NHS
North East London

North East London Fertility Policy – Health Inequality and Equality Impact Assessment
September 2022

Introduction and background

The following document summarises the Health Inequality and Equality Impact Assessments that were made as part of the development of the North East London Integrated Care Board (NEL ICB) draft fertility policy. These assessments were reviewed by clinicians as part of the development of the policy to ensure that the impact of the changes on people with protected characteristics under the 2010 Equality Act was considered.

The National Institute for Health and Care Excellence (NICE) provide national guidance and advice to improve health and social care. One of the ways that NICE does so is by publishing clinical guidelines, which are evidence-based recommendations for health and care in England. Organisations commissioning and delivering services are expected to take the recommendations contained within NICE clinical guidelines into account when planning and delivering services. NICE has published a Clinical Guideline (CG156) on fertility problems. The clinical criteria outlined in the draft policy took into account the latest clinical evidence, including these guidelines.

Based on the data we received from providers, we estimate approximately 1,000 NEL residents a year currently seek fertility treatments covered by the policy, such as IVF, IUI and egg and sperm freezing.

1. Age

1.1 Age: Eligibility criterion

The legacy NEL CCGs' fertility policies specified an upper age limit for women of either under 40 or under 42. The NEL ICB draft fertility policy specifies that in order to be eligible for NHS funded assisted conception treatments (ACT), the woman or person trying to get pregnant should be aged under 43 for the following reasons:

- NICE CG156 does not recommend NHS funded IVF for women aged 43 years or over. In their full guideline NICE state "The clinical and health economic evidence was overwhelming in indicating that IVF should not be offered to women aged 43 years or older." The NEL ICB draft fertility policy is consistent with this.
- NICE CG156 recommends three full IVF cycles for women aged under 40 and one full IVF cycle for women aged 40-42. These recommendations indicate the level of IVF provision NICE consider to be cost-effective for people of different ages. The NEL ICB draft fertility policy is consistent with this.
- The Human Fertilisation and Embryology Authority (HFEA) collect data on all fertility treatment cycles performed in the UK. This data shows the success rates decrease as the woman's age increases for IVF and other ACT, including donor insemination and

IUI. The NEL ICB draft fertility policy focuses resources on patients most likely to have a successful outcome as reported in HFEA data.

The NEL ICB draft fertility policy may be considered to have a positive impact for patients aged under 40 and those aged 40-41 who now have an increased number of IVF cycles funded. It would also be positive for eligible patients aged 42 who now have IVF funded. It may be considered neutral or negative for those aged 43 or over; although this group have no IVF funded, treatment is unlikely to be successful at this age, as outlined above.

1.2 Age: Ovarian reserve criteria

The NEL ICB draft fertility policy specifies there should be no evidence of low ovarian reserve (defined by meeting the threshold for low ovarian reserve in two or more of the three NICE specified tests); this criterion applies to eligible patients of all ages. This position remains largely unchanged from the legacy NEL CCGs' fertility policies, which requires sufficient ovarian reserve (defined by meeting the threshold for normal ovarian reserve in one of the three NICE specified tests); this criterion also applies to patients of all ages. Neither the draft policy nor the legacy policies are consistent with NICE CG156 which states there should be no evidence of low ovarian reserve in women aged 40-42; NICE do not specify that an ovarian reserve criterion should apply to women aged under 40. The NEL ICB draft fertility policy may therefore be considered to have a negative impact for younger patients. The NEL ICB draft fertility policy requires ovarian reserve criteria to apply to patients of all ages for the following reasons:

- In general, lower ovarian reserve is associated with a decreased chance of a live birth.
- Removing the ovarian reserve criterion will increase the number of patients accessing IVF by ~25% and therefore the associated expenditure considerably, which would have meant we wouldn't be able to afford the other increases in access we wanted to make.
- Funding more IVF cycles for patients with a good ovarian reserve is likely to lead to more live births than funding fewer IVF cycles and removing the ovarian reserve criterion

1.3 Age: Duration of trying to conceive (for patients without a known cause of infertility)

The NEL ICB draft fertility policy specifies that IVF can be offered to eligible patients who have not conceived after one year of regular unprotected intercourse if the woman or person trying to get pregnant is aged 36 or over. This is consistent with the legacy NEL CCGs' policies. It is not consistent with NICE CG156 which recommends two years trying to conceive for patients of all ages. Maintaining the existing policy may be considered a positive impact for patients aged 36 or over. The ICB felt this was fairer to older patients as early treatment would increase their chances of having a baby.

1.4 Age: Duration of storage of cryopreserved eggs, embryos and sperm for fertility preservation

The legacy NEL CCGs' fertility policies state storage of cryopreserved sperm, eggs or embryos for fertility preservation patients will be funded for either five or 10 years. The NEL ICB draft fertility policy states that for patients aged under 32 years at the time of cryopreservation, storage will be funded until the patient reaches their 43rd birthday. For patients aged 32 and over at the time of cryopreservation, storage will be funded for 10 years duration. Therefore, storage is funded for a minimum of 10 years for all patients and at least up until the patient's 43rd birthday. The new draft policy will have a positive impact for younger patients, who may not be ready to start a family within 10 years of cryopreservation of their gametes. The upper age limit is consistent with the NEL ICB draft fertility policy upper age limit criteria for assisted conception treatments for patients with fertility problems.

1.5 Age: Criteria for cryopreservation of eggs, embryos and sperm for fertility preservation

The legacy NEL CCGs' fertility policies specified an upper age limit for fertility preservation patients. This is not consistent with NICE CG156 which states eligibility criteria used for conventional infertility treatment should not apply to fertility preservation patients. Consistent with NICE CG156, the NEL ICB draft fertility policy specifies that to access cryopreservation and storage of sperm, eggs or embryos, fertility preservation patients do not need to meet the eligibility criteria which apply to other patients. This may be considered a positive impact for fertility preservation patients.

2. Disability

2.1 Disability: IUI for people who are unable to, or would find it difficult to, have vaginal intercourse because of a clinically diagnosed disability

The legacy NEL CCGs' fertility policies specified IUI is funded for people who are unable to, or would find it difficult to, have vaginal intercourse because of a clinically diagnosed disability. The NEL ICB draft fertility policy specifies that up to six cycles of unstimulated IUI using partner sperm is funded for eligible patients where there is evidence of normal ovulation, tubal patency and semen analysis and patients are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem, and have not conceived after six self-funded IUI cycles. Although the new position is more restrictive, and may therefore be considered a negative impact, it is consistent with NICE CG156 recommendations and ensures equitable provision compared to other groups of patients who are trying to conceive through artificial insemination (for example, same sex couples – see 'Sexual orientation' for more information and additional rationale).

2.2 Disability: Funding of sperm washing for people living with HIV

The NEL ICB draft fertility policy is consistent with NICE CG156 in funding of sperm washing for eligible patients who are living with HIV and are either non-adherent with antiretroviral treatment of have an HIV viral load of 50 copies/ml or greater. To ensure the important public health message that undetectable=untransmittable is not undermined, the NEL ICB draft fertility policy notes that most people living with HIV will not require sperm washing, and people living with HIV should speak to their HIV doctor or nurse about trying to get pregnant. In addition, to ensure that people living with HIV are not excluded from accessing NHS funded assisted conception treatments, the NEL ICB draft policy confirms people living with HIV who have fertility problems can access assisted conception treatments as per the policy. The new draft policy therefore has a positive impact on this patient group.

2.3 Disability: Funding of fertility preservation for people with cancer

The NEL ICB draft fertility policy states cryopreservation (freezing) of sperm, eggs and embryos is funded for eligible patients who are either due to undergo a gonadotoxic treatment or have a medical condition which is likely to progress such that it will lead to infertility in the future. Consistent with CG156, this would apply to some patients having treatment for cancer. This new draft policy therefore has a positive impact on this patient group.

2.4 Disability: Funding of assisted conception treatments involving surrogacy for patients with disability

The NEL ICB draft fertility policy states that assisted conception treatments (ACTs) involving surrogates are not routinely funded; this position is unchanged from NEL CCGs' legacy policies. This policy may have a negative impact on people who would not be able carry a pregnancy due to a disability and would therefore require a surrogate to have a biological child.

The NEL ICB draft fertility policy states that ACT involving surrogates is not funded for the following reasons:

- Specialist clinics report NHS services are not set up to provide ACT involving surrogates.
- There are considerably legal issues involved in surrogacy, for example: surrogacy agreements are not legally enforceable.
- Ethical issues may arise during the course of a surrogacy arrangement including intended parents or the surrogate changing their minds, or disagreeing whether a pregnancy should continue if complications arise.
- There is no national guidance on NHS funding of ACT involving surrogates.
- A surrogate is only available to those with means (surrogates' expenses typically cost between £12,000-£20,000) and, by parity of reasoning with the prohibition on mixing NHS and private care in one episode of care.

3. Race

3.1 Race: Access to assisted conception treatments

In 2021, the HFEA published a report on ethnic diversity in fertility treatment, this outlined ethnicity statistics for all IVF and DI fertility treatment undertaken in the UK and reported:

- In 2018, IVF treatment was predominantly used by White patients (78%), followed by Asian (14%), Black (3%), Other (3%) and Mixed (2%) patients. More Asian patients used IVF (14%) in 2018 compared to the UK population estimate (7%). In contrast, there were fewer White IVF patients (78%) compared to the UK population (87%).
- From 2014-2018, birth rates were typically lower among Black patients. Asian patients also commonly had lower birth rates. In contrast, higher birth rates were recorded for White and mixed ethnicity patients. The reasons for these variations are not certain but may relate to several factors, including socioeconomic related pre-existing health conditions such as obesity, and that fibroids are more common in the Black population.
- Black patients generally started IVF at later ages than other ethnic groups at an average age of 36.4, compared to the national average of 34.6 in 2018.

The NEL ICB draft fertility policy should have a positive impact on patients of all ethnicities by allowing increased access to assisted conception treatments to most eligible patients.

3.2 Race: Access to donor eggs and sperm

The NEL ICB draft fertility policy states the ICB would like to fund donor sperm and donor eggs for eligible patients, however they are aware that there are practical and logistical barriers to this. One such barrier is that there is a shortage of donor eggs and sperm in the UK, particularly from some ethnic minority groups.

4. Gender

4.1 Gender: Eligibility criteria

Some of the eligibility criteria specified in the NEL ICB draft fertility policy apply to women or the person trying to get pregnant, and not men or the person providing sperm for treatment; these are outlined below:

- The woman or the person trying to get pregnant must be aged under 43 in order to access NHS funded ACT. Although this criterion means patients aged 43 and over will have no NHS funded IVF available to them, treatment is unlikely to be successful at this age so the impact may be neutral. This upper age is consistent with NICE CG156 recommendations; NICE make no equivalent recommendation for men. Detailed rationale for the upper age criterion for women is outlined in the 'Age' section above.

- Treatment will not be funded for women or people trying to get pregnant who are aged under 40 years and have had three previous IVF cycles. Treatment will not be funded for women or people trying to get pregnant who are aged 40-42 years if any previous IVF has been received. These criteria may be considered a negative impact for patients who have had previous IVF cycles; however, likelihood of a live birth decreases with the number of unsuccessful IVF cycles undertaken so the impact for some may be neutral. The 'previous cycle' criteria are consistent with NICE CG156 recommendations; NICE make no equivalent recommendation for men.
- Women or people trying to get pregnant must have a BMI within the range 19-30 kg/m^2 to access NHS funded ACT. These criteria may be considered a negative impact for patients with a BMI outside of this range; however, a BMI outside this range is likely to reduce the success of assisted reproduction procedures so the impact for some may be neutral. NICE CG156 specifies women should be informed that BMI should ideally be in the range 19-30 before commencing assisted reproduction, and that a woman's BMI outside this range is likely to reduce the success of assisted reproduction procedures. The HFEA Commissioning Guide states women should have a BMI of 19-30 before commencing assisted reproduction. Neither NICE CG156, nor the HFEA commissioning guide recommend a BMI criterion for men or the person providing sperm.

5 Gender reassignment

5.1 Gender reassignment: Funding of fertility preservation for people undergoing gender affirmation treatments

The NEL ICB draft fertility policy specifies that eligible patients who are due to undergo a gonadotoxic treatment, including patients undergoing interventions for gender affirming treatment, will have NHS funded fertility preservation available to them (i.e. cryopreservation and storage of sperm, eggs or embryos). This policy has a positive impact on this patient group. The NEL ICB draft fertility policy is consistent with NHS England and NHS Improvement guidance for CCGs on formation of clinical commissioning policies for fertility preservation (2019) which stated: 'CCGs must not determine which patient groups might be offered fertility preservation service on a basis which discriminates against those patients because of a protected characteristic, including gender affirming treatment'.

6 Religion/ belief

6.1 Religion/ belief: Funding of IUI as an alternative to IVF

The NEL ICB draft fertility policy specifies that up to six cycles of unstimulated IUI using partner sperm is funded for people with unexplained infertility, mild endometriosis or mild male factor infertility who have social, cultural or religious objections to IVF. This would be an alternative to receiving IVF treatment and therefore IVF would not subsequently be funded for patients accessing IUI in these circumstances. This is consistent with NICE CG156 recommendations. This is a new policy which has a positive impact on this patient group.

7 Sexual orientation

7.1 Sexual orientation: Funding of assisted conception treatments for female same sex couples

The NEL ICB draft fertility policy specifies that up to six cycles of IUI using donor sperm is funded for individuals or couples trying to conceive using donor insemination who have not conceived after six cycles of self-funded IUI. These patients would also be eligible for IVF if they undergo a total of 12 unsuccessful IUI cycles (or if investigations show IVF is the only effective treatment option).

The NEL ICB draft fertility policy may have a positive impact on same sex couples because it specifies IUI is funded for these patient groups when previously it was not. However, it may also be considered to have a negative impact because in order to be eligible for NHS funded treatment, these patients must undergo six self-funded IUI cycles. This may impact on people who may not have the means to fund this treatment, it is however broadly consistent with NICE guidelines (see below) and an improvement on the requirement for this group to undergo 12 self-funded IUI cycles prior to receiving NHS funded treatment in the existing policies.

The NICE CG156 full guideline on fertility states: *'For women in same-sex relationships, there should be some 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*'. In order to determine when same sex couples should receive NHS assessment and possible treatment, the NICE CG156 Guideline Development Group (GDG) aimed to establish the number of AI cycles that would be equivalent to failure to conceive after 12 months of unprotected intercourse [the point at which heterosexual couples would access NHS assessment and possible treatment]. In doing so, the GDG discussed a number of ethical and practical issues relating to 'equivalence' including the financial cost of AI and disadvantage of those attempting to conceive by that route, and the time to conception and disadvantage of those attempting to conceive by vaginal intercourse. The GDG subsequently recommended same sex couples undergo six cycles of donor insemination before NHS funded IUI; this was included as a recommendation in NICE CG156 (see pages 77-79 of full guideline for more information).

The NEL ICB draft fertility policy is broadly consistent with NICE CG156 in their recommendations on IUI for same sex couples. NICE specify people in same sex relationships should have six cycles of AI prior to NHS funded IUI (the full guideline notes the GDG were of the majority view that ideally such AI should be undertaken in a clinical setting, however making recommendations on the setting was outside of their scope). The NEL ICB draft fertility policy requires this AI to be IUI for the following reasons:

- In the UK it is not legal for patients to purchase donated sperm from a licensed sperm bank to use at home.
- Donated sperm used at licensed clinics must be checked for infections including HIV, hepatitis, syphilis and gonorrhoea.
- The donor's family medical history will have been taken to identify any serious heritable diseases.
- Clinics undertaking IUI provide counselling to everyone involved in the donation process.
- Semen analysis (to check motility and morphology) will have been undertaken to ensure the donor sperm is good quality.
- IUI undertaken at a clinic will maximise efficacy (e.g. sperm will be placed in the uterus rather than the vagina and timing will be optimised).
- Having treatment at a clinic will mean that the donor is not a legal parent to any child born and the partner of the women or person trying to get pregnant (if they have one) will be recognised as the second legal parent.
- Local specialists are supportive of this requirement.

The Department of Health and Social Care's Women's Health Strategy for England (2022) highlights the financial burden that same sex couples experience as a result of NHS criteria for fertility treatments, and include as one of their 10 year ambitions the intention to make NHS funded fertility services accessible to female same sex couples in a more equitable way. NEL ICB will review the fertility policy again once guidance on this has been published.

7.2 Sexual orientation: Funding of assisted conception treatments for male same sex couples

The NEL ICB draft fertility policy specifies that assisted conception treatments involving surrogates are not routinely funded; this position is unchanged from NEL CCGs' legacy policies. This policy may have a negative impact on male same sex couples, who require a surrogate to carry a pregnancy. The reasons assisted conception treatments involving surrogates are not funded are outlined above under 'Disability'.

8 Marriage and civil partnership

The NEL ICB draft fertility policy does not specify any criteria that would negatively impact individuals who are married or in a civil partnership. People who are not in a relationship also have equal access to treatments under the policy.

9 Pregnancy and maternity

The content and nature of the NEL ICB draft fertility policy is such that it would not apply to patients who are pregnant or on maternity leave.

Conclusion and next steps

The changes in the NEL ICB draft fertility policy are, in the main, either neutral or positive to people with protected characteristics as defined by the Equality Act 2010. This assessment will form part of the governance process for sign off by the Quality, Safety and Improvement Committee and the Integrated Care Board.