Appendix 1

East of England
Specialised Commissioning Group

Fertility Services Commissioning Policy

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This policy replaces all previous versions. Where patients have commenced treatment in any cycle prior to this version becoming effective, they are subject to the eligibility criteria and scope of treatment set out in the relevant version.

Previous versions of this policy:

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Version 2 – Effective 1 July 2010 to 31 May 2011
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Action required	For dissemination within primary and secondary care providers
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1. Introduction

1.1.1 This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services for the population of the east of England, along with the commissioning responsibilities and service provision.

1.1.2 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.

1.1.3 The paper specifically sets out the entitlement and service that will be provided by the NHS for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI).These services are commissioned by the East of England Specialised Commissioning Group and provided via tertiary care providers.

1.1.4 This policy also supports the commitment made in the east of England clinical vision *Towards the best, together* to increase the overall number of NHS- funded IVF cycles against standard criteria.

1.1.5 It is the purpose of the criteria set out in this policy to make the provision of fertility treatment fair, clear and explicit. This paper should be read in conjunction with:

- The NICE Guidance CG011 "Fertility: assessment and treatment for people with fertility problems"(2004) available on their website at www.nice.org-pdfCG011niceguideline.pdf.url
- The Human Fertilisation & Embryology Authority (HFEA) document "The Best Possible Start to Life" (2007) available on their website www.hfea.gov.uk
- The report "One Child at a Time" published by the Expert Group on Multiple Births after IVF set up by HFEA available on their web site www.hfea.gov.uk/en/505.html

1.2 Review

1.2.1 The East of England Specialised Commissioning Group will review this policy annually and within 3 months of any legislative changes that should or may occur in the future. The date of the next review will be March 2012.

2. Commissioning responsibility

2.1.1 Specialist fertility services are considered as Level 3 services or tertiary services. Preliminary Levels 1 & 2 are provided and commissioned within primary care and secondary services such as acute trusts. To access Level 3 services the preliminary investigations should be completed at Level 1 & 2.

2.1.2 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between the East of England Specialised Commissioning Group and each tertiary centre. Quality Standards and clinical governance arrangements will be put in place with these centres, and outcomes will be monitored and performance managed in accordance with the Human Fertilisation & Embryology Authority Licensing requirements or any successor organisations.

2.1.3 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.

2.1.4 Couples who do not meet the criteria and consider they have exceptional circumstances should be considered under the Exceptional Treatment Policy of their local Primary Care Trust.

2.1.5 Couples will be offered a choice of providers that have been commissioned by the East of England Specialised Commissioning Group.

3. East of England Fertility services policy and criteria

3.1 Treatments funded

3.1.1 The East of England SCG only commissions the following fertility techniques regulated by the Human Fertilisation & Embryology Authority (HFEA).

3.2 In-Vitro Fertilisation (IVF)

3.2.1 An IVF procedure includes the stimulation of the women's ovaries to produce eggs which are then placed in a special environment to be fertilised. The fertilised eggs are then transferred to the woman's uterus.

3.2.2 For couples requiring IVF or ICSI, this policy supports a maximum of 6 embryo transfers with a maximum of three fresh cycles, this includes abandoned cycles. Where couples have previously self funded an IVF

cycle without PGD and pronucleate or cleavage stage frozen

embryos (not blastocysts) exist, then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

3.2.3 An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer. In all fresh cycles for women under the age of 37 years of age only one embryo, or blastocyst, will be transferred, unless there are medical mitigating circumstances.

3.2.4 A fresh cycle would be considered completed once administration of drugs for the purpose of superovulation has occurred, or if no drugs are used, with the attempt to collect eggs.

3.2.5 For couples where the woman is under 38 years of age, there should be a six month period between completion of the pregnancy test and commencement of drugs for the next fresh cycle.

3.2.6 If a cycle is commenced and ovarian response is poor, a clinical decision would need to be taken as to whether a further cycle should be attempted, or if the use of a donor egg may be considered for further IVF cycles.

3.2.7 Couples will be advised at the start of the treatment that this is the level of service that is available on the NHS in the East of England and that the NHS will fund storage of the embryos for one year only. Patients must be counselled by the clinician and infertility counsellor to this effect. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.

3.2.8 If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.

3.3 Sperm Recovery and Intra-Cytoplasmic Sperm Injection (ICSI)

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

3.3.2 In obstructive azoospermia, sperm needs to be obtained directly from the testis by aspiration (TESA) or biopsy (TESE). In some men sperm

can be recovered from naturally occurring spematoceles by percutaneous puncture.

3.3.3 In non obstructive azoospermia, sperm needs to be obtained directly from the testis by aspiration (TESA) or biopsy (TESE). The chance of finding sperm is reduced. PESA and TESA can be performed under local anaesthesia in an outpatient clinic. Percutaneous epididymal Sperm Aspiration (PESA) does not jeopardise future epididymal sperm retrieval.

3.3.4 Sperm recovery techniques outlined in this section are not available to patients who have undergone a vasectomy.

3.4 Intra Uterine Insemination (IUI)

3.4.1 Due to poor clinical evidence, IUI will only be offered under exceptional circumstances.

3.5 Donor insemination

3.5.1 Male infertility affects about 25% of couples. Until ICSI became available the main technique for treating male factor infertility where azoospermia or severe abnormalities of semen quality were present was insemination with donated sperm. The need to prevent transmission of sexually transmitted diseases (including HIV) by donor insemination has led to the mandatory quarantine of donor sperm for six months by cryopreservation prior to its use in the UK. Donor insemination may be indicated where the male partner is likely to pass on an inheritable genetic condition or severe rhesus incompatibility has been a problem because of the male partners homozygous status.

3.6 Egg and Sperm storage for patients undergoing cancer treatments

3.6.1 The procedures recommended by the Royal College of Physicians and the Royal College of Radiologists should be followed before commencing chemotherapy or radiotherapy likely to affect fertility, or management of post- treatment fertility problems.

3.6.2 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.

3.6.3 Local protocols should exist to ensure that health professionals are aware of the values of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively.

3.6.4 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, provided that this will not worsen their condition and that sufficient time is available.

3.6.5 Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria.

3.7 Egg donation where no other treatment is available

3.7.1 The patient may be able to provide an egg donor; alternatively the patient can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

3.7.2 This will be available to women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause before the age of 40 years or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

3.8 Pre-implantation Genetic Diagnosis (PGD)

3.8.1 This policy does not include pre-implantation genetic screening as it is not considered to be within the scope of fertility treatment. The separate East of England Specialised Commissioning Group policy should be referred to when considering PGD.

3.9 Chronic Viral Infections

3.9.1 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc requires the use of ICSI technology. This is a specialist service and is only available at a limited number of centres. The East of England Specialised Commissioning Group commission these services from an appropriately designated unit.

3.9.2 This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and therefore potentially her unborn baby.

3.10 Privately funded care

3.10.1 This policy covers NHS funded fertility treatment only. For clarity, Patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the Secondary or Tertiary Provider or experimental treatments.

3.10.2 Where a patient meets the East of England eligibility criteria but agrees to commence treatment on a privately funded basis, they may not retrospectively apply for any associated payment relating to the private treatment.

3.11 Surrogacy

3.11.1 Surrogacy is not commissioned as part of this policy. This includes part funding during a surrogacy cycle.

4. Eligibility criteria for accessing fertility services

4.1 Minimum and maximum age

Any treatment cycle will not be commenced before the female is 23 years of age but must be commenced before the female reaches her 40th birthday.

Any treatment cycle must be commenced before the male is 55 years of age.

4.2 East of England Resident

Couples must be resident within the east of England for 12 months prior to treatment. Active forces personnel are exempt from the 12 month east of England residency requirement.

4.3 Body Mass Index

The woman must have a body mass index of between at least 19 and up to and including 30 prior to referral for fertility treatment and at any time throughout treatment.

4.4 Maximum FSH Level

A maximum FSH level of 15U/L on day 2 of any menstrual cycle. Where couples are eligible for IUI treatment with donor eggs, the female must not have menstruated for 9 months.

4.5 Duration of sub-fertility

The criterion in this policy apply to couples who have an identified cause for their fertility problems or have infertility of at least three years duration.

4.6 Previous IVF treatment

Previous privately funded treatment will not preclude patients from being eligible to NHS funded cycles up to a maximum of 6 embryo transfers or 3 fresh cycles. However previous cycles, whether NHS or privately funded, will be taken into account by the responsible clinician in determining the clinical appropriateness of commencing further cycles. In line with current clinical evidence, couples should undergo no more than 5 fresh cycles in total.

4.7 Smoking status

Where couples smoke, only those who agree to take part in a supportive programme of smoking cessation will be accepted on the IVF treatment waiting list, and should be non-smoking at the time of treatment.

4.8 Parental status

There should be no living child from the couples current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.

4.9 Previous sterilisation

Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.

4.10 Child welfare

Couples must conform to the statutory 'Welfare of the Child' requirements.

4.11 Medical conditions

Treatment may be denied on other medical grounds not explicitly covered in this document.

5 REFERRALS

5.1 Couples who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The patients will be assessed within the Primary and Secondary Care setting.

5.2 A decision to refer a couple for IVF or other fertility services will be based on an assessment against the east of England eligibility Criteria which is based on the NICE guidelines and the HFEA recommendations as detailed in the clinical pathways.

5.3 Referral to the tertiary centre will be via a consultant gynaecologist or GP with Special Interest (GPSI) in primary care.