**Item Number: 8**
**Name of presenter: Dr Andrew Phillips, GP Governing Body Member**

| **GOVERNING BODY MEETING**<br><br>**7 August 2014** | <br>Vale of York<br>Clinical Commissioning Group |
|---|---|

**Access to Infertility Treatment: Commissioning Policy**

**For decision**

**1. Rationale**
Policy paper and options for implementation prepared following Governing Body decision in June to make one cycle of IVF treatment available to eligible couples.

**2. Actions for the Governing Body**
a) Consider the 3 options for implementation presented in this paper
b) Adopt the Access to Infertility Treatment: Commissioning Policy Document
c) Agree implementation date for the chosen option

**3. Engagement with groups or committees**
Governing Body and SMT have received an outline of the proposed approach.

**4. Significant issues for consideration**
Due to the unknown backlog following four years of no IVF funding in this area, implementing the Policy could cost anything from £350,000 – £2m pa. It is difficult to quantify as there is no evidence from elsewhere in the country of any other CCG dealing with the same situation.

**5. Implementation**
Depending on the option chosen, Dr Emma Broughton and team members within the CCG will need to work with primary, secondary and tertiary care providers and any other stakeholders involved to ensure the Policy is implemented according to the agreed implementation date.

**6. Monitoring**
Whichever option is chosen, it will be essential that costs and activity are closely monitored.

| **7. Responsible Chief Officer and Title** | **8. Report Author and Title** |
|---|---|
| Dr Emma Broughton<br>GP Governing Body Member | Sarah Kocinski<br>Innovation and Improvement Facilitator |

**9. Annexes:**
Appendix 1 – Access Criteria
Appendix 2 – NHS Vale of York CCG Access to Infertility Treatment: Commissioning Policy Document
Appendix 3 – Draft Application Form
Appendix 4 – Draft Weighted Eligibility List Pathway
Appendix 5 – Equality Impact Assessment

# Access to Infertility Treatment: Commissioning Policy

## 1. Background

At its meeting in June 2014 NHS Vale of York CCG (the CCG) Governing Body agreed to make one cycle of IVF treatment available to eligible couples in the Vale of York who meet the criteria set out at **Appendix 1**. This decision reflects the revised NICE guidance CG156 Fertility: Assessment and treatment for people with fertility problems (updated February 2013) http://publications.nice.org.uk/fertility-cg156.

As a result of this decision, the CCG Access to Infertility Treatment: Commissioning Policy Document (the Policy) is attached at **Appendix 2** and represents the Policy to be adopted by the CCG that focuses on the group of patients with the greatest chance of success as shown in **Table 1** below.

Table 1: Success Rates

- IVF success rates over age 40 are 10%, by age 44 they are down to 1%
- Success rates under age 35 are 40% at very best
- Success rates drop rapidly from age 39 (with most units quoting unto 35% success rates for 35-39yr olds)
- Ovarian function can be crudely assessed using a blood test (for FSH) and USS (for antral follicle count) - so it is possible to "grade" a woman's chances of success

## 2. Financial Implications of Implementing NICE Guidance

Due to the unknown backlog following four years of no IVF funding in this area, implementing the Policy could cost anything from £350,000 – £2m pa. It is difficult to quantify as there is no evidence from elsewhere in the country of any other CCG dealing with the same situation.

## 3. Procurement

There are no procurement issues as there are currently 5 providers of fertility treatments in the surrounding area in Leeds, Sheffield (x2), Hull and Middlesbrough offering IVF on the NHS within current contracts. There is little difference in costs. Patients may, however, request other providers via Choice as long as they are an NHS accredited provider on the HFEA approved list http://www.hfea.gov.uk/.

## 4. Implementation Plan Options

Following discussions with Assisted Conception Leads, the IFR team and Finance and Contracting Leads to develop some options to manage the flow and prevent initial large influx and spend, three implementation options have been considered:

**Option 1 – Open the policy and accept unknown costs**

This approach would enable any eligible couple who meet the access criteria to be referred for IVF treatment. This could result in unpredictable expenditure for the CCG as the numbers of eligible couples are unknown.

The introduction of any fixed financial cap of spending would be open to legal challenge. Costs could vary between £350,000 – £2m pa.

**Option 2 – Phased Implementation**

This approach focuses on those in need, based on a single criteria of female age, but still has a significant degree of financial unpredictability – the bulk of subfertility referrals are for women over 30. The proposed phasing could be:

- For the first 6m open the policy to women age 37-40
- Next 6m extend to 30-40
- Next 6m extend to 26-40
- By end of 18m the policy will be open to all.

This could be open to appeals on equality grounds and would require a policy for IFR for exceptionality. Costs could be potentially lower than Option 1, but are still unknown.

**Option 3 – Weighted Eligibility List managed by the IFR team and panel**

This option would allow the IFR team to hold a weighted eligibility list using a scoring system and allows for optimisation of those in greatest need of IVF (based on women's age, clinical score for priority on health or premature ovarian failure and acknowledgement of waiting time). **Table 2** shows the proposed scoring system.

Table 2: Weighted Eligibility List Scoring Criteria

| Criteria | | | | | | Score |
|---|---|---|---|---|---|---|
| **Age at referral** | **39 – <40** = 10 points | **37-39** = 8 points | **35-37** = 6 points | **30-35** = 4 points | **<30** = 2 points | |
| **Clinical priority** | **High** (needs therapy <6m) = 10 points | **Moderate** (needs therapy within 6m – 12m) = 5 points | **Low** = 0 points | | | |
| **Number of years waiting** | **4 years** = 4 points | **3 years** = 3 points | **2 years** = 2 points | **1 year** = 1 point | | |
| **Total score** | | | | | | |

This system would enable the CCG to identify 10-12 couples a month to be offered therapy thereby controlling cost and also prioritising based on clinical criteria (as proposed by tertiary care) and offers some degree of fairness.

It is suggested that this system would only be required for 18-24m whilst the backlog is managed in a controlled manner and would also prevent a huge year one influx.

The process would allow for exceptions and appeals to be made in the usual manner. A draft application form and proposed pathway are attached at **Appendices 3 and 4**.

## 6. Equality Impact Analysis

An Equality Impact Analysis has been developed in relation to having due regard to the Public Sector Equality Duty (PSED) of the Equality Act 2010 to: eliminate discrimination, harassment, victimisation; advance equality of opportunity; and foster good relations and is attached at **Appendix 5**.

## 7. Recommendation

Governing Body are asked to:

d) Consider the 3 options for implementation presented in this paper
e) Adopt the Access to Infertility Treatment: Commissioning Policy Document
f) Agree an implementation date for the chosen option

**Sarah Kocinski**
**24th July 2014**

**Appendices**

Appendix 1 – Access Criteria

Appendix 2 – NHS Vale of York CCG Access to Infertility Treatment: Commissioning Policy Document

Appendix 3 – Draft Application Form

Appendix 4 – Draft Weighted Eligibility List Pathway

Appendix 5 – Equality Impact Analysis

## Access Criteria

| **Partners: both must be**:- | |
|---|---|
| Female age – years at the time of treatment | The age of women at the time of treatment must be less than 40 years and over 23 years. |
| Female BMI 19 to 29 for 6 months prior to a referral | Body Mass Index within the range 19 to 29 kg/m2 (this means that a BMI of 29.1 is outside the criteria). GPs 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 29 kg/m2 for the previous 6 months. |
| 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. GPs 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. |
| Existing children | Neither partner should have any living children from either current or any previous relationships. The adoption of children confers the legal status of parent to the adoptive parents; this will apply to both adoptions *in* and *out* of the family.<br>If any fertility treatment results in a live birth (and the child is still alive), then the couple will not be eligible for further fertility treatments, including the implantation of any stored frozen embryos. |
| Stable 2 year relationship | Cohabiting couples must have been in a stable on-going relationship for more than 2 years before referral. |
| Having regular unprotected intercourse for the 2 years prior to referral within the same stable relationship | Couples must have been having regular unprotected intercourse for a 2 year period, reported to and documented by GP. Attempts to conceive should be based upon using recognised ovulation indicators at the appropriate time in the cycle.<br>Couples who conceive naturally and who subsequently miscarry up to twice within 2 years will be investigated for recurrent miscarriages. These women will not automatically received assisted conception treatment unless clinically appropriate as they are able to conceive naturally. |
| Previous treatment history | Any previous NHS funded IVF treatment will be an exclusion criterion. Couples who have previously self-funded treatment are eligible for 1 NHS funded cycle as long as they have not received more than 2 self-funded cycles. |

# Access to infertility treatment

Commissioning Policy Document
Yorkshire and Humber adopted by NHS Vale of York Clinical Commissioning Group

Version 3 August 2014 (Review period January - March 2015)

## Commissioning Policy Statement:

This document represents the commissioning policy of NHS Vale of York Clinical Commissioning Group (CCG) for the clinical pathway which provides access to tertiary fertility services. It is intended to provide a framework for the commissioning of services for those couples who are infertile and require infertility interventions.

The policy was developed jointly by Clinical Commissioning Groups in the Yorkshire and Humber area and provides a common view of the clinical pathway and criteria for commissioning services which has been adopted by **NHS Vale of York CCG**.

The policy on funding of tertiary fertility services for individual patients is a policy of this CCG and not part of the shared policy set out in the rest of this document. **The number of full IVF cycles currently funded by NHS Vale of York CCG for patients who meet the access criteria set out in section 6 of this policy is one.** This policy will be updated in accordance with the review period of the policy or earlier should sufficient changes in practice or evidence base require it.

This commissioning Policy has been developed in partnership with the Yorkshire and The Humber Expert Fertility Panel

## Panel Members:

| | |
|---|---|
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| Helen Brown | Service Manager Sheffield Teaching Hospital FT |
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| Will Cleary-Gray | Head of Collaborative Commissioning & Planning Sheffield CCG |
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## Conflicts of Interest

None stated by the authors.

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Appendix A – Abbreviations

Appendix B – Glossary

# 1. Aim of paper

1.1 This document represents the commissioning policy for tertiary fertility services for adults registered with a Clinical Commissioning Group (CCG) in the Yorkshire and Humber region.

1.2 The policy aims to ensure that those most in need and able to benefit from NHS funded treatment are given equitable access to tertiary fertility services across the Yorkshire and Humber Area, by identifying the clinical care pathway and relevant access criteria.

# 2. Background

2.1 On April 1st 2013 Clinical Commissioning Groups (CCGs) across the Yorkshire and the Humber regions adopted the existing Yorkshire and the Humber Fertility policy[1]. In February 2013 NICE published revised guidance [2] which updates previous NICE guidance published in 2004[3].

2.2 CCGs across the Yorkshire and the Humber agreed to work collaboratively to update the existing policy in light of the new NICE guidance and changing commissioning landscape.

2.3 In this policy document infertility is defined:

*For all couples: The presence of known reproductive pathology.*

*For heterosexual couples: The failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology.*

*For same-sex couples (and other couples for whom conventional methods of conception are impossible or very difficult): The failure to conceive after twelve rounds of donor or partner insemination, of which at least six will be carried out through IUI, in the absence of any known reproductive pathology. Six rounds of IUI treatment are expected to be self-funded in these circumstances.*

*For couples where ovulation can be induced with simple techniques such as clomiphene, these patients are not regarded as infertile on this basis alone and therefore would not meet the eligibility criteria for access to IVF at that stage.*

2.4 Fertility problems are common in the UK and it is estimated that they affect 1 in 7 couples with 80% of couples in the general population conceiving within 1 year, if :

- The woman is aged under 40 years and
- They do not use contraception and have regular sexual intercourse (NICE 2013)

Of those who do not conceive in the first year about half will do so in the second year (cumulative pregnancy rate is 90%).

[1] Yorkshire and the Humber Commissioning Policy for Fertility Services, 2010.
[2] Fertility: Assessment and treatment for people with fertility problems 2012, NICE Clinical Guideline 156.
[3] Fertility: Assessment and Treatment for people with fertility problems 2004, NICE Clinical Guideline 11.

The remaining 10% of couples will be unable to conceive without medical intervention and are therefore considered infertile.

2.5 In 25% of infertility cases the cause cannot be identified. However, it is thought that in remaining couples about a 3rd 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
- Blockage to the passage of the eggs

10% are due to problems with both partners.

2.6 The most recent DH costing tool estimates that there are 98 attendances at a fertility clinic for every 10,000 head of population. In Yorkshire and the Humber, this could range between 4,000 and 5,000 attendances per year which would result in 1,450 couples, likely to be assessed as eligible for IVF treatment.

2.7 Tertiary fertility services include IUI, ICSI and IVF. They may also include the provision of donor sperm and donor eggs. The majority of treatment in the UK is statutory 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.

2.8 NICE Clinical Guidelines 156 (2013) covering infertility recommends that:

Up to three full cycles of IVF will be offered to eligible couples where the woman is aged between 18 and 39 and 1 cycle for eligible couples where the woman is aged between 40 – 42.

2.9 In addition to commissioning effective healthcare, CCGs are required to ensure that resources are allocated equitably to address the health needs of the population. Therefore CCGs will need to exercise discretion on the number of cycles of IVF that they will fund up to the maximum recommended by NICE. After careful consideration, NHS Vale of York CCG (the CCG) have agreed to make:

One cycle of IVF treatment available to eligible couples in the CCG area, where the woman is aged between 23 – 39 and who meet the access criteria set out in section 6.

This decision reflects the revised NICE guidelines and although doesn't fully comply with the NICE guidelines, focuses on the group of patients with the greatest chance of success. Same sex and heterosexual couples will have equal access to services.

## 3. Clinical Effectiveness

It is considered to be clinically effective to offer up to 3 stimulated cycles of IVF treatment to couples in which the woman is aged between the age of 18 – 39 and 1 cycle where the woman is aged between 40 – 42 and who have an identified cause for their infertility or who

have infertility of at least 2 years duration. As outlined at 2.9, the CCG has agreed to make one cycle of IVF treatment available to eligible couples in the CCG area, where the woman is aged between 23 – 39 and who meet the access criteria set out in section 6.

## 4. Cost Effectiveness

4.1 Evidence shows (NICE 2013) that as the woman gets older the chances of successful pregnancy following IVF treatment falls. In light of this, NICE have recommended that the most cost effective treatment is for women aged 18 – 42 who have known or unknown fertility problems. As outlined at 2.9, the CCG has agreed to make one cycle of IVF treatment available to eligible couples in the CCG area, where the woman is aged between 23 – 39 and who meet the access criteria set out in section 6.

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

### 4.3 Risks

Fertility treatment is not without risks. A summary of potential risks are outlined below:

**Risks**

- There are risks of multiple pregnancies 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.
- 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 – 1% of all assisted reproductive 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 effects of ovulation induction agents.

## 5. Description of the treatment

### 5.1 Principles of care

5.1.1 Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.

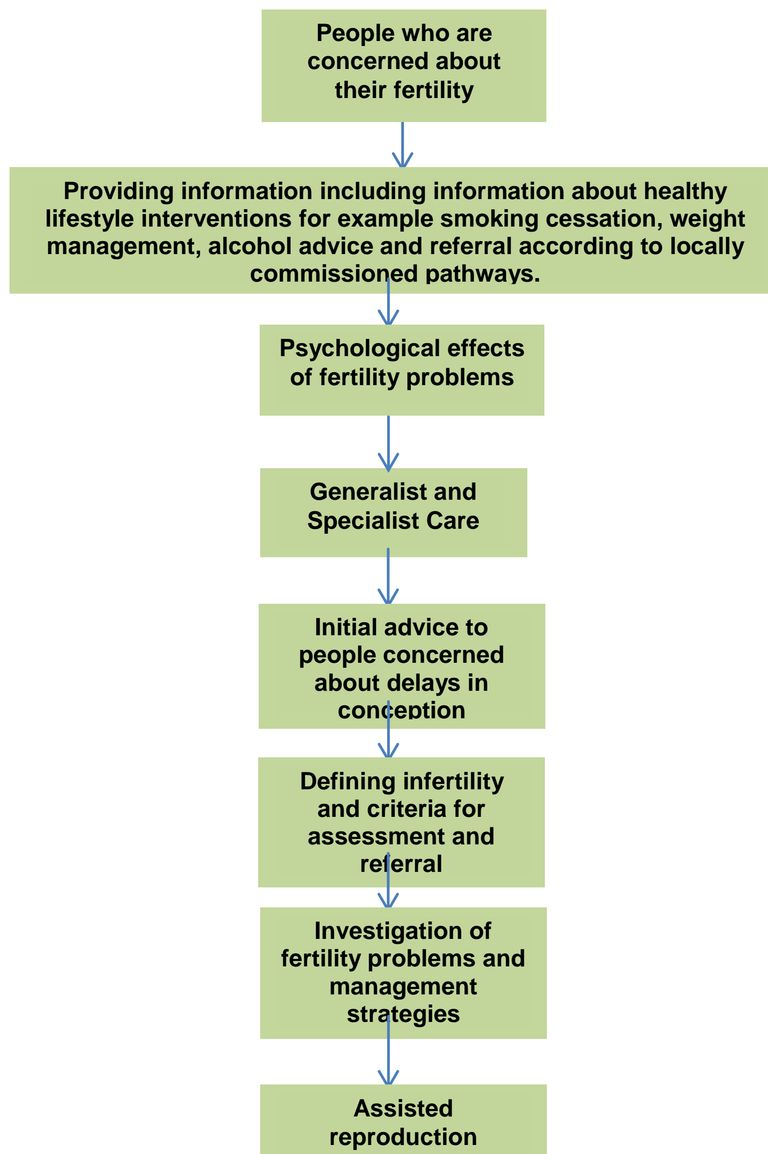
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.

5.1.3 As infertility and infertility treatments 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.

## 5.2 The Care Pathway (fig, 1)




5.2.1 Treatment for infertility problems may include counselling, lifestyle advice, drugs treatments, surgery and assisted conception techniques such as IVF.

The care pathway (fig 1) begins in primary care, where the first stage of treatment is general lifestyle advice and support to increase a couples chances of conception happening without the need for medical intervention.

If primary care interventions are not effective, initial assessment such as semen analysis will take place. Following these initial diagnostics it may be appropriate for the couple to be referred to secondary care services where further investigation and potential treatments will

be carried out, such as, hormonal therapies to stimulate ovulation. It may be appropriate at this stage for primary care clinician to consider and discuss the care pathway and potential eligibility for IVF. It may also be appropriate for healthy lifestyle interventions to be discussed.

If after secondary care interventions are not successful and the couple fulfil the eligibility criteria in section 6.0, they may then be referred through to tertiary care for assessment for assisted conception techniques, such as, IVF, DI, IUI, ICSI.

5.2.2 IVF involves:

- The use of drugs to switch 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
- 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

## 5.3 Definition of a full cycle

Full Cycle is the term used to define a full IVF treatment; it should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) (NICE 2013). Or

The definition of a single full treatment cycle is the replacement of a fresh embryo and subsequent sequential replacement of all frozen embryos derived from the cycle until pregnancy is successful or harvested embryos have been exhausted. (Not expected to be more than 4)

Adherence in this way to the NICE guidelines would encourage and not disadvantage patients agreeing to single embryo transfer.

## 5.4 Frozen Embryo Transfers

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use within the cycle.

## 5.5 Abandoned Cycles

An abandoned IVF/ICSI cycle is defined as the failure of egg retrieval, usually due to lack of response (where less that 3 mature follicles are present) or excessive response to gonadotrophins; failure of fertilisation and failure of cleavage of embryos. Beyond this stage, a cycle will be counted as complete whether or not a transfer is attempted.

## 5.6 IUI and DI

Up to three cycles of IUI and DI (Stimulated or non-stimulated) will be provided for couples with unexplained fertility, mild endometriosis or mild male factor. 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 donor Sperm.

## 5.7 Donor Gametes

The cost of donor sperm is included in the funding of treatment for which it is required which is to be commissioned in accordance with this policy and the funding policy of the CCG.

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 remains 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.

## 5.8 Gametes and Embryo Storage

The cost of egg and sperm storage will be included in the funding of treatment for which it is required which is to be commissioned in accordance with this policy and the funding policy of the CCG. 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 embryos storage funded privately prior to the implementation of this policy will remain privately funded.

## 5.9 HIV/HEP B/ HEP C

People undergoing IVF treatment should be offered testing for HIV, hepatitis B and hepatitis C (NICE 2013).

People found to test positive for one or more of HIV, hepatitis B, or hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE 2013).

## 5.10 Surrogacy

Any costs associated with use of a surrogacy arrangement will not be covered by funding from CCGs, but we will fund provision of fertility treatment (IVF treatment and storage) to identified (fertile) surrogates, where this is the most suitable treatment for a couple’s infertility problem and the couple meets the eligibility criteria for tertiary fertility services set out in this policy.

## 5.11 Single Embryo Transfer

Please refer to 5.3 for definition of a full cycle.

Multiple births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps are taken by providers to minimize 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%.

## 5.12 Counselling and 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.

## 5.13 Sperm washing and pre-implantation diagnosis

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

## 5.14 Service Providers

Providers of fertility treatment must be HFEA registered and comply with any service specification drawn up by Yorkshire and the Humber CCG Collaborative Commissioning Group.

# 6. Eligibility Criteria for Treatment

## 6.1 Application of Eligibility Criteria

Eligibility criteria should apply at the point patients are referred to tertiary care (with the exception of 6.11, which should be undertaken within tertiary care). Couples must meet the definition of infertility as described in section 2.3.

## 6.2 Overarching Principles

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

6.2.2 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. 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 Independent Funding Request Panel.

6.2.3 Treatment limits are per couple and per individual. Referrals should be as a couple and include demographic information for both partners in heterosexual and same sex couples.

## 6.3 Female Age

Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment.

The woman intending to become pregnant must be between the ages of 23 – 39 years. No new cycle should start after the woman's 40th birthday. Referrers should be mindful of the woman's age at the point of referral and the age limit for new cycles.

## 6.4 Female BMI

The female patient's BMI should be between 19 and 29 prior to referral to tertiary services. Patients with a higher BMI should be referred for healthy lifestyle interventions including weight management advice. Patients should not be re-referred to tertiary services until their BMI is within the recommended range. Assisted conception treatments will only be provided when BMI is within the range stipulated and has been maintained within 19 to 29 for the previous 6 months.

## 6.5 Smoking

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. GPs 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.

## 6.6 Existing Children

Neither partner should have any living children (this includes adopted children but not fostered) from that or any previous relationship. The adoption of children confers the legal status of parent to the adoptive parents; this will apply to both adoptions *in* and *out* of the family. If any fertility treatment results in a live birth (and the child is still alive), then the couple will not be eligible for further fertility treatments, including the implantation of any stored frozen embryos.

## 6.7 Length of relationship

Cohabiting couples must have been in a stable relationship for a minimum of 2 years to be entitled to treatment.

## 6.8 Having regular unprotected intercourse for the 2 years prior to referral within the same stable relationship

Couples must have been having regular unprotected intercourse for a 2 year period, reported to and documented by GP. Attempts to conceive should be based upon using recognised ovulation indicators at the appropriate time in the cycle.

Couples who conceive naturally and who subsequently miscarry up to twice within 2 years will be investigated for recurrent miscarriages. These women will not automatically received assisted conception treatment unless clinically appropriate as they are able to conceive naturally.

## 6.9 Previous self-funded couples

Any previous NHS funded IVF treatment will be an exclusion criterion. Couples who have previously self-funded treatment are eligible for one NHS funded cycle as long as they have not received more than two self-funded cycles.

## 6.10 Reversal of sterilisation

We will not fund IVF treatment for patients who have been sterilised or have unsuccessfully undergone reversal of sterilisation.

## 6.11 Welfare of the child

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

## Appendix, A

## 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 |
| CCG | Clinical Commissioning Group |

## Appendix, B

## Contents

| Term | Definition | Further information |
|---|---|---|
| **BMI** | The healthy weight rang 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<br><br>http://www.bbc.co.uk<br><br>NHS Direct<br><br>http://www.nhsdirect.nhs.uk |
| **ICSI** | **Intra Cytoplasmic Sperm Injection (ICSI)**: Where a single sperm is directly injected into the egg. | Glossary, HFEA<br><br>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 |

NHS
Vale of York
Clinical Commissioning Group
**Appendix 3**

**DRAFT APPLICATION FORM FOR ASSISTED CONCEPTION**

To access treatment for NHS-funded Assisted Conception treatment, the referring clinician should complete the checklist below. All sections below must be completed.

SECTION ONE – CLINICIAN DETAILS

| **Referring clinician (GP/consultant):** |
|---|
| **Referring clinician address:**<br><br>**Post code:**<br>**Contact Telephone Number:** |

| **Patient's GP (if different to referring clinician above):** |
|---|
| **GP practice name and address:**<br><br>**Post code:** |
| **Practice telephone number:**<br><br>**Practice fax number:** |

SECTION TWO – PATIENT DETAILS

| **FEMALE PATIENT** | **PARTNER**<br><br>**Male / Female** |
|---|---|
| **Name:** | **Name:** |
| **Date of birth:** | **Date of birth:** |

| **NHS No:** | **NHS No:** |
|---|---|
| **Home Address:**<br><br>**Post Code:** | **Home Address:**<br><br>**Post Code:** |

SECTION THREE – ELIGIBILITY

| Eligibility Criteria | Tick all that apply |
|---|---|
| **Age**<br><br>Female partner intending to become pregnant is aged between 23-40 years<br>OR<br>There is no evidence of low ovarian reserve<br><br>There has been a discussion of the additional implications of IVF and pregnancy at this age. No new cycle should start after the female partner's 40th birthday. Referrers should be mindful of the female partner's age at the point of referral and the age limit for new cycles i.e. female partner should be no more than 39yrs 8mths when referred for IVF. | ☐<br>☐<br>☐<br>☐ |
| **Length of relationship**<br><br>Couple have been cohabitating in a stable relationship for a minimum of 2 years | ☐ |
| **BMI**<br><br>Female partner intending to become pregnant has a BMI between 19 and 30<br>(Patients with a higher BMI should be advised about a healthy lifestyle interventions including weight management advice) | ☐ |
| **Smoking**<br><br>Both partners must be non-smokers for six months prior to a referral<br>(GPs should refer any smokers who meet all other criteria to a smoking cessation programme to support their efforts in stopping smoking in the same manner as the "Stop before your op" scheme for other elective referrals) | ☐ |
| **Duration of infertility**<br><br>Couple have not conceived after 2 years of regular unprotected intercourse<br>OR<br>For couples where intercourse is not possible, who have not conceived after 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination) | ☐<br>☐ |
| **Previous infertility treatment**<br><br>Female partner intending to become pregnant has never previously undergone any assisted conception under the NHS | ☐ |
| **Existing children**<br><br>Neither partner has any living children from this or a previous relationship (this includes adopted children but not fostered) | ☐ |
| **Welfare of the child**<br><br>The couple have been assessed as meeting the requirement contained within the HFEA Appendix entitled 'Welfare of the child' | ☐ |

Treatment is not funded where patients have undergone sterilisation or unsuccessful reversal of sterilisation

SECTION FOUR – STATEMENT CONFIRMING ELIGIBILITY

**STATEMENT TO BE SIGNED BY THE REFERRING CLINICIAN**

I confirm that the above information is correct and that this couple are eligible for NHS funded IVF treatment. They have been advised that they have a choice of provider for treatment, as listed below.

Referrer's name:

Referrer's signature:

Date of referral:

**Agreed Providers (please indicate patient preference)**

1. **Leeds RMU** ☐
2. **Sheffield Care** ☐
3. **Sheffield Teaching Hospitals** ☐
4. **Hull and East Yorkshire Hospitals NHS Trust** ☐
5. **South Tees Hospitals** ☐
6. **Any other accredited NHS provider** ☐

**This form will be returned to the referrer if any of the required information is incomplete**

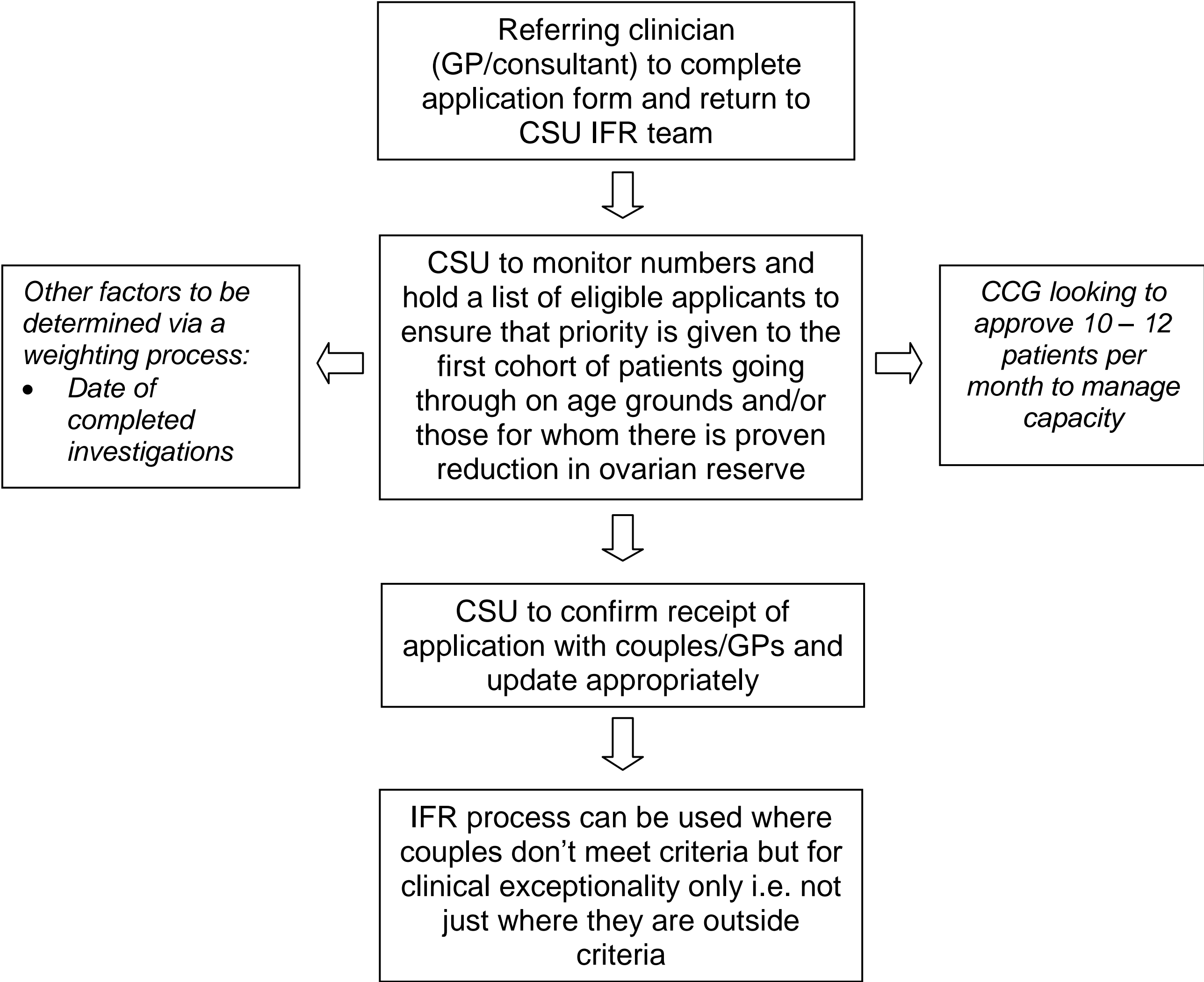
**Please send to:**

**IVF Funding Request Team**
**North Yorkshire & Humber CSU**
**Triune Court**
**Unit 1**
**Monks Cross North**
**York**
**YO32 9GZ**

**Safe Haven Fax: 01904 694702**

## Option 3 – Draft Weighted Eligibility List Pathway

Once couple identified as eligible for assisted conception in either primary or secondary care and having had full clinical work up, the following pathway will be followed, prior to referral to RMU:



## Equality Impact Analysis Form

| | |
|---|---|
| **1.** | **Title of policy/ programme/ service being analysed** |
| | Access to Infertility Treatment: Commissioning Policy |
| **2.** | **Please state the aims and objectives of this work** |
| | This is the commissioning policy for tertiary fertility service for adults registered with NHS Vale of York Clinical Commissioning Group (the CCG) and has been developed in partnership with the Yorkshire and The Humber Expert Fertility Panel.<br><br>In February 2013 NICE published revised guidance which updates previous NICE guidance published in 2004. On April 1st 2013 Clinical Commissioning Groups (CCGs) across the Yorkshire and the Humber regions adopted the existing Yorkshire and the Humber Fertility policy.<br><br>CCGs across the Yorkshire and the Humber agreed to work collaboratively to update the existing policy in light of the new NICE guidance.<br><br>The aims of this policy is to ensure that those most in need and able to benefit from NHS funded treatment are given equitable access to tertiary fertility services across the Yorkshire and the Humber Area. |
| **3.** | **Who is likely to be affected? (e.g. staff, patients, service users)** |
| | The CCG represents patients registered with 32 GP Practices across the Vale of York area, equating to a population of approximately 336,330 residents.<br><br>Equality is a key theme running through all the CCG's policies, strategies and plans and where possible we aim to improve access for our population, for example, increasing access to infertility treatment for eligible couples. |

| 4. | **What sources of equality information have you used to inform your piece of work?** |
|---|---|
| | The CCG has a duty under the Public Sector Equality Duty (PSED) of the Equality Act 2010 to eliminate discrimination, harassment, victimisation; advance equality of opportunity; and foster good relations. Our Equality, Diversity and Human Rights Strategy & Implementation Plan 2013-17 includes the following objectives:<br><br>• To provide accessible and appropriate information to meet a wide range of communication styles and needs<br>• To improve the reporting and use of equality data to inform equality analyses<br>• To strengthen stakeholder engagement and partnership working<br>• To be great employer with a diverse, engaged and well supported workforce<br>• Ensure our leadership is inclusive and effective at promoting equality<br><br>These objectives have been informed by evidence gathered from previous engagement activity, review of a wide range of documents and internal self-assessment using the Equality Delivery System. |
| **5.** | **What steps have been taken ensure that the organisation has paid due regard to the need to eliminate discrimination, advance equal opportunities and foster good relations between people with protected characteristics** |
| | This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility.<br><br>As stated in NICE 2013 guidance all couples without known reproductive pathology are required to test their fertility and meet a threshold definition of unexplained infertility before they will be eligible for funded tertiary treatment.<br><br>For couples that do not have identified fertility pathology preventing them from conceiving there are two options available to enable them to test their fertility to access tertiary services:<br><br>1. For couples where conventional methods of conception is an option a pathway of unprotected sex for a period of 2 years is followed. |

| | |
|---|---|
| | 2. For couples where conventional methods of conception is not an option (a pathway of unprotected sex is not an option); in order to support these couples to be able to access tertiary fertility services the policy enables couples to:<br><br>• demonstrate infertility (in the absence of pathology or conventional unprotected sex for a period of 2 years) by failing to conceive after 12 rounds of insemination of which 6 should be IUI and self-funded<br><br>The requirement to self-fund will have an adverse financial impact on same-sex couples and heterosexual couples who cannot have conventional intercourse but can reasonably be expected to attempt conception. It is likely that the number of same-sex couples affected is likely to be proportionately higher. It is also recognised that for same-sex couples there are innate biological issues which affect the couples' own resources to access the policy.<br><br>This policy relates to access to infertility treatment, i.e. tertiary services for those who have identified fertility problems (whether known reproductive pathology, physical disability or unexplained fertility as defined in the NICE 2013 guidance). The CCG is offering IUI in accordance with NICE guidelines.<br><br>The CCG will always consider exceptional cases on an individual basis via their Individual Funding Request Process. |
| **6.** | **Who have you involved in the development of this piece of work?** |
| | **Internal involvement:** Nursing; Finance and Contracting; Communications; Procurement; Governing Body members; GP Clinical Lead<br><br>**Stakeholder involvement**: Secondary and Tertiary Care Providers; Commissioning Support Unit Individual Funding Request team; neighbouring CCGs; Legal Services |
| **7.** | **What evidence do you have of any potential adverse or positive impact on groups with protected characteristics? Do you have any gaps in information?**<br>**Include any supporting evidence e.g. research, data or feedback from engagement activities**<br><br>**(Refer to** Error! Reference source not found. if your piece of work relates to commissioning activity to gather the evidence during all stages of the commissioning cycle) |

| | |
|---|---|
| **Disability** | Consider building access, communication requirements, making reasonable adjustments |

| People who are learning disabled, physically disabled, people with mental illness, sensory loss and long term chronic conditions (such as diabetes, HIV) | for individuals etc |
| --- | --- |

This commissioning policy as a whole aims to provide equal access to couples who meet the eligibility criteria to achieve conception who have infertility. Sensitivity to those with additional needs e.g. physical or cognitive, or sensitive disabilities will be taken into account.

| **Sex**<br>Men and Women | Consider gender preference in key worker, single sex accommodation etc |
| --- | --- |

This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility.

| **Race or nationality**<br>People of different ethnic backgrounds, including Roma Gypsies and Travelers | Consider cultural traditions, food requirements, communication styles, language needs etc |
| --- | --- |

The Vale of York population is majority white British (95%) and report their religious beliefs as Christian (64%) or of no religion (26%). There is a number of other significant ethnic groups including, Asian (2.2%), mixed race (1%), black (0.4%) and travellers & Roma Gypsy communities.

Information on fertility services will be provided in a wide range of formats to meet the diverse needs of couples taking into account the different cultural, social and health needs of our community.

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English

| | |
|---|---|
| **Age**<br>This applies to all age groups. This can include safeguarding, consent and child welfare | Consider access to services or employment based on need/merit not age, effective communication strategies etc |
| Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment. | |
| **Trans**<br>People who have undergone gender reassignment (sex change) and those who identify as trans | Consider privacy of data, harassment, access to unisex toilets & bathing areas etc |
| None. | |
| **Sexual orientation**<br>This will include lesbian, gay and bi-sexual people as well as heterosexual people. | Consider whether the service acknowledges same sex partners as next of kin, harassment, inclusive language etc |
| This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility. | |
| **Religion or belief**<br>Includes religions, beliefs or no religion or belief | Consider holiday scheduling, appointment timing, dietary considerations, prayer space etc |
| The Vale of York population is majority white British (95%) and report their religious beliefs as Christian (64%) or of no religion | |

(26%). There is a number of other significant ethnic groups including, Asian (2.2%), mixed race (1%), black (0.4%) and travellers & Roma Gypsy communities.

Information on fertility services will be provided in a wide range of formats to meet the diverse needs of couples taking into account the different cultural, social and health needs of our community.

- Face to face discussions with couples
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- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English

| | |
|---|---|
| **Marriage and Civil Partnership**<br>Refers to legally recognised partnerships (employment policies only) | Consider whether civil partners are included in benefit and leave policies etc |

This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility.

| | |
|---|---|
| **Pregnancy and maternity**<br>Refers to the pregnancy period and the first year after birth | Consider impact on working arrangements, part-time working, infant caring responsibilities etc |

None.

| | |
|---|---|
| **Carers**<br>This relates to general caring responsibilities for someone of any age. | Consider impact on part-time working, shift-patterns, options for flexi working etc |

None.

| | |
|---|---|
| **Other disadvantaged groups** | Consider ease of access, location of service, historic take-up of service etc |

| This relates to groups experiencing health inequalities such as people living in deprived areas, new migrants, people who are homeless, ex-offenders, people with HIV. | |
|---|---|
| None. | |

| 8. | **Action planning for improvement**<br><br>The CCG Infertility Policy aims to improve access to infertility treatment to eligible couples therefore having a positive impact to the population.<br><br>The Policy aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships. |
|---|---|

| **Sign off** |
|---|
| Name and signature of person / team who carried out this analysis<br>**Sarah Kocinski** |
| Date analysis completed<br>**23rd July 2014** |
| Name and signature of responsible Director<br>**Lucy Botting** |
| Date analysis was approved by responsible Director<br>**24th July 2014** |