

Commissioning Policy for In Vitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within tertiary Infertility Services

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Version Control Sheet

Draft	Version/Description of Amendments	Date	Author
1	1 st Draft	13.08.13	IH
2	Comments received from Andy Roylance Nicky Bird Andy Rix Lola Banjoko Dave Giffard	19.09.13	IH
3	Comments received from Clare Lewis-Jones (Infertility Network) Nicky Bird Sue Sims Heather Stringer (NURTURE) Dr Robert Wilson Julia Mehigan (Derbyshire Lesbian, Gay, Bisexual and Transgender Group Judith Smith (CARE Nottingham)	16.10.13	IH
4	Feedback from review meeting on 25/10/13	29.10.13	IH
5	Review of policy by Dr H Ewart	29.10.13	IH/HE
6	Final Policy approved by ICBs	31.03.14	LC
7	Due Regard Screening	01.04.14	LC
8.	Final Version issued	01.04.14	LC
9.	Revised on transition to single CCG	01.04.20	TF

Equality Commitment Statement

In carrying out their functions, the East Midlands Clinical Commissioning Groups and the Greater East Midlands Commissioning Support Unit (GEM CSU) are committed to having due regard to the Public Sector Equality Duty. This applies to all the activities for which the ICB's and GEM CSU are responsible, including policy development and review.

The IVF/ICSI policy has been reviewed 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.

The aim is to design and implement policy documents that meet the diverse needs of the populations to be served and the NHS workforce, ensuring that none are placed at a disadvantage over others. The policy considers current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equality of opportunity for all. This document has been designed to ensure that no-one receives less favourable treatment owing to their personal circumstances, in this instance their protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

Introduction

01. In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes circumstances in which the East Midlands Clinical Commissioning Groups (ICBs) will fund treatment for IVF including Intra-cytoplasmic Sperm Injection (ICSI).
02. This policy applies to any patient who is registered with a GP practice within the East Midlands ICBs who have adopted this policy. The eligibility criteria set out in this policy apply irrespective of where patients have their treatment (local NHS hospitals, tertiary care centres or independent sector providers).
03. This policy has drawn on guidance issued by the Department of Health, Infertility Network UK, and the revised NICE Clinical Guideline 'Fertility, assessment, and treatment for people with fertility problems' (CG156 February 2013).
04. The following are outside the scope of this policy:
 - Intra-Uterine Insemination(IUI)/ Donor Insemination (DI)
 - Surrogacy
 - Pre-Implantation Genetic Diagnosis (PGD)
 - Gamete and Embryo Cryopreservation for people undergoing treatment likely to impair their fertility
05. This policy replaces all previous IVF/ICSI policies and is inclusive of all protected groups.

General Principles

06. IVF can be a legitimate medical intervention as part of NHS provision where a couple has a medical reason for being unable to conceive a child. Couples (including same sex couples) who can demonstrate this and fulfil the following criteria will be eligible for tertiary infertility treatments under this agreement.
07. The eligibility criteria set out below do not apply to clinical investigations for subfertility which are available to anyone with a fertility problem as advised by a relevant clinician.
08. The eligibility criteria do not apply to the use of assisted conception techniques for reasons other than subfertility, for example in families with serious inherited diseases where (IVF) is used to screen out embryos carrying the disease or to preserve fertility, for example for someone about to undergo chemotherapy, radiotherapy, or other invasive treatments.
09. The East Midlands ICBs respect the right of patients to be treated according to the obligations set out in the NHS Constitution.

Definition and Access to Infertility Treatment

10. Fertility problems are common in the UK, and it is estimated that they affect one in seven couples. 84% of couples in the general population will conceive within one year if they do not use contraception and have regular sexual intercourse. Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate 92%). In 30% of infertility cases the cause cannot be identified.
11. Where a woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within 12 months should be taken as an indication for further assessment and possible treatment.
12. If the woman is aged 36 or over then such assessment should be considered after 6 months of

unprotected regular intercourse since her chances of successful conception are lower and the window of opportunity for intervention is less.

13. For women aged up to 42 years who have not conceived after 2 years of regular unprotected intercourse or a course of artificial insemination (in line with local ICB policy), this should be taken as an indication for consideration of IVF.
14. If, following investigations, a cause for the infertility is found, the individual should be referred for appropriate treatment without further delay.
15. This policy reflects the NICE guidelines that access to assisted conception treatments including IVF should be offered to women up to the age of 42. Ovarian stimulation should have been completed before the woman's 43rd birthday.
16. Women will be offered treatment provided their predicted ovarian response to gonadotrophin stimulation is satisfactory, as indicated by a Follicle Stimulation Hormone (FSH) of < 8.9 IU/l or one of the other measures recommended in NICE CG156 (section 1.3.3.2 – Ovarian reserve testing).

Definition of Childlessness

17. Funding for IVF/ICSI will be available to couples who do not have a living child from their current relationship nor any previous relationships.
18. A child adopted by a couple is considered to have the same status as a biological child. This does not include foster children.
19. A couple will cease to be eligible for treatment if a pregnancy occurs naturally leading to a live birth or if the couple adopts a child.

Treatment Options

20. This policy is intended, as per NICE Clinical Guidelines, for people able to have regular sexual intercourse who have failed to conceive due to a specific identified pathological problem or who have unexplained infertility.
21. ICBs will fund IVF treatment for **same sex couples** and/or **people with a physical disability** provided there is evidence of subfertility, defined as no live birth following artificial insemination (AI) as per local ICB policy or proven by clinical investigation as per NICE guidelines. AI should be undertaken in a licensed clinical setting with an initial clinical assessment and appropriate investigations.
22. Please refer to local ICB policy for details of eligibility criteria for NHS funding for AI.

Surrogacy

23. Please refer to the ICB surrogacy policy.

Sterilisation and Reversal of Sterilisation

24. IVF/ICSI treatment will not be funded where either partner has been sterilised or reversal of sterilisation has been undertaken.

Body Mass Index (BMI)

25. Where there is a statement on criteria for BMI the criterion has not been arbitrary applied and has been included on the grounds of evidence for clinical and safety reasons.
26. Couples should be advised that having a BMI of 30 or over (in either or both partners) is associated with reduction in fertility and chances of conceiving which may be reversed with weight loss.
27. Women being considered for IVF must have a stable BMI below 30 at the commencement of IVF treatment. A BMI below 30 is a requirement as there is evidence to show that oocyte collection rates are significantly lower and early pregnancy loss rates are significantly higher, in women with BMI of 30 or more, compared with those with BMI under 30.

Smoking

28. Both partners must be non-smoking for at least 28 days before treatment commences and must continue to be non-smoking throughout treatment. Providers will seek evidence from referrers and confirmation from each partner. Providers should also include this undertaking on the consent form and ask each partner to acknowledge that smoking will result either in cessation of treatment or treatment costs being applied.

Definition and Number Of Cycles

29. A cycle is the process whereby one course of IVF (+/- ICSI) commences with ovarian stimulation and is deemed to be complete when all viable fresh and frozen embryos resulting from that stimulation have been transferred.
30. Couples meeting the eligibility criteria will be eligible to receive a maximum of 1 completed cycle of IVF treatment (+/- ICSI).
31. For women aged up to 40 years the East Midlands ICBs offer funding for 1 full cycle of IVF treatment (+/- ICSI).
32. For women aged 40-42 years the East Midlands ICBs offer 1 full cycle provided:
 - They have never previously had IVF/ICSI.
 - There is no evidence of low ovarian reserve (NICE CG156 section 1.3.3.2 Ovarian reserve testing).
 - The implications of IVF and pregnancy at this age have been discussed with the patient.
33. Couples who have previously self-funded their IVF treatment will be entitled to one NHS funded cycle provided they have not received more than two complete cycles of privately funded treatment.
34. Where couples have previously self-funded and frozen embryos exist, the couple must utilise any viable embryos rather than undergo ovarian stimulation, egg retrieval and fertilisation again. The use of these embryos in this circumstance will require self-funding.

Number of Transferred Embryos

35. In keeping with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy couples will be counselled about the risks associated with multiple pregnancies and advised that they will receive a single embryo transfer (whether fresh or frozen) in line with NICE guidance unless there is a clear clinical justification for doing otherwise. In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).

36. Women with a good prognosis should be advised that a single embryo transfer, for both the fresh and any subsequent frozen embryo transfers, can almost remove the risk of a multiple pregnancy while maintaining a live birth rate which is close to that achieved by transferring 2 fresh or frozen embryos.
37. For women aged between 37-39 years double embryo transfer can be considered if no top-quality embryo is available.
38. For women aged between 40-42 years, double embryo transfer may be considered.

Cancelled Cycles

39. A cancelled cycle is defined by NICE as 'egg collection not undertaken'. Where IVF is charged by providers as an inclusive price, a cancelled cycle should not be charged. Couples will be eligible for one cancelled cycle as part of their NHS treatment.

Frozen Embryos

40. All stored and viable embryos should be used before a new cycle commences. This includes embryos resulting from previously self-funded cycles.
41. Embryos frozen as part of an NHS funded cycle will be stored for up to 3 years. After 3 years, couples will be required to self-fund storage of any embryos.

Surgical Sperm Retrieval

42. Surgical sperm retrieval for the treatment of male related fertility problems is a separate clinical procedure and will be commissioned where clinically appropriate. This will include cases of obstructive azoospermia or ejaculatory failure where this has not been corrected by other means.
43. Funding will be provided for men who, with their partner, would be eligible for NHS funded IVF/ICSI treatment.
44. Funding will not be provided for sperm retrieval in men who have undergone vasectomy even if the female partner also requires infertility treatment.

Oocyte Donation

45. Oocyte donation may be commissioned as part of this policy when clinically appropriate, for example:
 - Premature ovarian failure
 - Gonadal dysgenesis including Turner syndrome
 - Bilateral oophorectomy
 - Ovarian failure following chemotherapy or radiotherapy
46. NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation.

Egg/Sperm Donation

47. NHS funding will be available for women who fulfil the eligibility criteria and require donated eggs/sperm.
48. Egg and sperm donations will be sourced by providers.

Embryo and Sperm Storage

49. Embryo and sperm (when required after surgical retrieval) storage will be funded for couples who are undergoing NHS fertility treatment. Storage will be funded for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter.
50. The ICB will not separately fund access to and the use of frozen embryos remaining after a live birth. Couples may be charged separately by providers for the use of these embryos.


Cryo-Preservation


51. Please refer to the ICB policy for embryo, oocyte and sperm storage for patients undergoing treatment likely to impair fertility.

Policy Review

52. This policy will be reviewed should there be any material changes to the guidelines issued by NICE or as agreed by all participating ICBs.

Fertility Assessment & Treatment Pathway

Primary Care	
01. Patient with fertility problem goes to GP	
02. GP arranges further investigations	
<p><u>Woman</u></p> <ul style="list-style-type: none"> ▪ Rubella serology ▪ HVS & chlamydia screen ▪ FSH & LH day 1-4 of cycle * ▪ Progesterone day 21 of cycle (if cycle is regular) ▪ Prolactin (if cycle is irregular) ▪ TSH <p>* if the FSH is borderline <8.9 IU/l that the test is repeated to obtain an average over 3 readings All tests should be within the last 12 months except for the FSH/LH which should be within the last 6 months</p>	
<p><u>Man</u></p> <ul style="list-style-type: none"> ▪ Semen analysis (within last 12 months) ▪ Testosterone level 	
03. GP to inform patient of access criteria for NHS-funded assisted conception	
04. Refer couple for advice using fertility proforma on Ardens merged with the woman's medical record	
Secondary Care	Start 18w 
05. Referral accepted provided mandatory tests completed and included with referral	
06. Couple seen at 1 st outpatient appointment	
07. Additional investigations arranged	
<p><u>For women</u>, tests may include</p> <ul style="list-style-type: none"> ▪ Hormone profile taken between days 2 - 4 of a period to assess for any hormone imbalance. ▪ Blood tests to find out if the woman is ovulating. ▪ An ultrasound scan to look at the uterus and ovaries. ▪ Hysterosalpingogram – an x-ray to check fallopian tubes. ▪ Hysterosalpingo-contrast sonography (HyCoSy) – a vaginal ultrasound to check the fallopian tubes. ▪ Laparoscopy – an operation in which a dye is injected through the cervix as the pelvis is inspected via a telescope (laparoscope) with a tiny camera attached to check for tubal blockage. ▪ Hysteroscopy – a telescope with a camera attached is used to view the uterus to check for conditions such as fibroids or polyps. ▪ A tissue sample may be taken to be analysed from the endometrium lining of the uterus. 	

<p><u>For men</u></p> <ul style="list-style-type: none"> ▪ Semen analysis to check sperm numbers and quality. ▪ Sperm antibody test to check for protein molecules that may prevent sperm from fertilising an egg. ▪ FSH & LH levels ▪ Testosterone level ▪ Karyotype ▪ Cystic Fibrosis Screening 	
<p>08. Follow up appointment arranged to discuss further test results and diagnosis</p>	
<p>09. Treatment by secondary care</p>	<p>Stop 18w</p> 
<ul style="list-style-type: none"> a) Male factor → Gonadotrophin therapy b) Endometriosis → Laparoscopic surgery c) Tubal defect → Tubal surgery d) Ovulation issue → Clomiphene etc. e) Ovarian failure → refer to fertility centre f) Unexplained → refer to fertility centre 	
<p>10. Referral to tertiary centre of couple choice using proforma provided by the ICB</p>	
<ul style="list-style-type: none"> a) Male factor → Donor insemination → IVF ± ICSI b) Endometriosis → Intrauterine insemination → IVF ± ICSI c) Tubal defect → Intrauterine insemination → IVF ± ICSI d) Ovarian failure → IVF ± ICSI e) Unexplained → IVF ± ICSI 	
<p>11. Seen in tertiary fertility care centre</p>	
<p>12. Before processing patient sperm, eggs, or embryos for treatment and/or storage, the fertility clinic must carry out several screening tests to assess the risk of contamination, as follows:</p> <ul style="list-style-type: none"> ▪ HIV 1 and 2; Anti-HIV – 1, 2 ▪ Hepatitis B: surface antigen HBsAg and core Antibody Anti-HBc ▪ Hepatitis C: serology Anti-HCV-Ab ▪ Testing for HTLV-1, malaria and other conditions may also be performed if a patient's medical and/or recent travel history indicates they may be at risk. 	
<p>13. Patients who donate their eggs, sperm or embryos must also be screened for according to professional body guidelines (http://www.fertility.org.uk/news/pressrelease/09_01- ScreeningGuidelines.html).</p>	

Glossary

Term	Meaning
Blastocyst	Any undifferentiated embryonic cell (Lawrence, 2000: 75)
Body Mass Index (BMI)	Body Mass Index (BMI) is a number calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems.
Donor Insemination (DI)	The introduction of donor sperm into the vagina, the cervix or womb itself
Embryo	A fertilised egg.
Embryo transfer	The replacement of embryo(s) back into the female patient
Frozen Embryo Replacement (FER)	Where an excess of top-quality embryos is available, these embryos may be cryogenically frozen for future use. Once thawed, these embryos are transferred to the patient as a frozen cycle.
Gonadotrophins	Hormones that stimulate the function of the organs in which reproductive cells are produced (Lawrence, 2000; 254)
Human Fertilisation and Embryology Authority (HFEA).	UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. (HFEA, c, 2009)
Invitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in the laboratory.
Intra-cytoplasmic Sperm Injection (ICSI)	This is a technique that can be used in IVF whereby a sperm is injected into an egg to assist in fertilisation. (NHS Direct, 2009).
Intrauterine Insemination (IUI)	A procedure to separate fast moving sperm from more sluggish or non-moving sperm. The fast-moving sperm are then placed into the woman's womb close to the time of ovulation when the egg is released from the ovary in the middle of the monthly cycle.
National Institute for Health & Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
Oocyte	A not yet fully developed egg cell.
Ovarian Stimulation	The process of stimulating one or more follicles to grow by the administration of gonadotrophins'
Pre-implantation genetic diagnosis (PGD)	This is a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking the genes of embryos created through IVF for this genetic condition.

Schedule of Eligibility Criteria

<p>Women's Age</p>	<ul style="list-style-type: none"> ▪ For women up to 40 years the East Midlands ICBs offer funding for 1 full cycle of IVF treatment (+/-ICSI) ▪ Couples who have self-funded will be entitled to 1 NHS cycle provided they have not received more than 2 cycles ▪ For women aged between 40-42 years the East Midlands ICBs offer 1 full cycle provided: <ul style="list-style-type: none"> a) They have never previously had IVF. b) There is no evidence of low ovarian reserve c) There has been a discussion about the implications of IVF and pregnancy at this age ▪ Ovarian stimulation should have been completed before the woman's 43rd birthday
<p>Women's BMI</p>	<p>BMI 19-30</p>
<p>Welfare of the child</p>	<p>The welfare of any resulting children is paramount. The fertility centre should consider factors which are likely to cause serious physical psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.</p>
<p>Family Structure</p>	<p>Funding for IVF +/-ICSI will be available to couples who do not have a living child from their current relationship nor any previous relationship. A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child.</p>
<p>Smoking</p>	<p>Couples must be non-smoking for 28 days to access any fertility treatment and must continue to be non-smoking throughout treatment.</p>
<p>Sterilisation</p>	<p>Neither partner has been previously sterilised nor had sterilisation reversed</p>

Due Regard Screening

The NHS as a public body has a duty to have Due Regard to :

- The need to eliminate discrimination, harassment and victimisation and any other conduct prohibited by the Equality Act 2010.
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not.
- Foster good relations between people from different groups. This involves tackling prejudice and promoting understanding between people from different groups.

Step One : Overview of aims and objectives of the activity

Aim :

To outline the criteria for provision of IVF treatment on the NHS within the East Midlands Region

Objective:

To provide a statement the decisions made, and the outcomes of this policy are:

- Non discriminatory
- Promote equality of opportunity
- Foster good relations between people with any of the protected characteristics

Benefits:

- Remove or minimise disadvantages suffered by people due to their protected characteristics
- Take steps to meet the needs of people with protected characteristics that are different from the needs of people who do not share them.
- Encourage people with protected characteristics to participate in public life or in other activities where their participation is law.

Step Two : Details of consultation/involvement during development of revised IVF Policy

- Andy Roylance, Nottingham City CCG
- Nicky Bird on behalf of Mansfield a Ashfield CCG Newark and Sherwood CCG, Nottingham North East CCG Nottingham West CCG Rushcliffe CCG
- Andy Rix on behalf of Lincolnshire CCGs
- Lola Banjoko on behalf of Northampton and Rutland CCGs
- Helen Moss GEMCSU on behalf of Hardwick, Erewash, North Derbyshire CCGs
- Dr Fred Gravestock, Southern Derbyshire CCG
- Ian Hannah, GEMCSU
- Jonathan Skull, Consultant Gynaecologist,
- Fertility Providers : Care Fertility, Nottingham, Northampton, Sheffield, NURTURE Dr Robert Wilson
- Julia Mehigan (Derbyshire Friend (Lesbian, Gay, Bisexual and Transgender Group)
- Sue Sims on behalf of GEMCSU
- Clare Lewis-Jones (Infertility Network)
- Dr H Ewart, Reviewer of Policy implementation.

Step Three: Policy content

For the activity outlined within the policy identify whether there would be any impact for people of relevant protected characteristics : Age, Disability, Gender Re-assignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion and/or Belief, Sex.

The checklist below will help you identify any strength and/or highlight improvements required to ensure that the activity is compliant with the Equality Act 2010. Check for direct/indirect discrimination against any minority group of Service Users. Please justify your response for each area and action to be undertaken

Does your activity adversely impact people from using this service		Yes	No	Due Regard
1.0	Age	X		Challenges have been made under Article 8 of the Human Rights Act, right to respect for family life and Article 12, right to found a family.

The issue of age discrimination for access to IVF/ICSI treatment has been considered. As outlined in NICE Guideline 156, multivariate analysis has been used including a woman’s age, cause of infertility, previous obstetric history, and previous failed attempts, to help identify the clinical aspects for access to IVF treatments. The criterion for an age limit has been set following studies which indicated that the meta-analysis of three studies showed that an increase in female age leads to a decrease in pregnancy rates, and that there is an association between age and likely success of IVF, the studies identify that fertility decreases after the age of 35 years. The NICE Guideline 156 is specific in that a woman should be informed that the chance of a live birth following IVF treatment falls with rising female age. Reference NICE Guideline 156 page 223. The revised IVF/ICSI policy increases the age limit from 39 to 42 and is in line with NICE Guideline 156.

Does your activity adversely impact people from using this service		Yes	No	Due Regard
2.0	Disability	X		Section 3.2, Section 5.1, Section 8 of the IVF/ICSI policy

Challenge 1 - that disability is a protected characteristic and that because of this disability a person may not be able to have natural intercourse and as a result will be excluded from the policy despite being otherwise capable of having the child

Challenge 1. The IVF Policy has been drawn up to identify one form of treatment for infertility and is part of a care pathway. See Care Pathway illustration at the end of this document. Other treatments such as Intrauterine insemination are promoted as more appropriate courses of treatment for a person with a disability.
 NICE Guideline 156 pg. 126 Recommendation
 Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse

- People who are unable to who would find it very difficult to have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm
- For people who have not conceived after donor or partner insemination despite evidence of normal ovulation, offer unstimulated intrauterine insemination before IVF is considered.
- Alternative assisted conception treatments are available for this group of people.

Challenge 2 - that where a patient has a BMI higher than 30, this may be because of or linked to their disability. They may not be able to take action to reduce their BMI and as a result would be denied treatment.

Challenge 2. Extremes of BMI over 25-28 kg/m have been associated with negative effects on IVF parameters leading to a decreased chance of pregnancy. Obesity BMI 25.8 to 30.8 has been shown to be a risk factor for spontaneous abortion in women after IVF or intracytoplasmic sperm injection. Obesity is also associated with lower pregnancy rates after IVF compared with women with a BMI of 25 kgm.

NICE Guideline pg. 228

The limits for BMI have not been arbitrarily applied and patients will be supported in weight loss programmes which may improve ovulation and pregnancy outcomes in obese infertile women for all forms of fertility treatment, including ovulation induction, intrauterine insemination (IUI) and IVF treatment.

NICE recommendation 123

Women should be informed that female BMI should ideally be in the range of 19-30 before commencing assisted reproduction and that a female BMI outside this range is likely to reduce the success of assisted reproduction procedures. Pg 228

Does your activity adversely impact people from using this service	Yes	No	Please justify your response for each area and action to be undertaken
3. Gender Re-assignment		X	
4. Marriage & Civil Partnership		X	
5. Pregnancy & Maternity		X	
6. Race		X	
7. Religion & Belief		X	
8. Sex		X	
9. Sexual Orientation	X		

Challenge that the policy treats same sex couples less favourably than heterosexual couples on the grounds that requiring them to pay for their own Artificial Insemination prior to IVF is not fair and equitable; and to understand what the expectation is for same sex couples to demonstrate infertility.

For men and women in same sex relationships not having vaginal intercourse, the scope of the policy makes it clear that it is intended for people who have a possible pathological problem (physical or psychological) to explain their infertility. For women in same sex relationships there should be a period of unsuccessful artificial insemination (AI) before they would be considered to be at risk of having an underlying problem and be eligible to be referred for assessment and possible treatment in the NHS.

NICE Guideline 156 Section 5.13 indicates that :

- For the purpose of access to NHS services, AI should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.
- In the light of the AI (Artificial Insemination) data, the majority view of the GDG was that, for same-sex couples, failure to conceive after 6 cycles of AI within the 12 past months should be the indication for further assessment.

Note: There are no data for the success of AI outside a clinical setting (sometimes called a 'do-it-yourself' approach where fresh donor semen is deposited in the upper vagina or even into the cervical os).

Step 4: Determination questions	Status	Comments	
a) Is there any evidence that some protected characteristics are affected?	Yes	Age, Disability, Sexual Orientation	
b) Is there a need for external or user consultation?	Yes	Comments received from Julia Mehigan, Stonewall and GEM CSU Equality Inclusion and Human Rights Team have taken into consideration. Recommendation that CCGs undertake their own local level consultation as part of implementation of the policy.	
c) If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	Access criteria put in place is not arbitrary and put in place to ensure best outcomes	
d) Is the impact likely to be negative?	Yes	Those people not able to access treatment will be supported to enable access. The access criteria put in place is not arbitrary and put in place to ensure best outcomes	
e) Can we reduce the impact by taking different action?	No	In order to produce a policy which is fair, equitable and financially viable, limits have to be set. These limits, which have been set are in line with NICE Guidelines 156 and have been reviewed and assessed for their impact with the aim of minimising the impacts.	
Summary of actions required to remedy any adverse impact(s) identified above			
Request feedback from referring GPs of specific issues raised by couples.			
Step Five: Reference the policy/procedural document that this Due Regard Screening has been applied to East Midlands CCGs - Commissioning Policy for In Vitro Fertilisation (IVF) /Intracytoplasmic Sperm Injection (ICSI) Reviewed Policy implementation 01.04.14			
IMPACT	High	Medium	Low ✓
Name of author/reviewer of activity	Linda Clarke Collaborative Contracting GEM CSU		01.03.14
Date for next review	Change of Fertility Guidelines		

Due Regard Assessment Tool

The Equality Act came into force in 2010 and incorporates into domestic law the European Convention on Human Rights to which the UK has been committed since 1951. Section 6 of the Human Rights Act makes it unlawful for a public authority to act in a way, which is incompatible with a Convention right. The underlying intention of the Act is to create a Human Rights culture in public services.

As a result of undertaking this assessment and the Human Rights Act please consider the following :

Question	Response	Comments
1. Will it affect a person's right to life?	No	
2. Will someone be deprived of their liberty or have their security threatened?	No	
3. Could this result in a person being treated in a degrading or inhuman manner ?	No	
4. Is there a possibility that a person will be prevented from exercising their beliefs	No	
5. Will anyone's private and family life be interfered with ?	No	
If the answer is yes to any of the questions on this checklist, can the policy be amended to avoid impacting upon Human Rights ?	N/A	
<p>Step 6 Feedback on Due Regard Screening of IVF Policy</p> <p>If you wish to ask questions or raise any further issues around the Due Regard Screening and IVF Policy, please send details to :</p> <p>Linda Clarke GEMCSU 3rd floor, Cardinal Square 10 Nottingham Road Derby DE1 3QT</p> <p>linda.clarke@gemcsu.nhs.uk</p>		

References

- a) NICE Clinical Guideline 156, Assessment, and treatment for people with fertility problems (2013)
- b) EMSCG P006v2 Commissioning Policy for Invitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1st December 2010 v2)