North Central London
Clinical Commissioning Group

Fertility Policy Development – Policy Approval Report

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1. Executive Summary

Following the merger of the five CCGs to form North Central London CCG, a significant programme of work has been undertaken, with the aim of developing a single Fertility Policy for North Central London.

Following a Review that was undertaken to make Recommendations about the development of a single Fertility Policy, a draft NCL Fertility Policy was approved by NCL CCG Strategy & Commissioning Committee, with authorisation to commence an engagement period to receive feedback from stakeholders on the draft NCL Fertility Policy.

The feedback from the engagement on the draft NCL Fertility Policy was presented to NCL CCG Strategy & Commissioning Committee in March 2022. Taking into consideration the feedback received, further legal advice and input from the NCL Fertility Clinical Reference Group and the NCL CCG Governing Body, this report presents the final NCL Fertility Policy for approval.

The NCL Fertility Policy provides for a single, consistent Policy across the NCL area, and to a large extent provides greater alignment with NICE guidance compared to the existing policies. It increases the provision of specialist fertility treatments in the majority of boroughs, and if approved and subsequently implemented, will provide a significant improvement in the standard of provision for the majority of NCL residents. The Policy diverges from NICE guidelines in a limited number of scenarios (see section 4.3).

Overall, it is anticipated that the NCL Fertility Policy will result in an increased level of expenditure spent on specialist fertility treatments (c. £515k in 2022/23 (part year), £837k in 2023/24 (full year)), however there has been careful and measured consideration of the financial consequences of the proposed changes to the policy alongside a detailed consideration of best outcomes for those accessing fertility treatment and removing inequity in service access and provision.

An Equality Impact Assessment (EIA) and Quality Impact Assessment (QIA) have been undertaken. The EIA notes the varied impact that the Policy will have on people with different protected characteristics, depending on their personal circumstances, however, across the majority of the Policy, there will be at least a maintenance, and in many cases an improvement, in provision, aligned as closely as possible with NICE guidance and supported by clinical or other rationale.

If the NCL Fertility Policy is approved, implementation plans have been developed to undertaken preparatory activities, with a focus on communications activities, prior to the “go-live” of the Policy. It is currently estimated that the Policy will be launched in July 2022.

2. Purpose of this Report

On 1 April 2020, the previously five separate CCGs in North Central London (NCL), comprising of Barnet, Camden, Enfield, Haringey and Islington, merged to form NCL CCG. At the point of this merger, five fertility policies remained in existence in NCL and these policies are currently in operation, being applied on the basis of GP registration.

Whilst many aspects of the five policies are similar, there are some noticeable differences between them, for example the number of IVF cycles that are funded. In addition, clinical practice and research in this field has continued to evolve, along with changing views and attitudes in society.

Whilst there are many areas of good practice in the provision of fertility treatment in NCL, the current policy arrangements do not allow for equitable access to treatment for all of our residents. These differences in provision are increasingly difficult to justify with the establishment of a single NCL CCG.

A single NCL Fertility Policy has now been developed and is being presented to the NCL CCG Strategy & Commissioning Committee for approval. It is believed the following benefits will be achieved as a result of having one NCL Fertility Policy:

- Equitable access to specialist fertility treatments for all residents in NCL
- Greater clarity and consistency for residents, primary care clinicians, secondary care clinicians and specialist fertility providers on the eligibility, provision and funding of specialist fertility treatments in NCL
- Improved patient experience as a result of having equitable and consistent access to specialist fertility treatments.

This report:

- Provides a summary of the approach taken to develop the NCL Fertility Policy
- Presents the final NCL Fertility Policy, and considers how it meets the recommendations of the NCL Fertility Policies Review
- Describes how the feedback received on the draft policy has been considered and responded to
- Sets out the estimated implications of the NCL Fertility Policy, including equality and quality implications (with accompanying Equalities Impact Assessment and Quality Impact Assessment), financial implications and legal considerations
- Sets out the plan and next steps to support the implementation of the NCL Fertility Policy

Separate to the NCL Fertility Policy, a recent change in referral pathways has been made. This is documented in this report.

The Strategy & Commissioning Committee is asked to **approve:**

- The NCL Fertility Policy
- The approach and plans for the implementation of the NCL Fertility Policy

The Committee is further requested to **note:**

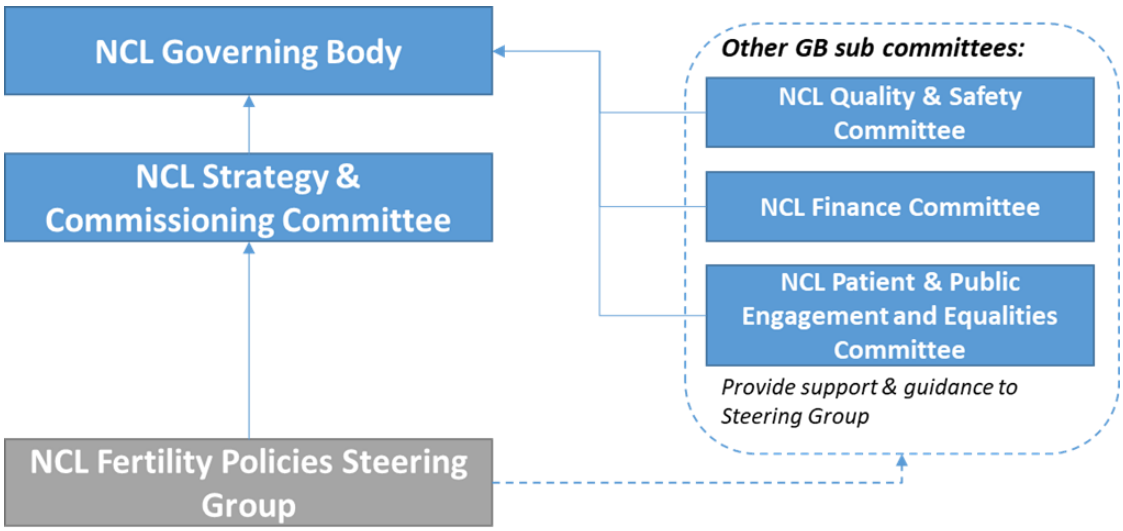
- The Equality Impact Assessment and Quality Impact Assessment on the NCL Fertility Policy
- The financial implications associated with the NCL Fertility Policy
- The changes to referral pathway arrangements for NCL patients eligible for specialist fertility treatments and the current operational status of fertility services at the Homerton

3. Development of the NCL Fertility Policy

3.1. Governance

The development of the Policy has been led by the NCL Fertility Policy Development Steering Group (Steering Group), chaired by the Clinical Responsible Officer (CRO), nominated by the NCL CCG Governing Body to lead the delivery of the Review and the Fertility Policy Development. Key parts of the Policy have also been influenced by feedback from the CCG Governing Body and the NCL Fertility Clinical Reference Group, where policy content considerations have been presented and discussed. Figure 2 sets out the governance structure for the NCL Fertility Policy Development programme.

Figure 2: Governance of the NCL Fertility Policy Development



The Steering Group, which includes two clinicians and a Governing Body member, has overseen the development of the content of the Policy. The NCL Clinical Reference Group has also reviewed the Policy, and this panel includes an embryologist, fertility nurse, and a number of secondary care consultants with relevant subject matter expertise. A specialist secondary care clinician from a non-conflicted specialist fertility provider organisation has also supported the programme.

3.2. Approach

By wanting to address unwarranted variation and recognising what an important issue that access to fertility treatment is for some of our residents, the CCG has followed a robust approach to developing a single NCL Fertility Policy. Therefore, the programme has been conducted in two stages:

Stage 1 – Review
The first stage undertook a Review of the five existing fertility policies in NCL, including understanding the latest national guidance and best practice and seeking views from stakeholders (including the public, service users, primary care, secondary care and specialist clinicians). A set of recommendations was developed to direct and support the subsequent development of a draft NCL Fertility Policy, with no decisions being made during this stage.

Stage 2 – Policy Development
The second stage developed an NCL Fertility Policy, taking into account the recommendations from Stage 1 of the programme. The Policy received input from the clinical leads for the project, from the NCL Fertility Clinical Reference Group and from a series of Governing Body seminars, which were instrumental in providing a steer on the direction that the policy should take. An initial draft policy was completed and it was approved to be taken for a second period of engagement with stakeholders. During this second period of engagement, comments and feedback were received on the draft policy. All the feedback was considered, with further specialist support (e.g. clinical, legal, financial), and the policy has been amended and updated, taking all relevant factors into account.

4. The NCL Fertility Policy

The NCL Fertility Policy provides for a single, consistent policy across the NCL area, and to a large extent provides greater alignment with NICE guidance compared to the existing policies. It increases the provision in

a number of boroughs, and if implemented, will provide a significant improvement in the level of provision of specialist fertility treatments for the majority of the NCL population.

The NCL Fertility Policy has been based on the draft policy and has been refined and updated following a detailed review process of the responses to our engagement process. This has involved:

- Documenting the detailed list of all responses to the engagement process, including the survey, online responses and feedback provided during engagement events;
- Considering our response to each of these points and categorising them into issues where we do not need to change our policy, issues for discussion with our CRG and issues for discussion with the Governing Body Seminar;
- Holding a Governing Body Seminar, providing an overview of the policy development process, including suggested policy amendments, areas of clarification and proposed changes. Where a steer was required, the Governing Body was informed of the options available and the preferred option of the GB was noted.
- Clinical issues were debated at the Clinical Reference group and key recommendations put forward that determined the proposal adopted in the final policy
- A further stage of legal review was undertaken to ensure that the policy meets all of the legal duties required of the CCG. Specific questions arising out of the engagement process were raised and, where necessary, the policy was amended.

4.1. Key Features of the NCL Fertility Policy

Key features of the NCL Fertility Policy include:

Policy Area	Feature
Number of IVF Cycles	• Increased number of IVF cycles available to women aged under 40 in four boroughs and maintained existing provision in the other borough. This feature of the policy consists of up to six embryo transfers, from a maximum of three fresh IVF cycles. This is broadly consistent with NICE guidelines which recommend three full cycles (where a 'full' cycle is defined as an episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos). This feature of the policy will be of major benefit to eligible residents in NCL, particularly those who are currently subject to policies that only provide funding for one fresh and one frozen cycle. This feature does not result in a reduction of provision for any NCL resident.
Use of Frozen Embryos Before Starting a Fresh Cycle	• All good quality frozen embryos should be transferred before starting the next NHS funded fresh cycle. This is because the likelihood of a live birth after frozen embryo transfer is similar to that for fresh embryo transfer, and using up the frozen embryos first is a less invasive procedure
Ovarian Reserve Criteria	• Ovarian reserve criteria for women of all ages will remain in place, however wording has been clarified to ensure these criteria are applied consistently by providers. This is not consistent with NICE CG156 (which recommends ovarian reserve criterion for women aged 40-42 only). This criterion has been retained because in general, lower ovarian reserve is associated with a decreased chance of a live birth and removing the ovarian reserve criterion will increase the number of patients accessing IVF by ~25% and therefore the associated expenditure considerably
Funding of IUI for Female Same Sex Couples and Single Women	• Funding up to six cycles of intrauterine insemination (IUI) for female same sex couples and single women who have demonstrated infertility by undergoing six unsuccessful self-funded cycles of IUI[1]. This is currently only available in two of the five NCL boroughs. The policy on IUI is now broadly aligned to NICE CG156 recommendations.

[1] If investigations show that IVF is the only effective treatment option, patients would not be required to undergo IUI prior to receiving IVF treatment

Policy Area	Feature
Time Trying to Conceive	• Current NCL borough policies allow heterosexual women aged 36 and over with unexplained infertility to access specialist fertility treatments after one year of trying to conceive. The policy requires women of all ages with unexplained infertility to try to conceive for two years because this is recommended by NICE[2].
Clear and inclusive language	• The layout of the policy has been amended to improve ease of use and the language used has been carefully considered. The policy has benefitted from being reviewed by a Readers Panel and NHS England/ Improvement LGBT+ advisor, both of whom suggested changes to improve inclusivity and clarity. For example, a glossary, flowcharts of some pathways and a matrix outlining which criteria apply to which interventions have been included in the policy document.

A full rationale for each feature of the NCL Fertility Policy is contained in Appendix 4. This appendix contains a table comparing the NCL Fertility Policy with NICE guidelines, the current policy in each of the boroughs and the rationale for this.

This Policy cannot anticipate every possible individual clinical presentation. Clinicians may submit Individual Funding Requests (IFRs) to the CCG for patients who they consider to have exceptional clinical circumstances falling within the CCG's policy on IFRs and whose needs are not fully addressed by this Policy.

4.2. The NCL Fertility Policy and NCL Fertility Policies Review Recommendations

The draft policy (developed in October 2021) was developed on the basis of the recommendations contained in the Review Report that was presented to the S&C Committee in September 2021. Now the NCL Fertility Policy has been finalised, we have reviewed how each of the recommendations has been used to form the basis of the NCL Fertility Policy. (For Recommendation 3 – supporting the application of the policy and the pathway, this is addressed in section 6 about the implementation plan for the NCL Fertility Policy).

Ref.	Review Recommendations	Response
1. A	NCL CCG should develop a single Fertility Policy across NCL and avoid variation between boroughs. The level of provision within the new NCL Fertility Policy should be aligned to national recommendations where feasible. Where relevant the evidence base is to be considered to inform decisions.	• There is now a single NCL Fertility Policy which applies to all residents registered with an NCL GP across all boroughs • The level of provision is aligned to NICE guidelines in most areas, save for those areas that have been outlined (see section 4.3). Legal advice has been sought on the policy to ensure that our interpretation of the guidance is accurate.
1. B	The new NCL Fertility Policy should aim to address inequalities and ensure equality of access across different service user groups. Particular consideration should be given to eligibility criteria for accessing treatments covered by the policy.	• The Policy responds to inequalities across different service users, and specific changes have been made to respond to this – for example funding 6 cycles of IUI prior to IVF is now funded for eligible same sex couples. We have also undertaken a detailed analysis of the impact of the policy on different protected groups (see section 5.1)
1. C	The new NCL Fertility Policy will be clearly written and avoid ambiguous terms and wording. The language should be easy to follow for the people who will read and use the policy, which includes primary care	• The NCL Fertility Policy is, by its very nature, a technical document and will need to be understood by medical professionals. It has also been written in plain English wherever possible and includes a glossary to explain

[2] If investigations show that specialist fertility treatments were the only effective treatment option, patients would not need to wait for the full duration of time trying to conceive

Ref.	Review Recommendations	Response
	clinicians, secondary care clinicians, service users and residents.	what the technical terms mean. We have tested the Policy with a Readers' Panel, who have advised on the "readability" of the document. Flow diagrams have also been added to show how patients would travel through the system. The Policy has also been reviewed by the clinical lead and CRO for the programme, as well as by the Clinical Reference Group (thereby seeking both primary and secondary care clinical input).
1. D	The new NCL Fertility Policy should ensure that it clearly articulates the overarching fertility pathway, the treatment options available and the relevant eligibility criteria for accessing treatments and interventions.	• A summary of the NICE pathway for patients concerned about their fertility and a matrix outlining which criteria apply to which interventions have been included in the policy document.
1. E	The new NCL Fertility Policy will utilise inclusive and up to date language, making use of expert advice in this area.	• The policy has benefitted from being reviewed by NHS England/ Improvement LGBT+ advisor who suggested changes to improve inclusivity.
1. F	A reading panel with community representation from across NCL should be established to read through and test the draft policy, as well as provide views on policy implementation plans. The reading panel will have no decision making power but their perspective will be influential.	• A Readers' Panel was established. It has reviewed and provided feedback on the Policy. Further meetings are due to take place to provide advice on its implementation (including communications materials).
1. G	The new NCL Fertility Policy will require regular review. The commencement of the new NCL Fertility Policy will be clearly dated with timeframes specified for the policy to be considered for review. Other trigger points that would initiate a process of review and potential update will be identified (e.g. updated NICE guidance, new technologies become available).	• The CCG is committed to reviewing the policy regularly, or when trigger points arise such as updated NICE guidelines or new technologies becoming available.

Ref.	Review Recommendations	Evidence base / Rationale
2. A	Communication plays a central role to ensuring the policy is successfully implemented. Communications should be targeted at the three core audiences: residents, primary care and secondary care.	• The CCG has a comprehensive communications and engagement plan to support the implementation and launch of the Policy. The key audiences will be service users, VCSE, special interest groups, primary care, secondary care, scrutiny colleagues and internal CCG stakeholders • The NCL Readers Panel (consisting of 6 community members) will meet with the communications & engagement team to: - provide advice and comment on the phrasing and 'readability' of the communications materials & - consider materials and activity to help promote awareness and - understanding of the published policy

Ref.	Review Recommendations	Evidence base / Rationale
2. B	Resident facing communications should be easy to understand, helping people to have a clear understanding of what the implications of the policy may mean for them. A range of communication methods should be utilised to support as wide access to the new NCL Fertility Policy as possible (including appropriate access to support people with different communication needs).	• The CCG has a comprehensive communications and engagement plan to support the implementation and launch of the Policy. We will utilise a variety of communications and engagement channels and activities tailored to specific audiences. This will include accessible materials such as translations, easy read, visuals, etc., where this is appropriate.
2. C	Primary care facing communications should utilise a range of methods to support penetration of the new NCL Fertility Policy across NCL. This will include updates to the NCL GP website, ensuring the policy and pathway is easy to access and follow by GPs, and communications to practice management (supporting GPs in dealing with patient queries).	• The CCG will utilise all primary care communications and engagement channels including: copy for the GP website, articles in the weekly GP bulletin, information for practice managers, a feature at the weekly GP webinar. As well as sharing information about the Policy, reminders about the pathway will also be included.
2. D	For service users who are within the current fertility pathway (for treatments and interventions covered by the new NCL Fertility Policy), clear information should be provided as to how the new NCL Fertility Policy will impact or affect their current service provision. This will be addressed in the transition plan.	• Information will be developed for current service users to inform them of the Policy and how it will impact or affect their treatment. This will include developing FAQs and scenarios to demonstrate the principles of the transitional arrangements, and highlighting the most common situations. This will also be shared with GPs to assist with conversations with their patients.

4.3. The NCL Fertility Policy and NICE guidelines

The Policy has been referenced back to NICE guidance to ensure that it complies with it wherever possible. Other national guidance has also been taken into consideration, e.g. NHS Constitution and DH guidance for CCGs on formation of clinical commissioning policies for fertility preservation. Where it has not been possible to comply with NICE guidance, this has been noted in the table below and, where relevant, within the Equality Impact Assessment.

The NCL Fertility Policy is aligned to NICE guidance in a number of key areas. The policy takes into account:

- The baseline position (epidemiology, existing borough policies, current activity and expenditure)
- NICE clinical guideline CG156, other national guidance and the evidence base
- The views of stakeholders including specialist clinicians, service users and residents
- The impact of different scenarios estimated through modelling
- Identification and consideration of potential equality and equity issues

In developing this policy, the CCG's starting point has been to consider the relevant NICE guidance. However, it has also taken into account competing relevant factors including affordability and outcomes, which has meant that in some sections the policy varies from the full recommendations made by NICE. Key areas where the Policy deviates from NICE are highlighted below:

NCL Fertility Policy	NICE CG156 recommendation	Rationale for Policy position
For eligible patients requiring IVF where the woman or person trying to conceive is aged under 40, the CCG will fund up to six embryo transfer procedures from a maximum of three fresh IVF cycles	In women aged <40 years offer three full cycles of IVF*.	The Policy is aligned to NICE CG156 in funding up to three fresh IVF cycles for women aged under 40. The CCG has set the maximum number of embryo transfers to six, which is in line with the current 'most generous' policy in Camden. Overall most residents in NCL will have the possibility of more IVF treatment if clinically appropriate. This level of provision has been carefully considered to balance alignment with NICE guidance alongside meeting the financial duties of the CCG. By offering this level of provision of IVF treatment, this will likely improve outcomes for service users undergoing these treatments.
For eligible patients requiring IVF where the woman or person trying to conceive is aged 40–42, the CCG will fund up to two embryo transfer procedures from one fresh IVF cycle	In women aged 40–42 years… offer one full cycle of IVF[3].	The Policy is aligned to NICE CG156 in funding one fresh IVF cycles for women aged 40–42. The ratio of frozen vs. fresh cycles available to women aged under 40 has been applied to this group.
Up to six cycles of unstimulated IUI is funded for eligible people with diagnosed physical disability or psychosexual problem and same sex couples who have not conceived after six cycles of self-funded IUI	Consider six cycles of unstimulated IUI for people with diagnosed physical disability or psychosexual problem and same sex couples who have not conceived after six cycles of artificial insemination (AI)	NICE specify people in same sex relationships should have six cycles of AI prior to NHS funded IUI (the full guideline notes the Guideline Development Groups 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 NCL 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 and the donor's family medical history will have been taken to identify any serious heritable diseases. In addition, semen analysis will have been undertaken to ensure the donor sperm is good quality • Clinics undertaking IUI provide counselling to everyone involved in the donation process • IUI undertaken at a clinic will maximise efficacy (e.g. sperm will be placed in

[3] A full cycle of IVF should comprise one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

NCL Fertility Policy	NICE CG156 recommendation	Rationale for Policy position
		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 mother's partner (if she has one) will be recognised as the second legal parent • The Clinical Reference Group is supportive of this requirement
Storage of sperm, embryos and eggs for fertility preservation: • For patients aged under 32 years at time of cryopreservation, storage funded until patient's 43rd birthday. • For patients aged 32 and over at time of cryopreservation, storage funded for 10 years duration.	For people with cancer who wish to preserve fertility store cryopreserved material for an initial period of 10 years. Offer continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility.	Younger fertility preservation patients may not be ready to start a family within 10 years of having their sperm, eggs or embryos cryopreserved. The Policy takes account of this by funding storage until at least until their 43rd birthday and for a minimum of 10 years. This upper age limit is consistent with the NCL Fertility Policy upper age limit criteria for assisted conception treatments for patients with fertility problems.
There should not be evidence of low ovarian reserve, defined in this policy as more than one of the following: • antral follicle count (AFC) of less than or equal to 4 • anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l • follicle-stimulating hormone (FSH) greater than 8.9 IU/l	In women aged 40–42 years offer 1 full cycle of IVF provided there is no evidence of low ovarian reserve. • antral follicle count (AFC) of less than or equal to 4 • anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l • follicle-stimulating hormone (FSH) greater than 8.9 IU/l	NICE only apply an ovarian reserve criterion to women aged 40–42; the NCL Fertility Policy applies an ovarian reserve criterion to all women aged <43 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 • Funding more IVF cycles for women with a good ovarian reserve is likely to lead to more live births than funding fewer IVF cycles and removing the ovarian reserve criterion

For a more detailed review of the NCL Fertility Policy in comparison with NICE guidelines, the existing CCG fertility policies and supporting rationale, please see Appendix 4.

4.4. Refinement of the NCL Fertility Policy in response to engagement

NCL CCG undertook engagement on the draft policy between 22 November 2021 and 13 February 2022 (12 weeks) to seek views from patients, residents, clinicians, voluntary and community groups, fertility groups and other audiences. The Fertility Policy Engagement Report provides an in-depth analysis of the qualitative and quantitative insights captured during the engagement.

A range of steps were taken to promote the engagement period, focused on directing people to the online survey or to attending events as the main way to give feedback. During the engagement period, the engagement website and hosted materials had over 2,258 page views and 1,988 documents downloaded.

A variety of approaches were taken to reach out to groups and individuals from different ethnic backgrounds and communities across our five boroughs. It should be noted that the engagement took place during the COVID-19 pandemic, which restricted engagement interactions to online and telephone methods. This regrettably resulted in moving from a public meeting that was planned to be held in person to be transferred to an online meeting. It is important to note that we received no negative feedback for taking this decision.

Wherever possible mitigations were put in place to enable and encourage people to take part; for example, by working with Voluntary and Community Sector (VCS) groups to reach ethnic minority communities whose first languages are not English, and by providing interpreting support (Arabic and Somali) at online events.

In relation to who responded: we received 439 responses during the engagement window, held 21 engagement meetings, 108 people responded to the survey (28% were current or previous service users and 48% were members of the public). The profile (where people disclosed the information) of the people who gave us feedback during the engagement window was as follows

- 56% of the public respondents were White British and 25% were from Black and other minority ethnic groups
- 13% of survey respondents had a disability
- 27% of survey respondents were aged between 25-34 and 33% between 35-44 and
- 17% of public respondents identified as Gay, Lesbian, Bisexual or other gender

Overall, there was a high level of support for the policy (68% of survey respondents and the majority of people who attended the public meetings (more than 80%)), with respondents seeing the draft policy as an improvement with recognition that its implementation would increase provision, standardise what is provided across the five boroughs and bring services offered more in line with NICE guidelines.

An extremely wide range of comments were provided through responses to the survey and in public meetings, across almost all aspects of the policy. Whilst the majority of responses received were in support of the draft policy, there were three areas that received the highest number of consistent comments, related to specific aspects of the draft policy:

- **Eligibility criteria should be reviewed** in the following areas: upper age limits of the woman, ovarian reserve and potentially removing criteria around previous IVF, BMI and previous children.
- It was strongly felt that **female same sex couples and single women should not have to self-fund intrauterine insemination (IUI)** prior to NHS treatment.
- Further consideration to **providing assisted conception treatments** for those seeking to use **surrogates**.

The CCG has outlined below the key engagement feedback points, together with our response. Where we have changed the policy as a result of the feedback this has been indicated.

Topic and summary of draft policy	Specific Engagement Feedback	Our Response
Age of the woman criterion: *Women must be aged under 43 years*	Feedback included: • age limits could result in pressure for women and increase gender imbalances in society • some women may be focused on other aspects of their lives or are not in a relationship until their late 30s or early 40s • some women aged over 40 are getting treatment in Europe so why not in the UK	The age criterion **remains in place** because the success rates of IVF decrease as the age of the woman increases. NICE does not recommend NHS funded IVF for women aged over 42 years noting, 'the clinical and health economic evidence was overwhelming in indicating that IVF should not be offered to women aged 43 years or older'.
Ovarian reserve criteria; *There should be no evidence of low ovarian reserve (NICE thresholds for AFC, AMH and FSH measures apply)*	Some stakeholders stated that the ovarian reserve criteria should not apply to younger women, noting that NICE guidance only recommends ovarian reserve criteria apply to women aged 40-42 years. The issue of how to define the specific tests that would determine low ovarian reserve was also raised in some of the clinical feedback.	Ovarian reserve criteria **remain in place** for women of all ages in the Policy, The rationale for this is that although NICE only apply an ovarian reserve criterion to women aged 40–42; • 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. • Funding more IVF cycles for women with a good ovarian reserve is likely to lead to more live births than funding fewer IVF cycles and removing the ovarian reserve criterion. However, the wording of the criteria has been amended to improve clarity and consistency of application across providers.
Previous IVF cycles criteria: *Women aged under 40 should not have had more than 3 previous fresh IVF cycles and women aged 40-42 should not have had any previous IVF treatment; the above applies irrespective of how the IVF cycles were funded*	Feedback received suggested that it was unfair that people who have previously paid for IVF cycles would have less or no access to NHS funded treatment.	The previous IVF cycle criteria **remain in place** because the likelihood of a live birth decreases with the number of unsuccessful IVF cycles undertaken. NICE have undertaken cost effectiveness analysis to determine in what circumstances IVF is cost effective and have based their recommendations on the results of this. Criteria relating to previous cycles in the Policy are consistent with NICE recommendations.

Topic and summary of draft policy	Specific Engagement Feedback	Our Response
BMI criteria: *Woman must have a BMI within the range of 19-30 kg/m2)*	Feedback regarding the BMI criteria included: • BMI as a measure does not take account of muscle tone, overall health or the reason why the individual is overweight or obese • There is cultural desirability in some communities for women to be larger and therefore losing weight may be difficult NICE do not recommend patients must be within a specific BMI range in order to access NHS treatment.	The BMI criteria **remain in place** because having BMI outside this range is likely to reduce the success of assisted conception treatments: • NICE CG156 specifies women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female 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. Local specialists support inclusion of the BMI criterion for women outlined in the Policy.
Previous children criteria: *At least 1 individual in a couple must not have a living child from their relationship or any previous relationship. Single persons should not have a living child. Adopted children are included but foster children excluded from the scope.*	Many people were in favour of the position of the draft policy which allowed treatment where one person in the couple (or an individual) does not have a living child. However additional feedback included: • These criteria do not have a scientific/ clinical rationale • It is unfair to people with one child who wish for the child to have a sibling • It is unfair to people who have adopted, especially where this is due to circumstances (e.g., they have adopted the chid of a family member who has died). • NICE state in their Quality Standards that the existence of a living child should not be a factor that precludes the provision of fertility treatment.	Previous children criteria remain in the Policy. It is recognised nationally that NHS organisations need to focus their resources on patients who have the most need and can obtain the maximum health gain. Local priority is therefore being given to those where at least one partner in a couple does not have a living child. Research on the parental status of people presenting to GPs with fertility problems in Oxfordshire indicates that removing the 'previous children' criterion would increase the number of patients presenting for treatment by ~22%. This would mean less cycles could be offered to all patients accessing assisted conception treatments. However, after discussion with adoption services, receipt of legal advice and discussion with Steering Group and Governing Body, it was agreed that **an amendment should be made** and reference to adopted children should be removed from the Policy.

Topic and summary of draft policy	Specific Engagement Feedback	Our Response
Assisted conception treatment using donor sperm: *Unless they have a diagnosed fertility problem which indicates IVF, same sex couples and single women are required to have undertaken 6 cycles of self-funded IUI before they are eligible for NHS funded IUI*	A large proportion of responses (including from a number of Healthwatch and voluntary organisations) supported reducing/ removing the number of self-funded cycles of IUI required for female same-sex couples or single women who do not have a diagnosed fertility problem prior to NHS treatment. Feedback included: • the draft policy does not allow equality of access to same sex couples as they would be financially disadvantaged by the requirement to pay for 6 IUI cycles. It is therefore discriminatory • same sex couples and single people cannot conceive without fertility treatment • this aspect of the draft policy is not in line with NICE guidelines as NICE only specify artificial insemination, not IUI specifically That this requirement could lengthen the process and, for some individuals, could mean they pass the age cut off for NHS treatment	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[4]. The draft policy was broadly consistent with NICE CG156 in their recommendations on IUI for same sex couples. NICE specify people in same sex relationships should have 6 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 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

[4] See pages 77-79 of NICE CG156 full guideline for more information

Topic and summary of draft policy	Specific Engagement Feedback	Our Response
		• 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 mother's partner (if she has one) will be recognised as the second legal parent • The Clinical Reference Group is supportive of this requirement. The CCG has therefore **retained the draft policy position** in this instance[5].
Assisted conception treatments involving surrogates: *Not routinely funded.*	Feedback included: • Surrogacy is the only option for some people to have a biological child • Not funding ACT involving surrogacy would exclude gay couples and some women who have uterine or cervical factor infertility from NHS treatment – this was felt by some to be discriminatory Some people felt that at least some aspect of surrogacy should be funded by the NHS.	The Policy not to routinely fund ACT involving surrogates **remains in place** for the following reasons: • 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. • 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.

[5] Should the position change as a result of any new case law or legislation, the CCG will review the policy in light of that ruling.

Topic and summary of draft policy	Specific Engagement Feedback	Our Response
		As with all other interventions not routinely funded, an IFR application may be submitted by the treating clinician for any situation where they believe the case is clinically exceptional or rare.

4.5. Other changes compared to the draft fertility policy

In addition to the consideration of feedback received during the engagement on the draft policy, the following table highlights other "material" changes in the NCL Fertility Policy, compared to the draft policy:

Policy Topic	Feedback on draft policy	Detail of change to NCL Fertility Policy
Extending storage for younger fertility preservation patients	The draft policy stated fertility preservation patients would have cryopreserved sperm, eggs and embryos stored for a maximum of 10 years. Feedback noted younger patients may not be ready to start a family within 10 years of having their genetic materials cryopreserved.	The Policy now funds storage until at least the patient's 43rd birthday and for a minimum of 10 years. This upper age limit is consistent with the NCL Fertility Policy upper age limit criteria for assisted conception treatments for patients with fertility problems.
Delay to funding of donor sperm/eggs	The draft policy stated the CCG would fund the cost of ACT and the cost of donor sperm / eggs for eligible patients. Feedback received from local providers highlighted significant practical and logistical issues relating to CCG funding of donor sperm and eggs.	The Policy states that the CCG will fund the cost of the ACT, but the donor sperm/ eggs need to be sourced and paid for by the patient. However, a footnote clarifies that NCL intends to fund donor eggs for use in NHS funded ACT in the future once arrangements have been put in place to resolve practical and logistical issues.
Changes/ additions to improve clarity of policy	Several requests for clarification were requested relating to different aspects of the draft policy.	Amendments and additions were made to the Policy to improve clarity.
Amendments to language	The wording used in the draft policy was described as 'heterocentric' and 'not gender inclusive'.	The Policy has been amended to use inclusive language.

5. Implications of the NCL Fertility Policy

An Equalities Impact Assessment and a Quality Impact Assessment have been completed on the NCL Fertility Policy. Expert advice has been sought regarding the legal considerations and financial implications of implementing the NCL Fertility Policy.

5.1. Equality Impact Assessment and Quality Impact Assessment

An Equality Impact Assessment (EIA) and Quality Impact Assessment (QIA) have been undertaken (see appendices 1 and 2), which note the key equality issues, with reasons, and sets out the mitigations that can be applied.

We note that due to the very individual and personal nature of undergoing fertility treatments, the impact of different elements of the NCL Fertility Policy will vary according to the individual situation. We recognise that this may be complex.

An EIA of the NCL Fertility Policy, covering the nine protected groups (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religious belief, sex and sexual orientation) as covered by current legislation, has been carried out. The findings of the EIA demonstrate that the Policy is

anticipated to result in a mixture of impacts for people with different protected characteristics – i.e. ranging from positive through to neutral, negative and unknown. In general, there was consistency in broadly complying with NICE Clinical Guideline 156, ensuring that the policy is applied equitably to all eligible individuals, in line with national best practice.

Where it has been identified that the Policy may have an impact on a person with a particular protected characteristic, the EIA has noted the clinical evidence, or for other legitimate reasons, that is the basis for the inclusion of that element (e.g. level of provision of eligibility criterion) in the Policy. These reasons have been clearly documented and outline that they have nothing to do with the protected characteristics themselves.

For example, the Policy specifies that in order to be eligible for NHS funded assisted conception treatments (ACT), the women or person trying to conceive should be aged under 43. Where the woman or person trying to conceive is aged under 40, up to six embryo transfer procedures from a maximum of three fresh IVF cycles are funded. Where the woman or person trying to conceive is aged 40-42, up to two embryo transfer procedures from one fresh IVF cycle is funded. Those aged 43 and over will not have NHS funded ACT available to them. These criteria are in place because the success rates of ACT decrease as the woman's age increases. The NCL Fertility Policy will therefore have a positive impact for patients aged under 40 who have an increased or maintained level of IVF provision available to them. It may be considered neutral/ negative to patients aged 40-42 who will be able to access the provision of one IVF cycle with up to two embryo transfers (remains the same as per existing policies, although less than for under 40s). It may also be considered neutral/ negative to those aged 43 as although they have no IVF available to them, treatment is unlikely to be successful at this age, as detailed in NICE guidance.

As another example, the Policy states that ACT involving surrogates are not funded by NCL CCG. This may result in a negative impact on people who would not be able carry a pregnancy due to a disability and male same sex couples who would require a surrogate to have a biological child. The Policy states that ACT involving surrogates is not funded because a surrogate is only available to those with means (surrogates' expenses typically cost between £12k–£20k) and, by parity of reasoning with the prohibition on mixing NHS and private care in one episode of care. In addition there are considerable legal and ethical issues relating to the use of surrogates.

The Policy addresses known inequalities and for example, is inclusive of individuals with HIV, a physical disability, psychosexual problems, people undergoing cancer treatment and people undergoing gender reassignment. For example, the Policy enables people who are undergoing cancer treatment or gender reassignment interventions which are gonadotoxic to store their gametes and use them at a later stage. Sperm washing is funded for eligible people living with HIV and ACT are funded for eligible people with physical disabilities and psychosexual problems.

Individuals with social, cultural or religious objections to IVF are accommodated in the Policy by making IUI available as an alternative to eligible patients.

The EIA notes the differential information and communication needs that some disabled people may have compared with non-disabled people. Both the publication of the Policy and the provision of specialist fertility services must meet the Accessible Information Standard Requirement.

Key elements of the Quality Impact Assessment (QIA) is that in general, the NCL Fertility Policy either improves or maintains the provision previously allocated in the boroughs thereby reducing unwarranted variation and improving patient experience across the whole of North Central London. Standardised approaches support patient safety and clinical effectiveness.

5.2. Legal Considerations

Since the legal advice is privileged, it is not being shared as part of this report. However, we can confirm that we have sought legal advice on the NCL Fertility Policy (and throughout its development) and a number of changes have been made as a result. Some of the most significant comments have been:

- While the CCG does not have a statutory duty to comply with NICE CG156 recommendations, it must record reasons / local factors that drive any departure from the NICE guideline.
- So long as all (and only) relevant information is considered and the CCG can provide a rational explanation for why it considers particular factors to have more or less weight, it is possible for the CCG to arrive at several different lawful conclusions as to the substantive content of the policy.
- Whilst it may be legally defensible for the CCG to depart from NICE guidelines, it is not sufficient to simply state that the reason is "affordability" or that resources are finite. A more detailed description should be recorded contemporaneously along with the approval of the policy, such as value for money within a particular area, or setting out which services the CCG would not be able to invest in should the funding not be spent on implementing the NICE guidelines;
  Some of the definitions within the policy have been tightened, based on the legal advice;
- The advice highlighted the need for a transition policy, for people who have already been referred or started treatment. We agree with this recommendation and will be incorporated into our preparation activities for implementing the policy (see section 6.7).

5.3. Financial modelling and cost implications

The CCG's finance team has worked with the project team to model the likely financial impact of implementing the Policy. Areas where the proposed elements of the policy are likely to lead to significant changes in activity and expenditure are:

- increasing the number of IVF cycles funded for women aged under 40 across NCL
- funding of IUI for same sex couples and single women with fertility problems
- funding of donor eggs and sperm for NHS funded ACT (though this aspect will not be implemented initially)
- funding longer storage of cryopreserved sperm, eggs and embryos for younger fertility preservation patients

It was not possible to use NICE costing templates for CG156 as this has been removed from the NICE website. The data available in order to inform modelling was limited but included the following:

- A sub-set of UCLH data which contained detailed information on the number of cycles Camden patients took up (who already receive up to 6 embryo transfers) was used to estimate the impact of different scenarios relating to IVF cycles funded.
- Information from an audit of IVF patients' ovarian reserve undertaken by a fertility clinic was used to estimate the impact of removing the ovarian reserve criteria for NCL women aged under 40.
- Prior approval data from another CCG that had implemented NICE recommendations on funding of ACT using donor sperm and eggs (including for same sex couples) was extrapolated to estimate the impact of funding these interventions in NCL
- Data received from providers on fertility preservation patients were used to estimate the cost of increasing the duration of storage for younger patients
- A weighted average of the cost of IVF cycles were used, updated for growth.
- Assumptions used were sense-checked with the Clinical Reference Group
- Sensitivity analysis was undertaken, for example by adjusting the cost of IVF to the upper and lower benchmark tariff and increasing the number of IVF cycles undertaken by 10%.

According to the methodology outlined above, the most likely total cost impact (i.e. cost in addition to baseline spend) of implementing the Policy is estimated to be £515,500 in 2022/23 (part year from August 2022) and £837,300 in 2023/24 (whole year).

Cost increase over baseline	2022/23 (part year, from 01.08.22)			2023/24 (whole year)		
	Best case	Most likely	Worst case	Best case	Most likely	Worst case
IVF - Maximum of 3 fresh cycles with 6 transfer limit	£166,800	£460,700	£1,034,300	£222,400	£614,200	£1,379,000

IUI - Funded for same sex couples and single women	£36,300	£41,300	£52,100	£48,400	£55,100	£69,500
Donor gametes - Not funded in 22/23, funded in 23/24[6]	£0	£0	£0	£148,900	£150,000	£150,800
Cryopreservation of gametes – increasing duration of storage for people aged <32	£13,500	£13,500	£13,500	£18,000	£18,000	£18,000
Total	**£216,600**	**£515,500**	**£1,099,800**	**£437,600**	**£837,300**	**£1,617,300**

The likely cost pressure as a result of the NCL Fertility Policy has been shared with Governing Body and S&C Committee previously. Whilst the financial pressures for the system are recognised, and have been taken into consideration during all stages of the programme, the importance of eliminating inequity in the provision of specialist fertility services to NCL residents has been a core principle and underpins many of the recommendations of the Fertility Policies Review (and therefore contributed to the development of the NCL Fertility Policy). Whilst noting that getting robust activity and expenditure data on these services has been difficult, we are continuing to encourage providers to improve data collection and analysis to support the system in working together to monitor the impact of the policy and consider options for efficiencies in the future, for example by reducing out of sector activity or considering alternative provider alliance models.

By having a single policy for all residents in NCL, resulting in equal access to services (single set of eligibility criteria) and equal provision of services (such as the amount of IVF offered), the CCG is also significantly reducing the risk of a potential legal challenge, and the sizeable costs and resources that would likely be incurred.

The financial implications of the Policy have been shared with the NCL ICS Financial Oversight Group and have been noted. The anticipated cost pressure has also been included in 22/23 finance plans.

6. Implementation of the NCL Fertility Policy

6.1. Overview

Between approving the NCL Fertility Policy and the formal "go-live" of the Policy, an implementation period will be necessary. We have provisionally allowed for a nine week implementation period, during which time we will undertake activities such as:

- Developing and refining communication materials to publicise the Policy
- Allowing provider organisations the opportunity to 'gear up' to deliver the improved level of provision and to familiarise themselves with the Policy
- Ensuring that the Policy is embedded in contracts
- Ensuring that administrative processes, such as Referral Support Services, are set up to support referrals in line with the new policy

6.2. Transition arrangements for NCL patients

The NCL Fertility Policy will replace all current fertility policies in NCL CCG for Barnet, Camden, Enfield, Haringey and Islington. However, transitional arrangements apply to the following groups:

1. people who are undergoing NHS funded assisted conception treatment[7] at the time the Policy is published, or

[6] Working assumption – no date has been confirmed for the implementation of this proposal
[7] Only applies to treatments within the scope of this policy document.

2. people who were referred for NHS funded assisted conception treatment[8] before the Policy was published.

The guiding principle for those people in either of those two groups is that they should experience no disadvantage or disbenefit as a result of the NCL Fertility Policy. Therefore:

- Where the Policy disadvantages the patient (i.e. specifies reduced provision compared to the relevant legacy policy), the legacy policy will apply; and
- Where the Policy is advantageous to the patient (i.e. specifies increased provision compared to the relevant legacy policy), the NCL Fertility Policy will apply

These transitional arrangements will apply to relevant patients until the course of treatment specified in the legacy policy is complete, or until the patient is no longer eligible for NHS funded treatment. After this time, the NCL Fertility Policy will apply to all NCL patients accessing NHS funded fertility treatments.

Transitional arrangements do not apply to patients who completed their NHS funded fertility treatment prior to the date the NCL Fertility Policy will be published. However, if patients who have previously had NHS funded fertility treatment are eligible for further treatment under the NCL Fertility Policy, they may access this as appropriate (for example, if a 36 year old woman in Barnet had completed her one cycle of IVF as provided under the legacy policy and was still eligible for the increased level of provision set out in the NCL Fertility Policy, then the additional treatment could be provided (subject to clinical decision making, etc.).

Frequently Asked Questions (FAQs) and some example scenarios will developed as part of communication materials to support patients and clinicians as they consider their individual situations. At all times, patients should speak with their treating clinician / clinical teams if they have any questions about their care and treatment, and the NCL CCG Fertility mailbox will also be able to receive queries.

6.3. Approach to implementation

The NCL Fertility Policy Development Steering Group will continue to provide oversight and steer for all implementation and preparation activities.

We will set up an Implementation Working Group and consider opportunities for links to provider service managers to ensure that we have the right people involved in implementation delivery.

Alongside this, the communications and engagement team will be developing materials for all of the relevant stakeholders to inform them of the new policy and how residents can access treatment. The contracting team are including information about the new policy in contracts to ensure awareness from the outset of 2022/23.

Through June and July, we will start to use the communications materials to inform stakeholders about the imminent policy ‘go-live’. We will use the relationships and partnerships that we have formed with many community groups in NCL through our engagement work to help spread awareness of the new policy.

As we approach the ‘go-live’ date, we will hold a series of ‘readiness checks’ with the provider organisations to ensure that they are ready and able to deliver the new policy and to accept referrals under the new criteria.

We will also prepare the public website and GP website to ensure that we are ready to change the contents on the go-live date. Information will also be cascaded to all NCL GP practices via the GP bulletin.

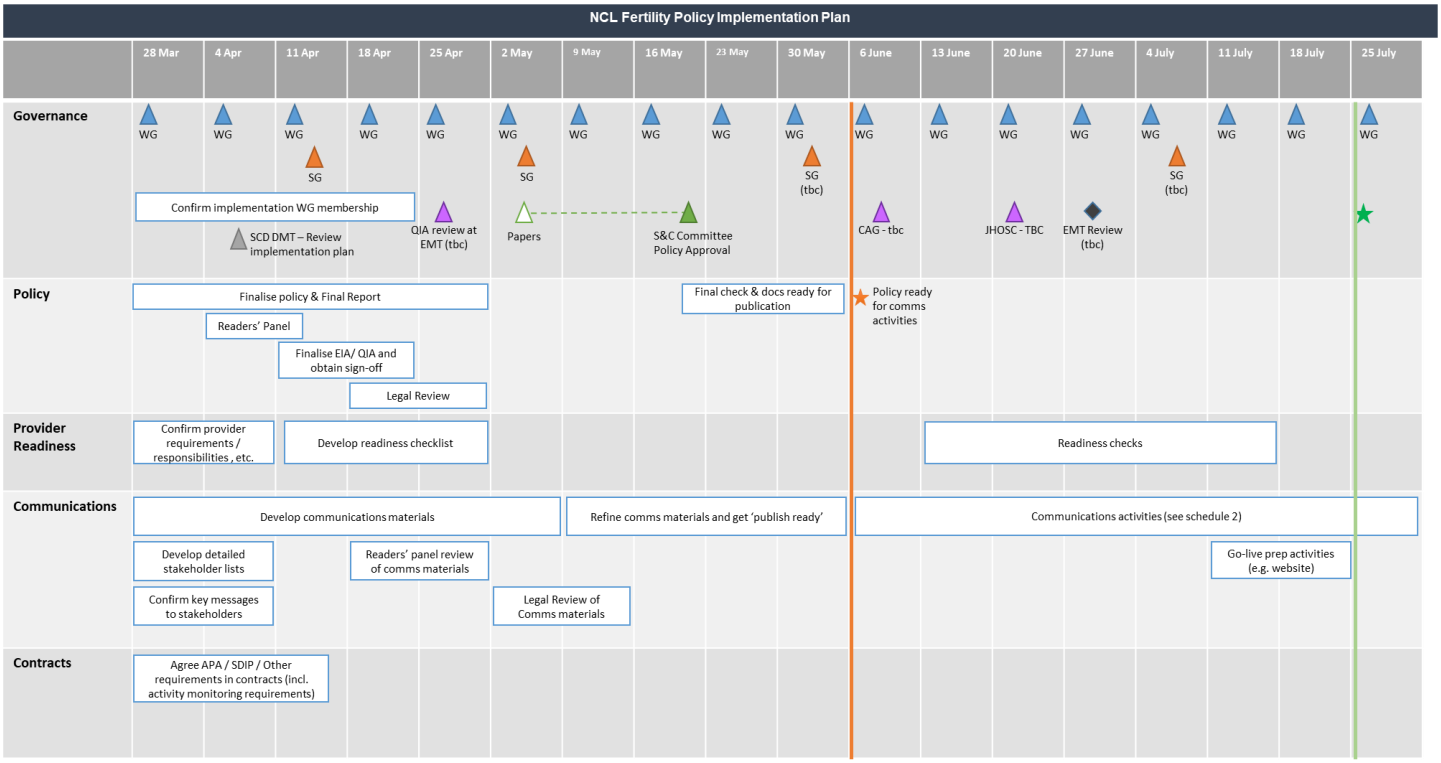
Importantly, two recommendations were identified as a result of the NCL Fertility Policies Review (completed in September 2022). These concerned a third category “supporting the application of the policy and the pathway”. The table below shows our response to these Recommendations given the completion of the NCL Fertility Policy.

[8] Only applies to treatments within the scope of this policy document.

Ref.	Review Recommendations	Response
3. A	GP update / education sessions should be delivered in NCL to support the awareness of the new policy and its implications. These sessions should include the provision of a refresh of the whole fertility pathway	• The CCG will develop clear information for GPs on to ensure that they fully understand the new policy and how to implement it. This will be done via a variety of methods including delivering dedicated education sessions to raise awareness, information on the GP website (included an updated pathway), a slot at the weekly NCL GP webinar and information shared via the weekly GP bulletin. Information will include an overview of the fertility pathway and where further information can be found.
3. B	Education events for secondary care clinicians (and their service management teams) who provide fertility treatments should be held across NCL to raise awareness about the new policy, ensuring that all providers understand and adhere to the requirements of the policy.	• The CCG is working with providers to best understand how we can work together to disseminate information about the Policy and support its adherence. The CRG will remain a key group for close working with the fertility services at each of the providers.

6.4. Outline Plan

The Outline Plan is set out below. Our current working assumption is that “go-live” will occur on 25 July 2022. Activities will be closely monitored to confirm readiness for the launch of the policy as per this plan, with support from Steering Group required. Strategic Commissioning Directorate Management Team (SCD DMT) and Executive Management Team (EMT) will also be utilised for oversight and assurance, with any issues or concerns escalated appropriately.



6.5. Communications and Engagement activities

A full NCL Fertility Policy implementation and launch communications and engagement plan has been produced with activity planned from April to September 2022 (see appendix 3)

The aims of the plan are to:

- Ensure key stakeholders (resident, patient, VCSE, political and health professional audiences) are aware of the new policy
- Support the smooth introduction of the new policy through implementation phase
- Ensure key stakeholders are confident that a robust process was followed to produce a fair and evidence-based policy
- Support the CCG to prepare for and effectively manage any challenges

The plan covers the following phases:

1. Preparing for the approval and publication of the new policy (April-May)
2. Announcing the approval of the new policy and implementation phase (mid-May to end of June)
3. Accounting the go live of the new policy (July)

Key audiences will include:

- Participants in phase 1 and 2 engagement periods
- Public, service users, VCSE, special interest groups, patient representative groups
- Fertility service providers and Trust leadership
- Primary care teams
- Health Overview and Scrutiny colleagues
- Governing Body, CCG primary care leads, borough commissioning leads, wider CCG staff (incl. enquiries team)
- Referral Support Services teams

Key messages will be developed as part of the policy launch preparation phase and will include a focus on:

- Emphasising the positive impact the new policy will have for those requiring fertility support
- Helping residents to understand how to access fertility support under the new policy (e.g. pathways)
- Communicating the robust, clinically-led and evidence based approach followed to produce the new policy
- Clearly demonstrating how the CCG listened, and responded to, stakeholder and resident feedback on designing the new policy
- Transparency on where feedback received through the engagement processes was not implemented in the new policy, and why

We will be developing a range of communications materials tailored to the different audiences including, where appropriate, easy read and translated materials. As in previous stages of the programme, all the communications materials will be tested with the NCL Readers Panel.

6.6. Resources

The Implementation Working Group will require support from internal NCL CCG colleagues and also close collaboration with provider Trust colleagues.

Resources required to support the review will include:

- Commissioning – clinical and officer
- Policy (to be continued to be provided by the Health Policy Support Unit)
- Legal (to be sourced as required)
- Communications & engagement

6.7. Risks and issues

A risk and issues log is maintained by the Fertility Working Group and the highest rated risks and any issues are regularly reviewed by the NCL Fertility Policy Development Steering Group on a monthly basis.

The following table sets out the highest rated risks identified for the implementation phase of the programme, and details proposed mitigating actions to minimise the likelihood of the risk occurring and the impact of the risk should it materialise:

Ref.	Risk	Overall risk rating	Mitigation
R13	There is a risk that the ability to deliver the Policy Development within timelines may significantly be delayed due to pressure on project resources or not enough project resource maybe a result of: ICS transition priorities, other priorities on time, etc.	**12**	Roles and resources to support the implementation have been identified. Additional communications & engagement resource capacity has been secured. Ongoing clinical leadership will be provided by the CRO and Fertility Clinical Lead. Implementation plans have been developed and will be closely monitored by the Working Group with clear escalation routes identified if required.
R11	There is a risk that other changes / circumstances (e.g. lifting of legacy provider arrangements and changes in Homerton services) may become conflated with the development of the fertility, causing confusion during implementation, and / or causing significant additional workload to the team, resulting in delays to the implementation of the single fertility policy	**10**	Careful management of all patient queries, with close working between the Fertility project team, the CCG Enquiries team and the CCG complaints team. Ongoing monitoring of volume and type of patient queries. Utilisation of agreed communications issued by Homerton as part of responding to individual patient queries. Clear messaging to differentiate these changes from the launch of the Policy will be maintained.
R10	There is a risk that the outcome of the Judicial Review in Frimley ICS for the provision of assisted conception treatments for same sex female couples may necessitate change in the NCL fertility policy, potentially with significant financial implications.	**10**	Ongoing monitoring for the outcomes of the Frimley case. Should any outcome be deemed to impact the NCL fertility policy, a mini action plan will be established, legal advice sought and discussion with finance and other colleagues.
R12	There is a risk there may be delays to the “go-live” of the Policy due to providers reporting that they are unable to complete their preparation activities within the required timescales.	**8**	Collaborative working with Providers and support in place for Policy implementation. Readiness checklist to be prepared. Weekly Working Group meetings to review implementation plan.

7. Other fertility related matters

Aside from the development of the NCL Fertility Policy, two recent changes affecting fertility services have occurred and are shared with S&C Committee for information.

7.1. Changes to referral pathway arrangements

As of mid-April, and with immediate effect, we have removed the legacy arrangements that were in place that restricted the providers that patients from different boroughs could go to for specialist fertility treatments, e.g. Camden patients could go to UCLH or Imperial, Barnet patients could only receive treatment at Guy's and St Thomas'.

No contractual or other legacy documentation could be confirmed for these arrangements, and feedback received during the Fertility Policies Review from both patients and clinicians requested that a review of these arrangements be considered.

The CCG was receiving an increasing number of enquiries testing the rationale for these arrangements, and given NHS guidance on patient choice, we confirmed with our legal advisors that the current situation was indefensible and that the restrictions should be removed.

Given the short time frame required to implement this change, it was agreed to sight the Chair of the S&C Committee (Jo Sauvage) and the Chair of the Audit Committee (Karen Trew) on the proposal and action plan to enact the changes. They were supportive and the team has undertaken communications activities as part of this change.

Therefore, any NCL resident who is being referred for specialist fertility treatments may be referred to any NHS-commissioned provider of such services. We will need to continue to monitor this situation and consider any unintended consequences as a result of the change, e.g. such as the choice of patients to be referred to private providers[9]. Some internal administrative processes may be required to be established as a result of this change.

7.2. Operational challenges at the Homerton fertility service

Homerton University Hospitals NHS Trust have recently confirmed that their fertility service has experienced some extraordinary and unforeseen operational challenges, including shortages of staff. The Trust has secured capacity at Imperial College Healthcare NHS Trust and Barts Health NHS Trust and will be writing to all patients about the situation and to discuss with them their options to start or continue with their treatment.

We have received the communications materials that the Homerton have released (with oversight from NEL CCG) and we will use consistent messaging to respond to NCL patients who are getting in touch with us about this situation. NCL residents will also have the option to request to be transferred to another provider, as per NHS guidance on patient choice, if they have waited over 18 weeks since referral.

We will continue to monitor the situation. We are ensuring that close collaboration is occurring with links between the NCL and NEL Quality Teams and the NCL and NEL contracting teams.

8. Next steps and Conclusion

The next steps will be focused on the implementation activities required to support the launch of the NCL Fertility Policy as set out in section 6.

As has been documented, the CCG (and subsequently the ICB) will need to work with provider partners across the NCL Integrated Care System (ICS) to plan and support the necessary activities to allow the implementation of the proposal to fund donor gametes for patients eligible for NHS funded specialist fertility treatments.

[9] Patient choice applies to private providers as long as the provider has an NHS contract with an NHS organisation – it does not necessarily have to be with NCL CCG

It is also noted that as a result of feedback received during engagement (from both stages of the programme) and through overall programme of work, further work will need to be considered and potentially acted upon. However, it is important that this should happen as an ICS so that we can maximise the opportunities and benefits that this will bring, and also in conjunction with a review of all the priorities for the ICB and the ICS. Potential areas for consideration include:

- Monitoring and review of impact of the NCL Fertility Policy – on patient experience, outcomes, activity and expenditure and patient flows
- Further development of pathways and associated provider models / arrangements, particularly in response to maintaining and improving high quality of service provision alongside the increased cost pressures expected as a result of the NCL Fertility Policy

The Strategy & Commissioning Committee is asked to **approve:**

- The NCL Fertility Policy
- The approach and plans for the implementation of the NCL Fertility Policy

The Committee is further requested to **note:**

- The Equality Impact Assessment and Quality Impact Assessment on the NCL Fertility Policy
- The financial implications associated with the NCL Fertility Policy
- The changes to referral pathway arrangements for NCL patients eligible for specialist fertility treatments and the current operational status of fertility services at the Homerton.

North Central London Clinical Commissioning Group

EQUALITY ANALYSIS
(Equality Impact Assessment)

Service/Policy title	**NCL Fertility Policy**
Service/Policy type	**Clinical Policy**
Author	**Penny Mitchell**
Lead Director	**Penny Mitchell**
Email	**penny.mitchell3@nhs.net**
Date approved	**May 2022**
Review date	**May 2024 (or earlier if the policy is updated before this date)**

Before completing the Equality Analysis (EQIA) please read the guidance on the intranet.

For further help and advice please contact Emdad Haque at emdad.haque@nhs.net
Tel: 07753836900

Brief description of the policy/service

Please provide only a brief description covering what this policy/service aims to achieve and which groups it will benefit.

North Central London Clinical Commissioning Group (NCL CCG) was formed in April 2020, with the merger of the five North Central London CCGs: Barnet, Camden, Enfield, Haringey and Islington. Each borough had its own fertility policy and with the formation of a single clinical commissioning group, NCL CCG has been working to develop a new, single policy, which will cover all five boroughs. North Central London has a population of over 1.5m residents. The population is relatively young with Camden, Haringey and Islington having more adults under the age of 30 than other NCL areas. Haringey, Islington and Enfield have on average, higher rates of deprivation compared to London, although pockets of deprivation are dispersed across NCL. More than half of NCL residents are White, with around 20% Asian and 20% Black. Barnet and Camden have larger Asian communities, whereas Haringey and Enfield have larger Black communities.

It is estimated that infertility affects about one in seven heterosexual couples in the UK. About 84% of couples will conceive naturally within a year if they have regular unprotected sex (every 2 or 3 days). NHS fertility treatment is available for eligible individuals and couples who want to become parents but who have a possible pathological problem (physical or psychological) leading to them being infertile. Not all patients who have fertility problems will require assisted conception treatments such as in vitro fertilisation (IVF). In NCL, an estimated 700 people receive NHS funded IVF each year.

The NCL fertility policy covers a small group of specialised treatments, including In Vitro Fertilisation (IVF), Intra Uterine Insemination (IUI) and fertility preservation, which may be used to support people who are experiencing some fertility problems. The NCL fertility policy sets out the criteria that NCL GP registered patients must meet, in order to access assisted conception treatments funded by NCL CCG. The eligibility criteria outlined in the NCL fertility policy document only apply to assisted conception treatments. Patients do not have to meet the eligibility criteria outlined in the policy to access NHS funded investigations or other medical or surgical treatment for fertility problems.

The CCG has a statutory duty to maintain financial balance, which means that it must make judgements about the affordability of any proposed service for local patients. In developing this policy, the CCG's starting point has been to consider the relevant NICE guidance. However, the need to balance service access demands with affordability has meant that in some sections the policy may vary from the full recommendations made by NICE.

Engagement with patients and stakeholders

Please provide a brief summary about engagement with patients, clinical leads, voluntary organisations Healthwatch- and the outcomes. If no engagement has been carried out then please explain why.

To develop a single Fertility Policy for the residents across North Central London the CCG broke the policy development into 2 stages.

Stage 1: Fertility Policies Review
The first stage was referred to as the NCL CCG Fertilities Policy Review. No decisions were taken at this stage, but a set of recommendations were developed and helped steer the work that was undertaken in the second stage. You can view the Recommendations Report here and the Public Engagement Report here.

During stage 1 a Steering Group has formed to lead the NCL CCG Fertility Policies Review. The Group has a clinical Chair, and its membership includes other clinicians, commissioners and two Community Members (a local resident and a representative from the Fertility Network UK). We sought the views of local NHS specialists and clinicians (e.g. GPs), residents and fertility service users, local Healthwatch and a range of other organisations in each borough.
The Review looked as:

- Latest scientific literature, clinical evidence and best practice
- National and regional guidance, and other CCG policies
- North Central London data – estimated number of patients experiencing fertility problems and accessing fertility treatments, types of treatments accessed, outcomes data for the clinics used by our populations, expenditure by the CCG
- The potential impact of changing policies for residents in our boroughs, especially for protected characteristics groups (defined by the Equality Act 2010).

Stage 2: Fertility Policy Development
Following the completion of stage 1, a draft NCL Fertility Policy was developed, utilising the Recommendations from Stage 1.

NCL CCG undertook engagement on the draft policy between 22 November 2021 and 13 February 2022 (12 weeks) to seek views from patients, residents, clinicians, voluntary and community groups, fertility groups and other audiences. The Fertility Policy Engagement Report provides an in-depth analysis of the qualitative and quantitative insights captured during the engagement.

A range of steps were taken to promote the engagement period, focused on directing people to the online survey or to attending events as the main way to give feedback. During the engagement period, the engagement website and hosted materials had over 2,258 page views and 1,988 documents downloaded.

A range of approaches were taken to reach out to groups and individuals from different ethnic backgrounds and communities across our five boroughs. It should be noted that the engagement took place during the COVID-19 pandemic, which restricted engagement interactions to online and telephone methods. This regrettably resulted in moving a public meeting that was planned to be held in person to be transferred to an online meeting. It is important to note that we received no negative feedback for taking this decision.

Wherever possible mitigations were put in place to enable and encourage people to take part; for example, by working with VCS groups to reach ethnic minority communities whose first languages are not English, and by providing interpreting support (Arabic & Somali) at online events.

To support and review our approach during the engagement window the Fertility Policy Development (FPD) team reported and sought advice from three fora (FPD Steering Group, NCL Community Member Readers Panel and Local Healthwatch Groups). In summary:

Fertility Policy Development (FPD) Steering Group
The membership of the Steering Group included two Community Members, one representative from Fertility Network UK and one resident (who has a role with the CCG on our Patient and Public Engagement Committee). The Community Members provided advice on our communications and engagement approach and advocated for residents and

services users during Steering Group discussions, including reviewing engagement findings throughout the engagement window.

NCL Community Member Readers Panel
Six CCG Community Members (one from each of the five boroughs in NCL and our resident Community Member on the Steering Group), were invited to form a Readers Panel, assisting the CCG in testing the communication and engagement materials (including the survey). They also reviewed the draft policy for it's' readability prior to the start of engagement. The Readers Panel will be involved in developing our plans to promote the final policy, once implemented, to ensure wide awareness and understanding of the policy across the diverse communities in NCL.

Meetings with local Healthwatch groups during the engagement period
We held regular meetings with local Healthwatch groups throughout the engagement period, to share emerging themes from the feedback and seek feedback on areas of focus / 'gaps' to tailor our engagement activity

In relation to who responded: we received 439 responses during the engagement window, held 21 engagement meetings, 108 people responded to the survey (28% were current or previous service users and 48% were members of the public). The profile (where people disclosed the information) of the people who gave us feedback during the engagement window was as follows:

- 56% of the public respondents were White British and 25% were from Black and other minority ethnic groups
- 13% of survey respondents had a disability
- 27% of survey respondents were aged between 25-34 and 33% between 35-44 and
- 17% of public respondents identified as Gay, Lesbian, Bisexual or other gender

Overall, there was a high level of support for the policy (68% of survey respondents and the majority of people who attended the public meetings (more than 80%)), with respondents seeing the draft policy as an improvement with recognition that its implementation would increase provision, standardise what is provided across the five boroughs and bring services offered more in line with NICE guidelines.

An extremely wide range of comments were provided through responses to the survey and in public meetings, across almost all aspects of the policy. Whilst the majority of responses received were in support of the draft policy, there were three areas that received the highest number of consistent comments, related to specific aspects of the draft policy:

- **Eligibility criteria should be reviewed** in the following areas: upper age limits of the woman, ovarian reserve and potentially removing criteria around previous IVF, BMI and previous children.
- It was strongly felt that **female same sex couples and single women should not have to self-fund intrauterine insemination (IUI)** prior to NHS treatment.
- Further consideration to providing assisted conception treatments for those seeking to use **surrogates**.

Impact analysis

This section should be used to analyse the likely impact of the policy/service on protected and disadvantaged groups. It should be noted that the CCG's default policy intent is to maximise opportunity (positive impact) for all groups by removing barriers so that they can access the service they need and enjoy good outcomes.

We note that due to the very individual and personal nature of undergoing fertility treatments, the impact of different elements of the NCL Fertility Policy will vary according to the individual situation. We recognise that this may be complex. Therefore, there are areas in this EIA that identifies multiple likely impacts for any given protected characteristic, e.g. an impact of an element of the NCL Fertility Policy may have a positive impact for some people depending on their individual situation, but for others it may be deemed as either neutral or negative. The rationale for these different impacts is included in the EIA.

<table>
<tr><th>Protected Group/Strands</th><th>Level of impact
Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.</th><th>Likely impact
See the keys at the end of the form</th><th>Recommendation /mitigating action
Please reference by entering the number from the list on the next page.</th></tr>
<tr><td>Age</td><td>ONS data indicates there are an estimated 386,500 women aged between 18–51 registered to a NCL GP (see table below).
ONS 2020 mid-year population estimates: Women registered to a NCL GP
<table>
<tr><th>Age range</th><th>Number of NCL women</th></tr>
<tr><td>18–39</td><td>263,300</td></tr>
<tr><td>40–42</td><td>32,900</td></tr>
<tr><td>43–51</td><td>90,300</td></tr>
</table>
N.B. the above details female population estimates by age not those who may require assisted conception treatment. The average age of menopause for women in the UK is 51.</td><td>Positive/ Neutral/ Negative</td><td>The NCL fertility policy includes age thresholds for the following reasons:
NICE CG 156 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 NCL fertility policy is consistent with this.
NICE CG 156 recommends 3 full IVF cycles for women aged under 40 and 1 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 NCL fertility policy specifies the same number of fresh cycles available to patients aged</td></tr>
</table>

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<tr><td></td><td>Success rates for fertility treatments decrease as women age (with the exception of IVF using donor eggs) – see Table of most recently published HFEA data below[10].

HFEA reported IVF birth rates per embryo transferred, 2019<table><tr><td>Age range</td><td><35</td><td>35–37</td><td>38–39</td><td>40–42</td><td>43–44</td><td>45–50</td></tr><tr><td>Birth rate</td><td>32%</td><td>25%</td><td>19%</td><td>11%</td><td>5%</td><td>4%</td></tr></table>The NCL fertility policy specifies that in order to be eligible for NHS funded assisted conception treatments (ACT), the woman or person trying to conceive should be aged under 43. Where the woman or person trying to conceive is aged under 40, up to 6 embryo transfer procedures from a maximum of 3 fresh IVF cycles are funded. Where the woman or person trying to conceive is aged 40-42, up to 2 embryo transfer procedures from 1 fresh IVF cycle is funded. Those aged 43 and over will not have NHS funded ACT available to them.
The NCL fertility policy will have a positive impact for patients aged under 40, with an increased level of IVF provision for residents from 4 out of 5 boroughs. There is no decrease in IVF provision for patients aged under 40. The impact of the policy may be considered neutral or negative to patients aged 40-42 who have some provision (remains the same as per existing policies, although less than under 40s). It may also be considered neutral or negative to those aged 43 as although they have no IVF available to them, treatment is unlikely to be successful at this age, as outlined above. The policy position for women aged over 43 is consistent with existing provision.</td><td></td><td>under 40 and aged 40–42 as NICE CG156 recommends.
• HFEA data on all fertility treatments undertaken in the UK shows the success rates decrease as the woman's age increases for IVF and other ACT including donor insemination, IUI and IVF using thawed eggs. The NCL fertility policy focuses resources on patients most likely to have a successful outcome as reported in HFEA data.
Recommendation / mitigating action (1)</td></tr>
<tr><td></td><td>Fertility clinics were closed to most patients for periods of time during 2020 and 2021 due to the COVID-19 pandemic. This has led to delays in accessing NHS funded assisted conception treatment for some</td><td>Negative</td><td>The rationale for the age criterion included in the NCL fertility policy is outlined in the row above.</td></tr>
</table>

[10] HFEA data

<table>
<tr><th>Protected Group/Strands</th><th>Level of impact
Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. <u>If the policy/service is not relevant to a group/strand then say 'N/R'.</u></th><th>Likely impact
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<tr><td></td><td>patients. Older patients may be eligible for less IVF cycles or may no longer be eligible for assisted conception treatments if they have surpassed the age criteria during this delay.
The NCL fertility policy does not allow for exemptions to the age criterion for patients who exceed the age limits due to delays in accessing treatment. Receiving no or less treatment would be considered a negative impact for this patient group.</td><td></td><td></td></tr>
<tr><td></td><td>The legacy NCL CCG policies state that in order for heterosexual couples to be eligible for NHS funded IVF, women aged under 36 should try to conceive for 2 years and women aged 36 and over should try to conceive for 1 year. The NCL fertility policy is aligned to NICE CG156 recommendations in specifying that patients of all ages must try to conceive through 2 years of regular unprotected intercourse*.
NICE noted data from Dunson (2004) when making their recommendations; this shows an additional 6-8% of women trying to conceive will do so in the second year of trying – see table below.
Percentage of women who will get pregnant after trying to conceive through intercourse, by age (Dunston, 2004)
<table>
<tr><th>Age (years)</th><th>Pregnant after 1 year</th><th>Pregnant after 2 years</th></tr>
<tr><td>19-26</td><td>92%</td><td>98%</td></tr>
<tr><td>27-29</td><td>87%</td><td>95%</td></tr>
<tr><td>30-34</td><td>86%</td><td>94%</td></tr>
<tr><td>35-39</td><td>82%</td><td>90%</td></tr>
</table>
The NCL fertility policy may be considered negative for patients aged 36 and over who now must try to conceive for 2 years prior to IVF because IVF becomes less successful as patients get older, and some patients may surpass the upper age threshold for access to NHS funded IVF in the second year of trying to conceive. However, the data above indicates 8% of patients aged 35–39 trying to conceive will do</td><td>Positive/ Negative</td><td>The NCL fertility policy requires patients of all ages to try to conceive for two years for the following reasons:
NICE CG156 indicates that in order to be eligible for IVF, [unless investigations show no chance of pregnancy with expectant management] heterosexual women should have unsuccessfully been trying to conceive for 2 years. NICE specifies that this criterion applies both to women aged under 40 and those aged 40–42. NICE have undertaken cost effectiveness analysis to determine in what circumstances IVF is cost effective and have based their recommendations on the results of this.
Reducing the duration of time trying to conceive may mean women who would have otherwise conceived naturally are undergo unnecessary IVF.
Recommendation / mitigating action (1)</td></tr>
</table>

Protected Group/Strands	Level of impact Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	so in the second year of trying, thereby avoiding unnecessary IVF; the new policy would lead to a positive impact for this group of patients. **The exception is where investigations show IVF is the only treatment option; in these cases patients can be referred directly for IVF.*		
	The legacy NCL CCGs' fertility policies stated storage of cryopreserved sperm, eggs or embryos for fertility preservation patients* would be funded for either 5 or 10 years. The new NCL fertility policy states storage of cryopreserved sperm, eggs or embryos for fertility preservation is funded for a minimum of 10 years for all patients and at least up until the patient's 43rd birthday**. The new 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. **Patients who have a condition or require treatment that is likely to cause fertility problems in the future (e.g., some chemotherapy treatments for cancer) and therefore cryopreserve their sperm, eggs or embryos is required.* ***NHS funding will cease sooner in some circumstances (where the patient no longer meets eligibility for NHS fertility treatment, or the patient dies and no writing consent has been left permitting posthumous use).*	Positive	Younger fertility preservation patients may not be ready to start a family within 10 years of having their sperm, eggs or embryos cryopreserved. The new policy takes account of this by funding storage until at least until their 43rd birthday. This upper age limit is consistent with the NCL fertility policy upper age limit criteria for assisted conception treatments for patients with fertility problems.
Disability	Based on the 2011 Census, 8.6% of men and 9.3% of women in London have an illness or disability that limited a lot of their daily activities. The NCL fertility policy specifies that up to 6 cycles of IUI using partner sperm is funded for people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem if they have not conceived after 6 cycles of self-funded IUI. These patients would also	Positive/ Negative	The NCL fertility policy is broadly consistent with NICE CG156 recommendations. The NICE CG156 full guideline states that people who are unable to, or would find it very difficult to, have vaginal intercourse (such as people with a clinically diagnosed disability or psychosexual problem) should have the same criteria apply as same sex couples. See below in the 'sexual

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	be eligible for IVF if they undergo a total of 12 unsuccessful IUI cycles*. The NCL fertility policy may have a positive impact on patients with disability/ psychosexual problem because it specifies IUI and IVF is funded for these patient groups. 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 6 self-funded IUI cycles. **If investigations show IVF is the only effective treatment option, patients would not be required to undergo IUI prior to receiving IVF treatment. This would include cases where the nature of the patient's disability/ psychosexual problem means they would require IVF to conceive.*		orientation' section of this document detailed rationale for the NICE decision on same sex couples. Recommendation / mitigating action (1)
	In 2018, Public Health England estimated that the prevalence rate for HIV was 5.7 per 1,000 people in London. This equates to an estimated 1,778 men aged 18-42 in NCL who are living with HIV. The NCL fertility policy is consistent with NICE CG156 in specifying sperm washing is funded for eligible people who are living with HIV where they are either non-adherent with antiretroviral treatment of have an HIV viral load of 50 copies/ml or greater. Provision of sperm washing for the above cohort of people living with HIV may have a positive impact for this patient group. Sperm washing is not funded for people with undetectable viral load but who are still anxious about transmission. Although this may be considered a negative impact by patients, local specialists feel NHS funding of sperm washing is not appropriate for this group as it contradicts the important U=U message (undetectable = untransmittable). Furthermore, conception rates are higher through unprotected intercourse compared to sperm washing and ACT so funding sperm washing for this indication could be doing patients a	Positive/ Neutral/ Negative	The NCL 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. Local HIV specialists do not feel sperm washing should be funded on the NHS for patients with undetectable viral load who are still anxious about transmission, for reasons outlined in the column to the left. Recommendation / mitigating action (1)

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	disservice. The impact of not funding sperm washing for this patient group may therefore be considered neutral.		
	Data from Public Health England Cancer Registry indicates around 1,900 NCL women and 1,500 NCL men aged 15-44 are likely to be diagnosed each year with cancer; a proportion of these patients are likely to be treated with a potentially gonadotoxic treatment however it is not possible to accurately quantify this. The NCL fertility policy specifies that fertility preservation interventions (cryopreservation of sperm, eggs and embryos) are 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. This would apply to eligible patients with conditions including cancer. This policy has a positive impact on this patient group.	Positive	The NCL fertility policy is broadly consistent with NICE CG156 recommendations in relation to funding fertility preservation for patients due to undergo a gonadotoxic treatment. Recommendation / mitigating action (1)
	The NCL fertility policy states that assisted conception treatments involving surrogates are not routinely funded by NCL CCG. This would 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.	Negative	The NCL fertility policy states that ACT involving surrogates is not funded for the following reasons: • 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. • 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.

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			As with all other interventions not routinely funded, an IFR application may be submitted by the treating clinician for any situation where they believe the case is clinically exceptional or rare.
	Disabled patients have differential information and communication needs than non-disabled people. Disabled people must be provided with accessible information and appropriate communication support when accessing and receiving the service.	Positive/ Unknown	Services must meet the Accessible Information Standard requirement

Gender	NCL Demographics (April 2019/20) estimate population of 809,362 males (49%) and 838,675 females (51%). Some of the eligibility criteria specified in the NCL fertility policy only apply to women, and not men; these are outlined below: • Women must be aged under 43 in order to access NHS funded ACT. Although this criterion means women 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 – see also 'age' section of this document above. • Treatment will not be funded for women aged under 40 years if 3 fresh IVF cycles have been previously received. Treatment will not be funded for women aged 40-42 years if any previous IVF has been received. These criteria may be considered a negative impact for women 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. • Women 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 women who have a BMI outside of this range; however, BMI outside this range are likely to reduce the success of assisted reproduction procedures so the impact for some may be neutral.	Neutral/ Negative	The NCL fertility policy specifies some eligibility criteria apply to women but not men for the following reasons: • The upper age limit for women 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 of this document. • The 'previous cycle' criteria are consistent with NICE CG156 recommendations; NICE make no equivalent recommendation for men. These criteria are in place because the likelihood of a live birth decreases with the number of unsuccessful IVF cycles undertaken. NICE have undertaken cost effectiveness analysis to determine in what circumstances IVF is cost effective and have based their recommendations on the results of this. • NICE CG156 specifies women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female 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. The criteria are in place because a female BMI outside this range is likely to reduce the success of assisted conception treatments. Local specialists support inclusion of the BMI criterion for women outlined in the policy. The CCG considered the research literature on the impact of male BMI on the outcome of fertility treatment. Although there appears to be an association between male BMI and the outcome of fertility treatments, the impact does not appear to be sufficient to include this as an eligibility criterion. Neither NICE CG156, nor the HFEA commissioning guide recommend a BMI criterion for men. Recommendation / mitigating action (1)

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Gender reassignment	NHS admissions data indicates that in 2018/19, just under 100 NCL patients were admitted to secondary care with a primary diagnosis of gender dysphoria. The NCL fertility policy states that eligible patients who are due to undergo a gonadotoxic treatment, including patients undergoing interventions for gender reassignment, 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.	Positive	The NCL fertility policy is consistent with NHS England and NHS Improvement guidance for CCGs on formation of clinical commissioning policies for fertility preservation 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 reassignment'
	The language used in the NCL fertility policy is gender neutral where possible and has taken account of trans and non-binary patients.	Positive	The language used in the NCL fertility policy has been reviewed by the NHS England/ Improvement National LGBT Project manager and the NCL CCG Readers Panel.
Marriage and civil partnership[11]	Not applicable.	-	-
Pregnancy and maternity	Not applicable.	-	-

[11] https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fbirthsdeathsandmarriages%2flivebirths%2fdatasets%2fbirthsbyparentscharacteristics%2f2019/parentscharacteristics2019121120201344 13.xls

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Race/ethnicity[12] [13]	Mid 2019 estimates NCL demography and diversity of have 63% White and 37% BAME.[14] The HFEA report on ethnic diversity in fertility treatment 2018 states: • Asian patients represented a larger proportion of IVF users at 14% of IVF patients in 2018 compared to 7% of the UK population • Black patients had lower IVF birth rates: for Black patients aged 30-34, the birth rate per embryo transferred was on average 23% compared to Mixed and White patients at 30% from 2014-2018. • 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. Local ethnicity data has not been available from providers to determine the pattern of activity and outcomes by ethnicity.	Neutral	When implementing the NCL fertility policy communications the CCG will ensure dissemination to relevant groups and support GPs in ensuring their local communities can access the relevant treatments and reduce inequalities in accessing services.

[12] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/parentscountryofbirthenglandandwales/2019
[13] https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fbirthsdeathsandmarriages%2flivebirths%2fdatasets%2fparentscountryofbirth%2f2019/parentscountryofbirth2019.xlsx
[14] https://intranet.northcentrallondonccg.nhs.uk/downloads/Governing%20Body/Meeting/Diversity%20%20Equality%20and%20Inclusion.pptx

Protected Group/Strands	Level of impact Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	Women must have a BMI within the range 19-30 kg/m^2 to access NHS funded ACT. The associations between ethnicity and BMI have been noted. For example, some cultures have different attitudes to BMI and some ethnic groups have increased health risks at lower BMIs than others. However, the BMI criteria specified in the NCL fertility policy are in line with national guidance published by NICE and the HFEA. This guidance does not specify different BMI thresholds for people of different ethnic groups. The impact of the BMI on people of different ethnicities is therefore considered to be neutral.	Neutral	NICE CG156 specifies women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female 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. The criteria are in place because female BMI outside this range are likely to reduce the success of assisted reproduction procedures. Local specialists support inclusion of the BMI criterion for women outlined in the policy. Recommendation / mitigating action (1)
Religion/belief	There are a number of religions that prohibit fertility treatments or aspects of fertility treatments. For example: Muslim patients may not accept donor gametes; Catholic patients may not wish to create embryos that risk being discarded; orthodox Jewish men may not have surgical sperm retrieval. The NCL fertility policy states 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 policy has a positive impact on this patient group.	Positive	Fertility clinics confirmed they are able to accommodate patients with religious beliefs (e.g. creating 1 embryo at a time, electro ejaculation for those not allowed to masturbate). As recommended in NICE CG156, the NCL fertility policy states IUI is funded as an alternative to IVF for patients who object to IVF on social, cultural or religious grounds. Recommendation / mitigating action (1)
Sexual orientation	People in same sex relationships who wish to have their own biological children will need assisted conception treatments to achieve this (donor insemination or assisted conception treatments involving surrogates). The HFEA report on family formations in fertility treatment reports that in 2018, 6.4% of fertility treatment undertaken in the UK was on	Positive/ Negative	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

Protected Group/Strands	Level of impact Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	patients in female same sex relationships. NHS-funded IVF cycles were more common for patients in heterosexual relationships (39%) compared to patients in female same-sex relationships (14%). The NCL fertility policy specifies that up to 6 cycles of IUI using donor sperm is funded for same sex couples, single people or other couples trying to conceive using donor insemination who have not conceived after 6 cycles of self-funded IUI. These patients would also be eligible for IVF if they undergo a total of 12 unsuccessful IUI cycles*. The NCL fertility policy may have a positive impact on same sex couples because it specifies IUI and IVF is funded for these patient groups. 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 6 self-funded IUI cycles. **If investigations show IVF is the only effective treatment option, patients would not be required to undergo IUI prior to receiving IVF treatment.*		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 6 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 NCL 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 6 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 NCL 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

Protected Group/Strands	Level of impact Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
			• 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 mother's partner (if she has one) will be recognised as the second legal parent • The Clinical Reference Group is supportive of this requirement
	People in same sex relationships who wish to have their own biological children will need fertility treatment to achieve this (donor insemination or assisted conception treatments involving surrogates). The NCL fertility policy states that assisted conception treatments involving surrogates are not routinely funded by NCL CCG. This would have a negative impact on male same sex couples and other couples requiring a surrogate to carry a pregnancy.	Negative	The NCL fertility policy states that ACT involving surrogates is not funded for the following reasons: • 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. • 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

Protected Group/Strands	Level of impact Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
			disagreeing whether a pregnancy should continue if complications arise. • There is no national guidance on NHS funding of ACT involving surrogates. • As with all other interventions not routinely funded, an IFR application may be submitted by the treating clinician for any situation where they believe the case is clinically exceptional or rare. Recommendation / mitigating action (1)
Disadvantaged groups [homeless, unemployed, single parents, asylum seekers, victim of domestic violence]	Not applicable		
Human Rights [how the policy/service will impact Human Rights of patients]	The policy intends to provide equity for patients that qualify for the treatment, regardless of their race, religion/belief or disability. The criteria have been set based on expert advice, and they must be applied equally without prejudice.	Neutral	A person centered approach from referral to treatment for fair and equitable access, experience and outcomes.

Recommendations/mitigating actions

No	Recommendation/mitigating action	Which protected group/ strand does this cover	Lead Person and Organisation	Deadline/ Review date
1	Across the country most, if not all, CCGs have a set of fertility policies addressing funding of assisted conception treatments such as in vitro fertilisation (IVF) and intrauterine insemination (IUI). The CCG has a statutory duty to maintain financial balance, which means that it must make judgements about the affordability of any proposed service for local patients. In developing this policy, the CCG's starting point has been to consider the relevant NICE guidance.	Age, Disability, Gender, Race/Ethnicity, Religion/Belief, Sexual orientation	NCL CCG	October 2024
2	This policy cannot anticipate every possible individual clinical presentation. Clinicians may submit Individual Funding Requests for patients who they consider to have exceptional clinical circumstances and whose needs are not fully addressed by this policy. The CCG will consider such requests in accordance with its policy on Individual Funding Requests.	All (where relevant as per case by case basis).	Individual Funding Request Panel	October 2024

Please send a copy of the EqIA with the original business case or policy for review to Emdad Haque at emdad.haque@nhs.net

Keys explaining the impact-

- Positive- Evidence including the policy/service objectives indicate that this protected group/strand will benefit equally like their counterparts. It should be noted that the default policy intent of the CCG is to maximise opportunity for all groups.
- Negative- Evidence including the policy/service objectives indicate that this protected group/strand may not benefit and experience disadvantage compared to their counterparts.
- Positive/unknown- The policy/service intent is clear about the equality in access and outcomes in its objectives/goals – and evidence is required to demonstrate the actual positive impact.
- Negative/unknown- There is no hard evidence of likely negative impact but anecdotes and engagement outcomes suggest the likelihood of negative impact.
- Not relevant- The policy/service is not relevant to equality or this protected group/strand. The general rule of thumb is that all patient facing services are equality relevant.

Appendix 1: Core Engagement Methods

- Review Questionnaire (hard copy available upon request, easy read version also available on request).
- Online version hosted on our website
- Shared with our key stakeholder database, which included Healthwatches, VCS groups, special interest groups, local authorities and local hospital

NCL CCG was committed to being flexible in how we heard from residents, service users and groups, and welcomed conversations as well as the opportunity to attend existing events and meetings to discuss the development of the draft policy. Written comments were welcomed and processed through a single document management system and a consistent analysis framework. As a result of the ongoing COVID-19 pandemic, engagement activities were undertaken through a digital first approach, ensuring engagement was as accessible and safe as possible. To support in reducing digital exclusion, options were provided to ensure accessibility for those without access to/ knowledge of digital devices and technology. The core engagement methods implemented by the CCG were:

Survey

- Online version hosted on our public and GP websites
- Shared with our key stakeholder database, which included Healthwatches, VCS groups, special interest groups, local authorities and local hospital patient/membership groups.
- Distributed to the North Central London Residents Panel – a group of nearly 1,000 local residents with an interest in health and care services
- Distributed via Nextdoor (online neighbourhood network) with impressions across North Central London residents timelines.
- Promoted via CCG public channels, notably social media, newsletters (to the wider NCL system and also our residents newsletter), news articles on our public-facing website and our intranet (recognising that our staff may wish to share their views).
- Information was shared by Provider organisations (not only those part of the North Central London health and care system, but also those out of area who provide fertility services to our population)
- Healthwatches, local VCS, local authorities and other key partners through the Development period.
- Shared with local general practice teams (both GPs and via Practice Managers and PPG Groups) across our boroughs via NCL CCG GP website and newsletter.

Public and service user-focused activity

- Seven open-access online events were held for members of the public. These events were spread throughout the engagement period and were run at different times of the day, with one held at the weekend in order to allow the greatest accessibility for attendees with differing responsibilities.
- A focus group supported and chaired by a representative from Fertility Network UK (FNUK) with residents who had lived experience attending as well as representatives from the Donor Conception Network and CHANA (Leading fertility support organisation for the Jewish community).
- Attending local LGBTQI+ community meetings.
- Attended meetings with PPG representatives and promoted opportunities to get involved.
- Hosting a public meeting in collaboration with an NCL Community Member, which welcomed people from local ethnic minority communities whose country of origin was not the UK.

- Outreach via fertility group social media channels (e.g. FNUK and The LGBT Mummies Tribe), including a pre-recorded YouTube Podcast).
- A pre-recorded question and answer session with the Fertility Policy Development Clinical Responsible Officer and Programme Director, which were shared on the CCG's YouTube channel and via Instagram, Facebook, and Twitter.

Wider stakeholder-focused activity

- Scheduled meetings with local Healthwatch groups to discuss engagement activity and feedback received.
- Meetings with local organisations, including online groups, discussion sessions with groups, attending/presenting at meetings organised by others, such as Haringey LGBTQI+ Network, Camden Parents Forum, Enfield Saheli, and local community group network meetings.
- Information shared with our communications counterparts in local authorities and Trusts
- Information shared and discussed with North Central London Joint Health Overview Scrutiny Committee and North Central London Clinical Advisory Group (CAG).
- Information shared with NHS provider – Chief Officers, Medical Directors, Head of Fertility Units and Fertility Clinical and Non-Clinical staff.

How was the engagement period promoted?

A range of steps were taken to promote the engagement period, focused on directing people to the online survey or to attending events as the main way to give structured feedback.

- Website – The engagement website1 hosted key materials, available in a number of formats, including:
  - Patient leaflet
  - Easy read patient leaflet (including an easy read version of the survey)
  - Link to the online survey
- Key supporting documents including; the draft NCL policy, current individual borough policies, equalities impact assessment and frequently asked questions

During the engagement period, the engagement website and hosted materials had over 2,258 page views and 1,988 documents downloaded. See below for a breakdown of the number of times each document has been download.

Document downloaded	Number of occasions
Draft Fertility Policy	89
Draft Fertility Policy Equality Impact Assessment	74
Barnet Fertility Policy	270
Camden Fertility Policy	355
Enfield Fertility Policy	251
Haringey Fertility Policy	264
Islington Fertility Policy	234
Recommendations report	70
Stage 1 Engagement report	68
Stage 2 Communication and Engagement strategy	58

Fertility Policy Development Patient Leaflet	64
Fertility Policy Development Slides	74
Easyread Patient Leaflet	54
Easyread Questionnaire	63

- Social media posts – on CCG Twitter, Youtube, Instagram and Facebook
- Mailing databases of voluntary and community organisations – these were reviewed and refreshed following stage 1 of the policy development and contacts were sent information about the engagement exercise to share with staff, service users, local residents, voluntary and community groups.
- Partner channels – content was provided for statutory and voluntary sector partners.
- Engagement with local/key community groups – Mailings, emails and phone calls proactively engaged more than 140 community groups or organisations to make them aware of the engagement exercise and help promote it within their networks. This included regular communications and materials to support promotion of the engagement exercise through their channels, e.g. newsletters, mailing lists, social media.
- Presentations at local/ key community groups – invited to make them aware of the engagement exercise and help them to promote it within their organisations and to their service users and members.
- Information was shared via the monthly NCL Residents' Newsletter and monthly NCL System Updates
- Partners and voluntary and community organisations were encouraged to retweet/ share posts made by NCL CCG.

Appendix 2 – Quality Impact Assessment

1. Could the initiative impact patients, public, staff or organisations positively or negatively against any of the 8 areas of quality below? Only provide a risk rating for areas of quality that you have identified potential negative impact. Positive impacts can be quantified in table 2.

Area of Quality	Impact question	Positive/Negative	Impact	Likelihood	Score	Full assessment required Yes /No
Duty of Quality	Could the proposal impact positively or negatively on any of the following – compliance with the NHS Constitution, partnerships, information governance, safeguarding children or adults and the duty to promote equality?	Positive				No
		Negative				
Patient Experience	Could the proposal impact positively or negatively on any of the following – positive survey results from patients, patient choice, personalised & compassionate care?	Positive	2	2	4	No
		Negative	1	1	1	
Patient Safety	Could the proposal impact positively or negatively on any of the following – safety, systems in place to safeguard patients to prevent harm, including infections?	Positive				No
		Negative				
Clinical Effectiveness	Could the proposal impact positively or negatively on evidence based practice, clinical leadership, clinical engagement and/or high quality standards?	Positive	1	1	1	No
		Negative				
Prevention	Could the proposal impact positively or negatively on promotion of self-care and health inequality?	Positive	1	1	1	No
		Negative				
Productivity and Innovation	Could the proposal impact positively or negatively on – the best setting to deliver best clinical and cost effective care; eliminating any resource inefficiencies; low carbon pathway; improved care pathway?	Positive				No
		Negative				
Vacancy Impact	Could the proposal impact positively or negatively as a result of staffing posts lost?	Positive				No
		Negative				
Resource Impact	Could this proposal impact positively or negatively with regard to estates, IT resource, community equipment service or other agencies or providers e.g. social care/voluntary sector/district nursing	Positive				No
		Negative				

What existing evidence (either presumed or otherwise) do you have to support positive impacts?
The single NCL fertility policy:
- provides improved provision of assisted conception treatments for the majority of eligble residents in NCL
- provides a single policy for all of NCL, thereby reducing variation across the boroughs (reducing likelihood of inequalities)
- is more closely aligned with NICE guidance, providing an evidence based approach for the full policy
- (compared to 4 out of 5 of the current policies) increases NHS funding for assisted conception treatments for some groups with protected characteristics (although noted not always to the full extent that some residents would like)
- is written to be as readable as possible, in culturally-comptent language

2. Positive quality impacts (Benefits)
The positive impact of the project on each of these areas should be considered and specific improvements documented in the table below.

If positive benefits are identified but 'How will we know if the quality improvement is happening' cannot be completed when Stage 1 QIA is documented then please indicate this in the table below. This can be identified when the PID and Service Specification are developed and documented here and transferred to the project workbooks. The proposed review date for this should be documented in the review date box below this table.

Quality area	Improvement identified	Rationale for improvement	How will we know if the quality improvement is happening (through a quality KPI e.g. patient outcome, patient feedback etc.)	Threshold (e.g. current achievement)	Trigger for escalation (when do we escalate if quality improvement is under threat)	Expected Impact Trajectory (e.g. when will the improvement be achieved)
Patient experience	- standardised provision for all residents in NCL - overall, increase in provision for all residents in NCL - well written, cultural competent document for residents to use	The new policy takes significant approaches in improving equality of access (single policy for NCL) Overall - level of provision of treatments has increased ((notably # cycles / embryo transfers allowed)	Patient feedback - GP survey / Family and friends test / secondary care surveys reduced number of complaints about variation in provision across NCL	Current achievement	Upon patient feedback	Jul-22
Clinical Effectiveness / Productivity & Innovation	- closer adherence to NICE guidelines (CG156) - policy has been developed with input of specialists, including a non-NCL specialist	Level of provision and eligibility criteria closer to evidence based guidance (NICE)	Patient feedback / Clinician feedback /Outcome measures (live birth rates etc.)	Current achievement	Upon patient feedback	Jul-22
Prevention	- single policy for NCL, thereby reducing variation and likelihood of potential for worsening inequalities of access for different communities in NCL - EIA completed. Where negative impacted for people with protected characteristics, rationale provided and/or mitigation detailed	Reduce inequalities of access	Patient/Public feedback. Clinician feedback. Reduced negative complaints and queries raised.	Current achievement	Upon patient feedback	Jul-22

3. Negative quality impacts (risks)

The negative impact of the project for each of these areas should be considered and actions to mitigate the risk documented in the table below. However, if you have identified negative impact / a risk score of 8 or more, please continue to Stage 2 below.

Quality area	Negative impact identified	What action will be taken to mitigate the risk(s) identified	When will the actions be completed?	Trigger for escalation and monitoring arrangements
Patient Experience	Due to the nature of this policy, eligibility criteria are identified that do restrict access to specialist fertility treatments. Some individuals may feel that these are unfair to their personal situation.	AN EIA has been completed, detailing where there may be negative impact for some protected characteristic groups. The EIA inclues a rationale for the provision / criteria in the policy (e.g. evidence base) and/or mitigating actions. Legal advice has been sought and utilised in the development of the policy.	Action completed. EIA to be included with final policy when approved by S&C Committee (due May 2022)	Monitoring for any query or complaint that is the start of a legal challenge or has a high likelihood of becoming a legal challenge will be escalated through governance channels.
Patient Experience	Not all interventions are funded, e.g. Surrogacy. Some interventions have limited funding, e.g. single women and female same sex couples must self-fund 6 cycles of IUI to determine whether they may have a fertility issue (assuming no previously known / identified pathological problem diagnosed)	AN EIA has been completed, detailing where there may be negative impact for some protected characteristic groups. The EIA inclues a rationale for the provision / criteria in the policy (e.g. evidence base) and/or mitigating actions. Legal advice has been sought and utilised in the development of the policy.	Action completed. EIA to be included with final policy when approved by S&C Committee (due May 2022)	Monitoring for any query or complaint that is the start of a legal challenge or has a high likelihood of becoming a legal challenge will be escalated through governance channels.

Have any adverse impacts been sufficiently mitigated to justify taking the project forward?

Yes
Please explain:

Significant consideration has been given to potential negative impacts of the policy on individuals and or groups/cohorts of people (including those with protected characteristics). The evidence base has been closely reviewed when developing the policy, legal advice has been sought, significant patient and wider stakeholder engagement undertaken and feedback considered and an EIA has been completed.

It is recommended that overall, the new single NCL fertility policy provides additional benefit for the vast majority of NCL residents who may need to make use of the policy.

Clinical Lead Signature  Date 06.04.22

Project Lead signature  Date 06.04.22

Appendix 3 – NCL Fertility Policy Implementation and Launch communications and engagement plan

NCL CCG fertility policy approval and implementation - communications and engagement plan
April-September 2022

Aims
- Ensure key stakeholders (resident, patient, VCSE, political and health professional audiences) are aware of the new policy
- Ensure key stakeholders are confident that a robust process was followed to produce a fair and evidence-based policy
- Support the smooth introduction of the new policy through implementation phase
- Support the CCG to prepare for and effectively manage any challenges

Phases
The plan covers the following phases:
4. Preparing for the approval and publication of the new policy (April-May)
5. Announcing the approval of the new policy and implementation phase (mid-May to end of June)
6. Announcing the go live of the new policy (Mid July)

The majority of activity will be focused in phases 1 and 2, to ensure wide awareness and support for the new policy and to support the smooth implementation of the new policy. The plan does not cover activity beyond the 'go live' announcement. If communications and engagement work is required beyond this point, capacity would need to be scoped and external / agency support may be required.

Key audiences
- Participants in phase 1 and 2 engagement periods
- Public, service users, VCSE, special interest groups, patient representative groups
- Secondary care / fertility service providers and Trust leadership, related community service providers (e.g. community gynae providers)
- Primary care teams
- Scrutiny colleagues
- Governing Body, CCG primary care leads, borough commissioning leads, wider CCG staff (incl. enquiries team)
- RSS teams

Key messages
To be developed in full as part of April/May policy launch preparation phase, tailored for different audiences. However, the key communications messages will include a focus on:
- Emphasising the positive impact the new policy will have for those requiring fertility support
- Communicating the robust, clinically-led and evidence based approach followed to produce the new policy
- Clearly demonstrating how the CCG listened, and responded to, stakeholder and resident feedback on designing the new policy

- Transparency on where feedback received through the engagement processes was not implemented in the new policy, and why
- Helping residents to understand how to access fertility support under the new policy (e.g. pathways)

Resourcing
The communications and engagement team will provide 0.4 WTE communications capacity to support the planning and implementation of the activity below. Once the full activity plan is scoped and agreed, it is likely that additional external / agency capacity will be required (in line with the capacity model for the FPD project to date). This will be costed in April 2022, for agreement (Note: we have £9,000 accrued under 21/22 invoice for CSU communications support)

If communications and engagement work is required beyond 'go live, this capacity would need to be scoped and external / agency support may be required.

Managing communications on wider fertility service issues
The CCG communications team will provide support on additional fertility service issues (change of patient choice provision, Homerton service issues), to minimise the risk of any confusion or conflation with the approval and implementation of the new NCL fertility policy.

Risks & mitigations

No.	Risk	Mitigations
1	Capacity to deliver the above communications and engagement activity is insufficient, leading to poorly coordination of approval, implementation and go live messages and stakeholder management	NEL CSU support to be secured for April – July.
2	Negative feedback / challenge received on the final approved policy, including feedback that themes received through engagement activity have not been responded to and/or that our policy does not adopt NICE guidelines in full.	• Early stakeholder engagement to manage message and identify any likely challenge early – including Healthwatches, HOSCs • Communications messaging to emphasise the significant improvements the policy represents for the majority of fertility service users • Communications materials to clearly demonstrate evidence base for final policy, and careful decision making process followed to finalise the policy • Reactive materials/FAQs in place to respond accurately and in a timely way to any challenges • Legal advice to be sought on communications materials
3	Clinical or public audiences misunderstand the phasing of approval, implementation and go live	• Early stakeholder communications (Trust, general practice, RSS etc.) to ensure clear understanding of different phases and timelines – and how to refer patients under correct policies.

		• Wider communications activity and messaging to provide clear, easy to understand information on when legacy policies will be replaced by new single policy
4	Patients previously or currently managed under a legacy policy are confused about how the new policy will affect their treatment or whether they will become eligible for additional treatment under the new policy	• Clear process agreed for managing patient enquiries • FAQs developed for most likely enquiries, with clinical and legal input.

Phase 1 – preparation for policy launch (April-May)

Comms activities

Timescales	Activity	Lead	Resource required
w/c 4 April	Identify comms materials required Confirm funding for CSU support to ensure sufficient resource available for delivery	Comms team	
w/c 4 April	Develop comms plan (including key messaging)	Comms team	• Comms lead – 2 days
w/c 4 April – w/c 2 May	Develop communication materials (using existing materials where possible), including: - FAQs - Reactive lines based on identified risks - Announcement letters - Internal and external content (web, bulletin copy etc.) - Social media assets (content planner, designed assets, video content) - Primary care comms materials (copy for the GP website, GP bulletin, practice managers bulletin, emails to RSSs) - Stakeholder toolkit for partner comms (e.g. Trusts, community service providers, local authorities, VCS)	Comms team	• Comms lead – 8 days • Design resource for assets • Videographer for filming
	Develop accessible materials (translations, policy summary, easy read, pathway visuals etc.)	Comms team	• Comms lead – 5 days • Design resource • Translation resource
	Engagement lead to support development of *You Said We Did* report section	Engagement lead	• Engagement lead – 2 days • Working Group
w/c 18 April – w/c 25 April	Test materials (in particular FAQ relating to service users currently in a pathway & those who previously accessed care under a legacy policy). Testing to include Readers Panel and SG Community Members	Comms team	• Comms lead – 2 days

w/c 2 May – w/c 9 May	As required, seek legal review of any specific FAQ / materials	Commissioning team	• Legal resource • Comms resource for any changes – 1 day
w/c 9 May	Readers panel meeting	Comms team	• Comms planning and attendance
Final sign-off in w/c 30 May	Sign-off on all comms materials	Commissioning team / comms team	• Commissioning team resource • Comms resource for any changes – 1 day

Engagement activities

Timescales	**Activity**	**Lead**	**Resource required**
w/c 2 May – w/c 23 May	Develop detailed list of stakeholders for early engagement and template stakeholder letter. Deliver early engagement to brief on upcoming policy change (Trust service leads, Borough MDT meetings, Healthwatches, JHOSC Chair) Includes attendance at June 2022 JHOSC.	Comms and commissioning team	• Comms lead – 2 days • Commissioning team – dissemination and conversations with CCG, Trust and JHOSC • Admin time to plan/ coordinate meetings / calls
w/c 2 May – w/c 23 May	Primary care engagement – briefing slots at PC borough events (e.g. practice managers forum, primary care forums, primary care facilitator meetings) Slot at Jo Sauvage Thursday webinar	Primary Care team and commissioning team	• Admin time to plan/ coordinate meetings / calls • Commissioning team time to attend

Phase 2 – policy approval & implementation planning (June)

Comms activities (once policy approved)

Timescales	**Activity**	**Lead**	**Resource required**
w/c 6 June	Finalise and prepare to launch and disseminate approval comms	Commissioning and comms	• Comms lead – 2 days • Commissioning team time to approve – and support some dissemination

w/c 13 June onwards	Publication of final policy and final policy report – including *You Said We Did* section to evidence how final decisions on the approved policy were taken & information on implementation plan and go live date	Comms team	• Admin time to upload
	Direct comms to those who participated in phase 1 and 2 engagement activity to share final policy and final policy report, with info on implementation	Comms team	• Admin time to facilitate dissemination
	Direct comms to Healthwatches, JHOSC and HOSC chairs	Comms team	• Admin time to facilitate dissemination
	Direct comms to Trust CEO, CMO and Service Heads	Commissioning team	• Admin time to facilitate dissemination
	Direct comms to RSS teams, commissioning staff, heads of primary care, general practices	Commissioning team & Primary care team	• Admin time to facilitate dissemination
	News item posted on website, intranet and GP website Proactive comms through internal and external channels (staff intranet/bulletin, external newsletters, social media)	Comms team	• Admin time to facilitate dissemination
	Promotion through stakeholder channels – bulletins, websites, social media, local authority magazines, trust comms / fertility providers	Comms team	• Admin time to facilitate dissemination
	Promotion through VCS channels – particularly different languages / formats	Comms team	• Admin time to facilitate dissemination

Engagement activities

Timescales	**Activity**	**Lead**	**Resource required**

w/c 13 June onwards	Primary care engagement – briefing slots at PC borough events (e.g. practice managers forum, primary care forums, primary care facilitator meetings) Slot at Jo Sauvage Thursday webinar Specific education events to inform primary care colleagues and raise awareness	Commissioning team & Primary Care team	• Admin time to coordinate meetings and write up any feedback • Commissioning team time to attend meetings and present
	Re-engaging with VCSE, fertility and other groups identified in EIA and those spoken to in phases 1 and 2 of engagement to feedback and raise awareness	Engagement lead	• Admin time to coordinate meetings and write up any feedback

Phase 3 – Go live communications (July)

Comms activities

Timescales	**Activity**	**Lead**	**Resource required**
Go live date	Legacy policies removed from website & website news item confirming new policy now live GP website updated – new text and new policy	Comms team	• Admin time to upload and test
	Primary care comms confirming new policy now live and publishing necessary referral documents, pushed out through primary care systems (e.g. EMIS, GP bulletin, Practice managers bulletin, RSSs, Community gynae providers)	Comms team / GP website team / Primary Care team	• Admin time to facilitate dissemination
	Provider comms confirming new policy now live		• Admin time to facilitate dissemination
	Go live comms through internal and external comms channels / stakeholder channels – including intranet.	Comms team	• Admin time to facilitate dissemination

Engagement activities

Timescales	**Activity**	**Lead**	**Resource required**
w/c 4July – August	Community engagement – raising awareness of the policy, where relevant, during ongoing engagement activities of the ICS	Engagement lead	N/A as links to BAU activities
w/c 4July – w/c 26 Sept	Primary care engagement – continuing to raise awareness of the policy and criteria through existing meetings	Primary Care team	N/A as links to BAU activities

Appendix 4 – NCL Fertility Policy – comparison with NICE, previous policies and rationale

Table 1 – Comparison of new single policy with NICE and previous policies: Interventions

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
1.	**IVF, with or without ICSI**			
1.1	In order to access IVF, with or without ICSI, that is routinely funded by the CCG, patients must meet relevant eligibility criteria set out in Section 9 of this document.	See Table 2.		
1.2a	For eligible patients requiring IVF where the woman or person trying to conceive is aged under 40, the CCG will fund up to six embryo transfer procedures from a maximum of three fresh IVF cycles… Once the patient has undergone six embryo transfer procedures, no further fresh IVF cycles or frozen embryo transfer cycles will be funded.	1.11.1.3 In women aged <40 years… offer 3 full cycles of IVF, with or without ICSI 1.11.1.2 A full cycle of IVF should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).	IVF for women aged <40 years: **Barnet:** 1 fresh + 1 frozen cycle funded **Camden:** 3 fresh + 3 frozen cycles funded **Enfield:** *As Barnet* **Haringey:** *As Barnet* **Islington:** 2 transfers funded	The NCL policy is aligned to NICE CG156 in funding up to three fresh IVF cycles for women aged under 40. The CCG has set the maximum number of embryo transfers to 6, which is in line with the current 'most generous' policy in Camden. Overall most residents in NCL will have the possibility of more IVF treatment if clinically appropriate. This level of provision has been carefully considered to balance alignment with NICE guidance alongside meeting the financial duties of the CCG.
1.2b	All good quality frozen embryos should be transferred before starting the next NHS funded fresh cycle.	*Not addressed in NICE CG156*	*Not addressed in current NCL policies*	Good quality frozen embryos should be used before progressing to the next fresh cycle because the former are less invasive (do not require ovarian stimulation and egg retrieval), have equivalent or higher birth rates (reported by HFEA data), and cost less than fresh cycles. Local specialists are supportive of this requirement.
1.3	For eligible patients requiring IVF where the woman or person trying to conceive is aged 40–42, the CCG will fund up to two embryo transfer procedures from one fresh IVF cycle.	1.11.1.4 In women aged 40–42 years… offer 1 full cycle of IVF, with or without ICSI 1.11.1.2 A full cycle of IVF should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).	IVF for women aged 40–42 years: **All NCL boroughs:** 1 fresh +1 frozen cycle funded	The NCL policy is aligned to NICE CG156 in funding one fresh IVF cycles for women aged 40–42. The CCG has set the maximum number of embryo transfers to 2. This level of provision has been carefully considered to balance alignment with NICE guidance and provision of IVF for women aged under 40, alongside meeting the financial duties of the CCG.
1.4	One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of commissioned cycles. However, further cycles will not be undertaken if not clinically appropriate.	NICE CG156: 1.11.1.8 Cancelled IVF cycle defined as one where an egg collection procedure is not undertaken. Cancelled cycles due to low ovarian reserve should be taken into	**Barnet:** First 2 abandoned/ cancelled cycles do not count towards establishing eligibility **Camden:** *As Barnet* **Enfield:** Abandoned/ cancelled cycles do not count towards establishing eligibility **Haringey:** *As Enfield*	The NCL policy is consistent with HFEA Commissioning Guide (CG). *NICE does not specify whether cancelled cycles count towards NHS funded cycles.*

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
		account when considering suitability for further IVF treatment. HFEA Commissioning Guide (CG): 1 cancelled cycle does not count towards the number of commissioned cycles.	**Islington:** *As Barnet* *Cancelled cycles: defined as NICE.* *Abandoned cycles: defined as treatment leading to failed embryo transfer.*	
1.5	Storage of cryopreserved supernumerary embryos will be funded for a maximum of two years following each fresh cycle.	1.12.6.10 Offer cryopreservation to store any remaining good-quality embryos after embryo transfer. *NICE does not make recommendations on the duration of NHS funded storage.*	*Not addressed in current NCL policies*	Considering the majority of patients will not have sufficient supernumerary embryos to undergo more than 2 frozen embryo transfers per full cycle (clinicians estimate 80–90% of patients will have <3 frozen embryo transfers per full cycle), 2 years appears to be sufficient time to complete a full cycle.
1.6	Embryo transfer strategies outlined in NICE CG156 should be followed in order to minimise the number of multiple births	*NICE CG156 sets out specific recommendations on embryo transfer strategies depending on the woman's age and quality of embryos (section 1.12.6).*	**Barnet:** As HFEA guidance[15] **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** *Not addressed* **Islington:** *As Barnet*	The NCL policy is consistent with NICE CG156.
1.7	Natural cycle IVF is not routinely funded by NCL CCG.	1.12.3.6 Do not offer women natural cycle IVF treatment.	*Not addressed in current NCL policies*	The NCL policy is consistent with NICE CG156 which specifically recommends 'Do not offer women natural cycle IVF treatment'. This recommendation was made because the available evidence shows that natural cycles result in lower clinical pregnancy rates than stimulated cycles.
2.	**IUI using partner sperm**			
2.1	In order to access IUI using partner sperm that is routinely funded by the CCG, patients must meet relevant eligibility criteria set out in Section 9 of this document.	See Table 2.		
2.2	Up to six cycles of unstimulated IUI using partner sperm is funded for eligible patients where there is evidence of normal ovulation (spontaneous or induced), tubal patency and semen analysis for: a) people who 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 cycles of self-funded IUI, or	1.9.1.1 Consider unstimulated IUI for: ○ people with diagnosed physical disability or psychosexual problem ○ people with conditions that require specific consideration in relation to methods of conception (e.g. after sperm washing) 1.9.1.2 For people in recommendation 1.9.1.1 who have not conceived after 6 cycles of AI, despite evidence of normal	All NCL boroughs fund IUI for: people with disabilities/ psychosexual problems those with conditions that require specific considerations in relation to methods of conception (e.g. after sperm washing).	The NCL policy is consistent with NICE guidance which state that people who are unable to, or would find it very difficult to, have vaginal intercourse (such as people with a clinically diagnosed disability or psychosexual problem) should have the same criteria apply as same sex couples (see 3.2 for rationale for these criteria).

[15] The HFEA does not make specific recommendations on embryo transfer strategies for clinics to follow. Instead they have set a maximum multiple birth target (10%) and have required clinics to develop their own strategies for meeting this target. Clinics are monitored and inspected by the HFEA to ensure they are working towards the target.

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
	b) people with the following conditions that require specific consideration in relation to methods of conception: ○ those living with HIV who have undergone a successful sperm washing procedure (access to NHS funded sperm washing is addressed in Section 7 of this document) ○ people with spinal cord injury or other conditions that means they require electro-ejaculation	ovulation, tubal patency and semenalysis, offer a further 6 cycles of unstimulated IUI		
2.3	IUI is not routinely funded for people with unexplained infertility, mild endometriosis or mild male factor infertility except in the following circumstances: • Up to six cycles of unstimulated IUI using partner sperm is funded in exceptional circumstances for people with unexplained infertility, mild endometriosis or mild male factor infertility who have social, cultural or religious objections to IVF [note: this would be an alternative to receiving IVF treatment and therefore IVF would not subsequently be funded for patients accessing IUI in these circumstances]. To access IUI in these circumstances, patients must meet the eligibility criteria to access IVF as set out in Section 9 of this document.	1.9.1.3 For people with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse: ○ do not routinely offer IUI (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF)	*Not addressed in current NCL policies*	The NCL policy is consistent with current NICE CG156 recommendations, which states IUI should not be routinely funded for people with unexplained infertility, mild endometriosis or mild male factor infertility. The exception to this is exceptional circumstances such as when people have social, cultural or religious objections to IVF. The NICE Guideline Development Group made this recommendation because they felt that several cycles of IUI with stimulation were required to match live birth rates achieved by a single IVF cycle, but with higher multiple birth rates as there was less control over the number of embryos produced (see page 214 of full NICE guideline).
3.	**ACT (IUI and IVF) using donor sperm**			
3.1	In order to access ACT using donor sperm that is routinely funded by the CCG, patients must meet relevant eligibility criteria set out in Section 9 of this document.	See Table 2.		
3.2	Up to six cycles of unstimulated IUI using donor sperm is funded for eligible patients where there is evidence of normal ovulation (spontaneous or induced) and tubal patency, AND where either criteria A, B or C are met: A. The patient has fertility problems associated with one of the following conditions: ○ obstructive azoospermia	1.9.1.1 Consider unstimulated IUI for…people in same-sex relationships. 1.9.1.2 For people in recommendation 1.9.1.1 who have not conceived after 6 cycles of AI, despite evidence of normal ovulation, tubal patency and semenalysis, offer a further 6 cycles of unstimulated IUI	**Barnet:** IUI not funded for same sex couples. Will not fund donor sperm but will fund associated ACT in line with the criteria in the policy *[indications not specified]*. **Camden:** IUI not funded for same sex couples.	The NCL 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 6 unsuccessful cycles of AI prior to NHS funded IUI. The NCL policy requires this AI to be IUI for the following reasons:

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
	○ non-obstructive azoospermia ○ severe deficits in semen quality in couples who do not wish to undergo ICSI B. Where one of the following have been confirmed/ diagnosed by an appropriate specialist: ○ using partner sperm would lead to a high risk of transmitting a genetic disorder to the offspring ○ using partner sperm would lead to a high risk of transmitting infectious disease to the offspring or partner ○ severe rhesus isoimmunisation C. Same-sex couples, single people or other couples trying to conceive using donor insemination but who have not conceived after six cycles of self-funded IUI	1.14.1.1 The use of donor insemination is considered effective in managing fertility problems associated with the following conditions: ○ obstructive/ non-obstructive azoospermia ○ severe deficits in semen quality in couples who do not wish to undergo ICSI. 1.14.1.2 Donor insemination should be considered in conditions such as: ○ where there is a high risk of transmitting a genetic/ infectious disorder to the offspring/ woman ○ severe rhesus isoimmunisation.	Will not fund donor sperm or associated ACT. **Enfield:** IUI funded for women in same sex relationships after 6 IUI Will not fund donor sperm but will fund associated ACT in line with criteria in the policy *[indications not specified]*. **Haringey:** IUI funded for women in same sex relationships Will not fund donor sperm but will fund associated ACT *[indications not specified]*. **Islington:** *As Barnet*	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 mother's partner (if she has one) will be recognised as the second legal parent The Clinical Reference Group is supportive of this requirement
3.3	IVF using donated sperm will be funded for eligible patients, as per Section 1 of this document, in either one of the following circumstances: 1. Patients fulfil one of the criteria A, B or C outlined above AND investigations show IVF is the only effective treatment option 2. Patients fulfil one of the criteria A, B or C outlined above AND have not conceived after 12 cycles of IUI	1.11.1.3 In women aged under 40 years who have not conceived after… 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI. 1.11.1.4 In women aged 40–42 years who have not conceived after… 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF 1.11.1.5 Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, refer directly for IVF.	**Barnet:** Same sex female couples and single women should be referred for ACT if a cause for infertility is found or after 12 IUI. **Camden:** *As Barnet.* **Enfield:** *As Barnet.* **Haringey:** Same sex couples can be referred for IVF if investigations show a cause for infertility. **Islington:** *As Barnet.*	The NCL policy is broadly consistent with NICE CG156. NICE specify people trying to conceive through AI should have undergone 12 AI where 6 or more are IUI prior to NHS funded IVF. The NCL policy requires all AI to be IUI for the reasons outlined in section 3.2.
3.4	The CCG will fund the cost of the IUI and/ or IVF; the donor sperm will need to be sourced and paid for by the patient	*Not specifically addressed in NICE CG156*	**Barnet:** Will not fund donor sperm but will fund associated ACT in line with the criteria in the policy *[indications not specified]*.	There are significant practical and logistical issues relating to NHS funding of donor sperm. NCL CCG intends to fund donor sperm for use in NHS funded assisted

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
			Camden: Will not fund donor sperm or associated ACT. **Enfield:** *As Barnet* **Haringey:** *As Barnet* **Islington:** *As Barnet*	conception treatments in the future once arrangements have been put in place to resolve these issues.
3.5	The CCG will only fund assisted conception treatment using donor sperm at UK HFEA licensed clinics, with all elements of treatment subject to HFEA regulations.	*Not specifically addressed in NICE CG156*	**Barnet:** Patients… are advised to check with the treating provider unit to ensure compliance with best practice guidance. **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** *Not specifically addressed* **Islington:** *As Barnet*	The HFEA has regulations in place relating to assisted conception treatments and donation of sperm/eggs. These aim to ensure the safety of all those involved, for example by ensuring health screening of donors and stipulating counselling is provided to patients and donors. NCL CCG will therefore only fund ACT using donor sperm at UK clinics which are subject to HFEA regulations.
4.	**IVF using donor eggs**			
4.1	In order to access IVF using donated eggs that is routinely funded by the CCG, patients must meet relevant eligibility criteria set out in Section 9 of this document. The ovarian reserve criterion does not need to be met by patients undergoing IVF using donor eggs.	See Table 2.		
4.2	IVF using donated eggs will only be funded for eligible patients, as per Section 1 of this document, where either criteria A or B are met: A. The patient has fertility problems associated with one of the following: ○ premature ovarian insufficiency ○ gonadal dysgenesis including Turner syndrome ○ bilateral oophorectomy B. Where it has been confirmed by an appropriate specialist that there is a high risk of transmitting a genetic disorder to the offspring.	1.15.1.1 Use of donor oocytes is effective in managing fertility problems associated with: ○ premature ovarian failure ○ gonadal dysgenesis including Turner syndrome ○ bilateral oophorectomy ○ ovarian failure following chemotherapy or radiotherapy ○ certain cases of IVF treatment failure ○ high risk of transmitting a genetic disorder	**Barnet:** Will not fund donor egg but will fund associated IVF in line with criteria in the policy *[indications not specified]*. **Camden:** Will not fund donor egg or associated IVF. **Enfield:** *As Barnet* **Haringey:** *As Camden* **Islington:** *As Barnet.*	The NCL policy is consistent with NICE CG156 with the exception that the NCL policy does not fund IVF using donor eggs for 'certain cases of IVF failure' because this criterion is not specific and did not have consensus of support from local specialists. In addition, 'ovarian failure following chemotherapy or radiotherapy' was not included as a criterion in the NCL policy because local clinicians noted this is superfluous as is covered by 'premature ovarian failure'.
4.3	The CCG will fund the cost of the IVF; the donor eggs will need to be sourced and paid for by the patient	*Not specifically addressed in NICE CG156*	**Barnet:** Will not fund donor egg but will fund associated IVF in line with criteria in the policy *[indications not specified]*. **Camden:** Will not fund donor egg or associated IVF. **Enfield:** *As Barnet* **Haringey:** *As Camden* **Islington:** *As Barnet.*	There are significant practical and logistical issues relating to NHS funding of donor eggs. NCL CCG intends to fund donor eggs for use in NHS funded assisted conception treatments in the future once arrangements have been put in place to resolve these issues.

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
4.4	The CCG will only fund assisted conception treatment using donor eggs at UK HFEA licensed clinics, with all elements of treatment subject to HFEA regulations.	*Not specifically addressed in NICE CG156*	**Barnet:** Patients… are advised to check with the treating provider unit to ensure compliance with best practice guidance. **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** *Not specifically addressed* **Islington:** *As Barnet*	The HFEA has regulations in place relating to assisted conception treatments and donation of sperm/eggs. These aim to ensure the safety of all those involved, for example by ensuring health screening of donors and stipulating counselling is provided to patients and donors. NCL CCG will therefore only fund ACT using donor sperm at UK clinics which are subject to HFEA regulations.
5	**Surgical sperm retrieval**			
5.1	Surgical sperm retrieval (SSR) is the commissioning responsibility of NHS England and will not be funded by NCL CCG	*SSR is NHS England commissioning responsibility. CCGs are responsible for commissioning the storage of surgically retrieved sperm and ICSI using surgically retrieved sperm.*	**Barnet:** Funded in appropriately selected patients **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** Not addressed **Islington:** *As Barnet*	The NCL policy is consistent with NHS England Clinical Commissioning Policy on surgical sperm retrieval.
5.2	NHS England state they will only fund SSR where the patient meets eligibility criteria and has confirmed funding for subsequent stages of the pathway (i.e. cryopreservation and/ or ICSI treatment), as set out in the NHS England Clinical Commissioning Policy: Surgical sperm retrieval for male infertility (2016). The responsible clinician should therefore ensure the patient meets the relevant eligibility criteria prior to undertaking SSR (see 5.4 and 5.6 below).	*Not specifically addressed in NICE CG156*	*Not addressed in current NCL policies*	The NCL policy is consistent with NHS England Clinical Commissioning Policy on surgical sperm retrieval.
5.3	Where a patient with azoospermia has undergone successful surgical sperm retrieval funded by NHS England, cryopreservation and storage will be funded by the CCG for a maximum of two years	*Not specifically addressed in NICE CG156*	*Not addressed in current NCL policies*	Internally consistent with duration of storage of embryos – see 1.5.
5.4	In order to access cryopreservation of surgically retrieved sperm that is routinely funded by the CCG patients must meet relevant eligibility criteria set out in Section 9 of this document.	See Table 2.		
5.5	Where a patient with azoospermia has undergone successful surgical sperm retrieval funded by NHS England, IVF with ICSI will be funded as per Section 1 of this document.	*Not specifically addressed in NICE CG156*	*Not addressed in current NCL policies*	Internally consistent with NCL IVF/ICSI policy.
5.6	In order to access IVF with ICSI using surgically retrieved sperm that is routinely funded by the CCG, couples must meet	See Table 2.		

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
	relevant eligibility criteria set out in Section 9 of this document.			
6.	**Assisted conception treatments involving surrogates**			
6.1	Assisted conception treatments involving surrogates are not routinely funded by NCL CCG.	*Outside of scope of NICE CG156*	**All NCL boroughs:** IVF using a surrogate is not funded	The NCL policy states that ACT involving surrogates is not funded for the following reasons: 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. 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. As with all other interventions not routinely funded, an IFR application may be submitted by the treating clinician for any situation where they believe the case is clinically exceptional or rare.
7.	**Sperm washing**			
7.1	In order to access sperm washing and subsequent assisted conception treatments that is routinely funded by the CCG, patients must meet relevant eligibility criteria set out in Section 9 of this document.	See Table 2.		
7.2	Sperm washing will be funded for eligible couples where the woman or person trying to conceive is not living with HIV but the sperm is from a partner who is living with HIV, and is either: • non-adherent with antiretroviral treatment, or	1.3.10.4 For couples where the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater, offer sperm washing. 1.3.10.6 If couples who meet all the criteria in recommendation 1.3.10.2 [the man is compliant with HAART; the man has had a plasma viral load of less than 50 copies/ml	**Barnet:** Funded where the man is HIV+ and woman is HIV- **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** *Not addressed* **Islington:** *As Barnet*	The NCL policy is consistent with NICE CG156 recommendation 1.3.10.4. The NCL policy is not consistent with NICE CG156 recommendation 1.3.10.6 as the risk of transmitting HIV to this patient group while trying to conceive through unprotected intercourse in these circumstances is described by NICE as negligible. In addition, local HIV specialists did not feel sperm

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
	• has an HIV viral load of 50 copies/ml or greater	for more than 6 months; there are no other infections present; unprotected intercourse is limited to the time of ovulation] still perceive an unacceptable risk of HIV transmission after discussion with their HIV specialist, consider sperm washing.		washing should be funded on the NHS for this indication. One specialist noted this would dilute the extremely important message that U=U and the risk of transmission is zero. The likelihood of conception through unprotected intercourse is higher than sperm washing so funding sperm washing for this indication could be doing patients a disservice.
7.3	Where a successful sperm washing procedure has been undertaken, cryopreservation and storage of washed sperm will be funded for a maximum of two years.	*Not specifically addressed in NICE CG156*	*Not addressed in current NCL policies*	Internally consistent with duration of storage of embryos and surgically retrieved sperm – see 1.5 and 5.3 respectively.
7.4	Where the sperm washing procedure is successful, depending on their clinical circumstances, couples may access IUI as set out in Section 2 of this document and/ or IVF/ICSI as set out in Section 1 of this document.	*Not specifically addressed in NICE CG156*	*Not addressed in current NCL policies*	Internally consistent with NCL policies on IUI using partner sperm and IVF/ICSI.
8. Cryopreservation of gametes for fertility preservation				
8.1	Cryopreservation of sperm, eggs or embryos will be funded for eligible patients (as defined in paragraphs 8.2 and 8.3 below) who do not currently have fertility problems but meet one of the following criteria: • patient is under the care of a specialist clinician who confirms they are due to undergo a gonadotoxic treatment; this may include patients undergoing interventions for gender reassignment • patient is under the care of a specialist clinician who has confirmed they have a medical condition that, in their case, is likely to progress such that it will lead to infertility in the future	NICE CG156: 1.16.1.8 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. 1.16.1.10 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile NHS E guidance for CCGs on formation of policies for fertility preservation: All patient groups whose medical treatment may compromise fertility should be in the contemplation of a CCG when its clinical commissioning policy for fertility preservation is being developed or is under review… including gender reassignment.	**Barnet:** Cancer or other conditions which may impact on their future fertility **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** Patients at risk of future infertility as a consequence of their need to undergo life preserving treatment for cancer or other relevant conditions **Islington:** *As Barnet*	The NCL policy is consistent with NICE CG156 and NHS E guidance. The scope of the NCL policy is limited to patients with infertility and other medical conditions that mean they need assisted conception treatments to help them conceive. Elective egg cryopreservation (i.e. cryopreservation of eggs for non-medical reasons) is not funded on the NHS.
8.2	Cryopreservation of sperm will be funded for fertility preservation if they fall within 8.1 above.	1.16.1.8 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile.	**Barnet:** Storage of sperm will be funded for men aged under 55.	The NCL policy is consistent with NICE CG156. The age criterion for men was not included in the new NCL policy because it was based on previous HFEA regulations

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
			Transgender patients must be on the approved NHS E funded care pathway and not self-treating. **Camden:** Storage of sperm will be funded for men aged under 55. **Enfield:** *As Camden*. **Haringey:** Patients must be on an approved NHS England funded care pathway and not self-treating. **Islington:** *As Barnet*	(that sperm could not be stored once a man reaches 55 years of age) which have now been withdrawn.
8.3	Cryopreservation of eggs or embryos will be funded for fertility preservation if the patient falls within 8.1 above and fulfils all of the following criteria: • The patient is aged under 43 years • The patient is well enough to undergo ovarian stimulation and egg collection, and this will not worsen their condition • Enough time is available before the start of their gonadotoxic treatment	1.16.1.10 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if: ○ they are well enough and ○ this will not worsen their condition and ○ enough time is available.	**Barnet:** Storage of eggs/embryos will be funded for women aged under 43. Transgender patients must be on the approved NHS E funded care pathway and not self-treating. **Camden:** Storage of eggs/embryos will be funded for women aged under 43. **Enfield:** *As Camden*. **Haringey:** Storage of eggs/embryos will be funded for women aged under 43 Patients must be on an approved NHS England funded care pathway and not self-treating. **Islington:** *As Barnet*	The NCL policy is consistent with NICE CG156 with the exception that the NCL policy requires women to be aged under 43 years to have eggs/ embryos cryopreserved. This is because it is well established through HFEA registry data and NICE recommendations that IVF has poor success rates for women aged over 42. This age threshold is internally consistent with the upper age limit for other assisted conception treatments – see 9.2.
8.4	Ovarian tissue cryopreservation is not routinely funded for adults.	*Not addressed in NICE CG156*	**Haringey:** Funds cryopreservation of ovaries *Not addressed in other NCL borough policies.*	Ovarian tissue cryopreservation (OTC) / Ovarian tissue transplantation (OTT) are relatively new interventions (first OTT was undertaken in 2000), therefore the clinical effectiveness of these interventions are not yet well established. NICE do not currently recommend funding OTC/ OTT for fertility preservation. This position will be reviewed if NICE guidance changes or additional data on outcomes becomes available.
8.5	Other than those listed in paragraphs 8.1-8.3 above, patients are not required to meet any additional eligibility criteria in order to access cryopreservation and storage of sperm, eggs or embryos for fertility preservation.	1.16.1.4 For cancer-related fertility preservation, do not apply the eligibility criteria used for conventional infertility treatment.	See 8.1 to 8.3 above. .	See 8.1 to 8.3 above.
8.6	For patients aged under 32 years at the time of cryopreservation: storage of sperm,	1.16.1.12 Store cryopreserved material for an initial period of 10 years.	**Barnet:** will fund storage for first 5 years only	The NCL policy is consistent with the NICE recommendation to store cryopreserved

NCL Fertility Policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
	embryos and eggs will be funded until the patient reaches their 43rd birthday. For patients aged 32 and over at the time of cryopreservation: storage of sperm, embryos and eggs will be funded for 10 years duration. NHS funding of storage will cease sooner where: • Patents are no longer eligible for NHS fertility treatment, or • The patient dies and no written consent has been left permitting posthumous use	1.16.1.13 Offer continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility.	**Camden:** will fund storage for first 10 years only **Enfield:** *Does not specify duration of storage funded* **Haringey:** *As Camden* **Islington:** *As Camden*	material for an initial period of 10 years. Additional duration of storage is funded for younger patients (those aged under 32 years at the time of cryopreservation) such that all eligible patients will continue to have their genetic materials stored at least until their 43rd birthday (internally consistent with upper age limit for ACT – see 9.2). This is because it was noted that patients who had their genetic materials stored at a very young age may not be ready to try to conceive within 10 years of cryopreservation.
8.7	In order to access assisted conception treatments using cryopreserved materials that is routinely funded by the CCG, fertility preservation patients must meet the same eligibility criteria as other patients with fertility problems as set out in Section 9 of this document. An exception to this is the ovarian reserve criterion, which does not need to be fulfilled by patients who have had their eggs or embryos stored for fertility preservation.	1.16.1.6 Eligibility criteria used in conventional infertility treatment do not apply in the case of fertility cryopreservation. However, those criteria will apply when it comes to using stored material for assisted conception.	**All NCL boroughs:** The eligibility criteria set out in this policy must be applied to any subsequent use of the stored material	The NCL policy is consistent with NICE CG156 with the exception that the NCL policy states women who have accessed NHS funded FP will not be required to meet the ovarian reserve criterion. This is because although the gonadotoxic treatment may have had a negative impact on the woman's ovarian reserve, previously stored eggs/embryos will not be affected by this.

Table 2 – Comparison of NCL Fertility Policy with NICE and previous policies: Eligibility criteria

New NCL policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
9.1	In order to be eligible for IVF, infertility must be demonstrated in one of the following ways: • Investigations show there is no chance of pregnancy with expectant management and IVF is the only effective treatment, OR • Patients have not conceived after either 2 years of regular unprotected intercourse OR 12 cycles of IUI.	1.11.1.3 In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF 1.11.1.4 In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF 1.11.1.5 Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, refer the woman directly to a specialist team for IVF treatment.	**All NCL boroughs:** People with a known cause for infertility should be referred without delay for appropriate assessment/ treatment. IVF treatment can be offered to women with unexplained infertility who have not conceived after 2 years of regular unprotected sexual intercourse (or 12 months for women aged 36 and over). **Barnet, Camden, Enfield and Islington:** For same sex couples and single women… where no cause of infertility can be identified women should be offered access to ACT if they have subfertility demonstrated by 12 IUI **Haringey:** For same sex couples… where investigations show a clear cause of infertility the women can be referred for IVF.	The NCL policy is broadly consistent with NICE CG156. NICE specify people trying to conceive through AI should have undergone 12 AI where 6 or more are IUI prior to NHS funded IVF. The NCL policy requires all AI to be IUI for reasons outlined in section 3.2. A reduced duration of trying to conceive for women aged 36 and over has been removed because NICE CG156 indicates that in order to be eligible for IVF, [unless investigations show no chance of pregnancy with expectant management] heterosexual women should have unsuccessfully been trying to conceive for 2 years. NICE specifies that this criterion applies both to women aged under 40 and those aged 40–42. NICE have undertaken cost effectiveness analysis to determine in what circumstances IVF is cost effective and have based their recommendations on the results of this. Reducing the duration of time trying to conceive may mean women who would have otherwise conceived naturally are undergo unnecessary IVF.
9.2	The woman or person trying to conceive who is receiving fertility treatment must be aged under 43 years. IVF medication must start with the provider before their 43rd birthday. Referrals should be made to fertility clinics allowing adequate time for work up.	1.11.1.3 In women aged under 40 years… offer 3 full cycles of IVF 1.11.1.4 In women aged 40–42 years… offer 1 full cycle of IVF	**All NCL boroughs:** IVF is offered to women aged under 43 years old. Referring clinicians should be aware of the work up time required by providers and ensure referrals are made in time for women commence a treatment cycle before their 43rd birthday.	The NCL policy is consistent with NICE CG156.
9.3	If the woman or person trying to conceive reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available. A full cycle of IVF treatment, with or without ICSI, should comprise one episode of ovarian stimulation and the transfer of resultant fresh and frozen embryo(s), in line with Section 1 of this document.	1.11.1.3 If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.	*Not addressed in current NCL policies*	The NCL policy is consistent with NICE CG156.
9.4	Treatment will not be funded for those aged under 40 years if three previous fresh cycles of IVF have been received, irrespective of how these were funded.	1.11.1.6 In women aged under 40 years any previous full IVF cycle, whether self- or NHS-funded, should count towards the	For women aged <40: **All NCL boroughs:** IVF is not funded when the woman has had 3 or more previous IVF	Criteria relating to previous cycles in the NCL policy are consistent with NICE CG156 recommendations. These criteria are in place because the likelihood of a live birth

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		total of 3 full cycles that should be offered by the NHS.	cycles, whether funded privately or by the NHS.	decreases with the number of unsuccessful IVF cycles undertaken. NICE have undertaken cost effectiveness analysis to determine in what circumstances IVF is cost effective and have based their recommendations on the results of this.
9.5	Treatment will not be funded for those aged 40–42 years if they have undergone any previous IVF treatment, irrespective of how this was funded.	1.11.1.4 In women aged 40–42 years… offer 1 full cycle of IVF, with or without ICSI, provided… they have never previously had IVF treatment	For women aged 40–42: **Barnet:** IVF will only be offered to women if they have never previously had IVF **Camden:** *As Barnet* **Enfield:** As for women aged <40 (see 9.4) **Haringey:** *As Barnet* **Islington:** *As Barnet*	See 9.4.
9.6	One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of 'previous' IVF cycles.	See 1.4		
9.7	The woman or person undergoing treatment with the intention of trying to conceive must have a BMI within the range 19–30 kg/m^2.	NICE CG156: 1.10.4.1 Women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female BMI outside this range is likely to reduce the success of assisted reproduction procedures. HFEA CG: Women should have a BMI of 19–30 before commencing assisted reproduction.	**All NCL boroughs:** The woman must have a body mass index (BMI) of between 19 and 30 at the time commencement of treatment.	NICE CG156 specifies women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female 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. The NCL policy criteria are in place because female BMI outside this range are likely to reduce the success of assisted reproduction procedures. Local specialists support inclusion of the BMI criterion for women outlined in the NCL policy.
9.8	Treatment will not be funded if the woman or person undergoing treatment with the intention of trying to conceive smokes	NICE CG156: 1.10.5.2 People should be informed that maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment. HFEA CG: Women and their partners should be non-smokers	**All NCL boroughs:** Patients must be non-smokers in order to access any fertility treatment and continue to be non-smokers throughout treatment.	NICE CG156 specifies people should be informed that maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment. The HFEA Commissioning Guide states women and their partners should be non-smokers in order to access NHS fertility treatment. The NCL policy criteria are in place because maternal and paternal smoking can adversely affect the success rates of assisted reproductive procedures.

New NCL policy		NICE CG156 recommendations (or other guidance)	Current NCL policies	Rationale for new policy
9.9	Treatment will not be funded if the man or partner providing sperm for treatment smokes	See 9.8.	See 9.8.	See 9.8.
9.10	There should not be evidence of low ovarian reserve, defined in this policy as more than one of the following: • antral follicle count (AFC) of less than or equal to 4 • anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l • follicle-stimulating hormone (FSH) greater than 8.9 IU/l	1.3.3.2 Use one of the following measures to predict the likely ovarian response to gonadotrophin stimulation in IVF: ○ total AFC of ≤4 for a low response and >16 for a high response ○ AMH of ≤5.4 pmol/l for a low response and ≥25.0 pmol/l for a high response ○ FSH >8.9 IU/l for a low response and <4 IU/l for a high response 1.11.1.4 In women aged 40–42 years… offer 1 full cycle of IVF, with or without ICSI, provided… there is no evidence of low ovarian reserve (see recommendation 1.3.3.2)	**Barnet:** patients must have demonstrated sufficient ovarian reserve (defined by NICE) **Camden:** will fund IVF for women whose scores fall within the limit for low ovarian reserve (defined by NICE) **Enfield:** will not fund IVF for women whose ovarian reserve limits fall below or above the usual limits for both tests (AMH and AFC as NICE) **Haringey:** *As Enfield* **Islington:** *As Camden*	NICE only apply an ovarian reserve criterion to women aged 40-42; the NCL policy applies an ovarian reserve criterion to all women aged <43 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 Funding more IVF cycles for women with a good ovarian reserve is likely to lead to more live births than funding fewer IVF cycles and removing the ovarian reserve criterion
9.11	Couples: At least one individual in a couple must not have a living child from their relationship or any previous relationship. Single persons: Individuals should not have a living child.	NICE Quality Standard 73 (equality and diversity considerations): The existence of living children should not be a factor that precludes the provision of fertility treatment	**All NCL boroughs:** IVF will not be offered to couples or single applicants who already have a child. IVF will be offered to couples where one of the partners has a child from a previous relationship, but the other does not.	It is recognised nationally that NHS organisations need to focus their budgets on patients who have the most need and can obtain the maximum health gain. Local priority is therefore being given to those where at least one partner in a couple does not have a living child. Research on the parental status of people presenting to GPs with fertility problems in Oxfordshire indicates that removing the 'previous children' criterion would increase the number of patients presenting for treatment by ~22%. This would mean less cycles could be offered to all patients accessing assisted conception treatments.
9.12	Foster children are excluded from the scope of this criterion. 'Child' refers to a living son or daughter irrespective of their age or place of residence.	*Not addressed in NICE CG156*	**Barnet:** Foster children are not included in these restrictions. **Camden:** *As Barnet* **Enfield:** *Not addressed* **Haringey:** *Not addressed* **Islington:** This will include adopted children, but exclude fostered children	For clarity regarding 9.11.
9.13	Couples: Neither individual in a couple should have undergone sterilisation. Single persons: Individuals should not have undergone sterilisation.	HFEA CG: CCGs may wish to restrict access based on either partner being sterilised.	**All NCL boroughs:** Treatment will not be funded where sterilisation has previously been undertaken.	Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are

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				made aware of this at the time of the procedure. It is inappropriate that NHS funds are used in reversing these procedures.
9.14	Criteria 9.13 still applies where sterilisation reversal has unsuccessfully been attempted.	*Not addressed in NICE CG156*	**Barnet:** Treatment will not be funded where subfertility remains after reversal of sterilisation **Camden:** *As Barnet* **Enfield:** *As Barnet* **Haringey:** *Not addressed* **Islington:** *As Barnet*	For clarity regarding 9.13.