



**Nottinghamshire County**

## **Assisted Conception Policy**

**NHS Eligibility Criteria for assisted conception services (excluding In vitro fertilisation (IVF) Intracytoplasmic sperm injection (ICSI) treatment) for people with infertility in Nottinghamshire County.**

**February 2011**

*Although Primary Care Trusts (PCTs) and east Midlands Specialised Commissioning Group (EMSCG) were abolished at the end of March 2013 with the formation of 5 Nottinghamshire County wide Clinical Commissioning Groups (CCGs) policies that were in place prior to the 1 April 2013 remain in place to ensure a consistent approach.*

*The NHS Mansfield and Ashfield Clinical Commissioning Group have adopted this policy, in its existing form, at a meeting of its Governing Body on 28 March 2013.*

*This policy sets out the overall parameters within which care will be delivered.*

## 1. Introduction

This paper sets out the criteria for access to NHS funded specialist fertility services for patients who are the responsibility of NHS Nottinghamshire County.

In response to the publication of the East Midlands Specialised Commissioning Group's Commissioning Policy on In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1<sup>st</sup> December 2010, version 2) NHS Nottinghamshire County have reviewed the existing infertility policy and made necessary revisions to ensure consistency in eligibility criteria between the interlinking policies.

This policy covers the provision of Donor Insemination (DI), Intrauterine Insemination (IUI) and Oocyte Donation (OD) only and should be read in conjunction with the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services, (1<sup>st</sup> December 2010, version 2).

It sets out the minimum entitlement and service that will be provided for NHS fertility services across the health community. IVF and ICSI services are commissioned separately by the East Midlands Specialised Commissioning Group.

Couples requiring Pre-Implantation Genetic Diagnosis will be considered under the current East Midlands Specialised Commissioning Group Commissioning Policy for Pre-Implantation Genetic Diagnosis.

Initial investigation of patients is usually carried out by a network of specialist gynaecologists at NHS Hospital Trusts throughout the Nottinghamshire area. Access to fertility services for routine tests, investigation and diagnosis is available via GP referral using the Assisted Conception Assessment Sheet (appendix C).

In any healthcare system there are limits set on what NHS funded care is available and on what people can expect. Primary Care Trusts (PCTs) are required to achieve financial balance; they have a complex task in balancing this with an individual's rights to health care. It is the purpose of the criteria set out here to make the limits on fertility treatment fair, clear and explicit.

The National Institute for Clinical Excellence (NICE) provides guidance on NHS fertility services and the same principles have been used to develop the local policy. This policy should be read in conjunction with the NICE Fertility Guidance available on their web site at [www.nice.org.uk-pdf-CG011niceguideline.pdf](http://www.nice.org.uk/pdf/CG011niceguideline.pdf).

The NICE Guidance places NHS assisted fertility services firmly in the mainstream of NHS provision, and therefore as a result, patients will expect the NHS to provide this.

Abbreviations used in the document are explained in Appendix A.

Definitions of technical terms are contained in Appendix B.

Appendix C is the assisted conception funding assessment sheet. It is a mandatory requirement that the assessment sheet is completed for NHS funding to be considered.

## Epidemiology

Infertility is defined, in accordance with the EMSCG Commissioning Policy for IVF / ICSI within Tertiary Infertility Services (1<sup>st</sup> December 2010v2), as failure to conceive after frequent unprotected sexual intercourse for one to two years in couples in the reproductive age group or by undertaking 6 cycles of Donor Insemination without conceiving or by having a defined tubal blockage thereby preventing conception.

Around 84% of couples attempting to conceive as a result of regular sexual intercourse are successful after trying for one year. After two years this figure rises to 92%. Female fertility declines with age and for women aged 38 about 77% of those who have regular unprotected sexual intercourse will get pregnant after 3 years.

At any point in time, the estimated prevalence of infertility is one in seven couples in the UK. A typical Primary Care Trust can expect about 230 new consultant referrals (couples) per 250,000 head of population per year (NICE CG11, 2004). Table 1 summarises the expected demand per year for Nottinghamshire County and Nottingham City PCTs.

The need for such services may increase due to the trend towards later first pregnancies and an increasing number of remarriages. Demand is also increasing due to increased public awareness of treatment possibilities. It is likely that there is unexpressed and/or unmet demand, particularly from women with secondary infertility (those who have conceived before but do not necessarily have a child).

The following table summarises the expected demand per year of infertile couples based on new consultant referrals for NHS Nottinghamshire and NHS Nottingham City.

**Table 1: Expected demand for infertility referral for treatment per year**

Area	Total population <sup>1</sup>	Demand estimate per year (230 couples per head population 250,000)
Nottinghamshire County PCT	650,000	598
Nottingham City PCT	305,000	281

<sup>1</sup> EMPHO: based on 2001 census

## Causes of infertility

Review of clinical studies of couples seeking treatment, provide the following approximated proportions for the principal causes of infertility. A significant proportion of couples will have more than one cause and the distribution varies between primary and secondary infertility.

- Ovulatory failure 27%
- Low sperm count or quality 19%
- Tubal damage 14%
- Endometriosis 5%
- Others 5%
- Unexplained 30%

There is evidence that infertility causes considerable emotional stress and distress, which may affect many areas of couples' lives and can result in social handicap.

### **Types of fertility treatment**

There are three main types of fertility treatment: medical treatment (such as drugs for ovulation induction); surgical treatment (e.g. laparoscopy for ablation of endometriosis); and assisted reproduction.

Assisted reproduction techniques include:

- Intrauterine insemination (IUI)
- In vitro fertilisation (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Donor insemination (DI), oocyte (egg) donation (OD) and cryo-preservation (oocytes and/or embryos)

NB: Provision for IVF/ICSI is not covered by this policy. Refer to the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services (1 December 2010v2)

NICE does not recommend assisted reproduction procedures like gamete intrafallopian transfer (GIFT) or zygote intrafallopian transfer (ZIFT) and these will not be funded by the NHS.

All couples are eligible to receive treatment of Clomifene Citrate. Medication should only be prescribed following clinical investigation in line with the NICE Clinical Practice Algorithm, Fertility - Assessment and treatment for people with fertility problems. February 2004

## **2. Eligibility Criteria**

### **Establishing eligibility under this Policy**

All couples are eligible for consultation and advice in primary care.

Guidance for referral of infertile patients is included in the assisted conception assessment sheet (See Appendix C.)

A couple in the reproductive age group who fail to conceive after frequent unprotected sexual intercourse for one to two years (or by undertaking 6 cycles of Donor Insemination without conceiving or by having a defined tubal blockage thereby preventing conception) should be offered further clinical investigation including semen analysis and assessment of ovulation as appropriate.

Where there is clear reproductive pathology, infertility of any duration will be considered. This will include couples who cannot achieve full sexual intercourse due to disability. Eligibility for NHS funded treatment will be assessed against the treatment referral criteria and this may, in turn, affect the decision to investigate.

### **Priority for treatment**

Agreed eligibility criteria have been set so that couples with the best chance of success are given priority over others in order to produce the best outcomes. Following referral, couples should have a prognostic estimate that the successful outcome of a cycle will be greater than 10%.

### **Criteria for referral**

In order to achieve the maximum benefit for the resources available the following referral criteria should be used by referring physicians.

**The establishment of these access criteria should be undertaken by the patients' GP to ensure that only appropriate couples who meet the terms of the policy are referred.**

**Table 2: Eligibility Criteria**

Woman's Age	23 – 39 years  Patient should be referred by the age of 39 years.  <b>NB: Patient should be informed that any stimulation treatment must take place before the patient's 40th birthday. This applies to stimulation treatment both for fertility procedures under this policy and IVF / ICSI.</b>
Man's Age	55 years or younger
Woman's BMI	>19 BMI <30
Man's BMI	BMI < <b>35</b>
Welfare of Child	The welfare of any resulting children is paramount. In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.
Family Structure	No living children from current or previous relationship(s), including adopted children, but excluding foster children. There needs to be an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child.
Smoking	Both partners must not be a current smoker
Registered GP	The couple are registered with a NHS Nottinghamshire County GP practice.
Consent	Written consent to treatment is required from both partners

Any cycle of infertility treatment already undertaken (whether self or NHS funded) will be taken into account when determining NHS funding entitlement.

### **3. Treatment Protocol**

The treatment protocol recommended by NICE (NICE CG11, 2004) should be followed. Lifestyle, medical and non-invasive surgical treatments for infertility should be attempted before considering options like IUI, IVF and ICSI.

#### **Treatment provision**

NHS funding will provide a maximum of 6 cycles of donor insemination (DI) or a maximum of 3 cycles of intrauterine insemination (IUI) treatment.

Treatment should be started no later than 12 months from the decision to offer assisted conception.

Suitable couples should undertake DI (subject to availability and/or patient choice) or IUI before being considered for IVF/ICSI under the East Midlands Specialised Commissioning Group Commissioning Policy for Tertiary Infertility Services.

#### **Availability of Intrauterine Insemination (IUI)**

Couples who fail to conceive after 1-2 years unprotected sexual intercourse or 6 cycles of DI and fulfill the eligibility criteria may be offered intrauterine insemination (IUI) if clinically appropriate.

Couples will normally be offered no more than a maximum of 3 IUI treatments.

Couples who do not conceive after IUI will have a full entitlement to IVF in line with the stated eligibility criteria in the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services 1<sup>st</sup> December 2010v2)

Couples who choose not to have IUI and progress straight to IVF, will not be permitted to be offered IUI if IVF fails.

#### **Donor Sperm**

This will be funded only where azoospermia or severe oligospermia is present or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

This would mean up to 6 cycles of donor insemination, or a maximum of 3 cycles of IUI if required, and in addition to IVF entitlement if required.

#### **Donor Egg**

One attempt at donor egg treatment will be available only to those women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria. NHS funding will cover the cost of the Donor Egg Register.

#### **Surrogacy**

NHS Nottinghamshire County will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement because:

(a) this treatment is not considered by NHS Nottinghamshire County to be a priority for NHS investment,

(b) NHS Nottinghamshire County is unlikely to be in a position to be able to reach an assessment as to whether the parties have concluded a lawful surrogacy arrangement, and

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

Surrogacy, or any assisted conceptions involving surrogacy do not form part of this policy. Refer to NHS Nottinghamshire County Policy for Surrogacy for further information.

### **Embryo Ovarian or Testicular Tissue, Egg and Sperm Storage**

Embryo freezing and storage is available to couples meeting the eligibility criteria for IVF / ICSI. Refer to the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services (1<sup>st</sup> December 2010 v2) for details.

Ovarian or testicular tissue storage will not be carried out outside a clinical trial. These are currently experimental.

Where clinically appropriate Pre-Treatment Sperm Freezing and storage will be offered as part of the core treatment for IVF / ICSI for those couples meeting the eligibility criteria for assisted conception. Sperm will be stored for three years according to HFEA Guidance.

### **Sterilisation**

Couples where one partner has been sterilised will not be eligible for treatment, even if a successful reversal has been achieved. Reversal of sterilisation is not routinely available as an NHS funded treatment.

## **4. Exceptional circumstances**

In the rare or exceptional circumstances where a couple or clinician feel that the couple represent a special case then an application can be made to the PCT's Individual Funding Request Panel for consideration of exceptional funding. For couples to be considered for exceptional funding, an Individual Funding Request Form must be completed in full and submitted to the Individual Funding Request Team for consideration.

## **5. Review**

These treatment criteria will be reviewed in February 2012 or in the light of any new guidance, whichever is the earliest.

### **References**

NICE Clinical Guideline 11, Fertility: assessment and treatment for people with fertility problems (2004)

EMSCG P006v2 Commissioning Policy for In Vitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1<sup>st</sup> December 2010 v2)

Van der Spuy, Z. M., Steer, P.J., McKusker, M., et al. (1988) Outcome of pregnancy in underweight women after spontaneous and induced ovulation. *BMJ* 296, 962-967.

**Appendix A**

<b>Abbreviations used</b>	
<b>BMI</b>	<b>Body Mass Index</b>
<b>DI</b>	<b>Donor Insemination</b>
<b>GP</b>	<b>General Practitioner</b>
<b>HFEA</b>	<b>Human Fertilisation and Embryology Authority</b>
<b>ICSI</b>	<b>Intracytoplasmic sperm injection</b>
<b>IUI</b>	<b>Intra-uterine insemination</b>
<b>IVF</b>	<b>In vitro fertilisation</b>
<b>NICE</b>	<b>National Institute of Clinical Excellence</b>
<b>OD</b>	<b>Oocyte (Egg) Donation</b>
<b>PCT</b>	<b>Primary Care Trust</b>



## Appendix B Definitions

Term	Definition	Further information
<b>BMI</b>	The healthy weight range is based on a measurement known as the <b>Body Mass Index (BMI)</b> . This can be determined if you know your weight and your height. This calculated as your weight in kilograms divided by the square of your height in metres. In England, people with a body mass index between 25 and 30 are categorised as overweight, and those with an index above 30 are categorised as obese.	<p>Patient. Uk <a href="http://www.patient.co.uk">www.patient.co.uk</a></p> <p>NHS Direct <a href="http://www.nhsdirect.nhs.uk">http://www.nhsdirect.nhs.uk</a></p> <p>BBC Healthy Living <a href="http://www.bbc.co.uk">http://www.bbc.co.uk</a></p>
<b>ICSI</b>	<b>Intra Cytoplasmic Sperm Injection (ICSI):</b> In conjunction with IVF, where a single sperm is directly injected, by a recognised practitioner, into the egg. A clinic may also use donor sperm or eggs.	Glossary, HFEA <a href="http://www.hfea.gov.uk">http://www.hfea.gov.uk</a>
<b>IUI</b>	<b>Intra Uterine Insemination (IUI):</b> Insemination of sperm into the uterus of a woman.	As above
<b>IVF</b>	<b>In Vitro Fertilisation (IVF):</b> Patient's eggs and her partner's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female patient.	As above
<b>DI</b>	<b>Donor Insemination (DI):</b> The introduction of donor sperm into the vagina, the cervix or womb itself.	As above
<b>OD</b>	<b>Oocyte (Egg) Donation:</b> The process by which a fertile women donates her eggs to be used in the treatment of others or for research	As above

**Appendix C**

**Assisted Conception Assessment Sheet**

Patient Name:  
 Patient DOB:  
 Patient NHS Number:  
 Patient Address:  
 Patient GP Details:

Partner Name:  
 Partner DOB:  
 Partner NHS Number:  
 Partner Address:  
 Partner GP Details:

**Please refer to the EMSCG IVF & ICSI Policy December 2010 & PCT Assisted Conception Policy Feb 2011 for guidance**

Criteria	True 'T' or False 'F'
Couple has failed to conceive after frequent unprotected sexual intercourse for 1- 2 years in those of reproductive age, or have a defined tubal blockage thereby preventing conception.	
Female partner is aged 23 to 39 at the start of the treatment cycle.	
The Female partner to have a body mass index (BMI) greater than 19 and less than 30	
The male partner to be aged 55 years or younger	
The male partner to have a body mass index (BMI) less than 35	
Neither partner has previously been sterilised	
Both partners must be a non-smokersa. Patients who wish to quit smoking should be referred to New Leaf Nottinghamshire, on 0800 3897712 or <a href="http://www.stopsmokingnotts.nhs.uk">www.stopsmokingnotts.nhs.uk</a>	
Both partners have no living children from a current or previous relationship(s) including adopted children, but excluding foster children	
The couples health and social circumstances would pose no significant risk to conception, pregnancy or the resultant child	
The couple are to be registered with a Nottinghamshire County GP	
<b>Overall Result (for use by PCT only)</b>	

Completed By:..... Designation.....  
 Signed..... Date.....

**Please complete and attach this form to your patient's chosen secondary care provider via the Choose & Book System.**

If the couple meet the eligibility criteria **please specify couple's preferred provider:** CARE Nottingham, NURTURE Nottingham, Burton Hospital, Burton, Bourn Hall Cambridge, University Hospitals of Coventry & Warwickshire Coventry, University Hospitals of Leicester Leicester, Jessops Hospital Sheffield, CARE Sheffield.