APPENDIX

East Midlands Fertility Policy Review

Case for Change

Author: Mark Sheppard, Associate Director of Commissioning Acute and Community Contracts, NHS Nottingham and Nottinghamshire ICB, on behalf of all ICB's in the East Midlands Region.

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1. Glossary of Acronyms

AI – Artificial Insemination

BMI – Body Mass Index

DI - Donor sperm Insemination

ICB – Integrated Care Board

ICSI – Intracytoplasmic Sperm Injection

IVF – In Vitro Fertilisation

LB – Live Birth

NICE - National Institute for Health and Care Excellence

UCI - Intrauterine insemination

2. Executive Summary

There are currently differences between Fertility Policies in the East Midlands, in terms of access to treatment, in relation to age, BMI and number of cycles available. Moreover, there are also inequalities inherent in the policies in that they exclude or limit access to same sex couples, couples with children from former relationships and single people.

This case for change sets out proposed criteria for access to Specialist Fertility Services for the population of the East Midlands, aimed at supporting a more collaborative approach to ICB Policy that will result in one policy to address fertility treatment across the whole of the East Midlands region.

The review aims to address inequalities to improve access to fertility treatment whilst prioritising treatment for people with proven fertility issues. The proposals outlined on pages 8,9 and 10 maintain elements of existing policy, and update others, giving the rationale or evidence base for each proposal.

It is felt that this case for change proposes commissioning arrangements for fertility services in a manner that is clear, fair, and transparent, and the proposed criteria has been developed in line with clinical evidence taking in to account the success rates of fertility treatments and the impact that different factors have on this.

However, at this stage in the review the proposals put forward are recommendations only and following agreement by decision making forums within each ICB to endorse the direction of travel, a period of engagement will then follow to determine the impact of these proposals on our populations in the East Midlands and gather feedback and thoughts on the proposals to be considered and fed into the final policy.

3. Introduction

Fertility refers to the ability to conceive a child**.** On the other hand, infertility is the difficulty or inability to conceive a child naturally. Infertility is the period people have been trying to conceive without success, after which formal investigation is justified and possible medical assistance implemented.

- Over 80% of couples in the general population will conceive within 1 year if the woman is aged under 40 years and they have regular (every 2–3 days) unprotected sexual intercourse.
- Of those who do not conceive in the first year, about half will do so in the second year bringing the cumulative pregnancy rate to over 90%.

- One in seven UK couples is estimated to have difficulty conceiving (approximately 3.5 million people).

Risk factors for infertility include:

- Increasing age
- Being under or over weight
- Smoking

Common causes of infertility can include:

- Lack of regular ovulation**:** When the monthly release of an egg does not occur as expected.
- Poor quality semen: Issues related to sperm health.
- Blocked or damaged fallopian tubes**:** Hindrance to the fertilisation process.
- Endometriosis: A disorder in which the tissue similar to the inner lining of the uterus (endometrium) grows outside the uterus.

Treatment for infertility varies based on the underlying cause and may include assisted conception techniques which may involve medical treatments and/or surgical procedures such as:

- Intrauterine insemination (IUI) **-** a type of fertility treatment that involves placing sperm inside a woman's uterus close to the fallopian tubes in order to increase the chances of conceiving.
- In vitro fertilization (IVF) - During IVF, an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory. The fertilised egg, called an embryo, is then returned to the woman's womb to grow and develop.

In the East Midlands there are five Integrated Care Boards (ICB's), who commission health and care services for their local population:

- NHS Derby and Derbyshire
- NHS Nottingham and Nottinghamshire
- NHS Northamptonshire
- NHS Leicester, Leicestershire and Rutland
- NHS Lincolnshire

Each ICB sets its own Fertility Policy outlining the guidelines relating to who can and cannot receive fertility treatment.

4. Reason for review of Fertility Policy

4.1. Differences between Fertility Policies in the East Midlands

There are currently differences between Fertility Policies in the East Midlands, in terms of access to treatment, in relation to age, BMI and number of cycles available. Moreover, there are also inequalities inherent in the policies in that they exclude or limit access to same sex couples, couples with children from former relationships and single people.

This review of fertility is therefore aimed at supporting a more collaborative approach to ICB Policy that will result in one policy to address fertility treatment across the whole of the East Midlands region. The review will aim to address inequalities to improve access to fertility treatment whilst prioritising treatment for people with proven fertility issues. The suggestion is to maintain elements of existing policy, and update others.

The majority of ICBs across the East Midlands have policies based on or fully reflective of the 2014 East Midlands policy written by the East Midlands Specialised Commissioning Group (no longer an entity). This policy does not account for changes in law or societal thinking and therefore needs review.

Currently the National Institute for Health and Care Excellence (NICE) has guidance in effect for fertility – Clinical Guideline CG156 'Fertility problems: assessment and treatment' 2013. This guidance is due to be reviewed and the current indication is that new guidance may be available at some point in 2025. This new guidance has been delayed a number of times and it is therefore felt that the East Midlands review cannot wait for the new guidance to be published. Once the new guidance is available a tabletop exercise can be undertaken to understand if this impacts on the East Midlands policy position.

It is also important to note that recent boundary changes initiated by the Secretary of State in 2022 have led to a misalignment of policies within the same ICB region. This is relevant to NHS Derby and Derbyshire ICB where the decision has been taken to move the area of Glossop from Greater Manchester into Derbyshire, and NHS Nottingham and Nottinghamshire where the decision has been taken to move the area of Bassetlaw from South Yorkshire into Nottingham and Nottinghamshire.

Some ICBs have also made amendments to the existing policies where locally it was appropriate to do so, hence this has made the provision across the region even more disparate.

4.2. Comparison of national and local policies

Current ICB policies differ across several policy areas:

- Closest to NICE CG156 – Fertility Problems: Assessment and Treatment - Bassetlaw and to a lesser extent Glossop are most closely aligned with NICE CG156. See scenarios 2 and 3 in Table 2. No policies currently meet the full guidance. However the former Bassetlaw CCG included funding for surrogacy which will be excluded from the East Midlands policy as NHS England clearly state that surrogacy is not available on the NHS.

- The policies for other East Midlands areas are more similar to each other but differ more significantly from NICE CG156. They do so in a number of key areas:

    - **Criteria for access to In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI)**: The majority require the woman's BMI to be between 19 and 30 kg/m2 and both partners to be non-smoking whereas Bassetlaw only expects the provider to provide advice on BMI and smoking (similar to NICE guideline recommendations).
    - **IVF/ICSI pathway**: For women under the age of 40, Bassetlaw and Glossop are in line with the NICE guideline, offering up to three IVF cycles (including privately funded cycles); all other policies offer one cycle. Glossop offers IVF with donor oocytes for women aged 40 to 42 with low ovarian reserve, unlike the other policies.
    - **Criteria for access to Intrauterine Insemination (IUI) and Donor sperm Insemination (DI)** vary, but most offer IUI where vaginal intercourse is very difficult or not possible including for same-sex relationships, and Glossop includes single women. Age and BMI criteria vary.

4.3. Financial constraints in the NHS

The NHS finite and scarce financial resources and ICBs are charged with ensuring that all services provide value for money and are affordable. The review looks at the current expenditure and considers the impact of any changes to the policy.

Using NHS tariff payments, the estimated total cost of IVF/ICSI and AI/DI/IUI (excluding costs of donor sperm) for each ICB using these baseline tariffs for the four years from 2019/20 to 2022/23 is shown in Table 1 below.

Table 1 Costs of IVF/ICSI cycles and AI/DI/IUI cycles by ICB and year - 2019/20 to 2022/23)

	2019/20	2020/21	2021/22	2022/23	Total
IVF/ICSI cost*					
NHS Derby and Derbyshire ICB	£584,800	£479,600	£472,800	£542,000	£2,079,200
NHS Leicester, Leicestershire, and Rutland ICB	£417,600	£523,400	£522,800	£515,400	£1,979,200
NHS Lincolnshire ICB	£281,000	£260,400	£254,600	£251,200	£1,047,200
NHS Northamptonshire ICB	£472,000	£218,200	£352,000	£372,200	£1,414,400
NHS Nottingham and Nottinghamshire ICB	£596,800	£473,200	£571,200	£441,000	£2,082,200
TOTAL FOR 5 EAST MIDLANDS ICBs	**£2,352,200**	**£1,954,800**	**£2,173,400**	**£2,121,800**	**£8,602,200**
	2019/20	**2020/21**	**2021/22**	**2022/23**	**Total**
AI/DI/IUI cost					
NHS Derby and Derbyshire ICB	£825	£2,475	£825	£1,650	£5,775
NHS Leicester, Leicestershire, and Rutland ICB	£172,425	£94,875	£141,900	£112,200	£521,400
NHS Lincolnshire ICB	£14,025	£16,500	£14,025	£10,725	£55,275
NHS Northamptonshire ICB	£1,650	£1,650	£2,475	£825	£6,600
NHS Nottingham and Nottinghamshire ICB	£0	£0	£0	£0	£0
TOTAL FOR 5 EAST MIDLANDS ICBs	**£188,925**	**£115,500**	**£159,225**	**£125,400**	**£589,050**

* These figures do not include the costs of frozen embryo transfer, luteal support, or cancelled cycles

Further analysis of the costs of fertility treatments can be found in appendix A.

The NHS is facing unprecedented levels of demand and costs, this is due to a number of factors including an aging population, the aftermath of the Covid-19 pandemic, continuing improvement to medicines and procedures to treat patients the impact of the cost-of-living crisis and the levels of inflation.

This sets the NHS both nationally and locally the challenge to ensure that patient care is delivered within the finances available.

ICBs are charged with managing a considerable amount of public money and are required to ensure that all expenditure is value for money and achieves the best possible outcomes for patients for every pound spent. The funding of fertility services, as demonstrated above is a significant pressure on these financial resources. This paper outlines a number of criteria and parameters to ensure that access to fertility is available to those patients that require access, ensures access is fair and equitable but is also measured in that it recognises additional investment in these services is not currently affordable and therefore isn't something that can be offered.

5. Evidence-based Decisions

Solutions for Public Health (SPH), a specialist Public Health Consultancy team at Arden and GEM Commissioning Support Unit, were commissioned to review existing fertility policies across the five East Midlands ICBs, to provide information to support a collaborative approach to ICB policy making. The work included a comparison of assisted conception policies; evidence enquiries; a discussion on the ethical considerations (for policy areas where evidence is not helpful); collation and analysis of data on activity, costs and outcomes; and modelling of a range of policy scenarios. The full report can be found as appendix A.

The report presented a series of scenarios to outline the impact of changes to policy in relation to access in terms of clinical criteria, i.e. a patients BMI and/or age, and also looked at the impact in relation to changing the number of cycles of Intracytoplasmic Sperm Injection (ICSI) and In-vitro Fertilisation (IVF) and the impact this would have on the number of babies delivered and the cost of provision.

Although the review did consider the impact of inequity of access in relation to same sex couples, couples with children from former relationships and single people, it was unable to offer robust modelling on the impact of removing the inequity due to the availability of limited data.

Table 2 below provides the modelled scenarios for IVF/ICSI policy provision in terms of age and BMI of the patient and the number of IVF/ICSI cycles provided. Scenarios higher in the table provide more cycles of IVF to more people and indicates more live births. This is, however, with lower overall cost effectiveness (higher cost per live birth) and higher overall costs to ICBs.

The scenarios range from nearly full NICE guideline implementation to scenarios closer to current policies in East Midlands ICBs (bearing in mind that they do not include all policy criteria due to data constraints). Separate tables for each ICB are provided in the full report provided in appendix A.

Table 2: A selection of modelled scenarios for IVF provision for the five East Midlands ICBs combined

Scenario		Number treated	Total number of IVF cycles	Live births (LBs)	Cost	Cost per live birth (LB)	Comments
1	**Close to full NICE guideline implementation**: *BMI 18.5 to <35 kg/m^2 3 IVF cycles for women <40 1 IVF cycle for 40 to 42 year olds No other restrictions	1,680	2,962	872	£10.8 million	£12,356	• Least restrictive • Highest number treated • Most live births • Highest cost • Highest cost per Live Birth (LB)
2	**Close to current Bassetlaw policy**: *BMI 18.5 to <35 kg/m^2 3 IVF cycles for women <40 1 IVF cycle for 40 to 42 year olds Other restrictions e.g., re smoking, childlessness, etc.	972	1,712	505	£6.2 million	£12,357	• Highest cost per LB • Similar to NICE for BMI and number of IVF cycles but includes some restrictions
3	**Current Glossop policy**: BMI 18.5 to 30 kg/m^2 3 IVF cycles for women <40 1 IVF cycle for 40 to 42 year olds Other restrictions e.g., re smoking, childlessness, etc.	793	1,369	423	£5.0 million	£11,907	• Similar to NICE and Bassetlaw re number of IVF cycles, but additional BMI criteria and other restrictions

4	**Between Bassetlaw/Glossop and other East Midlands policies, closer to Glossop:** BMI 18.5 to 30 kg/m^2 3 IVF cycles for women ≤37 2 IVF cycles for 38-39 year olds 1 IVF cycle for 40 to 42 year olds Other restrictions e.g., re smoking, childlessness, etc.	793	1,342	421	£4.9 million	£11,671	• Reducing number of IVF cycles (3, 2, 1) with increasing age of woman • Little change in numbers treated, LBs or cost compared to Glossop policy
5	**Between Bassetlaw/Glossop and other East Midlands policies, closer to latter:** BMI 18.5 to 30 kg/m^2 2 IVF cycles for women <40 1 IVF cycle for 40 to 42 year olds Other restrictions e.g., re smoking, childlessness, etc.	793	1,170	382	£4.3 million	£11,289	• Same number of women treated, but 1.3x more LBs, higher cost per LB and 1.5x higher overall cost compared to most current East Midlands policies
6	**Wider BMI criteria than most current East Midlands ICB policies:** 1 IVF cycles for women ≤42 BMI 18.5 to 35 kg/m^2 Other restrictions e.g., re smoking, childlessness, etc.	972	981	335	£3.6 million	£10,698	• Less restrictive BMI criteria than most East Midlands policies except Bassetlaw • Fewer cycles for women <40 than Bassetlaw and Glossop
7*	**Close to most current East Midlands ICB policies:** 1 IVF cycles for women ≤42 BMI 18.5 to 30 kg/m^2 Other restrictions e.g., re smoking, childlessness, etc.	793	793	283	£2.9 million	£10,343	• Most current East Midlands policies except more restrictive than Bassetlaw and Glossop
8	**Most restrictive:** BMI 18.5 – 30 kg/m^2 1IVF cycle for people <38 Other restrictions e.g., re smoking, childlessness, etc.	693	693	263	£2.5 million	£9,508	• Most restrictive • Lowest number treated • Lowest live births • Lowest cost • Lowest cost per LB

The above table is an extract from the Management of Assisted Fertility: review of policies and options attached at appendix A. Page 6.

In this table, scenario 7* is the closest modelled option to existing service provision in the East Midlands.

In making the decision about which criteria to adopt for the East Midlands Fertility Policy, ICB's need to consider the potential impact of the different scenarios in terms of:

- Numbers of patients treated
- Outcomes, i.e., live births
- The cost to the ICB at a time of financial constraint
- The capacity of locally commissioned services to deliver fertility services
- The impact this might have on quality of provision
- The impact this might have on waiting lists.

Please note: The modelled options do not take into account maternal or perinatal complications, or the additional cost of drugs associated with treating patients with a higher BMI. This means that the cost per live birth may be an underestimate, particularly for obese child bearers. (See main report for model assumptions and limitations. See ethical considerations section for population groups not included).

6. Proposals for East Midlands Fertility Policy

6.1. Surrogacy Statement

In line with NHS England Policy that surrogacy is not available on the NHS the East Midlands ICBs deem that assisted conception treatments involving surrogates for any patient group are not routinely commissioned. Support and funding will not be provided for any associated treatments related to those in surrogacy arrangements. The below link relates to the NHS England web page regarding surrogacy amongst others;

Having a baby if you are LGBT+ - NHS (www.nhs.uk)

6.2. Number of cycles

Considering that:

- The increase in the number of cycles for IVF is the major contributor to the modelled cost increases outlined in Table 1
- Most current fertility policies across the East Midlands only offer one cycle of IVF, with the exception of Bassetlaw and Glossop
- The financial pressures outlined above that dictate that there is no additional funding available.

The proposal for the East Midlands Fertility Policy is to offer one cycle only across the whole of the East Midlands region.

6.3. Funding for IUI/DI and the number of cycles

It is proposed that IUI/DI will be offered for those couples / individuals where vaginal intercourse is not possible or appropriate and there are no other identified fertility issues (must have regular ovulation, patent tubes, and normal sperm count for the partner/donor). The success rate for unstimulated IUI / DI is low therefore the option of proceeding straight to IVF should be discussed with the person wishing to become pregnant. The proposed policy does not require IUI / DI prior to consideration of IVF.

The proposal for the East Midlands Fertility Policy is to offer up to three cycles of unstimulated IUI/DI for those couples / individuals where vaginal intercourse is not possible or appropriate prior to considering IVF.

Single women or trans men with no known fertility issues (must have regular ovulation, and patent tubes) will also be offered for up to three cycles of unstimulated DI where the donor has a normal sperm count.

6.4. BMI and Age

It is recommended that the new policy maintains the age ranges and BMI ranges currently within the NICE Guidance these criteria have the clinical evidence and review to support them.

For heterosexual couples the age criteria apply to the female only men with a BMI of 30 or over should be informed that they are likely to have reduced fertility.

Same sex female couples the BMI and Age would be relevant to the pregnancy carrier and egg provider if different, it should be noted that IVF is funded per couple for shared motherhood.

The proposal for the East Midlands Fertility Policy is to offer access to services around BMI and Age in line with the clinical criteria set out in the NICE guidance.

6.5. Smoking

The NHS should encourage people to quit smoking at every opportunity. Studies have shown that women who smoke are at an increased risk for a delay in becoming pregnant and for both primary and secondary infertility. Research has also shown that women who smoke during pregnancy risk complications, premature birth, low birth weight (LBW) infants, stillbirth, and infant mortality.

The proposal for the East Midlands Fertility Policy is to include the requirement for all parties involved in the treatment to be non-smoking/vaping or have quite smoking/vaping.

6.6. Living Children

Most current policies require that both partners have no living children (except Glossop), this is not addressed by the NICE guidance.

The proposal for the East Midlands Fertility Policy is to maintain the majority position in that the person wishing to become pregnant and / or their partner must not have a Living Child from their current relationship or any previous relationship.

6.7. Partners who have been sterilised

Most policies do not currently fund IVF if either partner has ever been sterilised (except Bassetlaw and Glossop) again this is not addressed by the NICE guidance. Sterilisation is offered within the NHS as an irreversible method of contraception.

The proposal for the East Midlands Fertility Policy is to go with the majority and not provide fertility treatment for couples where their infertility arises wholly or partly from sterilisation of either partners.

6.8. Same-sex female couples

For same-sex female couples the requirements for proving infertility prior to access to IVF vary between policies with the majority being silent on the issue.

The proposal for the East Midlands Fertility Policy is that same sex couples are considered to have a known fertility issue and are therefore eligible for treatment if all other criteria are met.

6.9. Single women

For single women the requirements for proving infertility prior to access to IVF vary with the majority being silent on the issue.

The proposal for the East Midlands Fertility policy is that single women and trans men are considered to have a known fertility issue and are therefore eligible for treatment if all other criteria are met.

The new policy should include access for all individuals and couples with a fertility problem, regardless of their sexual orientation, gender identity or relationship status.

6.10. Gametes Storage

For cryopreservation of gametes and embryos to preserve fertility, all policies include funding for those about to start treatment that permanently affects fertility (as does NICE) although the conditions listed, and age criteria and duration of storage vary.

The proposal for the East Midlands Fertility policy is to include access to storage of gametes if the patient is due to commence a medical or surgical treatment likely to permanently affect their fertility.

6.11. Duration of storage

The legal duration of storage is governed by statutory Human Fertilisation and Embryology Authority (HFEA) legislation and regulations.

The proposal for the East Midlands Fertility policy is to include NHS funded storage of gametes or embryos for up to 3 years.

7. Next Steps

This case for change will be presented to decision making forums within each ICB to endorse the direction of travel.

Following this a period of engagement will then follow to determine the impact of these proposals on our populations in the East Midlands and gather feedback and thoughts on the proposals to be considered and fed into the final policy.

Appendices

Solutions for Public Health (SPH), a specialist Public Health Consultancy team at Arden and GEM Commissioning Support Unit, were commissioned to review existing fertility policies across the five East Midlands ICBs, to provide information to support a collaborative approach to ICB policy making. The work included a comparison of assisted conception policies; evidence enquiries; a discussion on the ethical considerations (for policy areas where evidence is not helpful); collation and analysis of data on activity, costs and outcomes; and modelling of a range of policy scenarios.

Appendix A

East Midlands ICBs assisted conception policy review – executive summary – Final October 2023.

Appendix B

East Midlands ICBs assisted conception policy review – Final October 2023.