Item Number: 9

Name of Presenter: Dr Tim Maycock

Meeting of the Governing Body

4 December 2014

Vale of York
Clinical Commissioning Group

Access to Infertility Treatment: Commissioning Policy

For Decision

1. Rationale

This is the updated policy paper for implementation that has been prepared following the Governing Body decision in August 2014 to defer the decision to make one cycle of IVF treatment available to eligible couples.

2. Strategic Initiative *(double click and select 'checked' for all relevant initiatives)*

- ☐ Integration of care
- ☐ Person centred care
- ☐ Primary care reform
- ☐ Urgent care reform
- ☒ Planned care
- ☐ Transforming MH and LD services
- ☐ Children and maternity
- ☐ Cancer, palliative care and end of life care
- ☐ System resilience

3. Actions / Recommendations

a) Ratify the decision of the Council of Representatives to recommence the commissioning of in-vitro fertilisation
b) Adopt the Access to Infertility Treatment: Commissioning Policy Document
c) Agree implementation with immediate effect

4. Engagement with groups or committees

Council of Representatives, Governing Body and Senior Management Team have received an outline of the proposed approach.

5. Significant issues for consideration

Due to the unknown backlog following five years of no IVF funding in the Vale of York, the exact cost of implementing the policy is uncertain. Forecast projections have therefore been based on estimations of what is known i.e. potential eligible couples aligned with recent referral rates of other CCGs who have opted to implement an IVF model.

6. Implementation

Dr Emma Broughton, as clinical lead, and team members within the CCG will work with primary, secondary and tertiary care providers and other key stakeholders involved ensuring that the policy is implemented according to the agreed implementation date.

7. Monitoring

It will be essential that costs and activity are closely monitored.

8. Responsible Chief Officer and Title	**9. Report Author and Title**
Dr Emma Broughton GP Governing Body Member	Sarah Kocinski Innovation and Improvement Facilitator

10. Annexes

Appendix 1 – Access Criteria
Appendix 2 – NHS Vale of York CCG Access to Infertility Treatment: Commissioning Policy Document
Appendix 3 – Draft Referral Form
Appendix 4 – Equality Impact Assessment

The appendices have been provided for Governing Body members and are available at www.valeofyorkccg.nhs.uk/about-us/governing-body-meeting

Governing Body Meeting: 4 December 2014

Access to Infertility Treatment: Commissioning Policy

1. Background

1.1 At the meeting of the NHS Vale of York CCG's (the CCG) Governing Body in August 2014, the Governing Body agreed to defer the decision to commission IVF treatment due to financial pressures.

1.2 The CCG agreed to review its position later in the financial year. This paper now proposes that one cycle of IVF treatment be made available to eligible couples in the Vale of York who meet the criteria set out at **Appendix 1**. This 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.

1.3 The proposed CCG Access to Infertility Treatment: Commissioning Policy Document (the policy) is attached at **Appendix 2** and represents the policy that is recommended and should be adopted by the CCG. This policy focuses on the group of patients with the greatest chance of success, based on clinical evidence as shown in **Table 1** below.

Table 1: Success Rates

- Average IVF success rates are 13.6% for women aged 40-42 and 5% for women aged 43-44, success rates go down to 1.9% for women aged 45+ (http://www.hfea.gov.uk/ivf-success-rate.html, 2011 data)
- Success rates drop rapidly from the age of age 39, with most specialist units quoting between 20.8% - 27.9% success rates for 35-39yr olds (www.hfea.gov.uk, 2012)
- Success rates overall are up to 48% in some units with new techniques for 25-45 yr olds (http://www.genesisivf.co.uk/about-us/success-rates/, 2013)
- Ovarian function can be crudely assessed using a blood test (for FSH) and USS (for antral follicle count). It is therefore possible to estimate a woman's chances of success

2. Financial Implications of Implementing NICE Guidance

2.1 Due to the unknown total number of eligible couples following five years of no IVF funding in the Vale of York the exact cost of implementing the policy is uncertain and remains challenging to quantify. However, information obtained from neighbouring North Yorkshire CCGs who have recently commissioned IVF shows the following activity in 10 weeks (1 August – 13 October 2014):

- Scarborough & Ryedale – 7 cases, 6 approved
- Harrogate & Rural District – 26 cases, 21 approved, 4 declined, 1 pending
- Hambleton, Richmondshire & Whitby – no data available yet from providers

2.2 It should also be noted that the CCG has to make provision for amounts it is probable (more likely than not) it will have to pay in the future where the reason for the liability has already occurred, but the timing or amount to settle it are as yet uncertain. This will apply to any decision to commission IVF and will therefore mean that the estimated value of any backlog will have to be provided for in the 2014/15 annual accounts.

3. Procurement

There are no procurement issues as there are currently 5 providers of fertility treatments in the surrounding area: Leeds, Sheffield (x2), Hull and Middlesbrough. All offer IVF on the NHS within their current contracts. When we have explored costs there is little difference. Patients may, however, request other providers using their right to patient choice and as long as they are an NHS accredited provider on the HFEA approved list this is also acceptable http://www.hfea.gov.uk/. Providers have no capacity issues and can start with immediate effect if the recommendations are approved.

4. Implementation Plan

4.1 The plan is to allow any eligible couple who meets the access criteria to be referred for IVF treatment with immediate effect.

4.2 We have been able to use the NHS Harrogate and Rural District CCG (HaRD) activity data and adjust this for the Vale of York population. On this basis the most likely projection of the first full year cost to offer 1 cycle of IVF therapy is £851k, and £300k on an on-going basis. Assuming a 5 December 2014 start date, this would equate to a pro-rata effect of £261k, with the balance of the £851k, £590k, to be accounted for as a provision. This will need to be reviewed as part of the final accounts process.

4.3 This has been calculated using the HaRD population of 22,219 women aged 18-42, which has resulted in 2.1 patients per week approved for IVF.

4.4 The Vale of York equivalent age population is 60,673, this means proportionally the CCG could expect to see 5.74 patients per week. Therefore this would equate to £851k. 5.74 x £2,853 (average cost of IVF cycle as per NICE costing template) x 52wks = £851k and could potentially treat 298 couples.

4.5 The draft referral form to be completed by all referrers is attached at **Appendix 3**.

5. 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 4**.

6. Recommendations

Following a review of the CCG's financial position and in line with the further analysis undertaken using local activity, the Governing Body is asked to:

6.1 Ratify the decision of the Council of Representatives to recommence the commissioning of in-vitro fertilisation.

6.2 Adopt the Access to Infertility Treatment: Commissioning Policy Document.

6.3 Agree implementation with immediate effect.

Appendices

Appendix 1 – Access Criteria
Appendix 2 – NHS Vale of York CCG Access to Infertility Treatment: Commissioning Policy Document
Appendix 3 – Draft Referral Form
Appendix 4 – Equality Impact Analysis

Appendix 1

Access Criteria

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.
Partners: both must be:-	
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. 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. 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.

Appendix 2

Access to infertility treatment

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

Version 4
December 2014
(Review period April - July 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:

Virginia Beckett	Consultant in Reproductive Medicine Bradford Teaching Hospital FT
Helen Brown	Service Manager Sheffield Teaching Hospital FT
Jill Bulmer	Leeds Teaching Hospitals
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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%).

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[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.

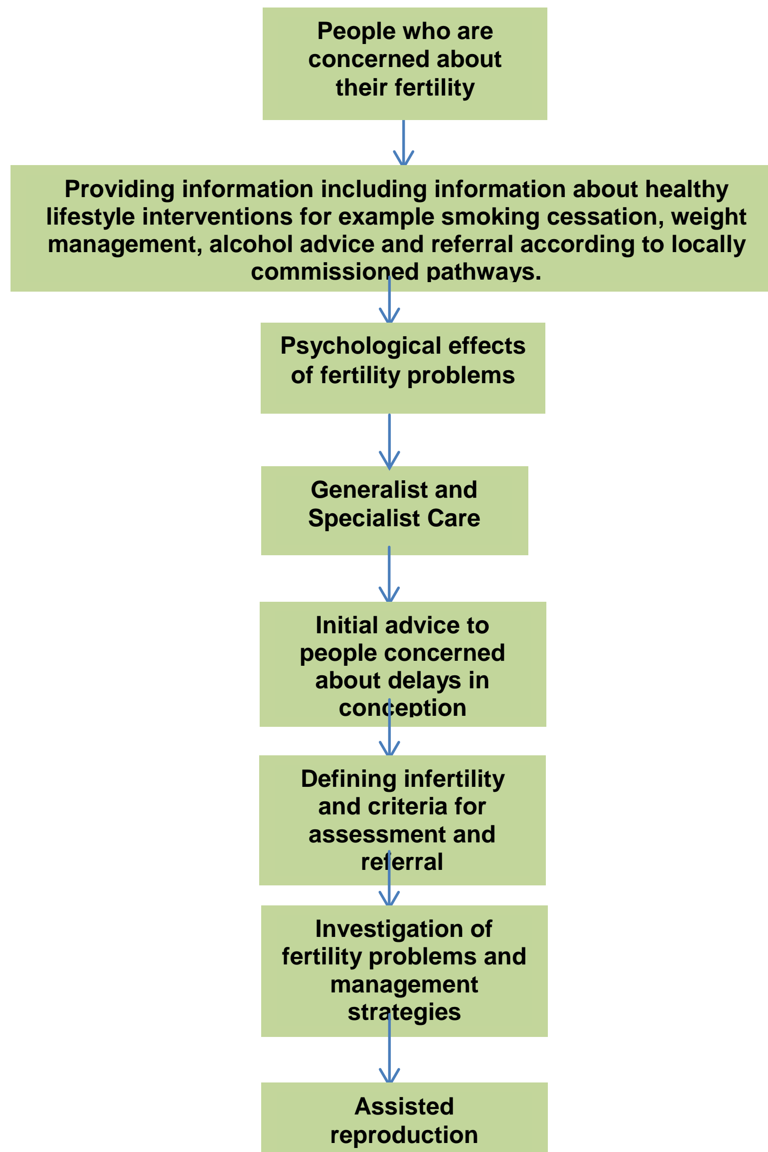
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

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.

Given the strict eligibility criteria and the relatively low success rates for IVF, couples and individuals may wish to consider finding out more about adoption, as another route to becoming parents. The Governments national information service is the best place to start http://www.first4adoption.org.uk/ or information line - 0300 222 0022.

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 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

Appendix 3

DRAFT REFERRAL 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: **Post code:** **Contact Telephone Number:**

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

SECTION TWO – PATIENT DETAILS

FEMALE PATIENT	**PARTNER** **Male / Female**
Name:	**Name:**
Date of birth:	**Date of birth:**

NHS No:	**NHS No:**
Home Address: **Post Code:**	**Home Address:** **Post Code:**

SECTION THREE – ELIGIBILITY

Eligibility Criteria	**Tick all that apply**
Age Female partner intending to become pregnant is aged between 23-40 years OR There is no evidence of low ovarian reserve 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.	☐ ☐ ☐ ☐
Length of relationship Couple have been cohabitating in a stable relationship for a minimum of 2 years	☐
BMI Female partner intending to become pregnant has a BMI between 19 and 29 (Patients with a higher BMI should be advised about a healthy lifestyle interventions including weight management advice)	☐
Smoking Both partners must be non-smokers for six months prior to a referral (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 Couple have not conceived after 2 years of regular unprotected intercourse OR For couples where intercourse is not possible, have not conceived after 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination)	☐ ☐
Previous infertility treatment Female partner intending to become pregnant has never previously undergone any assisted conception under the NHS * *Couples who have self-funded 2 cycles and not conceived are still eligible for one NHS funded cycle*	☐
Existing children Neither partner has any living children from this or a previous relationship (this includes adopted children but not fostered)	☐
Welfare of the child 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** ☐

SECTION FIVE – SUPPORTING DOCUMENTATION

Attached letter of support from secondary care	☐
If investigations more than 6 months prior to referral, please repeat and attach following results: FSH/LH/estrogen (blood test female) AND Sperm analysis (male)	☐ ☐

Please send via Referral Support Service (RSS)

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

Appendix 4

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. 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. CCGs across the Yorkshire and the Humber agreed to work collaboratively to update the existing policy in light of the new NICE guidance. 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. 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: • To provide accessible and appropriate information to meet a wide range of communication styles and needs • To improve the reporting and use of equality data to inform equality analyses • To strengthen stakeholder engagement and partnership working • To be great employer with a diverse, engaged and well supported workforce • Ensure our leadership is inclusive and effective at promoting equality 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. 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. 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: 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:

	• 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 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. 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. 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 **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?** **Include any supporting evidence e.g. research, data or feedback from engagement activities** **(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 People who are learning disabled, physically disabled, people with mental illness, sensory loss and long term chronic conditions (such as diabetes, HIV)	Consider building access, communication requirements, making reasonable adjustments for individuals etc

<table>
<tr><td></td><td></td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>Sex
Men and Women</td><td>Consider gender preference in key worker, single sex accommodation etc</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>Race or nationality
People of different ethnic backgrounds, including Roma Gypsies and Travelers</td><td>Consider cultural traditions, food requirements, communication styles, language needs etc</td></tr>
<tr><td colspan="2">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</td></tr>
<tr><td>Age
This applies to all age groups. This can include safeguarding, consent and child welfare</td><td>Consider access to services or employment based on need/merit not age, effective communication strategies etc</td></tr>
</table>

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 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 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 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 • 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

Marriage and Civil Partnership 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 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 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 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.	Consider ease of access, location of service, historic take-up of service etc
None.	

8.	**Action planning for improvement** The CCG Infertility Policy aims to improve access to infertility treatment to eligible couples therefore having a positive impact to the population. 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 **Sarah Kocinski**
Date analysis completed **23rd July 2014**
Name and signature of responsible Director **Lucy Botting**
Date analysis was approved by responsible Director **24th July 2014**