation is the freezing and storage of embryos that may be thawed for use in future in-vitro fertilisation treatment cycles. The patient will undergo the first stages of the IVF cycle, with the resulting embryos being frozen rather than implanted.

ICSI
Intracytoplasmic Sperm Injection (ICSI) is a variation of in-vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.

Infertility
In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years.

IUI
Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti- oestrogens or gonadotrophins (stimulated IUI).

IVF
In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body.

The term IVF usually refers to the full cycle of treatment, where one or two embryos which have resulted from the in-vitro fertilisation process are then transferred to the womb with the aim of starting a pregnancy.
The main procedures involved in IVF treatment are:

- pituitary down regulation: switching off the natural ovulatory cycle to facilitate controlled ovarian stimulation.
- ovarian stimulation: administration of gonadotrophins to encourage the development of several follicles followed by administration of HCG to mature eggs ready for collection.
- egg collection followed by semen production or sperm recovery.
- IVF.
- transfer of resulting embryos to the uterus.
- luteal support: administration of hormones to aid implantation of the embryos.

Oocyte cryostorage
Oocyte cryopreservation is the freezing and storage of eggs that may be thawed for use in future in-vitro fertilisation treatment cycles.

Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development.

Semen cryostorage

Semen cryostorage is the freezing and storage of semen that may be thawed for use in future in fertility treatment cycles. 22 Surgical sperm recovery

Spermatozoa can be retrieved from both the epididymis and the testes using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or nonobstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate.

Surgical spern recovery
Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymis) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI. Surgical techniques for sperm retrieval from the epididymis or the testis:

PESA
Percutaneous epididymal sperm aspiration (PESA)

TESA / TEFNA
Testicular sperm aspiration (TESA), which is also described as testicular fine needle aspiration (TEFNA)

TESE
Testicular sperm extraction (TESE) from a testicular biopsy

MESA
Micro-surgical epididymal sperm aspiration (MESA)

Frequently Asked Questions

1) **Why do we need to try to fall pregnant naturally for 2 years before we can be considered for assisted conception?**

   The evidence is that many people will conceive naturally within 2 years of unprotected sex and should not be investigated unnecessarily.

2) **Why is it recommended that we are both registered with the same general practice?**

   The reason for this is to ensure that of you are investigated, treated and supported and there is not duplication between different practices. However, it is personal choice if you wish to remain with your chosen GP practice, but one GP practice must take the lead in coordinating the referral process for assisted conception.

3) **Why do we have to be non-smokers?**

   The reason for this is that the likelihood of a successful pregnancy is higher in non-smokers. You will not be put on the waiting list for assisted conception services if you are a smoker. We can make a referral to a free NHS stop smoking programme to support you to stop smoking. The service will always consider a re-referral in line with the criteria based protocol once you have both ceased smoking for a period of 6 months.

4) **Why do we need to lose weight?**

   The reason for this is that the likelihood of a successful pregnancy is higher in people whose weight falls within a certain range. You will not be put on the waiting list for assisted conception services if you need to reduce your weight. The service will always consider a rereferral in line with the criteria-based protocol once you have both achieved the target BMI range.

5) **What are the age restrictions with this criterion-based protocol?**

   There is no defined lower age limit and referral into the service must allow for the final treatment to be completed by the last day of the women's 42 year. All other criteria must also be met (eg. BMI, non-smoking, etc) then you will be placed on the waiting list. After each fresh cycle of IVF or ICSI the couple will only be referred on to the next treatment if they continue to meet the criteria-based protocol *. If you fail to meet the criteria based protocol during your treatment, for example start smoking, you will be discharged back to your GP and any referral back to the service will be considered as a new referral and the criteria based protocol age restrictions will apply.

6) What do we do if we think we have special circumstances and should be considered as an exception to the criteria-based protocol?

The clinician responsible for your care can write to your commissioners seeking an exception to the criteria-based protocol. They will be required to supply clinical information to support a request which would then go before a Panel who consider such cases.

7) When will IVF be considered?

In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), couples should be offered 1 full cycle of IVF, with or without ICSI.

In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:

- they have never previously had IVF treatment
- • there is no evidence of low ovarian reserve
- • there has been a discussion of the additional implications of IVF and pregnancy at this age

8) When is ICSI considered:

ICSI is intracytoplasmic sperm injection and is a variation of IVF. A single sperm is injected into an egg. ICSI will be considered if IUI or IVF has not resulted in a live birth or IUI or IVF is inappropriate. The other reasons ICSI will be considered are when there is:
a. Poor sperm quality
b. Obstructive and nonobstructive azoospermia
c. When IVF has failed or there is very poor fertilisation ICSI may be selected if the quality of sperm is found to be poor on the day. There is no evidence that suggests ICSI improves the changes of a successful pregnancy with people with unexplained infertility problems, and therefore is not generally offered.

9) What happens if our first cycle of IVF is not successful?

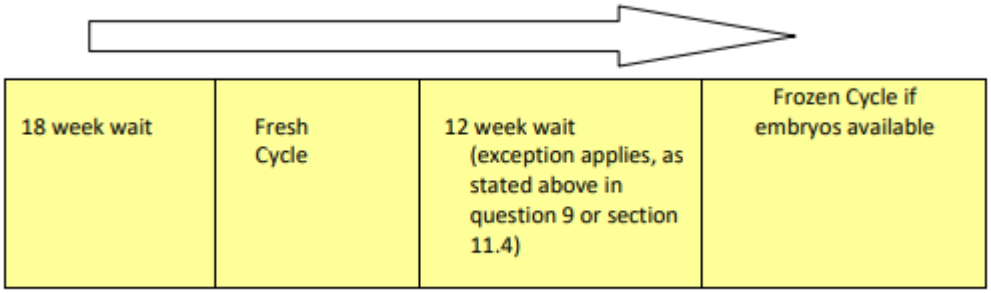
You will be seen by the team and you will jointly agree the next steps. There will be a minimum of 3 months between the first cycle and any frozen cycle. Patients can proceed to treatment ahead of the 3-month interval if is deemed clinically and emotionally appropriate by the service.

10)What happens if a cycle is abandoned for clinical reasons?

This is still counted as one cycle but see Section 11.7 and 11.8.

11)What is the time interval between cycles?

The following diagram shows the timescales for a treatment cycle



References

• Department of health (2008) choice at referral – supporting information for 2008/09 V1.0. AVAILABLE FROM HTTP://WWW.DH.GOV.UK/PUBLICATIONS;

• National collaborating centre for women's and children's health (2004) fertility: assessment and treatment for people with fertility problems. Clinical guideline: commissioned by the national institute for clinical excellence;

• Royal college of obstetricians and gynaecologists (rcog 2008) immunological. Testing and interventions for reproductive failure;

• Fertility assessments and treatment for people with fertility problems nice clinical guidelines (CG156) Published 20 February 2013. Last updated 06 September 2017(February 2013);

• Fertility problems nice quality standard (QS73) Published 23October 2014.

• Human Embryo Fertilisation Act (HFEA) Commissioning Guidance (May 2019)

NHS Dorset