Yorkshire and the Humber
Specialised Commissioning Group

REF: 21/11

COMMISSIONING POLICY
SPECIALISED FERTILITY SERVICES

Policy	**Specialised fertility services**
Effective from	September 2011
Date approved by SCG Board:	23 September 2011
Policy to be reviewed by:	September 2014
Version:	7.0
Supersedes:	Policy published May 2010
Date approved by CSSG/RPSG:	13 September 2011
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Distribution/Target Audience:	All commissioners, Yorkshire and the Humber All providers, Yorkshire and the Humber

CONFLICTS OF INTEREST

None stated by the authors.

Abbreviations

Abbreviations used	
BMI	**Body Mass Index**
DI	**Donor Insemination**
GP	**General Practitioner**
HFEA	**Human Fertilisation and Embryology Authority**
ICSI	**Intracytoplasmic sperm injection**
IUI	**Intra-uterine insemination**
IVF	**In vitro fertilisation**
NICE	**National Institute of Clinical Excellence**
PCT	**Primary Care Trust**

Glossary

Term	Definition	Further information
BMI	The healthy weight range is based on a measurement known as the **Body Mass Index (BMI**). 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.	BBC Healthy Living http://www.bbc.co.uk NHS Direct http://www.nhsdirect.nhs.uk
ICSI	**Intra Cytoplasmic Sperm Injection (ICSI)**: Where a single sperm is directly injected into the egg.	Glossary, HFEA http://www.hfea.gov.uk
IUI	**Intra Uterine Insemination (IUI)**: Insemination of sperm into the uterus of a woman.	As above
IVF	**In Vitro Fertilisation (IVF)**: 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
DI	**Donor Insemination (DI)**: The introduction of donor sperm into the vagina, the cervix or womb itself.	As above

1 AIM OF PAPER

1.1 This paper represents the Commissioning Policy on tertiary fertility services for adults registered with Primary Care Trusts in the Yorkshire and Humber Specialised Commissioning Group (Y&HSCG) area.

1.2 The policy aims to ensure that those most in need and able to benefit are given equitable access to tertiary fertility services across the Y&HSCG area.

2 BACKGROUND

2.1 Previously, commissioning of tertiary fertility services was carried out individually by the 14 PCTs in the region. This has led to a number of variations in who is able to access treatments and the number of treatment rounds available. In order to ensure equity of access and provision across the region the SCG agreed to adopt a regional policy from April 2010.

2.2 In this policy document infertility is defined either as the presence of known reproductive pathology, or, for heterosexual couples, as the failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology[1]. For same sex couples it is defined as the failure to conceive after six self-funded rounds of IUI treatment in the absence of known reproductive pathology.

2.3 Fertility problems are common in the UK and it is estimated that they affect one in seven couples. 84% of couples in the general population will conceive within 1 year if they do not use contraception and have regular sexual intercourse. Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate 92%). The remaining 8% of couples will be unable to conceive without medical intervention and are therefore considered infertile.

2.4 In 25% of infertility cases the cause cannot be identified. However, it is thought that in remaining couples about a third of cases are due to the male partner being unable to produce or ejaculate sufficient normal sperm, a third are due to problems found with the female partner such as failure to ovulate or blockage to the passage of the eggs and 10% are due to problems with both partners[2].

2.5 The most recent DH costing tool[3] estimates that there are 98 attendances at a fertility clinic for every 10,000 head of population. In Yorkshire and the Humber this would equate to an expected 4767 attendances per year which would result in 1450 couples who are likely to be assessed as eligible for IVF treatment.

2.6 Tertiary fertility services include IUI, ICSI and IVF. They may also include the provision of donor sperm and donor eggs. Fertility services fall under the 18-week maximum waiting time. The majority of treatment in the UK is statutorily regulated by the Human Fertility and Embryo Authority (HFEA). All tertiary providers of fertility services must be licensed with the HFEA in order to be commissioned under this policy.

[1] NICE Clinical Guideline 11, 2004.
[2] DH (2009) Regulated Fertility Services
[3] Ibid

2.7 There is a NICE clinical guideline on infertility (2004) which recommends that up to three cycles of IVF be offered to eligible couples where the woman is aged between 23 and 39.

2.8 The current economic climate demands that PCTs make difficult decisions regarding priority and efficiencies. The majority of PCTs are looking to stabilise or reduce expenditure over the coming few years in order to reflect current and future financial restrictions. This impacts on decision making regarding the expansion of existing services, such as specialist fertility services (see DH 2009 3.8.4).

4 DESCRIPTION OF THE TREATMENT

4.1 Principles of Care

4.1.1 Couples should be seen together as seeking fertility treatment concerns both partners.

4.1.2 Couples should be provided with information in a variety of formats about their condition, treatment and likely outcomes. This should include oral explanations, followed by written information. Information and advice should be given in a manner that is culturally sensitive to the individuals concerned. Information and advice should also take account of people who have additional needs, for example, those who do not speak or read English or who have physical, cognitive or sensory disabilities[4].

4.1.3 As infertility and infertility treatment have a number of psycho-social effects on couples, access to psychological support prior to and during treatment should be considered as integral to the care pathway.

4.2 The Care Pathway

4.2.1 Treatment for infertility problems may include counselling, lifestyle advice, drugs, surgery and assisted conception techniques such as IVF. The care pathway for infertility begins in primary care where the first stage of treatment is generally lifestyle advice to increase the chance of conception happening naturally. If this is not effective, initial assessment such as semen analysis will take place. If appropriate the couple will then be referred to secondary care services where further investigation and treatment will be carried out such as hormonal drugs to stimulate ovulation. If this is unsuccessful or inappropriate and the couple fit the eligibility criteria they will then be referred to tertiary care for assessment for assisted conception techniques such as IVF, DI, IUI and ICSI [5].

4.2.2 IVF involves:

- the use of drugs to switch off the natural ovulatory cycle;
- induction of ovulation with other drugs;
- monitoring the development of the eggs in the ovary;
- ultrasound-guided egg collection from the ovary;

[4] NICE Guideline (2004) Fertility
[5] DH (2009) Regulated Fertility Services

- processing of sperm;
- production of a fertilized embryo from sperm and egg cells in the laboratory;
- use of progesterone to make the uterus receptive to implantation;
- transfer of selected embryos and freezing of those suitable but not transferred.[6]

4.2.3 Fertility treatments are part of the 18-week target.

4.3 Definition of a full cycle

A fresh cycle plus all frozen embryo transfer cycles created in the fresh cycle. It is not anticipated that FETs will exceed four in any cycle.

4.5 Frozen Embryo Transfers

Good quality single embryos should be frozen.

4.6 Abandoned Cycles

Abandoned cycles will be funded up to the point of failed fertilisation. Beyond this, a cycle would not be considered abandoned.

4.7 IUI and DI

Up to three cycles of IUI (stimulated or non-stimulated) will be provided for couples with unexplained fertility, mild endometriosis or mild male factor infertility. They will then access IVF treatment if appropriate.

Up to six cycles (dependent on availability of donor sperm) will be offered for couples with male azoospermia.

4.8 Donor Sperm

Donor sperm will be funded.

4.9 Donor Eggs

Patients eligible for treatment with donor eggs will be placed on the waiting list for treatment with donor eggs. Unfortunately, the availability of donor eggs is severely limited in the UK. There is therefore no guarantee that eligible patients will be able to proceed with treatment. Patients will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the eligibility criteria are still met.

We will fund the additional costs associated with treatment using donor eggs but the responsibility for sourcing donor eggs sits with the provider.

4.10 Egg and Sperm Storage

Embryo and sperm storage will be funded for patients who are undergoing NHS fertility treatment. Storage will be funded for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter.

Any embryos frozen prior to implementation of this policy, will be frozen for a maximum period of 3 years from the date of policy adoption.

Any embryo storage funded privately prior to the implementation of this policy, will remain privately funded.

[6] Ibid

4.11 HIV/Hep B/Hep C

Special procedures for accessing treatment apply and patients may be referred from the Assisted Conception Unit to a different regional centre.

4.12 Surrogacy

Surrogacy arrangements will not be funded, but we will fund treatment (IVF component and storage) in identified (fertile) surrogates, where this is the most suitable treatment for a couples' infertility problem and the eligibility criteria are met.

4.13 Single Embryo Transfer

Multiple births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps be taken by providers to minimise multiple births. This is currently achieved by only transferring a single embryo for couples who are at high risk.

We support the HFEA guidance on single embryo transfer and will be performance monitoring all tertiary providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births was set at an upper limit of 24% of all pregnancies in 2009 and will progressively reduce to 10%.

4.14 Counselling & Psychological support

As infertility and infertility treatment has a number of negative psycho-social effects access to counselling and psychological support should be offered to the couple prior to and during treatment.

4.15 Sperm washing and pre-implantation diagnosis

Sperm washing and pre-implantation genetic diagnosis are not treatments for infertility so fall outside the scope of this policy.

5 EVIDENCE BASE

5.1 The NICE Clinical Guideline (2004) was based on a rigorous review of all available evidence of sufficient quality. The guidance addresses issues of clinical and cost effectiveness. All potential treatments for infertility have been assessed with the NICE guidance using the information available. Only those that are effective according to the evidence base are recommended in this policy.

5.2 Infertility has a number of negative effects on patients. Failure to offer people diagnosis and relevant treatment for fertility problems results in a loss of mental health and wellbeing for those patients[7]. Infertility is associated with anxiety and depression in women[8]. However, the NICE guideline recognises that more research is needed to assess the long term impact of investigation

[7] DH (2009) Regulated Fertility Services: A Commissioning Aid
[8] NICE Guideline (2004) Fertility

and treatment of people who perceive problems with their fertility, both in people who subsequently achieve a live birth and people who do not.

5.3 Chances of success as measured by a live birth after IVF or ICSI treatment have increased over time. In 1992 for every 100 women starting treatment only 17 of them gave birth (17%) but in by 2006, 29 women in every 100 treated gave birth (29%)[9]. Chances of success reduce with age.

5.4 Risks include the following:

- There are risks of multiple pregnancy during fertility treatment, which is associated with a higher morbidity and mortality rate for mothers and babies.
- Women who undergo fertility treatment are at slightly higher risk of ectopic pregnancy[10].
- Ovarian hyper stimulation, which is a potentially fatal condition, is also a risk. The exact incidence of this has not been determined but the suggested number is between 0.2 to 1% of all assisted reproduction cycles.
- Current research shows no cause for concern about the health of children born as the result of assisted reproduction.
- A possible association between ovulation induction therapy and ovarian cancer in women who have undergone treatment is uncertain.
- Further research is needed to assess the long term health effects of ovulation induction agents.

5.5 Clinical effectiveness

It is considered to be clinically effective to offer up to three stimulated cycles of IVF treatment to couples in which the women is aged 23-39 years and who have an identified cause for their infertility or who have infertility of at least two years duration.

5.6 Cost effectiveness

NICE used a cost effectiveness model which showed that costs per live birth were similar for ages 24-33 years after which they rose steeply with increasing age. In light of this they recommended that treatment be restricted to women aged 23-39 years.

Further research is needed in the area of infertility and fertility treatments. The NICE guideline (2004) makes 30 recommendations for research areas. These include a number of clinical factors and socio-psychological factors such as the long term physical, genetic, psychological and social development of children resulting from assisted conception.

As research within this field is fast moving, new interventions and new evidence needs to be considered on an ongoing basis to inform commissioning decisions.

6 SERVICE PROVIDERS

Providers of fertility treatment must be HFEA registered and comply with any

[9] HFEA figures (2009) http://www.hfea.gov.uk/2588.html#3039

[10] Human Fertilisation and Embryology Authority (2009) http://www.hfea.gov.uk/103.html

service specification drawn up by Yorkshire and the Humber Specialised Commissioning Group.

7 ELIGIBILITY CRITERIA FOR TREATMENT

7.1 Application of Eligibility Criteria

Eligibility criteria apply at the point patients are referred to tertiary care (with the exception of 7.9, which should be undertaken within tertiary care). Couples must meet the definition of infertility, as described in 2.2.

7.2 Overarching Principles

7.2.1 Eligibility criteria should apply equally to all assisted conception treatments (IUI, IVF, ICSI).

7.2.2 All clinically appropriate individuals / couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. Only couples meeting the eligibility criteria should be referred to tertiary care.

7.2.3 Treatment limits are per couple and per individual. I.e. a woman in a heterosexual relationship undergoes maximum number of cycles with one partner, she is not entitled to further cycles. A woman in a same sex couple undergoes maximum number of cycles with one partner, her partner is not then also entitled to maximum number of cycles.

7.2.4 Referrals should be as a couple and include demographic information for both partners.

7.3 Existing Children

Neither partner should have any living children (including adopted children) from that or previous relationships.

7.4 Female Age

The female patient must be between the age of 23-39 years unless there is an absolute indication to start fertility treatment younger. No new cycle should start after the patient's 40th birthday. Referrers should be mindful of patients' age at the point of referral and the age limit for new cycles.

7.5 Female BMI

The female patient's BMI should be between 19 and 30 prior to referral to tertiary services. Patients with a higher BMI should be directed to healthy lifestyle interventions prior to referral.

7.6 Reversal of sterilisation

We will not fund IVF treatment for patients who are sterilised.
(i.e. for patients who have been sterilised or have unsuccessfully undergone reversal of sterilisation).

7.7 Previous self funded couples

Previous self-funded cycles will not affect an individual's entitlement, but may be used when assessing capacity to benefit.

7.8 Length of relationship

Cohabiting couples who have been in a stable relationship for a minimum of 2 years.

7.9 Welfare of the Child

The couple should be assessed as meeting the requirement contained within the HFEA Appendix entitled ' Welfare of the Child'.

8 PATIENT NUMBERS

Current patient numbers (2008) provided by the HFEA are provided below, along with DH eestimates (calculated on 2010 population estimates).

It should be noted that it is impossible to predict how many patients will chose to access private treatment. Actual numbers form the HFEA shown that approximately two thirds of all IVF treatment is paid for privately. It is likely that many of these patients would not fit the NHS access criteria.

PCT	HFEA patient numbers (NHS only)	Eligible patients for IVF (DH costing tool)
East Riding	39	81
Hull	65	83
NE Lincs	18	43
N Lincs	6	42
N Yorks & York	16	209
Barnsley	44	63
Doncaster	100	78
Rotherham	78	72
Sheffield	89	161
Bradford	51	164
Calderdale*	16	60
Kirklees*	41	119
Leeds	155	268
Wakefield	102	92
Total	**820**	**1535**

* Calderdale and Kirklees figures are derived from PCT estimates not HFEA data.

In addition to the above figures, HFEA data shows that 1697 patients accessed IVF privately in 2008 in Yorkshire and the Humber. A further 490 patients were of unknown funding status.

9 POLICY STATEMENT

Couples will be entitled to up to the maximum number of cycles funded by their PCT, where clinically indicated. In order to be eligible for a second or third cycle, couples must have a greater than 10% chance of getting pregnant, based on clinically accepted predictive models.

Equality Impact Assessment – Specialised Fertility Services Commissioning Policy

Department/Team : **Yorkshire and the Humber Specialised Commissioning Group**			
Lead Officer: **Pia Clinton-Tarestad**			
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Function:	***Specialised Fertility Services Commissioning Policy***		
Policies used to carry out function:			
Groups who the function should benefit:	***Couples within Yorkshire and Humber, where the female is between aged 23 and 39, who are experiencing infertility***		
Are all groups affected equality by this function/policy?			
Step 1	**Who should be served by the function/policy?**	**Information Gathered**	
	Make use of …….. Baseline information on the general population and the groups the function should benefit e.g. ❖ Census data (or more up to date population projections) ❖ Other survey data ❖ Information of social and economic factors, such as age, income levels, health etc which are indicators of need.	*Yorkshire and Humber registered population* *Population size 4.88m (ONS 2001)* *Females aged between 23 and 39: 514,300 (DH, 2009)*	
Step 2	**Do you have monitoring data?**	If yes **(go to 3)**	If no **(go to 4)**
	Examples . . . ❖ Workforce Data ❖ Audit or Review information ❖ Satisfaction survey results Service user profile broken down into: Sexual Orientation. Gender, Race, religion, Belief & Disability		*Yes – currently the population receiving these interventions are not profiled in detail. Much of the information is held through the HFEA.* *Work will be undertaken with local clinicians, and the HFEA to obtain a better picture of who is receiving this intervention.*

Step 3	**Who is using the function/policy?**	**Notes**
	❖ What does your monitoring data on your service users tell you? ❖ Are any groups under or over represented compared to what you would expect to see from the baseline data ❖ What does your monitoring data outcomes tell you? E.g. are some groups more likely to be serviced better by your function, service and policies etc compared to what you would expect to see from the baseline data on their needs?	*Approximately 1010 IVF cycles are undertaken per year in the region.* *Currently there is insufficient routinely available data, or robust assessment of health need, to determine whether some population groups are underserved by fertility services.* *The SCG will be working with clinicians to undertake this needs assessment, and linking this to the HFEA data.*
Step 4	**What evidence do you have that your service is accessible equitably to all groups taking into account sexual orientation, gender, age, race, religion, belief and disability**	
	❖ Customer Satisfaction Survey results ❖ Local and national research ❖ Consultation ❖ Observation ❖ User Group	*None*
Step 5	**What action have you taken to ensure that your users are all serviced equitably?**	**Evidence of action implemented to date**
	❖ Staff trained in how to treat services users with specific needs ❖ Service information produced in a range of formats to assist all groups ❖ Service changes made directly to reflect changes in the service user profile ❖ Service users consulted prior to planned changes to the service being implemented ❖ Staff groups made aware of service user groups who may be being disadvantaged by existing policy, practice and procedure ❖ Staff being consulted to assess how new policies and procedures may impact on them	*The primary purpose of the commissioning policy is to ensure that specialist fertility services are equitably commissioned across the region.* *Future work in this area will focus on involvement of service users in planning and service delivery, a more robust needs assessment and a more strategic approach to commissioning of specialist fertility services.*
Step 6	**Do you know whether your service delivery is being compromised because of any issues relating to: Sexual Orientation, Gender, Race, Religion, Belief & Disability?**	**List reasons why this may or may not be the case and the evidence you have to support your belief.**
		A there is insufficient evidence to conclude this.

Action Plan	*1. conduct a robust and thorough needs assessment, including forward planning for future developments in this area* *2. establish systems to involve patients and the public in commissioning, service planning and service improvement* *3. Agree a programme of equity audits* *4. establish robust routine monitoring to inform commissioning, including collection of data on a number of population characteristics to inform equity audit.*	