NHS
North Central London
Clinical Commissioning Group

NCL CCG Fertility Policies Review: Recommendations Report

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Glossary

Abandoned cycle with IVF / ICSI	Abandoned cycle with IVF / ICSI prior to egg retrieval, usually due to a lack of response (where fewer than three mature follicles are present) or conversely if there has been an excessive response to gonadotrophins and the patient is at risk of severe ovarian hyperstimulation syndrome (OHSS). One abandoned cycle does not count towards the number of commissioned cycles.
Assisted reproduction technology (ART)/ Assisted reproduction	The collective name for treatments designed to lead to conception by means other than sexual intercourse, which include intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and donor insemination (DI).
Blastocyst	Blastocyst stage embryos are selected on day five of their development (or on day six if they have not developed by day five).
Cancelled cycle	An IVF cycle in which ovarian stimulation or monitoring has been carried out with the intention to treat but the woman does not proceed to follicular aspiration or, in the case of a thawed embryo, to embryo transfer.
Cleavage	Cleavage stage embryos are selected on day one or day two of their development
Clinical pregnancy	A pregnancy diagnosed by ultrasonographic visualisation of one or more gestational sacs. It includes ectopic pregnancy. Note: multiple gestational sacs are counted as one clinical pregnancy.
Cryopreservation	The freezing and storage of embryos, sperm or eggs for future use in IVF treatment cycles.
Donor insemination	DI is a type of fertility treatment in which high quality donor sperm is used when either the male partner has no sperm or for lesbian couples. This sperm is then injected directly into the womb (IUI).
Embryo transfer	The procedure in which one or more embryos are placed in the uterus.
Fertilisation	The union of an egg and sperm.
Fertility policies	CCGs are responsible for commissioning most fertility treatments; most therefore have policies in place specifying which interventions are funded and eligibility criteria for access to these. As well as including policies on fertility treatments for people with infertility, these typically also include policies on assisted conception treatments for patients who require interventions for other reasons e.g. fertility preservation for patients due to undergo a gonadotoxic treatment.
Fertility preservation	Involves freezing eggs, sperm, embryos or reproductive tissue with the aim of having biological children in the future. Can be considered for people who are having a treatment that might make them infertile, for example some types of chemotherapy
Full cycle	This term is used to define a full IVF treatment, comprising of one episode of ovarian stimulation and the transfer of any resultant fresh embryo(s). Where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos may be transferred to the patient as a frozen cycle and be included within the 'full cycle'. All frozen embryos from a previous cycle should be used before a further IVF cycle is initiated. Storage of frozen embryos will be routinely funded for one year unless the provider has agreed an alternative as part of a pathway agreement. Legally they can be stored for up to 10 years, other than in exceptional circumstances Any costs relating to the continued storage of embryos beyond this will ordinarily be the responsibility of the couple.

Gonadotoxic treatment	Treatments that can cause infertility such as some chemotherapies.
Infertility / Subfertility	In practice, infertility is defined as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.
Intracytoplasmic sperm injection (ICSI)	IVF with ICSI treatment is similar to standard IVF. However, instead of mixing the sperm with the eggs and leaving them to fertilise in a dish, a skilled embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation as it bypasses any potential problems the sperm will have in penetrating into the egg.
Intrauterine insemination (IUI)	IUI is a type of fertility treatment in which the best quality sperm are separated from sperm that are sluggish or non-motile. This sperm is then placed directly in the womb. This can either be performed with the woman's partner's sperm (IUI) or donor sperm (known as donor insemination or DI). Sometimes ovarian stimulation is used in conjunction with IUI.
In vitro fertilisation (IVF)	IVF involves ovarian stimulation and then collecting a woman's eggs and fertilising them with sperm in the lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred back to the woman's womb to hopefully continue to a pregnancy. Ideally one embryo is transferred to minimise the risk of multiple pregnancy. In older women, or those with poor quality embryos, two may be transferred with a maximum of three in those over 40 years. It is best practice to freeze any remaining good quality embryos to use later on in a frozen embryo transfer if the first transfer is unsuccessful.
Natural cycle IVF	An IVF procedure in which one or more oocytes are collected from the ovaries during a spontaneous menstrual cycle without any drug use
Oocyte (egg) donation	The process by which a fertile woman donates her eggs to be used it the treatment of others or for research.
Ovarian HyperStimulation Syndrome (OHSS)	A condition in which the ovarian response to stimulation results in clinical problems, including abdominal distension, dehydration and potentially serious complications due to thrombosis and lung and kidney dysfunction. It is more likely in women who are excessively sensitive to medicines used for ovarian stimulation.
Ovarian reserve	A woman's fertility is related to the number of oocytes (eggs) remaining in her ovaries, referred to as 'ovarian reserve', which influences the chance of becoming pregnant.
Ovarian stimulation	Stimulation of the ovary to achieve growth and development ovarian follicles
Sperm washing	Sperm washing is used to reduce the viral load in prepared sperm to a very low or undetectable level for men who are HIV positive.
Surgical sperm extraction/ surgical sperm retrieval	If a man has no, or extremely low numbers of sperm in his semen, he may have sperm collected surgically.
Surrogacy	Surrogacy is where a woman carries and gives birth to a baby for another person or couple.
Unsuccessful cycle of IVF/ ICSI	Includes failure of fertilisation, failure of cleavage of embryos and failure to conceive following transfer of embryos. An unsuccessful cycle counts towards the number of commissioned cycles.

Contents

Executive summary

North Central London Clinical Commissioning Group (NCL CCG) was established in April 2020. Prior to this, each of the five North Central London Clinical Commissioning Groups (NCL CCGs) had their own fertility policies in operation, and this has continued into the present day as a legacy of the separate CCGs.

Since we are now a single organisation, there is no longer a reason for having five separate policies. Reducing health inequalities and ensuring fair access to treatments across North Central London (NCL) is a strategic priority for us, and so our Governing Body has commissioned a review into our fertility policies to make recommendations on the way forward.

The process consists of two stages: the first is a review of the current position (with recommendations) and the second is to develop a new policy. This report relates to the first stage, and makes final recommendations and principles for a single policy.

The review is led by NCL Fertility Policy Steering Group, which reports into the Strategy and Commissioning Committee. The Steering Group is led by a Clinical Responsible Officer nominated by the Governing Body and includes a number of relevant subject matter experts, including an independent fertility expert from the University of Southampton who is not associated with any of the provider organisations in NCL.

The methodology undertaken for the review has included the following key stages:

1. Review our current policies and understand how they differ from each other, as well as understanding our care pathways and how many procedures of each type we undertake each year, in each borough.
2. Review the scientific evidence and understand how it might influence policy development, ensuring that our policies are based on the latest evidence available. We have only focussed on areas where our policies depart from the National Institute for Health and Care Excellence (NICE) guidelines, as NICE has its own system to ensure that its policies are based on the latest evidence.
3. Engagement to seek the views of our residents, service users, voluntary and community organisations, fertility groups and wider stakeholder audiences, both on our current fertility policies and also what the CCG should consider when developing the future policy. A set of recommendations will be made for the way in which future policy is to be developed.

Throughout the review, the impact of equality issues needs to be fully understood and taken into account as part of any change in future policy, and so these have been researched and referenced.

Recommendations

A detailed set of recommendations are outlined on page 33. The recommendations focus both on the policy itself, and on the way that it is communicated and disseminated to the key stakeholders, which include service users and clinicians.

Given that we are now a single CCG across NCL, and that we should be providing fair and equal access to treatments across the whole of our area, the review has reached the conclusion that a single fertility policy should be developed and adopted across NCL CCG.

The policy should be aligned to national considerations such as NICE guidelines and recommendations wherever this is feasible, to encourage consistency with the national approach, unless there are clear reasons why our population's needs are different.

It is recommended the policy should address inequalities and issues of access to different population groups and to ensure there is fair access, based on the ability to benefit from the treatments offered.

The policy should be clearly written in language that is unambiguous to service users, clearly articulating the fertility pathway. A reading panel should be established to review the policy once it is drafted to support the policy's "readability".

In order to ensure the policy remains current, there should be regular review with clear timeframes established at the start.

The review found raising awareness and understanding of the future policy with residents is key, and there should be a robust communications plan around publication.

Equally important are primary care-facing communications and materials for acute hospital clinicians, with accompanying education sessions to raise awareness. In this way, all clinicians should be able to give a consistent message when communicating with residents who seek their advice.

Finally, the report acknowledges that cost will need to be taken into account when setting policy. It notes that investment in one area could redirect resources away from other areas, and therefore levels of funding do need to be balanced against those other areas and against the general resource envelope. Further modelling is taking place to understand the financial implications of changes to the policy under different scenarios.

The next steps will be:

- Policy drafting
- Engagement on the final draft Policy
- Equality Impact Assessment

The final output will be the single NCL Fertility Policy, with accompanying plans and materials to support the successful launch and implementation of the new policy.

It is currently estimated that the single NCL Fertility Policy will be published by the end of March 2022.

1. Introduction

On 1 April 2020, the previously five separate CCGs in 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.

The fertility policies cover 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 forms of sub-fertility.

The existing five fertility policies were approved by their respective CCGs during 2014/15. Whilst many aspects of the policies are similar, there are some noticeable differences between them, e.g. 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.

While 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.

It is anticipated that in due course, the finalisation of a single NCL fertility policy will result in the following benefits:

- 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

The CCG is committed to addressing unwarranted variation across NCL, and recognising what an important issue that access to fertility treatment is for some of our residents, the CCG sought to follow a robust approach to developing a single NCL fertility policy. Therefore, the programme to develop a single NCL fertility policy is being conducted in two stages:

Stage 1 – Review
The first stage is to undertake 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 will be developed to direct and support the subsequent drafting of a single NCL fertility policy, with no decisions about a policy being made during this stage.

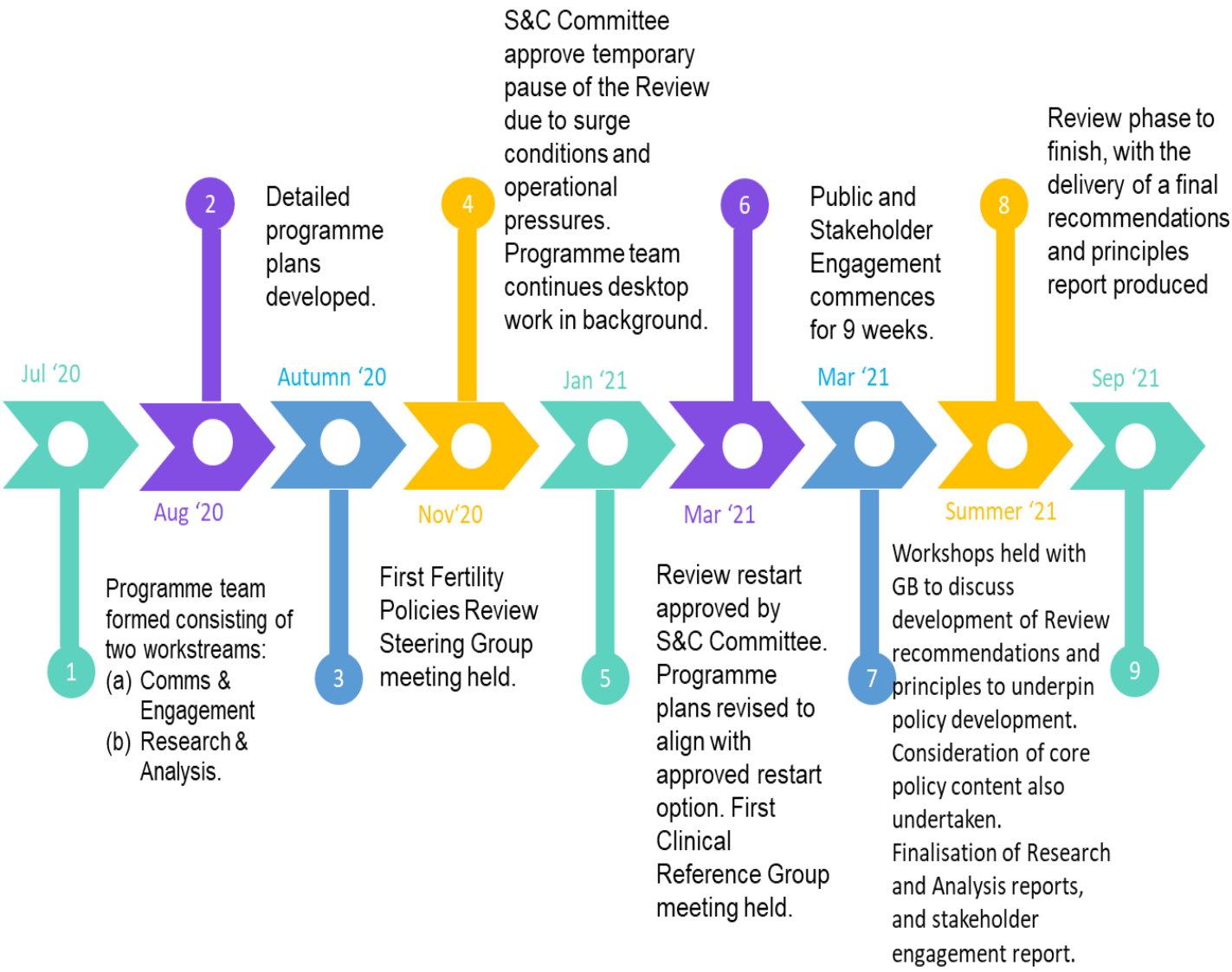
Stage 2 – Policy Development
The second stage is to develop a single NCL fertility policy. It is anticipated that further stakeholder engagement will be undertaken once a draft single NCL fertility policy is available, and will be accompanied by an Equalities Impact Assessment. Once a final NCL fertility policy has been approved, this stage will support the implementation of the policy across the region.

This report concludes the Review stage and sets out:

- The approach taken to carry out the Review

- The findings of the Review, including feedback received during a period of public and wider stakeholder engagement
- The recommendations of the Review to inform the subsequent development of a single NCL fertility policy.

Figure 1: Overview

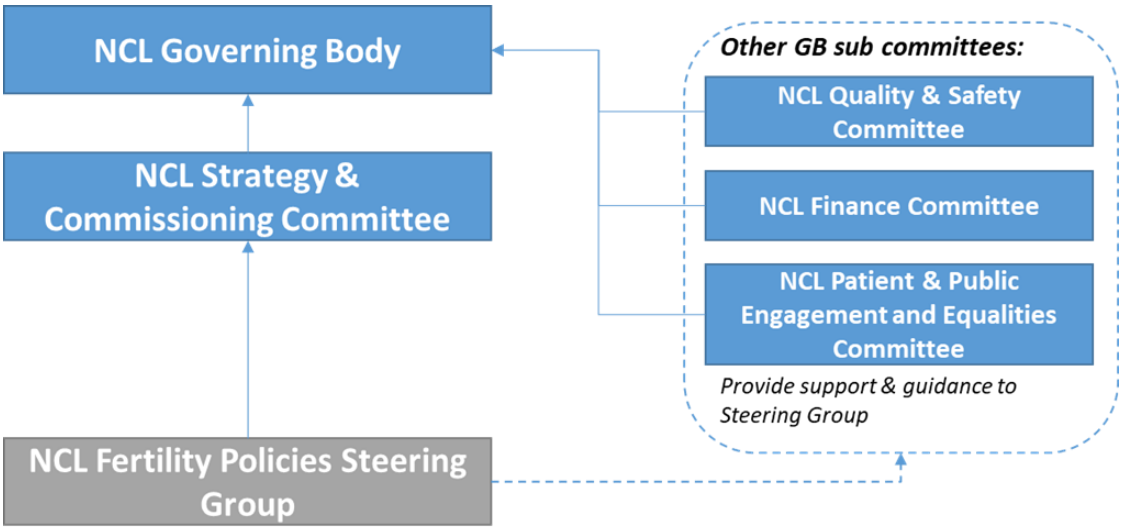


2. Approach to the NCL Fertility Policies Review

Governance

The NCL Fertility Policies Review is led by the NCL Fertility Policies Steering Group (Steering Group), led by a Clinical Responsible Officer (CRO), nominated by the NCL CCG Governing Body to lead the delivery of the Review. The establishment of the Steering Group was confirmed by the NCL Strategy & Commissioning Committee (a sub-group of the NCL CCG Governing Body), and the NCL Strategy & Commissioning Committee has oversight of the Review.

Figure 2: Governance of the NCL Fertility Policies Review



Details of the membership of the Steering Group and its Terms of Reference can be found in Appendix 1. Given the complex and sensitive nature of this Review, it was agreed that the membership of the Steering Group would include a Governing Body lay member, two community members and two clinical leads (one of whom is the NCL CCG Evidence Based Interventions Clinical Lead).

In further recognition of the complexity and technical nature of the Review, the Steering Group asked a specialist fertility expert to join the Steering Group. It was requested that this person have no connection to providers of fertility services for NCL residents, and with support from the British Fertility Society, Professor of Reproductive Medicine, University of Southampton agreed to join the Steering Group.

Clinical Reference Group

To support the work of the Steering Group and to provide clinical "check and challenge" to the methods and outputs of relevant activities undertaken during the Review, a Clinical Reference Group (CRG) was established. The CRG brought together appropriate clinical expertise from across NCL and its partners. The CRG is a non-decision making body and its membership includes fertility consultants, a counsellor and psychotherapist and senior fertility nurse from across providers commissioned by NCL to deliver fertility and associated services. Professor of Reproductive Medicine, University of Southampton also agreed to be part of the CRG.

Further information on the membership of the CRG, please see Appendix 2.

a.) Workstreams

The Review has been comprised of two workstreams:

- Research and Analysis – led by the Health Policy Support Unit (HPSU) of North East London Commissioning Support Unit (NELCSU)
- Communications and Engagement – led by the NCL CCG Communications and Engagement team

The Research and Analysis workstream has included:

- Confirming the baseline position (epidemiology, detailed comparison of existing policies against each other, NICE guidance and other CCGs' policies, understanding current patient pathways, activity & expenditure, outcomes of providers)
- Establishing the evidence base (review of national guidance, analysis of HFEA[1] registry data, completing literature reviews)
- Obtaining the views of specialists
- Collating equality issues

The Communications and Engagement workstream has been responsible for setting the engagement strategy and carrying out engagement activities with stakeholders as part of the Review.

Further information on these workstreams and their findings can be found in Chapter 3 and 4 of this report.

The Review has also been supported by finance, legal, quality and equality expertise from within the CCG and its partners.

b.) Plan

It was originally anticipated that the Review would take approximately six months to complete. Unfortunately, due to the operational pressures and surge conditions experienced by the CCG and its partners across the health and care system as a result of the Covid-19 pandemic, a temporary pause was confirmed by the Strategy & Commissioning Committee in January 2021. The programme resumed in late March 2021, although some activities (notably in the Communications and Engagement workstream) were further delayed due to the need to observe the requirements of purdah prior to the London Mayoral and London Assembly elections in May 2021.

For an overview of the plan of the Review, please see Appendix 3.

c.) Scope of the Review

The scope of the Review was agreed by the NCL Strategy & Commissioning Committee and set out the parameters for the Review, ensuring that it is clear to stakeholders which interventions and eligibility criteria would be included in the Review. The scope has been determined following consideration of other CCGs' fertility policies, NICE clinical guidance, NHS England guidance and HFEA information.

[1] Human Fertilisation and Embryology Authority (www.hfea.gov.uk)

Figure 3: Summary of the scope of the NCL Fertility Policies Review

<table>
<tr><th colspan="2">Service users included in scope:</th></tr>
<tr><td colspan="2">
• Patients who are the commissioning responsibility of NCL CCG
• Patient groups broadly consistent with NICE scope: people with explained or unexplained infertility and some specific patient subgroups:
  ○ People in same-sex relationships or single women who have infertility after donor insemination
  ○ People who are unable to or have been advised not to have heterosexual intercourse
  ○ People with conditions that require specific consideration in relation to methods of conception
  ○ People preparing for medical treatments who may wish to preserve their fertility
</td></tr>
<tr><th colspan="2">Interventions included in scope:</th></tr>
<tr><td colspan="2">
• IVF (with or without ICSI)
• IUI
• ACT using donor sperm and eggs
• Cryopreservation of gametes for patients undergoing gonadotoxic treatments
• Sperm washing
• Storage of and ACT using surgically retrieved sperm
• ACT involving surrogates
</td></tr>
<tr><th colspan="2">Eligibility criteria included in the scope:</th></tr>
<tr><td>
• Definition of infertility
• Age of the woman
• Previous IVF cycles
• Body Mass Index
• Alcohol intake and recreational drug use
</td><td>
• Smoking status
• Ovarian reserve
• Previous children
• Previous sterilisation
</td></tr>
</table>

3. Research and Analysis workstream – Findings

The Research and Analysis workstream has covered a wide range of activities.

Figure 4: Summary of activities undertaken within the Research and Analysis workstream

Baseline position	Establishing the evidence base	Obtaining views of specialists	Collating equality issues
• **Epidemiology**, estimated demand, patient characteristics, risk factors • **Current NCL fertility policies** compared against each other, NICE guidance and other CCGs' policies • **Existing patient pathways** • **Activity and expenditure** • **Current cost of services** • **Outcomes** for providers treating NCL patients	• **Review of national guidance** e.g. NICE, NHS England, Department of Health, HFEA, Royal Colleges • **Analysis of HFEA registry data** (national repository of all fertility treatment activity, including outcomes) • **Literature reviews** undertaken on selected topics	• **Clinical Reference Group (CRG),** including fertility specialists across referral Trusts have met 4 times since March '21 to review the outputs from the R&A workstream • **Questionnaires** have been completed by specialists to confirm the baseline position and formally provide their views on interventions / criteria included within the scope of the Review	• **Equality Analysis Data Collection Tool** used to collate issues that may have an adverse equality impact on protected groups (as defined in the Equality Act 2010) and other disadvantaged groups • Approach agreed with CCG Equality, Diversity and Inclusion team • Working document updated throughout Review process

This chapter sets out a summary of the work undertaken under each of these areas and the key findings.

a.) Baseline position

The Review has confirmed the baseline position with regard to the following:

- **Epidemiology** – estimated demands for treatments, patient characteristics and prevalence of risk factors for infertility
- **Local policies and eligibility criteria** – comparison of current NCL CCG policies against NICE recommendations and equivalent policies in London and Kent
- **Patient pathways** – existing patient pathways and interventions provided by providers treating NCL NHS patients
- **Activity and expenditure** – previous NHS funded activity and expenditure undertaken on fertility treatments for NCL patients
- **Costs** – costs of providing fertility treatments obtained from providers treating NCL NHS patients

- **Local outcomes** – HFEA reported outcomes (birth/ pregnancy rates for IVF, IUI and donor insemination and multiple birth rates) for providers treating NCL NHS patients

Epidemiology

The HFEA estimate that in 2018, 54,000 patients underwent IVF or donor insemination (DI) at HFEA licensed fertility clinics in the UK (HFEA 2020)[2]. This equates to 0.45% of the UK population of women aged between 18 and 45. The HFEA also estimate that in 2018 in London, 27% of IVF cycles were funded by the NHS. Applying these rates to the NCL CCG population it can be estimated that around 400 patients might access NHS funded treatment per year (Figure 5)[3].

Figure 5: Estimated number of NCL residents undergoing specialist fertility treatments (per annum)

Borough	1. Estimated number of women aged 18-45	2. Estimated number undergoing fertility treatment (0.45% of column 1)	3. Estimated number undergoing NHS funded fertility treatment (27% of column 2)
Barnet	76,742	348	94
Camden	62,501	284	77
Enfield	65,690	298	80
Haringey	59,240	269	73
Islington	65,232	296	80
Total	**329,405**	**1,495**	**404**

Sources: ONS Mid 2018 population estimates for CCGs in England (2019); HFEA Fertility treatment 2018: trends and figures (2020).

According to the HFEA, in 2018 the vast majority of people (90%) undergoing fertility treatment (IVF and DI combined) were in heterosexual relationships, with 6.4% in female same sex relationships, 3.2% were single women and 0.4% were surrogates. Only 3% of heterosexual couples underwent IUI, whereas for female same sex couples and single women this rate was over 50%.

Figure 6 sets out the proportion of fertility treatments undertaken by patients of different ethnicities in the UK in 2018. More Asian patients used IVF (14%) compared to the UK population estimate (7%). In contrast, there were fewer White IVF patients (78%) compared to the UK population (87%). The variation between the UK population and DI patients was mainly underrepresentation in Asian patients (3% DI, 7% UK). This may be due in part to fewer Asian patients having treatment with a female partner than other ethnic groups.

Figure 6: Proportion of UK service users by ethnicity and treatment use (2018)

	Proportion by ethnicity				
	White	Asian	Black	Other	Mixed
UK population	87%	7%	3%	2%	2%
IVF patients	78%	14%	3%	3%	2%
DI patients	92%	3%	2%	1%	2%

[2] https://www.hfea.gov.uk/about-us/publications/research-and-data/fertility-treatment-2018-trends-and-figures/

[3] These estimates should be treated with caution as the proportion of fertility treatment funded by the NHS varies considerably across England (from 60% in North East England to 26% in Yorkshire and Humber and East of England) due to variations in CCG commissioning of these interventions. The overall estimate for England is 35%

Sources: https://www.hfea.gov.uk/about-us/publications/research-and-data/ethnic-diversity-in-fertility-treatment-2018/ *(HFEA 2021).*

The risk factors for infertility are generally well recognised as the following:

- age of the woman
- obesity
- underweight
- smoking

When looking at NCL, all boroughs have a higher proportion of women aged 18-42 (the age that the vast majority of women access NHS funded fertility treatments) than compared with the England rate. Barnet has the largest volume of women in this age group, but Islington has the highest rate per 100,000 population.

Obesity (BMI >30) and being underweight (BMI <18.5) puts people at a higher risk of fertility problems. Data from the Public Health England Active Lives Survey (2017/18)[4], indicates that all NCL boroughs have lower incidences of adult obesity than compared with England. Haringey has the highest incidence of people who are obese (20%), and Camden has the lowest (11.3%). Overall, the number of women who are underweight is significantly lower than those who are obese. With the exception of Haringey (where the rate of underweight adults is 2.2%), NCL boroughs have lower rates of underweight people compared to the national average in England (1%).

Smoking puts people at higher risk of fertility problems. NCL is estimated to have similar rates of smoking (13.2%) as compared with London (12.9%) and England (13.9%). However both Enfield and Haringey have higher levels of smoking (15.8% and 14.9% respectively).

For fertility preservation, there are typically two main groups of potential service users: people undergoing gender reassignment and people undergoing treatment for cancer. It is estimated that just under 100 NCL patients were admitted to secondary care with a primary diagnosis of gender dysphoria per year. Rates of admissions were highest in Camden and Islington[5].

Cancer Registry data suggests that annually c. 1,900 women and 1,500 men aged 15-44, in NCL are likely to be diagnosed with a cancer that might be treated with a potentially gonadotoxic treatment. However, not all of these patients will receive the treatment and not all of those who are will opt for fertility preservation (e.g. they may have completed their families or their prognosis may be too poor to consider this option).

Summary

Comparison of existing policies[6]

A comparison of the five existing fertility policies has been made – comparing them against each other, other CCG policies and NICE guidance.

[4] Public Health England (PHE, 2017-18) based on Active Lives Survey, Sport England applied to ONS Mid 2018 population estimates for CCGs in England (2019). Note, these estimates should be treated with caution; rates specific to gender and age groups are not available.

[5] Data should be treated with caution as it will not reflect those undertaking private treatment.

[6] NCL Fertility Policies for Barnet, Camden, Enfield, Haringey & Islington: https://northcentrallondonccg.nhs.uk/fertilitypolicies/document-library/

Figure 7 provides a summary of some of the main inconsistencies that are flagged to the CCG by service users and clinicians. For a full summary of the comparison of the current policies, please see Appendix 4.

Figure 7: Summary of most noted inconsistencies between the five NCL fertility policies

Aspect of policy	NICE recommendations	Barnet	Camden	Enfield	Haringey	Islington
No. IVF cycles in women <40	3 full cycles*	1 fresh + 1 frozen	3 fresh + 3 frozen	1 fresh + 1 frozen	1 fresh + 1 frozen	2 embryo transfers
IUI for same sex couples	6 cycles for sub-fertility	Not funded	Not funded	Funded for patients with sub-fertility	Funded	Not funded
ACT using donor sperm	Recommended for specific indications	ACT funded where donor sperm funded by patient	Not funded	ACT funded where donor sperm funded by patient	ACT funded where donor sperm funded by patient	ACT funded where donor sperm funded by patient
IVF using donor egg	Recommended for specific indications	IVF funded where donor egg funded by patient	Not funded	IVF funded where donor egg funded by patient	Not funded	IVF funded where donor egg funded by patient
Duration of expectant management**	2 years; applies to women of all ages	Aged <36: 2 years Aged ≥36: 1 year	Aged <36: 2 years Aged ≥36: 1 year	Aged <36: 2 years Aged ≥36: 1 year	Aged <36: 2 years Aged ≥36: 1 year	Aged <36: 2 years Aged ≥36: 1 year
Ovarian reserve criterion	Applies to women aged 40-42	Applies to women of all ages	Applies to women of all ages	Applies to women of all ages	Applies to women of all ages	Applies to women of all ages

Note:
** NICE definition of full cycle = 1 episode of ovarian stimulation plus transfer of any resultant fresh and frozen embryos.*
*** Does not apply if there is a known cause of infertility where patients should be referred for IVF without delay. Criteria shown for heterosexual couples*
ACT = Assisted Conception Treatments (includes IVF and IUI)

The vast majority of CCGs in England have fertility policies. An audit of fertility policies in 2017[7] noted that nationally:

- 12% of CCGs funded 3 cycles of IVF (reduced from 24% in 2013)
- 61% of CCGs funded 1 IVF cycle (increased from 48% in 2013)
- 3% funded no IVF cycles (increased from 1% in 2015)

Patient pathways

Consistent with NICE guidance, all current NCL fertility policies state that investigations should be undertaken after 1 year of unprotected vaginal sexual intercourse (or after 6 months if the women is over 36), or after 6 cycles of IUI, unless there is a known cause of infertility. Figure 8 outlines the referral pathways for NCL service users for people with infertility.

[7] This audit was carried out by Fertility Fairness (a group that campaigns for people to have comprehensive and equal access to a full range of appropriate NHS investigations and treatments for infertility; this includes the right to access up to three full cycles of IVF treatment free on the NHS).

Figure 8: Referral pathways for infertility for residents in NCL

Borough	Referral for women	Referral for men	Assisted conception unit
Barnet	Community Gynaecology Clinic.	If no motile sperm or azoospermia refer to Urology. If low count and motility refer to Community Clinic who will forward directly to GSTT only if appropriate	GSTT only
Camden	Refer infertility service in secondary care for further investigations to UCLH, Imperial or the Whittington.		UCLH or Imperial (GPs cannot refer directly) UCLH or Imperial (GPs cannot refer directly)
Enfield	Community Gynaecology Clinic.	If no motile sperm or azoospermia refer to urology. If low count and motility refer to Community Clinic who will forward directly to Homerton assisted conception unit if appropriate	Homerton Hospital only
Haringey	*No referral pathway document identified*		
Islington	Referral to fertility services usually at UCLH or the Whittington.		UCLH or Imperial (GPs cannot refer directly)

Sources: Referral pathways downloaded from NCL GP. GSTT = Guy's and St Thomas' NHS Foundation Trust; Homerton = Homerton University Hospital NHS Foundation Trust; Imperial = Imperial College Healthcare NHS Trust; UCLH = University College London Hospitals NHS Foundation Trust; Whittington = Whittington Health NHS Trust.

NCL residents may be referred to a number of providers for care and treatment depending on their diagnosis and needs. There are four providers that deliver the most specialist of treatments (including IVF), which are Guy's and St Thomas' NHS Foundation Trust, Homerton University Hospital NHS Foundation Trust, Imperial College Healthcare NHS Trust and University College London Hospitals NHS Foundation Trust.

For further information on the treatments provided by each provider, please see Appendix 5.

Activity and expenditure

Significant difficulties were experienced in ascertaining the current volumes of activity and expenditure on specialist fertility treatments in NCL. There is no single source of data, therefore multiple sources were obtained, including:

- SLAM data (service level agreement monitoring dataset)
- SUS admissions data (national repository of NHS activity data)
- Trust data (a minimum data set was requested from all providers; a varied response was received)

- Prior approval data (this relates to patients from Camden and Islington attending UCLH only)

Figure 9: Summary of estimated IVF activity and expenditure on IVF for NCL service users (per annum)

Borough	Number of IVF patients	Patients/ 100,000 population*	No. IVF cycles funded in policy (fresh + frozen)	Fresh IVF cycles completed		Frozen embryo transfers completed		Total expenditure
				Total number	Number/ patient	Total number	Number/ patient	
Barnet	111	145	1 + 1	111	1.0	49	0.4	£452,300
Camden	147	236	3 + 3	189	1.3	91	0.6	£841,000
Enfield	124	189	1 +1	124	1.0	55	0.4	£350,700
Haringey	167	282	1 +1	167	1.0	73	0.4	£507,900
Islington	139	214	2 transfers	168	1.2	46	0.3	£695,000
NCL Total	**688**	**209**	**-**	**759**	**1.1**	**314**	**0.5**	**£2,846,900**

Note:
** Service users per 100,000 female population aged 18-45*

An estimated 688 NCL service users undergo NHS funded IVF annually at a cost of just under £2.9million (Figure 9).The number of service users undergoing NHS funded IVF per 100,000 female population aged 18-45 appears to be highest in Haringey and lowest in Barnet. Consistent with the number of cycles currently funded in each area, Camden patients (for whom up to 3 cycles of IVF are funded) receive the most fresh and frozen IVF cycles per patient, followed by Islington service users (who may receive up to 2 cycles). Levels of expenditure follow as per activity, with total expenditure highest in Camden, followed by Islington.

Of note, even where up to 3 fresh and 3 frozen cycles are offered, the proportion of people using that full quota is low, with an average of 1.3 fresh cycles and 0.6 frozen cycles per service user. CRG indicate this is typically because a proportion of service users will conceive from the first fresh and frozen cycle, a number who have responded poorly will not proceed to further cycles and a proportion may suspend further participation due to the psychological and emotional burden of the treatment.

With regard to other interventions covered by the existing policies data was severely limited however, the following has been estimated:

- IUI – data from providers indicates 249 cycles are undertaken annually at a cost of £193,700; between 38 and 48 of these used donor sperm
- Assisted conception treatments using donor eggs – in 2018 and 2019 there were 4 applications for IVF using donor eggs that were considered by the Individual Funding Request (IFR) panel, 1 of which was approved
- Sperm washing – Local HIV specialists advise that service users will only very rarely require sperm washing, with an estimated 0-5 service users per year referred for sperm washing
- Surgical sperm retrieval – extrapolating UCLH data (Camden and Islington only) it has been estimated that across NCL ~31 episodes of surgical sperm retrieval occur per year at a cost of £9,400 for storage (per annum) and £112,400 for subsequent ICSI
- Oocyte / embryo cryopreservation – an estimated 36 IFRs for cryopreservation of oocytes / embryos were approved in 2018, and 37 in 2019. Assuming the mean cost of a cycle is just over £3.3k, annual expenditure is estimated at c. £122,500
- Sperm cryopreservation – extrapolating UCLH data (Camden and Islington only) it has been estimated that in NCL 136 episodes of sperm cryopreservation occurred, at a cost of £271,800

Taking all treatments into account, it is estimated that overall expenditure per year is less than £4million.

Costs

Prices for IVF cycles depend on the different components they include (e.g. drugs, storage, ICSI etc.). For NHS providers used by NCL patients, the price of a fresh IVF cycle is generally between £3,000 and £4,000. The price of a frozen cycle is between £800 and £1,000. For most providers, this is slightly higher than the National Tariff Benchmark prices for IVF services (£3,144 - £4,057 for 1 fresh and 1 frozen cycle; £1,014 for subsequent frozen cycles). Additional costs apply when donated eggs are used (additional ~£2,000). Storage of embryos/ genetic materials is around £300 to £500 per year. IUI is between £700 and £1,000 per cycle.

Local Outcomes

HFEA reported outcomes have been reviewed for the fertility clinics commonly used by NCL residents for NHS funded treatments. Where data is available, it appears that outcomes are consistent with the national average. UCLH is reported as being above national average in one area – births per egg collection.

Figure 10 HFEA reported outcomes for fertility clinics used by NCL NHS patients.

Provider	Births per egg collection[1]	Multiple birth rate[2]	IUI – pregnancies/ treatment[3]	Donor insemination – births/treatment[4]
National average	Under 38: 45% 38 and over: 22%	Under 38: 8% 38 and over: 10%	Under 38: 13% 38 and over: 7%	Under 38: 17% 38 and over: 7%
Guy's and St Thomas' NHS Foundation Trust (Guys Hospital Assisted Conception Unit)	Under 38: 46% (based on 1,606 egg collections) 38 and over: 21% (based on 804 egg collections) *Consistent with national average*	Under 38: 7% (based on 795 births) 38 and over: 9% (based on 192 births) *Consistent with national average*	Under 38: 18% (based on 28 cycles) 38 and over: 9% (based on 11 cycles) *Consistent with national average*	Under 38: 8% (based on 53 cycles) 38 and over: 11% (based on 18 cycles) *Consistent with national average*
Homerton University Hospital NHS Foundation Trust (Homerton Fertility Centre)	Under 38: 39% (based on 563 egg collections) 38 and over: 15% (based on 250 egg collections) *Consistent with national average*	Under 38: 11% (based on 265 births) 38 and over: 17% (based on 70 births) *Consistent with national average*	Under 38: 20% (based on 90 cycles) 38 and over: 3% (based on 36 cycles) *Consistent with national average*	Under 38: 25% (based on 32 cycles) 38 and over: 4% (based on 27 cycles) *Consistent with national average*
Imperial College Healthcare NHS Trust (Wolfson Fertility Centre at Hammersmith Hospital)	Under 38: 46% (based on 604 egg collections) 38 and over: 26% (based on 197 egg collections) *Consistent with national average*	Under 38: 12% (based on 290 births) 38 and over: 13% (based on 60 births) *Consistent with national average*	Not reported	<10 cycles therefore data unavailable
North Middlesex University Hospitals NHS Trust	N/A – intervention not provided.	N/A – intervention not provided.	Not reported	N/A – intervention not provided.
University College London Hospitals NHS Foundation Trust (Centre for Reproductive and Genetic Health)	Under 38: 63% (based on 582 egg collections) 38 and over: 38% (based on 289 egg collections) *Above national average*	Under 38: 11% (based on 503 births) 38 and over: 13% (based on 160 births) *Consistent with national average*	Under 38: 19% (based on 73 cycles) 38 and over: 10% (based on 83 cycles) *Consistent with national average*	Under 38: 17% (based on 24 cycles) 38 and over: 3% (based on 64 cycles) *Consistent with national average*
Whittington Health NHS Trust (Whittington Fertility Centre)	N/A – intervention not provided.	N/A – intervention not provided.	<10 cycles therefore data unavailable *Consistent with national average*	Under 38: 30% (based on 10 cycles) 38 and over: No data reported *Consistent with national average*

Sources: HFEA website. 1. Birth rates per embryo collection shows the chance of success from all the fresh and frozen embryo transfers within two years of one egg collection. Birth rates per egg collection were for 2016. 2. Multiple birth rates were for 2018. The HFEA target for all clinics is a multiple birth rate of 10% or lower. 3. IUI pregnancy rates were for 2019. 4. Donor insemination birth rates were for 2018.

Summary of baseline position

HFEA data indicates around 1,500 NCL residents undergo fertility treatments (IVF or DI) each year. Around 27% of treatments in London are funded by the NHS. NCL appears to have a high proportion of women of the ages likely to access NHS funded fertility treatment. However, the NCL population has lower rates of some risk factors for infertility including obesity, underweight and smoking.

Significant difficulties were experienced in ascertaining the current volumes of activity and expenditure on specialist fertility treatments in NCL; data from multiple sources were therefore used to estimate this. An estimated 688 NCL service users undergo NHS funded IVF annually at a cost of just under £2.9million. Consistent with the number of cycles currently funded in each area, Camden patients (for whom up to 3 cycles of IVF are funded) receive the most fresh and frozen IVF cycles per patient. However, even where up to 3 fresh and 3 frozen cycles are offered, the proportion of people using that full quota is low, with an average of 1.3 fresh cycles and 0.6 frozen cycles per service user.

Limited data on other interventions indicates 249 NHS funded IUI cycles and 31 surgical sperm retrieval procedures are undertaken on NHS residents per year. In addition around 36 oocyte/ embryo cryopreservation cycles and 136 sperm cryopreservation procedures are undertaken for fertility preservation annually.

Total expenditure on all specialist fertility treatments is estimated to be less than £4million per year for NCL NHS residents.

b.) Establishing the evidence base

The evidence base for the interventions and eligibility criteria set out in the scope for the Review was established by completing the following:

- Review of national guidance including:
  - NICE Clinical Guideline 156 on fertility problems (CG156, 2013)
  - NICE Quality Standard 73 on fertility problems (QS73, 2014)
  - HFEA commissioning guidance (CG) for fertility treatment (2019)
  - NHS England/ Improvement guidance for CCGs on formation of clinical commissioning policies for fertility preservation (2019)
  - NHS England clinical commissioning policy on surgical sperm retrieval for male infertility (2016)
- Review of relevant European guidance including:
  - European Society of Human Reproduction and Embryology Guideline on female fertility preservation (2020)
  - European Association of Urology Guideline on male infertility (2016)
- Analysis of HFEA registry data – Clinics in the UK are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The HFEA holds this information in a Register, which contains information about patients, the treatment they received and their outcome. HFEA registry data has been analysed to estimate:
  - the clinical effectiveness and safety of the interventions included within the scope of the policy review

- the impact of different eligibility criteria on the outcome of treatments
- outcomes of interest will be live birth rates and multiple birth rates[8].

- Literature reviews[9] – the Fertility Policies Review Steering Group have agreed that literature reviews will not be undertaken:
  - where existing NCL CCG policies/ criteria are consistent with NICE clinical guidelines[10]. In these cases it is unlikely the policies/ criteria will be changed and therefore a literature review would be unnecessary, OR,
  - where outcome data from the HFEA registry is available to establish the evidence base and therefore literature review is not necessary.

Figure 11 provides a summary of the evidence base considered for each of the interventions and eligibility criteria within the scope of the Review.

Figure 11: Summary of evidence base considered for interventions and eligibility criteria in Review

Intervention within scope	National guidance	HFEA outcome data	Literature review
IVF/ ICSI	✓	✓	-
IUI using partner sperm	✓	✓	-
ACT using donor sperm	✓	✓	-
IVF using donor oocytes	✓	✓	-
Fertility preservation	✓	✓	✓
Sperm washing	✓	-	✓
Surgical sperm retrieval	✓	-	-
ACT involving surrogates	-	✓	-

Criteria within scope	National guidance	HFEA outcome data	Literature review
Defining infertility	✓	-	-
Female age	✓	✓	-
Previous IVF cycles	✓	✓	-
BMI	✓	-	✓
Smoking status	✓	-	✓
Ovarian reserve	✓	-	✓
Previous children	✓	-	-
Previous sterilisation	-	-	-
Alcohol/ drug use	✓	-	-

Focus of literature reviews as follows:

1. Clinical effectiveness of ovarian tissue cryopreservation and impact of male age on sperm cryopreservation for fertility preservation.
2. Clinical effectiveness of sperm washing.
3. Impact of male BMI on fertility outcomes.
4. Impact of vaping on fertility outcomes.
5. Impact of ovarian reserve on fertility outcomes in women aged under 40 years.

The majority of interventions and eligibility criteria that are included within the scope of the Review have either national guidance and/or HFEA outcome data to provide the evidence base. A summary of HFEA reported outcome data can be seen in Figure12. This indicates:

[8] The HFEA state that multiple births are the single greatest risk associated with fertility treatment. Multiples are six times more likely to be born prematurely than single babies, which can lead to long-term health problems such as difficulty breathing, cerebral palsy and other physical and learning difficulties. Women carrying more than one baby are at an increased risk of miscarriage, high blood pressure (hypertension), pre-eclampsia, gestational diabetes and caesarean section. The risk of death in pregnancy is also 2.5 times higher.

[9] Literature reviews involve searching, identifying and critically appraising published research on a specific topic. Relevant data may then be extracted and combined to provide a picture of published research on a specific topic.

[10] NICE Clinical Guideline 156 on Fertility was published in 2013 and reviewed in 2015. CCGs must have regard to current NICE guidance and to provide clear reasons for any clinical commissioning policy that does not follow NICE guidance.

- IVF has higher live birth rates than IUI, but lower multiple birth rates compared to unstimulated IUI
- IVF using donor eggs and/ or donor sperm has higher success rates compared to IVF using patient eggs
- Live birth rates following IVF decrease as the age of the woman increases

Figure 12: HFEA reported outcome data on fertility treatments

Intervention	Live birth rate	Multiple birth rate
IUI using partner sperm	12%	1%
IUI using donor sperm:		
Stimulated	14%	9%
Unstimulated	13%	2%
IVF by cycle type:		
Fresh cycle	25%	10–13%*
Frozen cycle	30%	7–11%*
IVF using donated materials:		
Donor sperm, patient eggs	31%	8%
Partner sperm, donor eggs	33%	6%
Donor sperm, donor eggs	37%	6%
Partner sperm, patient eggs (ref)	26%	8%
IVF using thawed patient eggs:		
NHS and private patients	18%	11%
NHS patients only**	9%	-
ACT involving surrogates:		
Fresh IVF cycle	31%	-
Frozen IVF cycle	30%	14%
IVF by age (fresh cycles; own eggs, own sperm)		
Under 35	32%	
35-37	26%	
38-39	20%	
40-42	12%	
43-44	4%	
Over 44	1%	

*Where data is not presented this is usually due to numbers of patients undergoing this intervention being too small to report outcomes. *Range depending on age of woman. **Likely to be limited to those undergoing fertility preservation for medical reasons (rather than for social reasons).*

Literature reviews

It was agreed that literature reviews would not be undertaken on topics where:

- Existing NCL CCG fertility policies are consistent with NICE Clinical Guideline 156 on fertility; **or**
- Outcome data from the HFEA registry can be used to establish the evidence base

Using this criteria, six topics were identified for literature review:

1. Ovarian tissue cryopreservation
2. Male age when cryopreserving sperm for fertility preservation
3. Sperm washing
4. Impact of male BMI on fertility / fertility treatment
5. Impact of vaping on fertility / fertility treatment
6. Ovarian reserve in women aged <40 years

The principles and approach for carrying out the literature reviews were confirmed with the CRG. The findings of the literature reviews were subsequently considered by the CRG, who was asked to

confirm whether all relevant research was included, confirm whether conclusions were fair and provide comment from the perspective of specialists' clinicians. Figure 13 sets out a summary of findings of the six literature reviews.

Figure 13: Summary of Literature Reviews

Topic	Reason required	Method	Summary conclusions	CRG comments
Ovarian Tissue Cryopreservation (OTC)	OTC is funded in one borough in NCL; not recommended by NICE; no HFEA data	Studies included if they compared OTC with cryopreservation of oocytes / embryos	2 studies identified indicate that birth rates per patient are higher for those who have undergone cryopreservation of oocytes / embryos compared to cryopreservation of ovarian tissue. However, the differences between interventions mean that comparison is inherently difficult such that it is not possible to make robust conclusions.	European Society of Human Reproduction and Embryology (ESHRE) Guideline on Female Fertility Preservation (2020) should be noted which are based on a robust literature review.
Impact of male age on cryopreservation of sperm	4/5 of current NCL policies require men undergoing fertility preservation to be aged ≤55; not recommended by NICE; no HFEA data	Studies included if assessing impact of age of the man when he cryopreserved the sperm on live births / pregnancies following IUI or IVF using sperm	No studies identified. No evidence was identified to support the inclusion of an upper age eligibility criterion for men accessing medical fertility preservation.	CRG agreed with the conclusion of the evidence review.
Sperm washing	4/5 current NCL policies funds sperm washing; recommended by NICE (but NCL policies not all consistent); no HFEA data	Studies included if assessed clinical effectiveness / safety of sperm washing for HIV discordant couples where the male is HIV positive	No studies including comparison group. Sperm washing appears to be effective in preventing transmission of HIV to the female partner and any babies born, including where the man is not taking antiretroviral drugs or is not virally supressed. However, as no comparison studies exist, the benefits of sperm washing vs. unprotected timed intercourse are unclear.	CRG requested the views of HIV specialists on this topic [see Specialists' views section].
Male BMI	None of the existing NCL CCG policies include male BMI criterion; NICE states men with BMI ≥30 should be informed they are likely to have reduced fertility; no HFEA data	Studies included if they stratified male weight by WHO defined BMI ranges and controlled for potential confounding factors (e.g. woman's BMI, woman's age)	A systematic review of the impact of male BMI on fertility reported that infertility may be more prevalent in overweight and obese men. Studies assessing the impact of male BMI on the outcomes of fertility treatments report inconsistent results. However a systematic review on this topic indicated obesity in the male partner may lead to reduced live birth rates following fertility treatment.	CRG agreed that there is an association between male BMI and fertility/ the outcome of fertility treatments, but did not feel the impact was sufficient to include this as an eligibility criterion.
Vaping	Vaping not addressed in current policies; not addressed by NICE; no HFEA data	Studies included if involving humans and included live birth rates / pregnancy rates as outcomes	Evidence from a single prospective observational study did not identify a statistically significant association between e-cigarette use and fecundability[11]. More research is required to confirm whether an association exists or not. No studies on the association between vaping and fertility treatment outcomes were identified.	CRG agreed that there is a paucity of evidence on this topic and therefore vaping should not currently be an exclusion criterion for NHS funded fertility treatment.

AMH	All current NCL fertility policies include AMH criterion for women of all ages; NICE recommend AMH criterion only in women aged 40-42; no HFEA data	Studies included if they controlled for potential confounding factors (e.g. woman's age) and included live birth rates as an outcome. Retrospective studies excluded if N<1,000	A systematic review and additional primary studies indicate that low AMH is associated with a reduced likelihood of live birth following IVF.	CRG agreed that there is an association between AMH and the outcome of fertility treatments, however they noted some patient groups with low AMH still have a good chance of pregnancy. They therefore felt clinical input is required in relation to decision-making for these patients.

[11] The probability of achieving a pregnancy within a given period of time, especially during a specific month or menstrual cycle.

Summary of evidence base

The evidence base of the interventions included within the scope of the Review was established through reviewing national and European guidance and analysing HFEA outcomes data. Where existing policies were not aligned to national guidance and HFEA data was not available, literature reviews were undertaken. Outcomes of interest were live birth rates and multiple birth rates.

c.) Obtaining the views of specialists

The views of specialists were obtained during the course of the Review in the following ways:

- **Establishing a Clinical Reference Group (CRG)** of fertility specialists from across NCL and its partners to provide clinical "check and challenge" to the methods and outputs of relevant activities being undertaken by the Review (for more information about the CRG see Chapter 2b)
- **Collating responses to questionnaires** to obtain the views of fertility specialists (and other specialist clinicians who see patients who might require fertility treatments) on the interventions and eligibility criteria included within the scope of the Review
- **Considering findings of interviews** with specialist clinicians who provide ovarian tissue cryopreservation[12]

Responses to questionnaires

Questionnaires were drafted to collate specialist clinicians' views; one for fertility specialists (including a shortened version for urologists), and one for HIV specialists (in relation to sperm washing only). The questionnaires were considered by the CRG, updated in light of CRG suggestions, before being agreed by the NCL Fertility Policies Review Steering Group.

Questionnaires were designed to obtain the following types of information:

- Confirmation of the baseline position
- Current capacity / barriers to providing fertility treatments
- Benefits and limitations of fertility treatments included within the scope of the Review[13]
- Benefits of limitations of eligibility criteria included within the scope of the Review[11]
- Equalities and equity issues

Questionnaires for fertility specialists were emailed to fertility clinic leads, medical directors and appropriate specialists. Questionnaires for urologists and HIV specialists

[12] Note that these interviews were undertaken as part of a different policy review for a group of CCGs based in the south east in October 2020.

[13] With regard to these points, the aim was to: (a) obtain the strength of feeling for specific issues by asking for views using a Likert scale (i.e. scale of 1 to 5 where 1= strongly against and 5= strongly for), allowing some quantification of views. Respondents were also asked to note rationale for their views in free text boxes; (b) elicit information which would not be obtained from activity / outcome data or the research literature.

were sent directly to specialists with an interest in fertility (or where these did not exist, heads of department).

Clinicians from the following Trusts were sent questionnaires:

- Trusts providing NHS funded IVF treatments for NCL patients (4 Trusts)
- Trusts providing NHS funded IUI treatments for NCL patients (2 Trusts)
- Additional Trusts located in the NCL geography (Royal Free London NHS Foundation Trust)

Departmental views were requested, but the opportunity for individuals to complete the questionnaire was also welcomed. Responses received were:

- Fertility specialists: 3 departmental responses and 2 individual responses
- Urology specialists: 2 departmental responses and 1 individual response
- HIV specialists: 4 departmental responses and 2 individual responses

The summary findings were:

- Level of support increased with the proposed number of IVF cycles offered to women aged <40. Advantages of offering more than 1 NHS funded IVF cycle included:
  - Patients may respond better to subsequent IVF cycles if outcome of previous cycles can be taken into consideration
  - If additional NHS cycles are not available patients may seek treatment at clinics abroad which have higher multiple pregnancy rates (as therefore higher associated risks)
- Preference for funding full IVF cycles, as opposed to funding a set number of fresh and frozen. All respondents felt that patients should have all existing good quality embryos transferred before starting their next NHS funded fresh cycle.
- Support for funding all the interventions within the scope of the review, generally in line with NICE recommendations with the following exception:
  - IUI, which some clinicians felt should be available to subfertile heterosexual couples
- There was variation in support for the majority of eligibility criteria proposed for access to fertility treatments, though the following consensus were reached:
  - Support for female BMI criterion
  - No support for requiring same sex couples to undergo 12 IUI to be eligible for IVF
- Generally HIV specialists supported the NICE recommendations on sperm washing but note the vast majority of patients now have undetectable viral loads so very few patients are likely to be referred for this intervention
- View of specialist clinicians providing ovarian tissue cryopreservation services varied as to when this intervention should be offered to patients requiring fertility preservation

d.) Collating equality issues

When a draft NCL fertility policy is available, a full Equalities Impact Assessment will be completed. Given that the core purpose of the Review was to ensure that inequalities regarding funding of specialist fertility treatments are removed, throughout

the Review we have sought to capture points and feedback that may be important from an equalities perspective.

An equality analysis data collection tool has been populated with issues identified relating to protected groups (as defined by the Equality Act 2010) through:

- Establishing the evidence base (including consideration of NICE guidance)
- Establishing the baseline position (including consideration of activity and outcome data and the HFEA report on ethnic diversity in fertility treatment[14])
- Collating the view of specialists who were specifically asked to highlight any issues they were aware of
- Undertaking the engagement exercise

Appendix 6 provides a outlines issues that have been identified relating to the topics considered as part of the Review that may have an adverse equality impact or health inequality impact on any of the protected groups as defined by the Equality Act 2010.

[14] Ethnic diversity in fertility treatment 2018 | Human Fertilisation and Embryology Authority (hfea.gov.uk)

4. Communications & Engagement workstream – Findings

Please note: a full report on the engagement programme undertaken for the first phase of the Fertility Policies Review can be found here.[15]

A key strand of the Review has been to seek the views of our residents, service users, voluntary and community sector (VCS) organisations, fertility groups and wider stakeholder audiences, both on our current fertility policies and also what the CCG should consider when developing the future policy. The engagement window for this work ran from 10 May to 9 July 2021.

We sought views from as many people and groups as possible and our methodology was rigorously designed to support this aim. Proactive communications and engagement activities were undertaken throughout the engagement window to promote awareness of the Review, including social media content across a number of channels, detailed information on our website, with an online questionnaire (also available as a hard copy (and easy read) on request), articles featured in our stakeholder and resident newsletters. 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 Review took place during the COVID-19 pandemic, which restricted engagement interactions to online and telephone methods. 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 interpreters at online events.

The numbers of people who took part in the engagement were relatively small, likely reflecting the challenges presented by the pandemic, but also the small numbers of people for whom this topic is relevant:

- 52 people completed the survey
- 44 people were involved in group discussions, public online sessions and interviews.

It is important to note that some stakeholders, such as local Healthwatch and local VCS groups, felt that it would be easier for residents and service users to provide feedback when the draft policy was available. We also received feedback from groups that residents and members had engagement 'fatigue' due to both local (NHS and Local Authorities) and national (central Government departments) undertaking a wide range of engagement through the pandemic period.

However, good and detailed qualitative insights and data were collected. The majority of people who engaged during the Review stage were past or present service users, and were well-informed about policies and treatments available. Every opportunity was given to hear views from across the board and the survey did draw a very small number of

[15] [Review Engagement Report]

comments from people who thought that fertility treatment should not be available on the NHS.

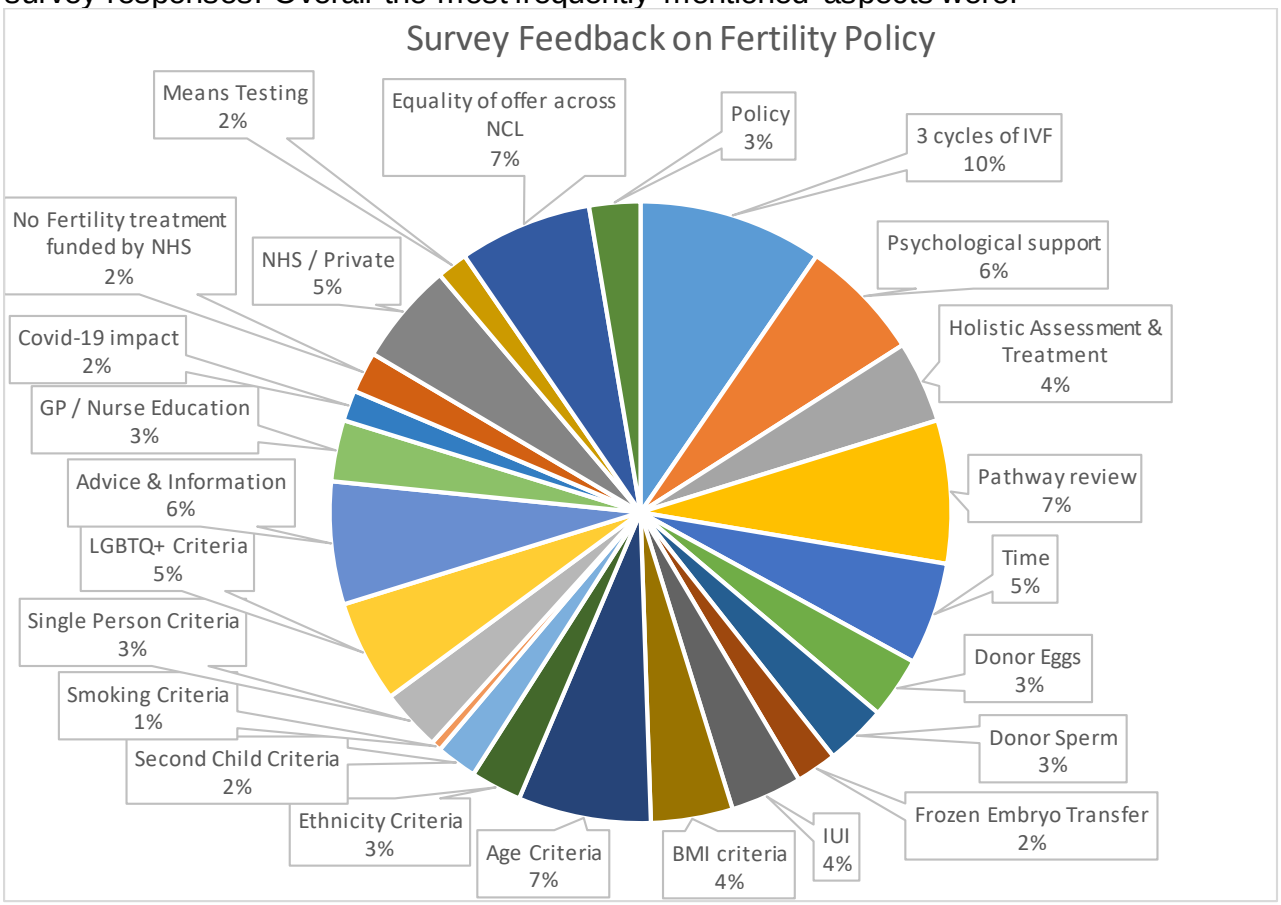
As well as sharing views on current and future policy, many participants also shared information about their own experiences of accessing local services, which are detailed in the Engagement Report. NCL CCG will consider how we use these insights, working collaboratively with our Providers and residents, to improve local commissioning decisions and service provision.

We were committed to being flexible in how we heard from residents, service users and groups, and welcomed 1:1 conversations as well as the opportunity to attend existing events and meetings to discuss the Review. Written comments were welcomed and processed through a single document management system and a consistent analysis framework.

However, the core engagement methods implemented by the CCG were:

- Review questionnaire
- Public and service user-focused activity
- Wider stakeholder-focused activity
- General Practice-focused activity.

There was a general consistency of views across all the engagement sessions and survey responses. Overall the most frequently mentioned aspects were:



These issues are discussed in the Engagement Report under the themes of participants' views on: current policies; what should be considered in developing the new policy; policy implementation; clinical education and training; and service provision and service users' experiences.

The following summary of findings draws out the themes from engagement activity undertaken in respect of the Fertility Policies Review. The key headlines are categorised under policy, service experience and other points.

Policy:

- Development of a single policy is welcomed and there is a strong feeling that the future policy should follow NICE guidance and to level up, not down (for example, 3 full cycles offered and Intrauterine Insemination (IUI) support offered across all boroughs)
- Outdated terminology is used in policies (more inclusive language needed for LGBTQ+ community)
- The new policy eligibility criteria should consider:
    - Previous child policy
    - Exclusions of young women with low AMH levels
    - BMI in some circumstances (e.g. for African women)
    - Clarity on donor assisted conception
- Clarity is needed around the policy, inclusion and exclusion criteria, permissible add-ins, and the treatment journey
- There should be equality of access for all, including same sex couples and single women
- New policy should consider including surrogacy
- Questions asked honouring commitments to treatment: will people on waiting list or part way through treatment be assured that they will get what they were expecting when the policy changes?
- IUI should be offered before IVF if women prefer for unexplained fertility

Service experience:

- Fertility treatment is considered a luxury, distress is not fully taken into account
- Mental health support (counselling) for women from Black, Asian and minority ethnic communities could be better due to the pressures (from within the extended family) placed on them to conceive
- Male partners should be referred for tests beyond a sperm count earlier. There were long wait times for appointments, and referrals were only made when female partners were quite some way into the process
- The whole process needs streamlining, from referrals to waiting times, to reduce the delay
- Timescales and delays a common theme, including:
    - Going through primary care to get a referral
    - Timescales to qualify for referral (incl. referral time for male partners)
    - Waiting times to get appointments- Timescales between each stage of the fertility journey from referral to `treatment

- Distress around operational elements – waiting rooms shared with maternity services (distressing when attending for fertility diagnostics, scans for miscarriage etc.)
- Access to psychological support should be available
- Impact of the pandemic: delays to access treatment, inability of partners to attend appointments
- Mental health is a concern for people even prior to their first engagement with a GP, and throughout the whole process
- Ad hoc approach to male investigations. Infections not excluded

Other points:

- Improve training for GPs and others so they understand and communicate the new policy
- Are there ethnicity differences in fertility in women?
- Lack of knowledge from healthcare professionals (including GPs) about the details of existing policies:
    - Patients need to educate GPs about policies, tests, and treatments.
    - GPs either did not know / misinterpreted details of their borough policy
- Risk that people from ethnic minority communities who live in NCL think the National Health Service is similar to the health provision in their country of origin which means they could miss out on fertility support
- Requirement to have three miscarriages before investigations undertaken (distressing and delays timings for treatment)
- Some people through that fertility treatment is not a necessity and should not be NHS funded. There are limited resources available for health care in general and huge backlogs for NHS treatment for life threatening and life changing conditions

The views shared with the CCG through the engagement work as part of this Review were used to inform the development of principles and recommendations for the future policy.

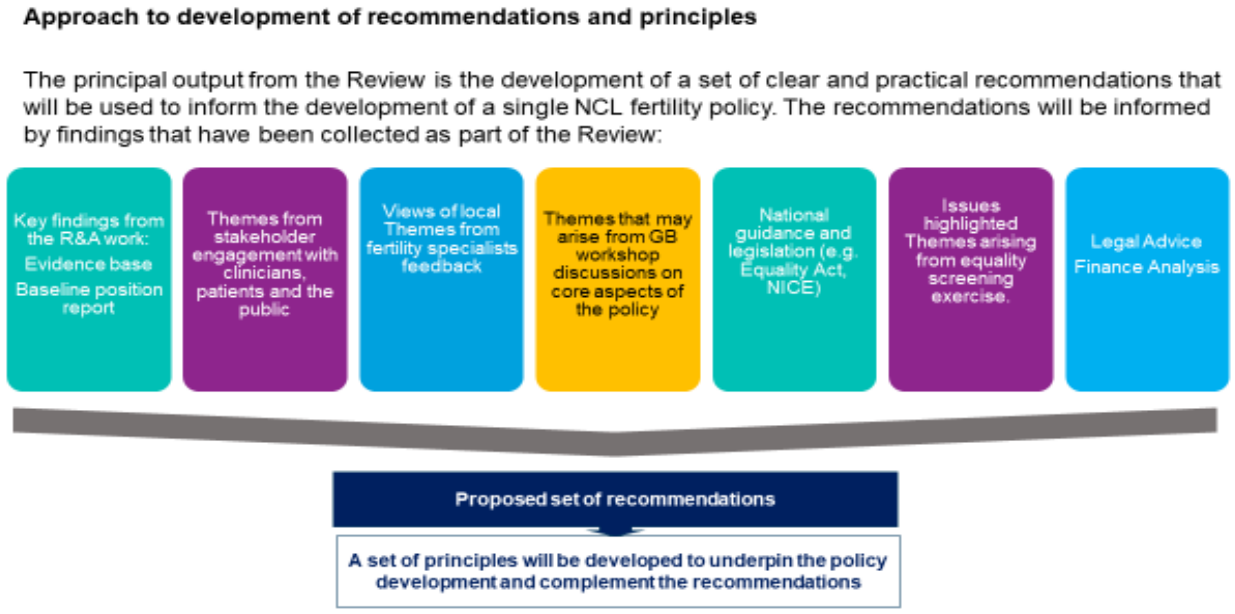
Learning from this phase will be used to develop and refine the Communications and Engagement Strategy for the next stage, and to seek views on the final draft policy, commencing later this year. Individuals and organisation whom have given their time to contribute views during the engagement activity to date will be supported to participate during the second engagement stage. We will also seek to harness the positive relationships developed through the work to help raise awareness and understanding of the future policy once in place.

5. Review Recommendations

Approach to the development of recommendations and principles

As set out in Chapter 1, the principal output of the Review is a set of clear and practical recommendations that will be used to inform the development of a single NCL fertility policy. All of the work that has been undertaken as part of the Review is to support and direct the development of the recommendations.

Figure 14: Summary of approach to develop recommendations and principles

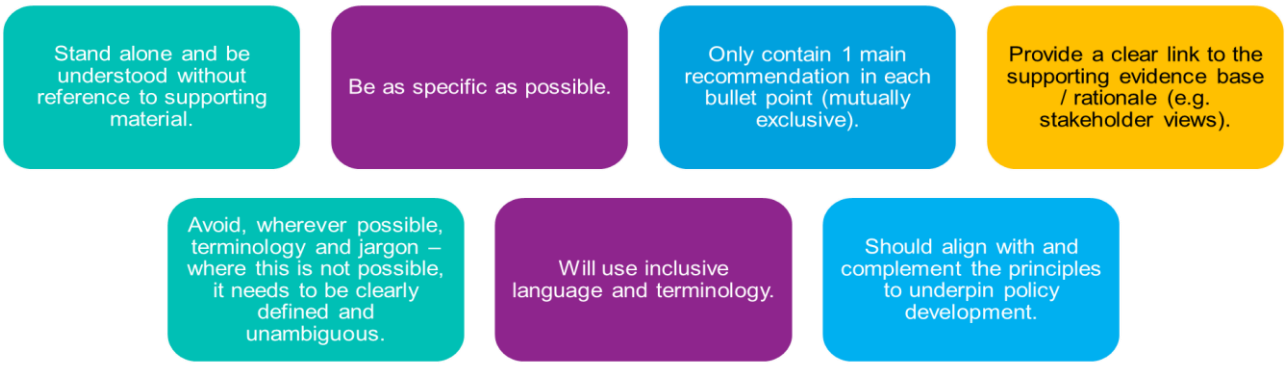


Developing the recommendations and principles has been an iterative process, resulting from discussion with the Fertility Policies Review Steering Group and the NCL Governing Body (via workshop sessions).

Review Recommendations

In forming the Review Recommendations, it was agreed that each recommendation should be articulated as clearly and simply as possible.

Figure 15: Approach to articulation of Review Recommendations[16]



As set out in Chapter 1, the scope for the Review has been clearly defined, therefore the Review Recommendations are solely in regard of those matters that can be addressed by any future NCL fertility policy. The Review Recommendations have been collated into three groups:

- Policy
- Policy Communication and Implementation
- Support the application of the policy and pathway

See Figures 16, 17 and 18 for the Review Recommendations.

[16] Based on NICE guidance: developing recommendations Fertility overview - NICE Pathways

Figure 16: Review Recommendations – Group 1: Policy

Ref.	Review Recommendations	Evidence base / Rationale
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.	• Feedback from stakeholder engagement; National guidance; feedback from fertility specialists; experience from other CCGs across the country; Legal advice
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.	• Feedback from stakeholder engagement; Feedback from fertility specialists
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 clinicians, secondary care clinicians, service users and residents.	• Feedback from stakeholder engagement
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.	• Feedback from FPR Steering Group
1. E	The new NCL fertility policy will utilise inclusive and up to date language, making use of expert advice in this area.	• Feedback from stakeholder engagement
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.	• Feedback from stakeholder engagement
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).	• Feedback from stakeholder engagement; Feedback from fertility specialists

Figure 17: Review Recommendations – Group 2: Policy Communication and implementation

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.	• Feedback from stakeholder engagement
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).	• Feedback from stakeholder engagement
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).	• Feedback from stakeholder engagement
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.	• Feedback from stakeholder engagement

Figure 18: Review Recommendations – Group 3: Support the application of the Policy and pathway

Ref.	Review Recommendations	Evidence base / Rationale
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.	• Feedback from stakeholder engagement
3. B	Education events for secondary care clinicians (and their service management teams) who provide fertility treatments should held across NCL to raise awareness about the new NCL fertility policy, ensuring that all providers understand and adhere to the requirements of the policy.	• Feedback from stakeholder engagement

Principles for development of a single NCL fertility policy

A set of principles has been collated to support the development of a single NCL fertility policy and sit alongside the Review Recommendations. The principles provide parameters for the development of the policy, ensuring that the CCG does not step beyond its responsibilities and function and takes into account the requirements set out in its statutory duties.

The principles are set out in Figure 19 and are comprised of three groups:

- National guidance / legislation
- Local principles to support decision making
- Specific principles in relation to fertility policy development

Figure 19: NCL Fertility Policies Review – principles for development of a single NCL fertility policy

National guidance / legislation
The development of a single NCL fertility policy will have regard to the Public Sector Equality Duty, Equality Act 2010 (eliminate unlawful discrimination, advance equality of opportunity and foster good relations).
The development of a single NCL fertility policy will take into consideration principles set out in the of the NHS Constitution (2012, updated 2015)), such as: • Decisions on funding of drugs and treatments are to be made rationally. • Decisions are to be made in a clear and transparent way. • Access to NHS services is based on clinical need, not an individual's ability to pay.
CCG's expenditure must not exceed the income allotted to it for that year. (The NHS Act (2006))
The development of a single NCL fertility policy will take into consideration principles set out in Guidance on NHS patients who wish to pay for additional private care (2009): • NHS care should not be withdrawn because a patient chooses to buy additional private care. • Additional private care must be delivered separately from NHS care. • The NHS must never charge for NHS care (except in certain circumstances) and the NHS should never subsidise private care.

Local Principles for decision making	
Decision making should be clear and open to scrutiny.	Cost should be take into account – noting investment in one area of healthcare could divert resources away from other areas.
Decision making should be equitable.	New treatments considered on the same basis as existing treatments.
Healthcare should be allocated justly and fairly according to need and capacity to benefit.	Balance the needs of the individual against the wider community.
Treatments and services with good evidence of clinical effectiveness and patient safety will be promoted.	Consider national policy directives and guidance during decision making.
Evidence of clinical and cost effectiveness should be considered.	

Specific principles in relation to fertility policy development
NICE Clinical Guideline 156 on fertility problems will be adopted wherever possible.
NCL CCG will provide clear reasons should NICE guidance not be followed.
The policy will describe fertility treatments available for people who have a pathological problem to explain their infertility.
Not all possible clinical scenarios can be addressed by the policy. IFR is available.

Further considerations

As has been confirmed in this report, the remit and scope of the NCL Fertility Policies Review explicitly focused on the requirement to establish Recommendations to inform the subsequent development of a single NCL fertility policy.

However, as explained in Chapter 4, the Review has heard from residents and service users, in particular about the way in which fertility services are accessed, provided and experienced. Whilst not directly within the scope of the Review, the CCG believes that it is important to capture and listen to all feedback that it receives through engagement activity.

The CCG is also aware that the way in which it works with its partners, including providers (both specialist and primary), is undergoing significant change through the transition to the NCL Integrated Care System (ICS). Whilst there are existing tools and mechanisms for system partners to utilise to support transformation in the way services are commissioned, designed and delivered, the ICS will provide further opportunities for such transformation to occur in an integrated and effective way.

Given the feedback the Review has captured about service user experience and the direction of travel for the system, the Review has also collated a set of considerations for the future commissioning and provision of services in the NCL ICS.

- Commissioning arrangements – these are currently varied across NCL due to historical arrangements. The ICS should consider reviewing the current commissioning and service arrangements.
- Patient pathway – service users have noted confusion about the current pathways and concerns about waiting times, delays experienced and some "back and forth" elements of some treatments. The ICS should consider reviewing how the whole pathway (from primary care to specialist services) can be transformed – potentially being simplified, standardised and improved. The ICS should also consider what information can be developed to support service users throughout the fertility pathway to understand the different types of support and treatments that are available. [17]
- Facility / clinic estates arrangements – service users have noted distress that can be experienced in some locations due a potential inadequate consideration of service user requirements, e.g. both fertility and maternity service users being co-located for fertility diagnostics, scans for miscarriage, etc. The ICS should consider reviewing current estate / facility arrangements to support effective and improved user experience throughout the pathway.
- Activity and expenditure data – the Review experienced difficulties in accessing activity and expenditure data that would support the optimal commissioning and provision of fertility

[17] https://www.healthwatch.co.uk/advice-and-information/2021-07-26/top-tips-get-most-out-your-gp-appointment

services. The ICS should consider reviewing future data requirements (in alignment with the considerations outlined for commissioning arrangements and the patient pathway).

This report is also mindful of the significant volume of feedback that it received from service users about psychological support for people undergoing fertility treatments. Service users have noted that undergoing fertility treatment can be stressful and emotional and have highlighted the importance of psychological support alongside medical and surgical interventions. The CCG will write to the Medical Directors of the providers of fertility services for NCL residents to remind them of the requirements of their HFEA licence to adhere to the Code of Practice and its associated guidance, drawing attention to Chapter 3 – Counselling and patient support.

In the short term, this Review Report will be shared with providers of fertility and associated services for NCL residents. We believe that these considerations and some of the information contained within the report will be useful to contribute to ongoing internal service development and continuous service improvement that we know our providers undertake.

It is anticipated that the majority of the considerations set out will be most effectively responded to as an ICS in due course, recognising the need to balance this work with other ICS priorities and programmes of work from 2022/23 onwards.

6. Next Steps

Following approval of the Final Recommendation Report by the Strategic Commissioning Committee, the project will move into the policy development phase.

An outline plan has been prepared for the Policy Development phase. There are two major workstreams as part of this phase:

- Policy Drafting
- Communications & Engagement (including an Equality Impact Assessment)

The final output will be the single NCL Fertility Policy, with accompanying plans and materials to support the successful launch and implementation of the new policy. The final policy will be informed by the outcome of the Equality Impact Assessment to understand whether there are any positive or negative impacts as a result of the proposed change on any of the protected groups. An assessment of the financial impact of the proposed policy will also need to be undertaken.

It is currently estimated that the single NCL Fertility Policy will be completed by the end of March 2022.

Once the policy is approved, there will need to be ongoing review and monitoring of the implementation of the policy, and annual reviews to ensure that the policy remains relevant and up to date.

Appendices

Appendix 1: NCL CCG Fertility Policies Review Steering Group Membership and Terms of Reference

1. Introduction

1.1 The North Central London ('NCL') Fertility Policies Review Steering Group ('Steering Group') has been established by the Governing Body's Strategy and Commissioning Committee.

1.2 These Terms of Reference set out the membership, remit, responsibilities and reporting arrangements of the Steering Group.

2. Purpose

2.1 The purpose of the Steering Group is to:

2.1.1 Deliver a review of the existing five fertility policies in NCL to make recommendations to enable the development of a single Fertility policy for the CCG ('the Review').

3. Role

3.1 The Steering Group will:

3.1.1 Oversee and manage the Review;

3.1.2 Consider appropriate next steps – including recommendations for scope of future Fertility policy for NCL

3.1.3 Not draw conclusions at this point – developing future policy will be in the next phase (pending conclusions of the Review)

3.1.4 Review the existing five legacy policies;

3.1.5 Engage with service users and members of the public to understand their views on the considerations that NCL should take into account when developing a single policy;

3.1.6 Identify issues that may have an adverse equality impact/ health inequality impact on any of the protected groups as defined by the Equality Act 2010;

3.1.7 Complete a gap analysis to understand where existing policies may not be comprehensive, up to date or robust in line with latest best practice or guidance;

3.1.8 Analyse each of the existing five fertility policies[18] in NCL (Barnet, Camden, Enfield, Haringey & Islington), with a particular focus on the following questions:

- What are the areas of commonality and divergence within the existing policies?
- What is the latest guidance and best practice in providing fertility support and treatment?
- What are the latest regional / national policies and/or guidance to determine access to fertility support and treatment (including access criteria)?
- What precedents or requirements have been set by the courts to guide the setting of fertility policies?
- What is the 'patient cohort' that a fertility policy needs to address?

3.1.9 Determining the baseline position including: estimated local prevalence of infertility and other indications for fertility; existing care pathways; previous activity; expenditure; and local prices.

[18] https://northcentrallondonccg.nhs.uk/fertilitypolicies/document-library/

3.1.10 Ascertain the safety, clinical and cost effectiveness of interventions included within the scope of the Review through either nationally collated outcome data or evidence reviews;
3.1.11 Estimate the impact of different scenarios on clinical outcomes, cost and equity/ equality etc.
3.1.12 Obtain legal advice on any relevant issues as required;
3.1.13 Develop the communications and engagement plan to support the Review, including with clinicians, service practitioners, service users, members of the public and other stakeholders;
3.1.14 Draw together clinicians, researchers and other experts in the field to provide specialist advice to inform the Review;
3.1.15 Make recommendations on next steps required to develop a single NCL policy;
3.1.16 Provide updates to the CCGs Governing Body via the Strategy & Commissioning Committee; and,
3.1.17 Collate the findings and outcomes of the Review into a single report to be presented to the Strategy and Commissioning Committee.

3.2 The Steering Group will not consider:

3.2.1 The development of a single NCL policy;
3.2.2 Any communications and engagement activities that would be associated with the development and approval of a single NCL policy, e.g. wider public engagement on a draft policy;
3.2.3 Services that fall outside the confirmed Review scope (to be recommended by the Steering Group and endorsed by the Strategy & Commissioning Committee);
3.2.4 The decision taken by the CCG (July 2020) to update the existing policies to increase the upper age limit for fertility assessment and any subsequent treatment; and,
3.2.5 Any enquiries, complaints or legal challenges received by the CCG on the existing policies (whether connected with the change in upper age limit or not). However, learnings or feedback from the investigation and actions taken in regards to any such enquiries, complaints or legal challenges will be fed into the Review.

4. Membership

4.1 The Steering Group shall comprise of the following voting members:

4.1.1 Clinical Responsible Officer (CRO), who shall be a Governing Body member;
4.1.2 Senior Responsible Officer (SRO); who shall be a CCG Executive Director
4.1.3 Governing Body Lay Member;
4.1.4 Two Community Members;
4.1.5 Two Clinical Leads;
4.1.6 Assistant Director for Planned Care and Transformation – Camden Directorate; and,
4.1.7 Head of Communications & Engagement.

4.2 The roles referred to in the list of voting members above describe the substantive roles and any equivalent successor roles and not the individual title or titles.

4.3 The list of voting members is set out in Schedule 1. Schedule 1 does not form part of the Terms of Reference and may be amended without the need to formally amend these Terms of Reference.

4.4 Voting members may nominate deputies to represent them in their absence.

5. Attendance

5.1 The Steering Group may invite or allow additional people to attend meetings as attendees. Attendees may present at meetings and contribute to the relevant discussions but are not allowed to participate in any formal vote.

5.2 Attendees at the Steering Group will include other team members / resources supporting the Review as and when required.

5.3 Attendees at Steering Group meetings are non-voting.

5.4 The Steering Group may call additional experts to attend meetings on a case by case basis to inform discussion.

6. Chair

6.1 The Steering Group Chair shall be the Clinical Responsible Officer. In the absence of the Chair, the Governing Body Lay Member will deputise where required.

7. Voting

7.1 Each voting member of the Steering Group shall have one vote with resolutions passing by simple majority. In the event of a tied vote the Steering Group Chair shall have the casting vote.

8. Quorum

8.1 The Steering Group will be considered quorate when at least five voting members are present which must include:

8.1.1 Two Clinicians; from the Clinical Responsible Officer and/or Clinical Lead(s);
8.1.2 The Senior Responsible Officer; and
8.1.3 Any two of the following:

- Governing Body Lay Member; and/or
- Community Members.

8.2 If any representative is conflicted on a particular item of business they will not count towards the quorum for that item of business. If this renders a meeting or part of a meeting inquorate a non-conflicted person may be temporarily appointed or co-opted onto the Steering Group to satisfy the quorum requirements.

8.3 If a meeting is not quorate the Steering Group Chair may adjourn the meeting to permit the appointment or co-option of additional members if necessary.

9. Secretariat

9.1 The Secretariat to the Steering Group shall be provided by the Camden Directorate.

10. Frequency of Committee Meetings

10.1 Steering Group meetings will be held monthly. The Steering Group Chair may call additional meetings or cancel meetings as necessary.

11. Notice of Meetings

11.1 Notice of a Steering Group meeting shall be sent to all Steering Group members no less than 7 days in advance of the meeting.

11.2 The meeting notice shall contain the date, time and location of the meeting.

12. Agendas and Circulation of Papers

12.1 Before each Steering Group meeting an agenda setting out the business of the meeting will be sent to every Steering Group member no less than 7 days in advance of the meeting.

12.2 Before each Steering Group meeting the papers of the meeting will be sent to every Committee member no less than 7 days in advance of the meeting.

12.3 If a Steering Group member wishes to include an item on the agenda they must notify the Steering Group Chair via the Secretariat no later than 10 days prior to the meeting. The decision as to whether to include the agenda item is at the absolute discretion of the Review Group Chair.

13. Minutes of Meetings

13.1 The minutes of the proceedings of a meeting shall be prepared by the Secretariat and submitted for agreement at the following meeting.

14. Authority

14.1 The Steering Group is accountable to the Strategy and Commissioning Committee. The Steering Group must act within the remit of these terms of reference and has no executive powers other than those specifically set out in these terms of reference.

15. Reporting Responsibilities

15.1 The Steering Group will report to the Strategy and Commissioning Committee on all matters within its duties and responsibilities. The Steering Group will provide updates to the CCG's Governing Body via the Strategy & Commissioning Committee.

15.2 The Steering Group may make recommendations to the Strategy and Commissioning Committee or any other committee it considers appropriate on any area within its remit.

16. Delegated Authority

16.1 The Steering Group may agree to delegate its authority to a Steering Group member or members to make decisions on the Steering Group's behalf outside of a Steering Group meeting at its absolute discretion on a case by case basis.

16.2 There are circumstances where time-critical decisions need to be made and it is not possible and/or reasonably practicable and/or a good use of resources to hold a physical meeting in

sufficient time. In these circumstances decisions may be made virtually using the protocol for virtual decision making.

17. Sub-Groups

17.1 The Steering Group will appoint a Clinical Reference Group to provide appropriate clinical expertise and advice. Except for the Clinical Reference Group, the Steering Group may not appoint sub-groups to advise the Steering Group and assist it in carrying out its duties. The Steering Group may not delegate any of its functions, powers or decision making authority to a sub-group.

18. Conflicts of Interest

18.1 Conflicts of Interest shall be dealt with in accordance with the Conflicts of Interest Policy and NHS England statutory guidance for managing conflicts of interest.

18.2 The Steering Group shall have a Conflicts of Interest Register that will be presented as a standing item on the Steering Group agenda. In addition, an opportunity to declare any new or relevant declarations of interest will be listed as a standing item on the Steering Group agenda.

19. Gifts and Hospitality

19.1 Gifts and Hospitality shall be dealt with in accordance with the Conflicts of Interest Policy, and NHS England statutory guidance for managing conflicts of interest.

19.2 The Steering Group shall have a Gifts and Hospitality Register and Steering Group members will have an opportunity to declare any new or relevant declarations of relevant gifts and hospitality as a standing item on the Steering Group's agenda.

20. Standards of Business Conduct

20.1 Steering Group members and any attendees or observers must maintain the highest standards of personal conduct and in this regard must comply with:

20.1.1 The law of England and Wales;
20.1.2 The NHS Constitution;
20.1.3 The Nolan Principles;
20.1.4 The standards of behaviour set out in the CCG's Constitution;
20.1.5 The Standards of Business Conduct Policy;
20.1.6 The Conflicts of Interest Policy;
20.1.7 The Counter Fraud, Bribery and Corruption Policy; and,
20.1.8 Any additional regulations or codes of practice relevant to the Committee.

21. Review of Terms of Reference

21.1 Terms of Reference will be reviewed from time to time, reflecting the experience of the Steering Group in fulfilling its functions and the wider experience of the CCG.

21.2 These Terms of Reference will be formally reviewed annually. These Terms of Reference may be changed, or amended by the Strategy and Commissioning Committee.

Date Approved by Strategy and Commissioning Committee: 14th January 2021

Schedule 1
List of Members

The voting members of the Steering Group are:

Position
Clinical Responsible Officer (CRO)
Senior Responsible Officer (SRO)
Governing Body Lay Member
Two Community Members
Two Clinical Leads
Assistant Director for Planned Care and Transformation – Camden Directorate
Head of Communications & Engagement

Steering Group Chair:

Position
Clinical Responsible Officer (CRO)

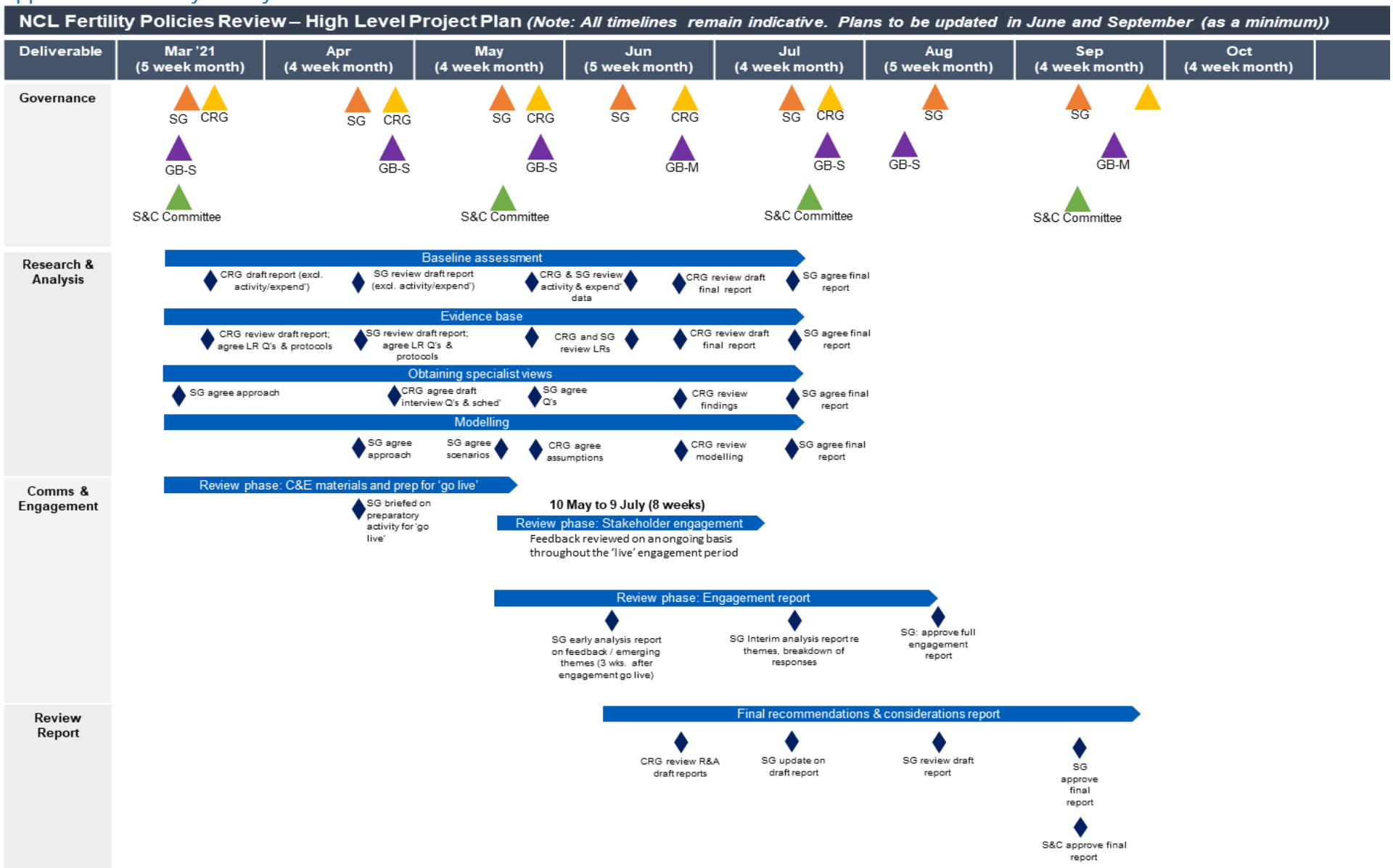
The attendees are:

Position
Clinical Quality Assurance Manager, NEL
Senior Policy Advisor, NEL

Appendix 2: NCL Clinical Reference Group Membership

Clinical Reference Group Membership
NCL Fertility Policies Review Clinical Responsible Officer (Chair)
NCL Fertility Policies Review Review Clinical Leads
Provider Trust Consultants / Head of Service (UCLH, Homerton, GSTT, Imperial, RFL, WH, NMUH)
Fertility Nurse
Embryologist
Counsellor

Appendix 3: Fertility Policy Review Plan



Appendix 4: Comparison of existing NCL Fertility Policies against NICE CG156

i) Comparison of current NCL CCG Fertility Polices against NICE CG156: Funding of treatments

ii) Comparison of current NCL CCG fertility policies and NICE CG156: Eligibility criteria

iii) Comparison of London and Kent ART policies - Interventions

iv) Comparison of London and Kent ART policies – Eligibility Criteria

v) Comparison of London and Kent ART policies – Fertility preservation policies

i) Comparison of current NCL CCG fertility policies and NICE CG156: Eligibility criteria

Intervention	Comparison of current NCL CCG fertility policies against NICE CG156
In vitro fertilisation (IVF)	• The number of cycles of IVF funded for eligible women aged under 40 varies across NCL: o Barnet, Enfield and Haringey fund 1 fresh cycle and 1 frozen embryo transfer o Camden funds 3 fresh cycles and 3 frozen embryo transfers o Islington funds 2 embryo transfers (either 2 fresh or 1 fresh cycle and 1 frozen cycle) NICE CG156 recommends offering 3 full cycles for eligible women aged under 40 (where a full cycle = 1 episode of ovarian stimulation plus transfer of any resultant fresh and frozen embryos) • Across NCL, eligible women aged 40–42 have 1 fresh and 1 frozen embryo transfer funded. NICE CG156 recommends 1 full IVF cycle for eligible women aged 40-42 (where a full cycle = 1 episode of ovarian stimulation plus transfer of any resultant fresh and frozen embryos)
Intrauterine insemination (IUI)	• Consistent with NICE CG156, all NCL policies fund IUI as an alternative to vaginal sexual intercourse for: o 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 o people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) NICE CG156 recommends up to 6 cycles of IUI should be considered for the patient groups outlined above where infertility has been established through 6 cycles of unsuccessful artificial insemination (not funded by the NHS). NCL policies indicate up to 6 IUI cycles are funded for the patient groups outlined above, however they do not state infertility needs to be established prior to treatment. • In addition to the above patient groups, NICE CG156 recommends 6 cycles of IUI for eligible female same-sex couples where infertility has been established through 6 cycles of unsuccessful artificial insemination (not funded by the NHS). In NCL, IUI for same-sex couples is only funded in Enfield and Haringey; policies indicate 6 IUI cycles are funded in both boroughs: o The Enfield policy states is intended for people who have a possible pathological problem to explain their infertility however, it is unclear what previous treatment female same-sex couples should have had in order to be eligible for NHS funded IUI o The Haringey policy does not require same-sex couples demonstrate infertility in order to be eligible for IUI
Treatments using donor sperm	• All NCL policies indicate donor sperm is not funded. In Barnet, Enfield, Haringey and Islington the associated assisted conception treatments will be funded for eligible people (where the patient funds the donor sperm); in Camden this is not funded. • NICE CG156 recommends consideration of the use of donor insemination in specific circumstances; none of the NCL policies set out the indications for which assisted conception treatments using donor sperm will be funded.
Treatments using donor oocytes (eggs)	• All NCL policies indicate donor oocytes are not funded. In Barnet, Enfield and Islington associated IVF will be funded for eligible people (where the patient funds the donor oocytes); in other NCL boroughs this is not funded. • NICE CG156 recommends consideration of the use of donor oocytes in specific circumstances; none of the NCL policies which fund IVF using donor oocytes set out the indications for which this intervention will be funded.

Intervention	Comparison of current NCL CCG fertility policies against NICE CG156
Treatments involving surrogates	• All NCL policies indicate IVF using surrogates is not funded. • NICE CG156 make no recommendations on these interventions
Fertility preservation[19]	• Consistent with NICE CG156, all NCL policies state cryopreservation of sperm, oocytes (eggs) and embryos are funded for eligible patients requiring fertility preservation. In addition Haringey also funds ovarian tissue cryopreservation. • The duration of storage that is funded differs across NCL: consistent with NICE CG156 Camden, Haringey and Islington fund 10 years; Barnet funds 5 years; and Enfield does not specify duration of storage. • The eligibility criteria for access to fertility preservation differ slightly across NCL: all boroughs require women to be aged 42 or under; all boroughs require men to be aged 55 or younger (with the exception of Haringey which does not specify an upper age limit for men); and Barnet, Haringey and Islington require transgender patients to be on the NHS England pathway. • Consistent with NICE CG156 all boroughs require patients to meet criteria for infertility treatment when using stored materials.
Surgical sperm retrieval	• Four of the five NCL policies state that surgical sperm retrieval is funded; the exception is the Haringey policy which does not address this intervention. • CCGs are no longer responsible for commissioning surgical sperm retrieval; NHS England is now the responsible commissioner (though CCGs are responsible for funding storage of and ICSI using surgically retrieved sperm).
Sperm washing	• Consistent with NICE CG156, four of the five NCL policies state that sperm washing will be funded for men who are HIV positive where their female partner is HIV negative; the exception is the Haringey policy which does not address this intervention. • NICE CG156 recommends offering sperm washing in specific circumstances; none of the NCL policies set out the indications for which sperm washing will be funded.

[19] Cryopreservation of sperm, oocytes (eggs) or embryos for patients who are due to undergo a treatment that may leave them infertile e.g. chemotherapy for cancer or gender reassignment.

ii) Comparison of current NCL CCG fertility policies and NICE CG156: Eligibility criteria

Eligibility criteria	Comparison of current NCL CCG fertility policies against NICE CG156
Defining infertility for access to IVF	• Consistent with NICE guidance, all NCL policies state that where there is a known cause of infertility patients should be referred for IVF without delay. • All NCL policies indicate that heterosexual couples with unexplained infertility must have unsuccessfully been trying to conceive for 2 years in order to be eligible for NHS funded IVF. The exception is for women aged 36 and over, where the duration is 12 months. NICE CG156 recommends women aged up to 42 should have been trying to conceive 2 years (i.e. they do not specify a shorter duration for women aged 36 and over). • Four of the five NCL policies indicate that female same-sex couples with unexplained infertility must have unsuccessfully undergone 12 cycles of IUI to be eligible for NHS funded IVF, the exception is Haringey which only requires 6 IUI be undertaken. NICE CG156 specifies patients should have unsuccessfully undergone 12 cycles of artificial insemination, where only 6 of these must be IUI. In all NCL boroughs this criterion applies to single women as well as female same-sex couples, the exception being Haringey which does not mention single women; NICE does not address IVF for single women.
Woman's age	• Consistent with NICE CG156, all NCL policies state women must be aged 42 and under to access NHS funded fertility treatment.
Body mass index (BMI)	• Consistent with NICE CG156, all NCL policies state women must have a BMI of between 19 and 30 in order to access NHS funded fertility treatment.
Smoking status	• Consistent with NICE CG156, all NCL policies state people must be non-smokers in order to access NHS funded fertility treatment.
Previous children	• All NCL policies indicate at least 1 partner must be childless in order to access NHS funded fertility treatment. • NICE CG156 makes no recommendations on this issue

Previous cycles	• Consistent with NICE CG156:
	  ○ All NCL policies state women aged under 40 must have previously had less than 3 IVF cycles in order to access NHS funded fertility treatment
	  ○ Four of the five NCL policies state women aged 40–42 must have had no previous IVF cycles in order to access NHS funded fertility treatment; the Enfield policy is the exception which indicates this group must have previously had less than 3 IVF cycles

Ovarian reserve	• All NCL policies have ovarian reserve criteria which apply to women of all ages:
	  ○ Barnet, Camden and Islington require AFC >4, AMH >5.4 or FSH <8.9
	  ○ Enfield and Haringey require AMH 5.4–25 and AFC 8–16
	• NICE CG156 recommends requiring confirmation that ovarian reserve is not low in women aged 40–42: AFC >4, AMH >5.4 or FSH <8.9; NICE CG156 does not suggest ovarian reserve criteria for women aged under 40

Previous sterilisation	• All NCL policies state fertility treatment is not funded if infertility is due to previous sterilisation. • NICE CG156 makes no recommendations on this issue

iii) Comparison of London and Kent ART policies – Interventions

CCG	IVF cycles	Cancelled/ abandoned cycles	IUI (with partner or donor sperm [DS])	Oocyte (egg) donation	Sperm donation	Surgical sperm retrieval	Sperm washing	Surrogacy	Additional
Central London CCG and West London CCG (North West London CCGs IVF document [October 2016])	1 fresh + 1 frozen. Storage of frozen embryos for 1 year or until live birth. Embryo transfer strategy as per NICE.	1 cancelled cycle (egg collection not undertaken) or OHSS = not counted towards cycle. Poor response = not eligible for further stimulation. Failed fertilisation = eligible for ICSI.	6 cycles for sperm washing.	Donor oocyte not funded but IVF may be for POF or to avoid transmission of inherited disorders. Donor oocyte must be from UK clinic, not sourced through other channels.	Not funded.	Storage for 1 year or until live birth.	Male HIV+, not compliant with HAART or plasma viral load is ≥50 copies/ml. 6 cycles of IUI or 1 IVF funded using washed sperm.	Not funded	-
South East London CCG (Treatment Access Policy 2019/2020)	1 full IVF +/- ICSI (up to 2 FET). Storage of up to 2 frozen embryos for 2 years.	-	3 IUI [indications not specified]	Not routinely funded.	Not routinely funded.	-	NICE guidelines should be followed.	Not funded	-
South West London CCG (Assisted Conception Treatment and Fertility Preservation policy V1.0 2020)	1 IVF cycle (1 fresh + 1 frozen). Storage of frozen embryos for 12 months. Embryo transfer strategy as	If egg collection not undertaken = cancelled. Patients may be eligible for another IVF cycle if ovarian	Up to 12 unstimulated IUI for heterosexual couples with disabilities or psychosexual problems.	Does not fund cost of expenses associated with donor oocytes but will fund associated IUI/ IVF/ ICSI.	Does not fund cost of expenses associated with donor sperm but will fund associated IUI/ IVF/ ICSI.	Storage of surgically retrieved sperm is funded.	Funded where male is HIV+ and compliant with HAART, plasma viral load is ≥50 copies/ml and female	Not funded	Not funded: • Natural IVF • In vitro maturation • Endometrial scratch • Aneuploidy screening

CCG	IVF cycles	Cancelled/ abandoned cycles	IUI (with partner or donor sperm [DS])	Oocyte (egg) donation	Sperm donation	Surgical sperm retrieval	Sperm washing	Surrogacy	Additional
	NICE. ICSI for indications recommended by NICE.	reserve criterion met.					partner is HIV-.		• Varicocele surgery • Experimental investigations Modifications of IVF • Tubal embryo transfer • 'Add-on' IVF interventions unless received 'green light' from HFEA
Kent and Medway CCG (Schedule of Policy Statements for ART, June 2019)	Up to 4 embryo transfers (no more than two from fresh cycles). Cannot progress onto 2nd fresh if frozen embryos stored. Storage of frozen embryos for 2 years.	Abandoned cycle (egg collection not undertaken) does not count towards previous or NHS cycles.	Up to 6 unstimulated IUI for patients with physical disability/ psychosexual problem who have not conceived after 6 AI over 12 months, patients who require IUI after sperm washing or patients eligible for treatment with donor sperm.	IVF using donor egg funded for management of fertility problems or where patients are high risk of transmitting disease.	IUI/ IVF using donor sperm funded for patients with azoospermia / severe deficits in semen quality, at high risk of transmitting disease or subfertile same sex couples or single people.	Storage funded for 2 years for men with obstructive azoospermia.	1 procedure funded where male HIV+, not compliant with HAART or plasma viral load is ≥50 copies/ml, and female partner is HIV-. IVF or IUI available as per relevant policies.	Not funded	Not funded: • IUI for heterosexual serodiscordant couples where the woman is living with HIV. • Time-lapse systems for embryo incubation and assessment. • Adherence compounds in embryo transfer media for ART. • Culture media containing

CCG	IVF cycles	Cancelled/ abandoned cycles	IUI (with partner or donor sperm [DS])	Oocyte (egg) donation	Sperm donation	Surgical sperm retrieval	Sperm washing	Surrogacy	Additional
									GM-CSF for IVF.

iv) Comparison of London and Kent ART policies – Eligibility criteria

CCG	Woman's age	BMI-	Smoking status	Previous children	Previous cycles	Ovarian reserve	Duration unexplained infertility			Previous sterilisation	Additional
							Hetero-sexual couples	Same sex female couples/ single women	Same sex male couples/ single men		
Central London CCG and West London CCG (North West London CCGs IVF document October 2016)	Ovarian stimulation by 40; transfer of embryos within 12 months	Woman's BMI 19-30	Both partners non-smokers for 6 months	No living children from current or previous relationships	No NHS. <3 self-funded. All embryos from previous self-funded cycles used before NHS.	No low ovarian reserve (as defined by NICE)	2 years	12 cycles of self-funded AI by a licensed provider (6 must be IUI). Applies to SSFC and single women.	N/A	Not funded if previous sterilisation	Have been advised on risks and implications of treatment.
South East London CCG (Treatment Access Policy 2019/2020)	Partner receiving treatment 23-39 years at time of fresh cycle (<23 if conception is impossible without fertility treatment)	Woman's BMI 19-30 (women >30 BMI should be referred to obesity management pathway)	Non-smoking at time of treatment. Couples who smoke should be referred to smoking cessation.	No living children from current or previous relationships	Neither partner should have >2 previous IUI/ IVF/ ICSI. No NHS IVF and no more than 3 NHS IUI. Applies to both partners.	-	3 years	3 self-funded IUI (but no more than 2 IVF/ICSI). Applies to SSFC and single women*.	Assisted conception not provided	Not funded if previous sterilisation	Couples living together and in stable relationship. Welfare of Child form is signed. No medical problems making success rate <20%.

South West London CCG (Assisted Conception Treatment and Fertility Preservation policy V1.0 2020)	<43 years.	Woman's BMI 19-30 for 6 months.	Both partners non-smokers for 6 months.	No living child from current relationship and at least 1 of the couple has not living child from previous relationship.	No NHS IVF. Should not have >2 full IVF cycles previously.	FSH and AMH should be as recommended by NICE	2 years. If unable to have vaginal intercourse – same as same sex female couples and single women.	12 IUI over 12 months at a licensed clinic.	Semen analysis only	Not funded if previous sterilisation	Conform to HFEA code of practice including welfare of the child. Alcohol intake within DH limits and no recreational drugs.
Kent and Medway CCG (Schedule of Policy Statements for ART, June 2019)	<40 years. Current full cycle can be completed if woman turns 40 during treatment.	Woman's BMI 19-30. Man's BMI <30.	Those participating in treatment non-smokers.	No living child from current or previous relationships	<3 fresh cycles IVF. <2 previous NHS fresh IVF.	AMH >5.4	2 years or 12 cycles of AI (6 IUI) over 24 months.	6 AI over 12 months to be eligible for IUI. 12 AI over 24 months (including 6 IUI) to be eligible for IVF.	N/A	Not funded if previous sterilisation	-

*Document states not funded for single women however this policy was changed in January 2020 – IVF is now funded for single women on the same basis as female same sex couples.

v) Comparison of London and Kent ART policies – Fertility preservation policies

CCG	FP funded	Indications for FP	Duration of storage	Eligibility criteria for FP	Eligibility criteria for subsequent ACT	ACT funded
Central London CCG and West London CCG (North West London CCGs Cryopreservation of oocytes, embryos and sperm for patients at risk of permanent infertility policy [February 2020])	Collection, cryopreservation and storage of oocytes, embryos and sperm.	Patients undergoing treatment with significant risk of permanent infertility.	5 years	Patients who smoke should have attempted to stop smoking 8-12 weeks before referral. Patients should be routinely offered referral to smoking cessation services.	Must fulfil IVF criteria for subsequent ACT. In women aged over 40 who meet the rest of the IVF criteria, funding of re-implantation will be at the discretion of fertility consultant.	Maximum of 2 FET funded.
South East London CCG (Treatment Access Policy 2019/2020)	Cryostorage of semen, oocytes and embryos. One collection cycle funded.	Person requires treatment likely to have permanent harmful effect on sperm or egg production OR person requires ongoing treatment that causes harmful effect on sperm or egg production, impotence or has teratogenic effects, and stopping treatment for a prolonged period of time to enable conception is not an option.	5 years (additional storage will be self-funded)	Age <40. Women should be well enough to undergo ovarian stimulation and egg collection, this will not worsen there condition and there is sufficient time available.	Must fulfil IVF criteria for subsequent ACT.	
South West London CCG (Assisted Conception Treatment and Fertility Preservation policy V1.0 2020)	Storage of sperm, egg or embryo funded (1 cycle)	Patients preparing to undergo treatment likely to have permanent harmful effect on sperm or egg production such as treatment for malignant disease or treatment for gender dysphoria where the	Aged <23: storage funded until aged 28. Aged >23: storage funded for 5 years or until live birth or women is 43. Patients may self-fund additional storage.	Woman aged <43.	Must fulfil IVF criteria for subsequent ACT (with the exception of the ovarian reserve criteria of FSH and AMH).	2 FET funded; if thawing fails this does not count as FET and patients may be eligible for another.

CCG	FP funded	Indications for FP	Duration of storage	Eligibility criteria for FP	Eligibility criteria for subsequent ACT	ACT funded
		patient is following a NHS pathway OR patients whose ongoing medical condition or treatment causes harmful effects on sperm or eggs production or has teratogenic effects and stopping treatment for a prolonged period of time to enable conception is not possible.				
Kent and Medway CCG (Schedule of Policy Statements for ART, June 2019)	Cryopreservation of sperm, embryos and oocytes available.	Patients due to receive gonadotoxic treatment.	10 years or fertility is established, live birth has occurred, the patient dies and no written consent has been left permitting posthumous use.	As IVF with exception of duration of infertility.	Must fulfil IVF criteria for subsequent ACT.	As IVF policy [i.e. up to 4 embryo transfers].

Appendix 5: Assisted conception treatments provided by fertility clinics used by NCL NHS patients

Provider	IVF / ICSI	IUI	Surgical sperm retrieval	Fertility Preservation	Sperm Washing	ACT involving surrogates	Egg donor programme (waiting times by ethnicity)	Sperm donor programme (waiting times by ethnicity)
Guy's and St Thomas' NHS Foundation Trust (Guys Hospital Assisted Conception Unit)	✓	✓	✓	✓	X	Unknown	Known donors and recruits donors (1-6 months for all ethnic groups)	
Homerton University Hospital NHS Foundation Trust (Homerton Fertility Centre)	✓	✓	✓	✓	X	X	X	Does not recruit donors – known donor programme or patients may purchase donated sperm.
Imperial College Healthcare NHS Trust (Wolfson Fertility Centre at Hammersmith Hospital)	✓	✓	✓	✓	X	X	Does not recruit donors – known donor programme only	
North Middlesex University Hospitals NHS Trust	X	✓	X	X	X	X	X	X
Royal Free London NHS Foundation Trust	X	X	X	Ovarian tissue freezing only	X	X	X	X

University College London Hospitals NHS Foundation Trust (Centre for Reproductive and Genetic Health [CRGH])	✓	✓	✓	✓	X	✓	Known donors and recruits donors (white: immediately; black, Asian or other: >6 months; mixed: 1-6 months)	Known donors and recruits donors (white or black: immediately; Asian, mixed or other: <1 month)
Whittington Health NHS Trust (Whittington Fertility Centre)	X	✓	X	✓ (sperm only)	X	X	X	Recruits donors (white or black: immediately; Asian, mixed or other: no data available)

Sources: HFEA website and clinic websites.

Appendix 6: Equality Analysis Data Collection Tool

Protected Group	Issue	Source
Age	• Fertility decreases as women age. • Success rates for fertility treatments decrease as women age (with the exception of IVF using donor eggs). • NICE recommends 3 cycles of IVF for eligible women aged under 40 years and 1 cycle for eligible women aged under 43 years. • Service users commented that NCL women aged 40-45 years are in a position to start a family due to good career/ life balance. • Older women may be over the age threshold if they have to undergo 1/ 2 years of unprotected intercourse before they are eligible for investigations/ IVF. • Older people and people with medical conditions may find it more difficult to lose weight than younger people.	NHS website HFEA data NICE CG156 (2013) Engagement exercise Engagement exercise Engagement exercise
Disability	• Sperm washing may be an option for some men who are HIV+. • IUI may be an option for people unable to have vaginal intercourse because of a physical disability or psychosexual problem. • Cryopreservation of genetic materials is commonly undertaken for patients who are about to undergo a gonadotoxic treatment for conditions such as cancer. • Assisted conception treatments using donated genetic materials may be required for patients who have completed a gonadotoxic treatment for conditions such as cancer.	NICE CG156 (2013) NICE CG156 (2013) NICE CG156 (2013)

	• Patients with some comorbidities may have difficulty access fertility services. • Legislation prevents donation of sperm/ oocytes from people living with HIV. This impacts on surrogacy for gay male couples, co-maternity for lesbian couples. • People with HIV who require fertility treatment need to be referred to clinics licensed to treat them. • If surrogacy is not funded this may exclude some women with severe disability, and therefore cannot carry a pregnancy, from accessing NHS funded treatment. • There are variations in access to assisted conception by ethnicity which may impact on people living with HIV as some ethnic groups are disproportionately affected.	Engagement exercise CCG Clinical Lead Local HIV specialists HFEA Local fertility specialists Local HIV specialist
Gender	• Some fertility treatments are specific to either men or women and as such require different considerations when developing policy. • NICE make specific recommendations regarding the woman's age; no equivalent recommendations are made regarding the man's age. • Current NCL fertility preservation policies have an upper age limit for men of 55 and an upper age limit for women of 42. • NICE recommend IUI for eligible people in same sex relationships, however these only apply to women in same sex relationships (surrogacy, which is required by male same sex couples, is not address in NICE CG156).	Scope of Review NICE CG156 (2013) Current NCL policies NICE CG156 (2013)
Gender reassignment	• People undergoing gender reassignment interventions such as hormone therapy or surgery may wish to cryopreserve their genetic materials to preserve their fertility. • NHS England and NHS Improvement issued 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'.* • Due to the nature of policies on assisted reproductive technologies, it is necessary to refer to the sex of patients as defined by their biological anatomy on occasion. This may not necessarily be the gender to which individual patients identify.	HFEA NHS England & NHS Improvement (May 2019) Review Working Group
Pregnancy/ maternity	• Multiple births are the single greatest risk of fertility treatment. • NCL couples who already have a child together, including those with secondary infertility are currently excluded from NHS funded fertility treatment due to the 'previous child' criterion. • Some CCGs do not fund fertility treatments for couples where one individual in a couple has a child from a previous relationship.	HFEA Current NCL policies Other CCG policies
Race	• NICE note that there is a shortage of oocyte and semen donors from specific ethnic groups. • The HFEA report that more Asian patients use IVF and less White patients use IVF compared to the relative proportion of these groups in the UK population.	NICE Full Guideline for CG156 (2013) HFEA (2021)

	• The HFEA report birth rates following IVF are lower among Black and Asian patients and higher among White and Mixed ethnicity patients. • A study of 809 women indicated that compared with white women, average AMH values were lower among black and Hispanic women. • Age-related decline in fertility may occur sooner for Asian/ Chinese women compared to Caucasian and African women. • Ethnicity impacts on BMI; it has been suggested by service users that this should be taken into account in relation to the BMI eligibility criterion for women. • Some NCL community groups were not aware that they could access fertility treatment on the NHS.	HFEA (2021) Seifer (2008) Local specialists and Gleicher (2012) Engagement exercise Engagement exercise
Marriage/ Civil Partnership	• Some CCGs do not fund ACT for single women; this may indirectly discriminate against those who are not married or in a civil partnership. • Some CCGs require patients to be in a 'stable relationship' for a specified period of time.	Other CCGs policies Other CCGs policies
Religion/ Belief	• There are a number of religions that prohibit fertility treatments or aspects of fertility treatments (e.g. 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). • Fertility clinics confirmed they are able to accommodate for patients with religious beliefs (e.g. creating 1 embryo at a time, electro ejaculation for those not allowed to masturbate) • Service users noted that people of some cultures feel pressured to bear children and/or have lots of children.	Local fertility specialists Local fertility specialists Engagement exercise
Sexual orientation	• People in same sex relationships who wish to have their own biological children will need fertility treatment to achieve this (donor insemination for women and assisted conception treatments involving surrogates for men). • NICE CG156 recommends IUI for eligible people in same sex relationships. • Heterosexual couples are required to try to conceive through unprotected intercourse for 1 year before accessing NHS investigations and 2 years before accessing NHS funded IVF. Survey respondents noted equitable equivalent criteria need to be determined for same sex couples which take into account the cost of IUI in a clinical setting. • If assisted conception treatments involving surrogates are not funded this will exclude male same sex couples from accessing fertility treatments.	Review working group NICE CG156 (2013) Engagement exercise Local fertility specialist
People with low incomes	• Some CCGs require patients to obtain donor eggs or sperm to be used in their NHS funded cycles; this may disadvantage people with low incomes. • Some patients who have frozen embryos from NHS funded cycles available may not be able to afford treatment using these.	Other CCG policies Engagement exercise

	• Patients who have previously undergone private treatment but can no longer afford this may be ineligible for NHS funded treatment if they have had 3 or more IVF cycles.	Engagement exercise
Other	• The COVID-19 pandemic has delayed access to NHS funded fertility treatment for some patients which may have led to some patients no longer being eligible (e.g. if they are now too old).	Engagement exercise