

# Developing a Fertility Policy for North Central London

Joint Health & Overview Scrutiny Committee 26 November 2021



### Setting the scene

### Introduction



- In 2020, the clinical commissioning groups in Barnet, Camden, Enfield, Haringey and Islington
  joined to become the North Central London Clinical Commissioning Group (NCL CCG). Each
  CCG had an individual Fertility Policy and these are still being used.
- To inform the development of a new, single Fertility Policy the CCG undertook a Review seeking views of patients, residents, clinicians and examining clinical evidence, national guidance etc. From this, a set of recommendations were produced to inform development of a new policy.
- A draft single policy has now been produced. We are seeking views on this, and the feedback we
  receive will be used to finalise the Policy.
- The engagement window is open for 12 weeks (22 November 2021 to 13 February 2022), and you can feed in views in a range of different ways (see slides 16-20).

### What have you seen before



- JHOSC Chair, HOSC Chairs and Cllr leads for Adult and Social Care Services have received communications throughout the engagement window during stage 1 (the Review) informing members of:
  - opening and length of the engagement window (10 May to 9 July 2021).
  - how to have your say (for example, completing the survey, inviting CCG staff to a meeting to discuss the review and having the opportunity to attend the public meetings that were held during the first engagement period).
- A Joint Health Oversight and Scrutiny Committee (JHOSC) Briefing Paper sent to the JHOSC Chair and members (dated 20 September) setting the scene following the engagement window, summarising themes of public feedback received and providing information on the Review Recommendations\*.

<sup>\*</sup> The 20 September briefing paper is attached to the draft fertility policy for information





#### Every CCG in England has a fertility policy. Typically, a CCG fertility policy sets out:

- Assisted conception treatments (e.g. IVF, intrauterine insemination) and other services (e.g. sperm washing for men living with HIV, freezing of eggs, sperm or embryos for people undergoing treatment that may affect fertility) that are available to patients in that area
- The eligibility criteria patients must meet to receive these fertility treatments (e.g. age, smoking status)
- It is not possible for a fertility policy to anticipate every possible individual circumstance.
   Therefore, GPs can submit Individual Funding Requests for patients who have exceptional clinical circumstances

### What help is available to people wanting to conceive?



- There are a range of medicines and treatments available that can help people to conceive, and many of these are available through the NHS
- Everyone's fertility 'journey' will differ depending on personal circumstances for example, whether
  you are in a heterosexual couple, LGBT+ people or you are an individual who wants to conceive
  independently
- Many people start by speaking to their GP who may undertake, or refer a person or couple for, initial investigations. These can include blood tests, sperm-testing and scans
- People may then be referred by their GP to a specialist clinic (at a local hospital) that can prescribe fertility medicines and offer a range of different treatments
- One of the most widely known treatments is in-vitro fertilisation (IVF) but, in fact, not all of people
  who have difficulty conceiving will need a treatment such as IVF

## What do our current NCL fertility policies cover?



- In vitro fertilization (IVF) with or without intracytoplasmic sperm injection (ICSI)
- Intrauterine insemination (IUI)
- Assisted conception treatments (for example, IVF or IUI) using donated oocytes or sperm
- Fertility preservation for patients who are about to have medical treatment such as chemotherapy that will affect their future fertility (egg, embryo or sperm storage)
- Surgical sperm retrieval in four of the five boroughs
- Sperm washing (for people with blood born viruses such as HIV) in four of the five boroughs
- Assisted conception treatments involving surrogates

## Reflecting the aims of the NCL Integrated Care System in policy development



- The main aims of an Integrated Care System are to:
  - improve outcomes in population health and healthcare
  - tackle inequalities in outcomes, experience and access
  - enhance productivity and value for money
  - help the NHS to support broader social and economic development.
- Each ICS has a responsibility to coordinate services and plan health and care in a way that improves
  population health and reduces inequalities between different groups.
- NCL CCG prioritised the development of a new Fertility Policy, recognising the current inequity of access to specialist fertility services across our boroughs (through five different policies)
- The draft policy would increase spending on NHS-funded treatment as it increases access to
  treatment in a number of boroughs. We carefully considered affordability alongside evidenced-based
  and equitable access to treatment, with the aim of maximising the opportunity of successful outcomes
  for people undergoing treatment within available funding.



## Draft single Fertility Policy

## Considerations in producing the draft policy



- The development of the draft policy was informed by:
  - The recommendations from the Review stage\* (incorporating feedback from local residents and stakeholders\*\*)
  - National guidance (including NICE guidelines)
  - Input from a group of specialist fertility clinicians & CCG clinical leaders
  - Data on current use of specialist fertility services, and NHS spending on these
  - A review of potential equality, equity and quality issues
- The CCG sought to adopt NICE guidance wherever feasible, but also considered other relevant factors including affordability. In a limited number of areas, the draft policy therefore varies from the full recommendations made by NICE\*\*\*.

<sup>\*</sup>The full set of recommendations produced from the Review can be read <a href="here">here</a>.

<sup>\*\*</sup> The findings from the stage 1 engagement window can be read <a href="here">here</a>.

<sup>\*\*\*</sup> National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE guidelines are evidence-based recommendations for health and care in England.

## How we have applied our recommendations



In response to feedback received from clinicians and the public the Review Recommendations have been collated into three groups and we have applied our recommendations a number of way. For example;

Policy	Policy Communication and Implementation	Support the application of the policy and pathway
<ul> <li>Drafted a draft single fertility policy across NCL that avoids variation between boroughs</li> <li>Working to address inequalities and ensure equality of access</li> <li>Established an NCL readers panel (a reading panel with community representation from across NCL to test the draft policy for ease of readability, as well as provide views on policy implementation plans).</li> </ul>	<ul> <li>Communications will be targeted at the three core audiences: residents, primary care and secondary care, ensuring that staff and communities have the opportunity to have their say</li> <li>The NCL Readers Panel/Healthwatch will meet with CCG staff throughout the engagement window to advise on activity and to ensure our communications are clear and easy to understand</li> <li>To assist the communication of the policy the public leaflet will be made available in easy read and will be available in other languages when requested.</li> </ul>	<ul> <li>GP update/education sessions will be delivered in NCL to support the awareness of the new policy and its implications.</li> <li>Education events for secondary care clinicians (and their service management teams) who provide fertility treatments to be 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.</li> </ul>

## Draft single fertility policy – the benefits for our local communities



- Implementing a single policy will offer residents and clinicians greater clarity and consistency on the provision and funding of specialist fertility treatments.
- The draft policy represents a significant improvement for most of our population as it expands the provision of NHS-funded fertility treatment in a number of boroughs.
- By offering more equitable and consistent access to treatments, we envisage this will improve patients' experience and reduce inequity between residents.
- We have carefully considered the equality impact of the draft policy on age, race, religion, sexual orientation, disability and other protected characteristics. Overall, the draft policy has a positive impact for most protected characteristic groups.
- The draft policy is more closely aligned to the main national guidance (NICE) than our current five policies.

### Comparison table: draft NCL policy, national guidance and current policies

Policy aspect	Draft new policy	NICE recommendations	Barnet	Camden	Enfield	Haringey	Islington
No. IVF cycles in eligible women <40	6 embryo transfers from a max of 3 fresh cycles (all good quality frozen embryos should be transferred before starting next fresh cycle)	3 full cycles*	1 fresh + 1 frozen	3 fresh + 3 frozen	1 fresh + 1 frozen	1 fresh + 1 frozen	2 embryo transfers
IUI for eligible same sex couples	Up to 6 cycles funded for patients who have not got pregnant following 6 cycles of self-funded IUI	6 cycles for patients who have not got pregnant following 6 cycles of artificial insemination	Not funded	Not funded	Funded for patients who have not got pregnant following 6 cycles of self-funded IUI	Funded	Not funded
IVF and IUI using donor sperm	IVF and IUI and donor sperm funded for NICE recommended indications	Recommended for specific indications	IVF and IUI funded where donor sperm funded by patient	Not funded	IVF and IUI funded where donor sperm funded by patient	IVF and IUI funded where donor sperm funded by patient	IVF and IUI funded where donor sperm funded by patient
IVF using donor egg	IVF and donor egg funded for NICE recommended indications	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 trying to conceive by sexual intercourse **	2 years: applies to women of all ages	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 of all ages	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

<sup>\*</sup>Full cycle = 1 episode of ovarian stimulation plus transfer of any resultant fresh and frozen embryos.

<sup>\*\*</sup>Does not apply if there is a known cause of infertility where patients should be referred for IVF without delay

### Equality considerations



#### The draft policy:

- Is inclusive of individuals with HIV, a physical disability, psychosexual problems, people undergoing cancer treatment, and undergoing gender reassignment.
- Accommodates couples with unexplained infertility, mild endometriosis or mild male factor infertility who have social, cultural or religious objections to undergoing IVF.
- Follows NICE guidance on preserving donor gametes (e.g. eggs or sperm) where a person is about to undergo a procedure that could harm their gametes. This could include procedures such as chemotherapy or gender reassignment.
- Supports patients from different socio-economic backgrounds to access NHS fertility treatments by not requiring patients to pay for donor eggs or sperm to be used in their NHS treatment.
- Includes single women on the same basis as female same sex couples.
- Follows NICE guidance on age of the woman, body mass index and no smoking eligibility criteria to access
  fertility treatment.

#### However, the draft policy:

- Does not fund treatment involving surrogates for any patient groups\*. This may impact on male same sex couples, single men and those with a disability that means they cannot carry a pregnancy.
- Only funds fertility treatment for people who do not already have a child (for those in a couple, at least one
  partner should not have a child), to prioritise those with the most need.

### The Financial Context



- We are operating in a system under significant pressure and facing financial challenges, therefore we
  need to consider how we ensure our resources are deployed as effectively as possible:
  - The NCL health system is amongst the most financially challenged systems across London (both pre & post pandemic)
  - The national message as we move into the second half of the 2021/22 financial year is for systems to focus on restoration and recovery of services and recovering finances back to a sustainable footing
  - NHS England have been clear that the funding for the second half of the 2021/22 financial year includes an increased efficiency requirement which will continue to increase into 2022/23
  - The CCG and future Integrated Care System (ICS) will need to carefully consider the impact of any investment decisions or patient pathway changes on the aforementioned efficiency requirements and the need to return the NCL system to financial balance.
- The draft policy would increase spending on NHS-funded treatment as it increases access to
  treatment in a number of boroughs. We carefully considered affordability alongside evidenced-based
  and equitable access to treatment, with the aim of maximising the opportunity of successful outcomes
  for people undergoing treatment within available funding.



Stage 2 engagement: Sharing your views on the draft single Fertility Policy

### Engagement on the draft policy



- The engagement window will run from 22 November 2021 to 13 February 2022 (12 week period)
- We will use a variety of different mediums and formats, and will include key stakeholder groups such as our service users, residents, general practice, secondary care clinicians, Healthwatch\*, VSC partners, and special interest groups.
- We will be running a number of public events at which the CCG will share information about the
  development of the single fertility policy and seek views on the proposed single policy.
- Online events will be held for Barnet, Camden, Enfield, Haringey and Islington (one per borough).
   An NCL-wide online public meeting will also be held during the engagement window.
- We are planning to hold a pan-NCL event face-to-face in January, although this will be subject to COVID-19 guidance at the time.
- The CCG is happy to come along to discuss the draft fertility policy at any meetings or events
  happening across North Central London, for example, local Fertility Support Groups or GP Patient
  Participation Groups.

<sup>\*</sup> Meetings with local Healthwatch groups will be held throughout the engagement window to focus on engagement activity and where the communications should be targeted if responses from certain communities are low.

### How to give your views



How local residents can contribute their views and experiences in the following ways:

- By attending one of our public meetings
- By inviting us to a meeting
- By completing the online questionnaire (hard copies are available upon request)

Residents will also be able to access the opportunities via our <u>website</u> or you can contact us by:

Email: <u>nclccg.fertility-development@nhs.net</u>

Telephone: 020 3688 2038

The views shared will be carefully considered by the CCG as we finalise the single policy, and will inform planning for how we promote the policy when it is in place.

## What are your views on the draft single Fertility Policy?



We are seeking feedback from residents, fertility services and clinicians on the draft single policy. We would welcome your feedback:

- What are your views on the single draft policy?
- Do you have any specific concerns about any areas of the policy?
- Are there specific actions / changes you can suggest which would address your concerns?
- Is there anything else you would like to tell us about these proposals?

You may also want to share any experience of being referred for, or undergoing, fertility treatment under the NHS in North Central London.

## What are your views on the draft single Fertility Policy?



In providing feedback, you may want to consider what the draft policy says on:

- Eligibility criteria for access to NHS treatment
- Assisted Conception Treatments (IVF and IUI)
- Assisted Conception Treatments using donated sperm and eggs
- Other Assisted Conception Treatments (surgical sperm retrieval, IUI and IVF involving surrogates)
- Assisted Conception Treatments for people with conditions other than infertility (people with HIV and conditions that may impact on future fertility)

We would be interested in your views on:

- How easy or difficult the Fertility Policy is to understand?
- How we can make sure local residents are aware of the approved Fertility Policy?



## Additional information:

- Stage 1: engagement activity overview
- Reports from stage 1 of the policy review work
- Stage 2 public meeting dates



## Engagement during stage 1

### Stage 1: engagement activity overview



#### Engagement activity – public and stakeholder engagement ran from 10 May for eight weeks

- ✓ People with lived experience focus group (in collaboration with Fertility Network UK)
- ✓ Focus groups with representatives from diverse communities (LGBT BAME people who live in the UK whose country of origin is not the UK)
- ✓ Three public meetings
- ✓ Online survey
- ✓ In-depth interviews with individuals from the African Health Forum, Hopscotch Asian Women's Centre and LGBT networks
- ✓ Discussions with local voluntary and community groups
- ✓ Webinar with The LGBT Mummies Tribe (posted on Facebook, Instagram and public websites)
- ✓ Webinar with Programme and Clinical Lead (posted on public website and Twitter)
- ✓ Attending borough GP events
- ✓ NCL CCG Governing Body GPs and Clinical Leads meeting.
- Ongoing communications to promote survey and public meetings (e.g. social media promotion, CCG resident newsletters, NCL GP Bulletin, inclusion on agendas for BAU borough MP and Councillor meetings)

#### Themes from stage 1 engagement: policy

North Central London

**Clinical Commissioning Group** 

Development of a single policy is welcomed

Outdated terminology is used in policies (more inclusive language needed for LGBTQ+ community)

Clarity provided on donor assisted conception

New policy should consider including surrogacy

There is strong feeling the future policy should follow NICE guidance / level up, not down (e.g. 3 full cycles offered)

The new policy eligibility criteria should reconsider:

- Previous child policy
- Exclusions of young women with low AMH levels
- **BMI** in some circumstances (e.g. for African women)

Clarity is needed around the policy, inclusion / exclusion criteria, permissible add-ins, and the treatment journey

Question asked honouring commitments to treatment: will people on waiting list / part way through treatment be assured that they will get what they were expecting when policy changes?

Respondents aware of differences in the policies across the five boroughs, which was often described as "...a bit of a postcode lottery"

There should be equality of access for all, including same sex couples and single women

IUI should be offered before IVF if women prefer for unexplained fertility

### Themes from stage 1 engagement: service experience

NHS
orth Central London

Fertility treatment is considered a luxury, distress is not fully taken into account

The whole process needs streamlining, from referrals to waiting times, to reduce the delay

Access to
psychological
support should be
available

North Central London
Clinical Commissioning Group

Impact of the pandemic: delays to access treatment, inability of partners to attend appointments

Mental health support (counselling) for women from BAME 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

**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

Mental health is a concern for people even prior to their first engagement with a GP, and throughout the whole process

Distress around operational elements – waiting rooms shared with maternity services (distressing when attending for fertility diagnostics, scans for miscarriage etc.)

Adhoc approach to male investigations.
Infections not excluded

#### Themes from stage 1 engagement: other points



Improve training for GPs and others so they understand the new policy

Is there ethnicity
differences in
fertility in
women?

Risk that **people from BAME communities**who live in NCL think the National Health
Service is similar to the health provision in their
country of origin which means they **miss out on fertility support**.

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

Requirement to have three miscarriages before investigations undertaken (distressing and delays timings for treatment)

Fertility treatment is not a necessity and shouldn't 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.

## Reports from the Fertility Policies Review North Central London (stage 1)

- If you want to know more about the first stage of work (the Fertility Policies Review) the following two reports set the scene:
  - NCL CCG Fertility Policies Review: Recommendations Report the Recommendations Report will
    inform you of the findings of the review, including feedback received during a period of public and wider
    stakeholder engagement; and the recommendations of the review to inform the subsequent
    development of a single NCL Fertility Policy.
  - NCL CCG Fertility Policies Review: Engagement Report this document reports the findings from the stage 1 public engagement window (10 May to 9 July 2021).
- You can also access all our archived information used during the review stage <u>here</u>.

### Stage 2 public meeting dates



Public online meetings	Date	
Barnet (Barnet residents only)	Thursday 9 Dec (15:00 – 16:30)	
Camden (Camden residents only)	Tuesday 14 Dec (10:30 – 12:00)	
Enfield (Enfield residents only)	Thursday 16 Dec (15:00 – 16:30)	
Haringey (Haringey residents only)	Wednesday 12 Jan (10:00 - 11:30)	
Islington (Islington residents only)	Monday 17 Jan (15:00 – 16:30)	
NCL wide (open to all residents across North Central London)	Saturday 29 Jan (11:30 – 13:00)	

Face to Face public meeting	Date
NCL wide (open to all residents across North Central London)	Thursday 20 Jan (17:30 – 19:00) To be held in Islington (venue to be confirmed)

It is important to note that the CCG will be actively promoting the draft fertility policy to residents through local community groups, local authorities and NHS providers. In the communications local people will also have the opportunity to invite CCG staff to group and committee meetings to discuss the draft single policy.



#### **DRAFT**

### North Central London CCG Fertility Policy

#### **22 November 2021**

This policy will, if implemented, replace the legacy policies of the previous Barnet CCG, Camden CCG, Enfield CCG, Haringey CCG and Islington CCG.

#### **Contents**

Glossary	/	3
Backgro	und	6
Purpose	of this document	8
Scope o	f this document	9
Policies:	Assisted conception treatments (ACTs)	10
1.	IVF, with or without ICSI	10
2.	IUI using partner sperm	
Policies:	ACTs using donated genetic materials	12
3.	ACT (IUI and IVF) using donor sperm	
4.	IVF using donor eggs	
Policies:	Other ACT interventions	
5.	Surgical sperm retrieval	14
6.	Assisted conception treatments involving surrogates	14
Policies:	ACTs for people with conditions other than infertility	
7.	Sperm washing	15
8.	Cryopreservation of gametes for fertility preservation	16
Eligibility	r criteria	
9.	Eligibility criteria	18
Matrix of	f which eligibility criteria apply to which policies	20
Flow cha	arts of pathways for fertility treatments	21

#### Glossary

Abandoned IVF cycle	Defined as an IVF cycle where an egg collection procedure has not been undertaken. Usually occurs due to a lack of response (where fewer than three mature follicles are present) or conversely if there has been an excessive response to ovarian stimulation and the patient is at risk of severe ovarian hyperstimulation syndrome (OHSS). May also be referred to as a 'cancelled cycle'.
Artificial insemination (AI)	Al is the introduction of sperm into cervix or uterine cavity. Intrauterine insemination (IUI) is a type of Al undertaken at a fertility clinic where sperm is filtered to produce a concentrated 'healthy' sample which is placed directly into the uterus. Al undertaken at home would normally be intra-cervical insemination (ICI).
Assisted conception treatment (ACT)	The collective name for treatments designed to lead to conception by means other than sexual intercourse. Includes: intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and donor insemination (DI).
Azoospermia	Where there are no sperm in the ejaculate.
Cryopreservation	The freezing and storage of embryos, sperm or eggs for future use in IVF treatment cycles.
Donor insemination (DI)	DI is a type of fertility treatment in which high quality donor sperm is injected directly into the womb (IUI) or cervix (ICI). DI is commonly used when either the male partner has no sperm or for lesbian couples/ single women.
Egg (oocyte) donation	The process by which a fertile woman donates her eggs to be used in the treatment of others.
Embryo transfer	The procedure in which one or more embryos are placed in the uterus.
Embryo transfer strategies	Defines the number of embryos that should be transferred in an embryo transfer procedure, depending on factors such as the age of the woman and the quality of the embryos.
Endometriosis	A condition where tissue similar to the lining of the womb starts to grow in other places, such as the ovaries and fallopian tubes.
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. These policies typically explain when the CCG will fund fertility treatments for people experiencing infertility and 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 (FP)	Fertility preservation involves freezing eggs, sperm, embryos or reproductive tissue with the aim of having biological children in the future.
Fresh IVF cycle	Comprises an episode of ovarian stimulation and the transfer of embryos created that have not previously been frozen.
Frozen embryo transfer (FET)	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 embryo transfer'. Also known as a 'frozen IVF cycle'.
Full IVF cycle	Defined by NICE as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).
Gonadal dysgenesis	Abnormal development of a gonad (ovary or testicle).
Gonadotoxic treatment	Treatments that can cause infertility such as some chemotherapies.

Infertility	Infertility is the period of time people have been trying to get pregnant (conceive) without success after which formal investigation is justified and possibly treatment implemented.
In vitro fertilisation (IVF)	IVF involves ovarian stimulation and then collection of a woman's eggs. They are then fertilised with sperm in a 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. 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.
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, an embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation as it bypasses any potential problems the sperm may have in penetrating 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 or donor sperm (known as donor insemination or DI). Sometimes ovarian stimulation is used in conjunction with IUI.
Male factor infertility	Problems with male fertility are related to sperm, sperm production and the reproductive tract.
Men/ male	Due to the nature of policies on assisted reproductive technologies, it is necessary to refer to the sex of patients on occasion. This document therefore refers to 'men' and 'male'. When these terms are used in this document, unless otherwise specified, this refers to sex defined by biological anatomy. It is acknowledged that this may not necessarily be the gender to which individual patients identify.
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.
NICE	National Institute for Health and Care Excellence. NICE provide national guidance and advice to improve health and social care. NICE guidelines are evidence-based recommendations for health and care in England. Organisations commissioning and delivering services are expected to take the recommendations contained within NICE clinical guidelines into account when planning and delivering services. NICE has published a Clinical Guideline (CG 156) on fertility problems.
Oophorectomy	An operation to remove one or both ovaries.
Ovarian Hyper- Stimulation 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 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 of ovarian follicles with the aim of increasing the number of eggs released.
Ovarian tissue cryopreservation	Involves removing and freezing ovarian tissue from a girl or woman. At a later date, the ovarian tissue strips can be thawed and either re-implanted into the ovary, to allow them to try to conceive naturally, or the eggs can be retrieved and fertilised in vitro and the embryo implanted in the uterus.
Pathological problem	One that relates to medical conditions/ diseases (physical or psychological).
Pre-implantation	A technique used to identify inherited genetic defects in embryos created through

genetic diagnosis	IVF. Only embryos with a low genetic risk for the condition are then transferred back to the woman's uterus. Any resulting pregnancy should be unaffected by the condition for which the diagnosis is performed.
Premature ovarian failure	When a woman's periods stop before the age of 45. Also known as primary ovarian insufficiency or early menopause.
Rhesus (Rh) isoimmunisation	A condition where antibodies in a pregnant woman's blood destroy her baby's blood cells. Also known as rhesus disease.
Sperm donation	The process by which a fertile man donates his sperm to be used it the treatment of others. The HFEA regulates sperm donation undertaken at UK fertility clinics.
Sperm washing	Sperm washing is used to reduce the viral load (for example, of HIV) in prepared sperm to a very low or undetectable level. The washed sperm can then be transferred to the women using IUI or used to fertilise eggs in IVF or ICSI.
Supernumerary embryos	Un-transferred embryos created from a fresh IVF cycle.
Surgical sperm retrieval (SSR)	Surgical sperm retrieval means extracting sperm by a surgical procedure. Types of SSR include: percutaneous epididymal sperm aspiration (PESA), microsurgical epididymal sperm aspiration (MESA), testicular sperm extraction (TESE) and microscope-assisted testicular sperm extraction (MicroTESE).
Surrogacy	Surrogacy is where a woman carries and gives birth to a baby for another person or couple. This may involve the eggs of the surrogate, the intended mother or a donor.
Unsuccessful cycle of IVF/ ICSI	Includes failure of fertilisation, failure of development of embryos and failure to conceive following transfer of embryos.
Women/ female	Due to the nature of policies on assisted reproductive technologies, it is necessary to refer to the sex of patients on occasion. This document therefore refers to 'women' and 'female'. When these terms are used in this document, unless otherwise specified, this refers to sex defined by biological anatomy. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

#### **Background**

It is estimated that infertility affects about one in seven heterosexual couples in the UK. About 84% of couples will conceive naturally within a year if they have regular unprotected sex (every 2 or 3 days).

NHS fertility treatment is available for eligible individuals and couples who want to become parents but who have a possible pathological problem (physical or psychological) leading to them being infertile.

People concerned about their fertility are normally referred for clinical assessment and investigation where:

- there is a known clinical cause of infertility or a history of predisposing factors for infertility, or
- the individual or couple has been trying to conceive through either 1 year of unprotected vaginal sexual intercourse or 6 cycles of artificial insemination.

The treatment options offered will often depend on what the cause of the fertility problems are. Fertility treatments may include:

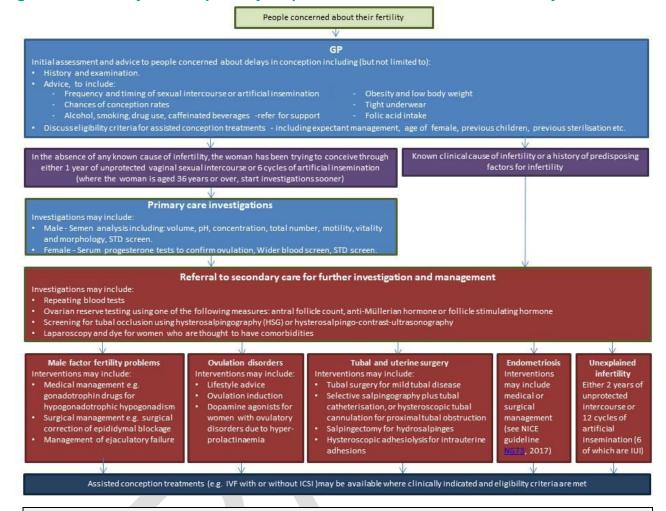
- medical treatment such as ovulation induction for ovulation disorders (no periods or irregular periods).
- surgical procedures such as those used to treat endometriosis or tubal obstruction.
- assisted conception such as intrauterine insemination (IUI) or in vitro fertilisation (IVF)

Not all patients who have fertility problems will require assisted conception treatments like IVF. This policy document sets out the criteria patients must meet in order to access assisted conception treatments funded by NCL CCG.

Figure 1 outlines a summary of the NICE pathway for people who are concerned about their fertility.

The eligibility criteria outlined in this policy document only apply to assisted conception treatments. Patients do not have to meet the eligibility criteria outlined in this document to access NHS funded investigations or medical or surgical treatment for fertility problems which do not fall within the definition of assisted conception treatments.

Figure 1 – Summary of NICE pathway for patients concerned about their fertility



Note: The above pathway does not apply to all patient groups, for example, where treatment is planned that might result in infertility (such as treatment for cancer) or where people are known to have chronic viral infections (e.g. HIV) and are concerned about their fertility; in such cases other pathways will be followed.

#### **Purpose of this document**

North Central London Clinical Commissioning Group (CCG) is responsible for commissioning a range of health services including hospital, mental health and community services for the local population. The CCG has a statutory duty to maintain financial balance. When exercising its discretion to determine what service it will commission it must make judgements about which services are appropriate and affordable for its local population.

Across the country most, if not all, CCGs have a policy or set of fertility policies addressing funding of assisted conception treatments such as in vitro fertilisation (IVF) and intrauterine insemination (IUI). This policy document describes the circumstances where NCL CCG will fund these treatments.

This policy has been developed following:

- Consideration of NICE Clinical Guideline (CG) 156, other national guidance and the current evidence base
- Discussions with stakeholders including specialist clinicians, service users and residents
- Identification and consideration of potential equality and equity issues

In developing this policy, the CCG has sought to adopt NICE guidance wherever feasible. However, it has also taken into account wider system factors such as service demand and population health needs. Consequently some sections of the policy vary from the full recommendations made by NICE.

This policy cannot anticipate every possible individual clinical presentation. Clinicians may submit Individual Funding Requests (IFR) to the CCG for patients who they consider to have exceptional clinical circumstances falling within the CCG's IFR policy and whose needs are not fully addressed by this policy. The CCG will consider such requests in accordance with its policy on Individual Funding Requests; you can read about this on the NCL CCG website.

# **Scope of this document**

The scope of the NCL CCG fertility policy is limited to setting the criteria for CCG funding for treatment for patients for whom it is the responsibility of NCL CCG to pay for the provision of healthcare services as outlined in *Who pays?* guidance (NHS England, 2020)<sup>1</sup>.

The following groups of patients are excluded from the scope of the policy:

- Members of the Armed Forces, their families or veterans; NHS England commission assisted conception services for these groups
- Patients who pay the immigration surcharge; assisted conception services are not included in the scope of services available for free for these patients

The following interventions are excluded from the scope of the policy:

- Interventions which do not fall within the scope of assisted conception treatments (for example: investigations of conditions causing infertility, and medical or surgical treatments to restore fertility)
- Pre-implantation genetic diagnosis (PGD), which is the commissioning responsibility of NHS England
- Surgical sperm retrieval, which is the commissioning responsibility of NHS England
- Treatment add-ons with limited evidence (as outlined on the <u>HFEA website</u>), which are not funded by NCL CCG

NCL CCG will follow Department of Health <u>Guidance</u> on the interface between NHS and private care, Principles of which include the following:

- The NHS provides a comprehensive service, available to all; access to NHS services is based on clinical need, not an individual's ability to pay
- Public funds for healthcare will be devoted solely to the benefit of the people that the NHS serves
- The NHS should never subsidise private care with public money, which would breach core NHS principles
- Patients should never be charged for their NHS care, or be allowed to pay towards an NHS service (except where specific legislation is in place to allow this) as this would contravene the founding principles and legislation of the NHS.

<sup>&</sup>lt;sup>1</sup> The individual who will be undergoing the fertility procedure will need to be of NCL CCG responsibility. It is not necessary for their partner (if they have one) to also be of NCL CCG responsibility.

# **Policies: Assisted conception treatments (ACTs)**

# 1. IVF, with or without ICSI

- 1.1 In order to access NHS funded IVF, with or without ICSI, patients are required to fulfil relevant eligibility criteria set out in <u>Section 9</u>.
- 1.2 For eligible patients requiring IVF where the woman is aged under 40, the CCG will fund up to six embryo transfers from a maximum of three fresh cycles. All good quality frozen embryos should be transferred before starting the next NHS funded fresh cycle.
- 1.3 For eligible patients requiring IVF where the woman is aged 40–42, the CCG will fund up to two embryo transfers from one fresh cycle.
- 1.4 One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of commissioned cycles.
- 1.5 Cryopreservation of supernumerary embryos will be funded for a maximum of two years following each fresh cycle<sup>2,3</sup>
- 1.6 Embryo transfer strategies outlined in <u>NICE CG156</u> should be followed in order to minimise the number of multiple births.
- 1.7 Natural cycle IVF is not funded by NCL CCG.

<sup>&</sup>lt;sup>2</sup> Patients will have the opportunity to fund continued storage of any unused embryos for future self-funded frozen embryo transfer after the NHS funded storage period concludes.

<sup>&</sup>lt;sup>3</sup> Cryopreservation of embryos for fertility preservation for patients receiving gonadotoxic treatment is addressed by a separate policy (see <u>Section 8</u>).

# 2. IUI using partner sperm

- 2.1 In order to access NHS funded IUI using partner sperm, patients are required to fulfil relevant eligibility criteria set out in <u>Section 9</u>.
- 2.2 Up to six cycles of unstimulated IUI using partner sperm is funded where there is evidence of normal ovulation, tubal patency and semen analysis for:
  - (a) people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem and have not conceived after six cycles of [self-funded] IUI, or
  - (b) people who are clinically indicated to receive IUI following a successful sperm washing procedure where the man is HIV positive (access to NHS funded sperm washing is addressed in a separate policy see Section 7)
- 2.3 IUI is not routinely funded for people with unexplained infertility, mild endometriosis or mild male factor infertility<sup>4</sup> except in the following circumstances:
  - Up to six cycles of unstimulated IUI using partner sperm is funded in exceptional circumstances for people with unexplained infertility, mild endometriosis or mild male factor infertility who have social, cultural or religious objections to IVF [note: this would be an alternative to receiving IVF treatment and therefore IVF would not subsequently be funded for patients accessing IUI in these circumstances]

Draft North Central London CCG Fertility Policy

<sup>&</sup>lt;sup>4</sup> Defined by NICE as: Two or more semen analyses that have one or more variables which fall below the 5th centile as defined by WHO, 2010, and where the effect on the chance of pregnancy occurring naturally through vaginal intercourse within a period of 24 months would then be similar to people with unexplained infertility or mild endometriosis.

# Policies: ACTs using donated genetic materials

# 3. ACT (IUI and IVF) using donor sperm

- 3.1 In order to access NHS funded ACT using donor sperm, patients are required to fulfil relevant eligibility criteria set out in <u>Section 9</u>.
- 3.2 Up to six cycles of unstimulated IUI using donor sperm is funded where either criteria A, B or C are met:
  - A. The patient has fertility problems associated with one of the following conditions:
  - obstructive azoospermia
  - o non-obstructive azoospermia
  - severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection (ICSI)
  - B. Where one of the following have been confirmed/ diagnosed by an appropriate specialist:
  - o there is a high risk of transmitting a genetic disorder to the offspring
  - there is a high risk of transmitting infectious disease to the offspring or woman from the man
  - severe rhesus isoimmunisation
  - Same-sex couples or single people who have evidence of normal ovulation and tubal patency, but who have not conceived after six cycles of [self-funded] IUI.
- 3.3 IVF using donated sperm will be funded for eligible patients as per the IVF/ICSI policy (see <u>Section 1</u>) in either one of the following circumstances:
  - Patients fulfil one of the criteria A, B or C outlined above AND investigations show IVF is the only effective treatment option
  - Patients fulfil one of the criteria A, B or C outlined above AND have not conceived after 12 cycles of IUI
- 3.4 The CCG will fund the cost of the IUI and/ or IVF and the donor sperm where required.
- 3.5 The CCG will only fund assisted conception treatment using donor sperm at UK clinics subject to HFEA regulations.

# 4. IVF using donor eggs

- 4.1 In order to access NHS funded IVF using donated eggs, patients are required to fulfil relevant eligibility criteria set out in <u>Section 9</u>. Women accessing IVF using donor eggs will not be required to fulfil the ovarian reserve criterion.
- 4.2 IVF using donated eggs will only be funded for eligible patients as per the IVF policy (see <u>Section 1</u>) where either criteria A or B are met:
  - A. The patient has fertility problems associated with one of the following:
    - premature ovarian failure
    - o gonadal dysgenesis including Turner syndrome<sup>5</sup>
    - bilateral oophorectomy
    - ovarian failure following chemotherapy or radiotherapy
  - B. Where it has been confirmed by an appropriate specialist that there is a high risk of transmitting a genetic disorder to the offspring.
- 4.3 The CCG will fund the cost of the IVF and the donor egg where required. Patients may be able to provide an egg donor<sup>6</sup>. Alternatively the patient can be placed on a waiting list until a donor becomes available. If, during their time on the waiting list, patients waiting for a donor egg no longer fulfil the eligibility criteria, NHS funding will not be available.
- 4.4 The CCG will only fund IVF using donor eggs at UK clinics subject to HFEA regulations.

-

<sup>&</sup>lt;sup>5</sup> Pre-treatment screening should have excluded phenotypic manifestations of Turner syndrome that might jeopardise successful pregnancy, including aortic dilation and cardiac lesions.

<sup>&</sup>lt;sup>6</sup> Known donors will need to meet and follow HFEA regulations for donating eggs.

# **Policies: Other ACT interventions**

# 5. Surgical sperm retrieval

# Surgical sperm retrieval

- 5.1 Surgical sperm retrieval (SSR) is the commissioning responsibility of NHS England and will not be funded by NCL CCG
- 5.2 NHS England state they will only fund SSR where the patient meets eligibility criteria and has confirmed funding for subsequent stages of the pathway (i.e. cryopreservation and/ or ICSI treatment), as set out in the <a href="NHS England Clinical Commissioning Policy: Surgical sperm retrieval for male infertility">NHS England Clinical Commissioning Policy: Surgical sperm retrieval for male infertility</a> (2016). The responsible clinician should therefore ensure the patient meets the relevant eligibility criteria prior to undertaking SSR (see 5.4 and 5.6 below).

## Cryopreservation and storage of surgically retrieved sperm

- 5.3 Where a man with azoospermia has undergone successful surgical sperm retrieval funded by NHS England, cryopreservation and storage will be funded by the CCG for a maximum of two years<sup>7</sup>.
- 5.4 In order to access cryopreservation of surgically retrieved sperm, men are required to fulfil relevant eligibility criteria set out in <u>Section 9</u>.

## IVF with ICSI using surgically retrieved sperm

- 5.5 Eligible couples, where the man has undergone successful surgical sperm retrieval funded by NHS England, will have ICSI funded as per the IVF/ICSI policy<sup>7</sup> (see Section 1).
- 5.6 In order to access ICSI using surgically retrieved sperm, couples are required to fulfil relevant eligibility criteria set out in Section 9.

# 6. Assisted conception treatments involving surrogates

6.1 Assisted conception treatments involving surrogates are not routinely funded by NCL CCG for any patient group

<sup>&</sup>lt;sup>7</sup> Cryopreservation of sperm for fertility preservation and subsequent assisted conception treatments for patients receiving gonadotoxic treatment is addressed by a separate policy (see <u>Section 8</u>).

# Policies: ACTs for people with conditions other than infertility

# 7. Sperm washing

- 7.1 In order to access NHS funded sperm washing and subsequent assisted conception treatments, patients are required to fulfil relevant eligibility criteria set out in Section 9.
- 7.2 Sperm washing will be funded for couples where the man is HIV positive and the female partner is HIV negative and either:
  - the man is not compliant with antiretroviral treatment, or
  - his plasma viral load is 50 copies/ml or greater
- 7.3 Where a man has undergone successful sperm washing procedure, cryopreservation and storage of washed sperm will be funded for a maximum of two years.
- 7.4 Where the procedure is successful, couples may access IVF/ICSI or IUI, depending on their clinical circumstances, in line with the relevant policy (see Section 1 and Section 2 respectively)

# 8. Cryopreservation of gametes for fertility preservation

- 8.1 Cryopreservation of sperm, eggs or embryos will be funded for eligible patients (as defined in paragraphs 8.2 and 8.3 below) who are not currently infertile but meet one of the following criteria:
  - The patient is under the care of a specialist clinician who confirms they are due to undergo a gonadotoxic treatment; this may include patients undergoing interventions for gender reassignment
  - The patient is under the care of a specialist clinician who has confirmed they
    have a medical condition that, in their case, is likely to progress such that it will
    lead to infertility in the future
- 8.2 Cryopreservation of sperm will be funded for fertility preservation for men if they fall within 8.1 above
- 8.3 Cryopreservation of eggs or embryos will be funded for fertility preservation for women if they fall within 8.1 above and fulfil all of the following criteria:
  - They are aged under 43 years
  - They are well enough to undergo ovarian stimulation and egg collection, and this will not worsen their condition
  - Enough time is available before the start of their gonadotoxic treatment.
- 8.4 Ovarian tissue cryopreservation is not routinely funded for adult women.
- 8.5 Other than those listed in paragraphs 8.1–8.3 above, patients are not required to meet any additional eligibility criteria in order to access cryopreservation of sperm, eggs or embryos
- 8.6 Storage of sperm, embryos and eggs will be funded for up to ten years after cryopreservation<sup>8</sup>. NHS funding of storage will cease either after ten years or sooner where:
  - Patents are no longer eligible for NHS fertility treatment, or
  - The patient dies and no written consent has been left permitting posthumous use

<sup>&</sup>lt;sup>8</sup> Patients will have the opportunity to fund continued cryopreservation of any unused sperm, embryos or eggs for future self-funded assisted conception treatment after the NHS funded storage period concludes.

8.7 In order to access assisted conception treatments using cryopreserved materials, fertility preservation patients will be required to fulfil the same eligibility criteria as other patients with infertility (Section 9). An exception to this is the criterion for ovarian reserve, which women who have accessed NHS funded fertility preservation will not be required to fulfil.



# **Eligibility criteria**

# 9. Eligibility criteria

See matrix of which eligibility criteria apply to which policies on page 20 of this document.

# Demonstrating infertility for eligibility of IVF

- 9.1 In order to be eligible for IVF, infertility must be demonstrated in one of the following ways:
  - Investigations show there is no chance of pregnancy with expectant management and IVF is the only effective treatment, OR
  - Patients have not conceived after either 2 years of regular unprotected intercourse<sup>9</sup> OR 12 cycles of IUI.

## Age of the women

- 9.2 The woman receiving fertility treatment must be aged under 43 years. Women undergoing IVF must start medication with the provider before their 43<sup>rd</sup> birthday. Women must only be referred to fertility clinics if there is adequate time to complete work up.
- 9.3 If the woman reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available. A full cycle of IVF treatment, with or without ICSI, should comprise one episode of ovarian stimulation and the transfer of resultant fresh and frozen embryo(s), in line with the IVF policy (see Section 1).

## **Previous IVF cycles**

- 9.4 Treatment will not be funded for women aged under 40 years if three previous fresh cycles of IVF have been received, irrespective of how these were funded.
- 9.5 Treatment will not be funded for women aged 40–42 years if they have undergone any previous IVF treatment, irrespective of how this was funded.
- 9.6 One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of 'previous' IVF cycles.

### Body mass index (BMI)

9.7 Women undergoing treatment must have a BMI within the range 19–30 kg/m².

<sup>&</sup>lt;sup>9</sup> Defined by NICE as unprotected vaginal intercourse every 2 to 3 days.

# Smoking

- 9.8 Treatment will not be funded if the woman undergoing treatment smokes<sup>10</sup>.
- 9.9 Treatment will not be funded if the man undergoing treatment or providing sperm for treatment smokes<sup>10</sup>.

### Ovarian reserve

- 9.10 There should be no evidence of low ovarian reserve in women undergoing treatment. Low ovarian reserve is defined as:
  - antral follicle count (AFC) of less than or equal to 4
  - anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l
  - follicle-stimulating hormone (FSH) greater than 8.9 IU/I

### Previous children

9.11 Couples: At least one partner in a couple should not have a living child from their relationship or any previous relationship.

Single persons: Individuals should not have a living child.

9.12 An adopted child is considered to have the same status as a biological child.
Foster children are excluded from the scope of this criterion. 'Child' refers to a living son or daughter irrespective of their age or place of residence.

## Previous sterilisation

9.13 Couples: Neither individual in a couple should have undergone sterilisation.

Single persons: Individuals should not have undergone sterilisation.

9.14 The above criteria still apply where sterilisation reversal has unsuccessfully been attempted.

<sup>&</sup>lt;sup>10</sup> Vaping is not included within the definition of smoking.

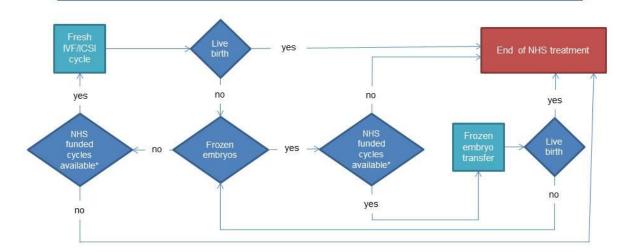
# Matrix of which eligibility criteria apply to which policies

							Policy*					
Eligibility criteria (see <u>Section 9</u> for details)	1. IVF/ICSI	2. IUI using partner sperm	3. IUI using donor sperm	3. IVF using donor sperm	4. IVF using donor eggs	5. Cryopreservation of surgically retrieved sperm**	5. ICSI using surgically retrieved sperm	7. Sperm washing	8. Cryopreservation of sperm for FP	8. Cryopreservation of embryos or eggs for FP	8. ACT using sperm cryopreserved for FP	8. ACT using embryos or eggs cryopreserved for FP
Demonstrating sub-fertility (prior to IVF)	~			~		~	<b>&gt;</b>				<b>&gt;</b>	~
Age of woman	~	>	>	<b>&gt;</b>	~		<b>&gt;</b>	>		<b>&gt;</b>	<b>&gt;</b>	
Previous IVF cycles	~	>	>	>	~	•	<b>&gt;</b>	>			<b>&gt;</b>	<b>&gt;</b>
Body mass index (BMI)	~	~	•	~	•	~	<b>\</b>	<b>&gt;</b>			<b>&gt;</b>	<b>~</b>
Smoking	•	>	>	<b>&gt;</b>	~	~	<b>&gt;</b>	>			<b>&gt;</b>	<b>&gt;</b>
Ovarian reserve	•	>	>	<b>&gt;</b>			<b>\</b>	>			<b>&gt;</b>	
Previous children	~	~	>	~	~	~	<b>\</b>	<b>&gt;</b>			<b>&gt;</b>	~
Previous sterilisation	~	>	>	<b>&gt;</b>	~	~	<b>\</b>	<b>&gt;</b>			<b>&gt;</b>	~

ACT = Assisted conception treatment; FP = Fertility preservation; \*Additional criteria apply – see relevant policy for details.

# Flow charts of pathways for fertility treatments

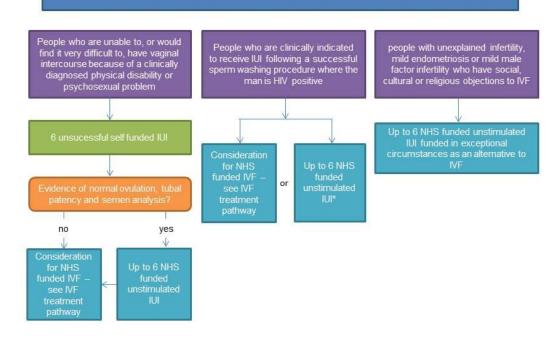
# IVF treatment pathway- IVF with or without ICSI



\*For women aged under 40, the CCG will fund up to 6 embryo transfers from a maximum of 3 fresh cycles. For eligible patients requiring IVF where the woman is aged 40–42, the CCG will fund up to two embryo transfers from one fresh cycle.

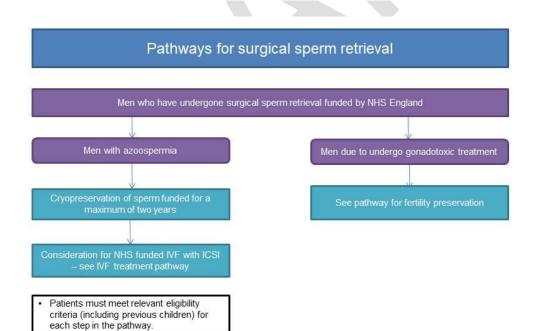
- · All good quality frozen embryos should be transferred before starting the next NHS funded fresh cycle.
- Patients must meet relevant eligibility criteria (including previous children) each time they start a cycle of treatment.
- Storage of frozen embryos will be funded for a maximum of two years for each fresh cycle.
- In order to undergo FET frozen embryos must be deemed by the clinician suitable for implantation.

# Pathways for intra-uterine insemination (IUI) using partner sperm

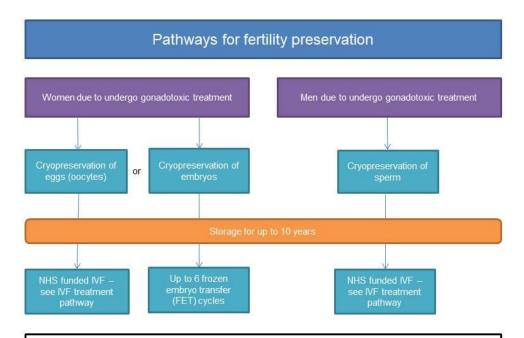


Patients must meet relevant eligibility criteria (including previous children) each time they start a cycle of treatment.
 \*Where there is evidence of normal ovulation, tubal patency and semen analysis.

# Pathways for assisted conception treatments using donor sperm - Male factor fertility problems\* - Risk of transmitting genetic disorder/ infectious disease - Severe rhesus isoimmunisation - Known fertility problem - Risk of transmitting genetic disorder/ infectious disease - Severe rhesus isoimmunisation - Known fertility problem in female partner - Yes - No - Confirm woman is ovulating - Yes - On NHS funded unstimulated IUI - Consideration for NHS funded IVI - See NF funded IVF - see NF treatment pathway - Azoospermia or severe deficits in semen quality in couples who do not wish to undergo ICSI.



Patients must meet relevant eligibility criteria (including previous children) each time they start a cycle of treatment.



- Patients do not need to fulfil the same eligibility criteria as patients with infertility in order to access cryopreservation of eggs, embryos or sperm for fertility preservation. See policy in Chapter 8 for more information
- However, in order to access assisted conception treatments (IVF or IUI) using cryopreserved materials, fertility
  preservation patients will be required to fulfil the same eligibility criteria as other patients with infertility. An
  exception to this is the criterion for ovarian reserve, which women who have accessed NHS funded fertility
  preservation will not be required to fulfil.





# **EQUALITY ANALYSIS**

# (Equality Impact Assessment)

Service/Policy title	Draft NCL Fertility Policy
Service/Policy type	
Author	
Lead Director	Penny Mitchell
Email	penny.mitchell3@nhs.net
Date approved	October 2021
Review date	October 2024 (or earlier if the
	policy is updated before this
	date)

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

For further help and advice please contact Emdad Haque at <a href="mailto:emdad.haque@nhs.net">emdad.haque@nhs.net</a> Tel: 07753836900

# Brief description of the policy/service

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

North Central London Clinical Commissioning Group (NCL CCG) was formed in April 2020, with the merger of the five North Central London CCGs: Barnet, Camden, Enfield, Haringey and Islington. Each borough had its own fertility policy and with the formation of a single clinical commissioning group, NCL CCG has been working to develop a new, single policy, which will cover all five boroughs. North Central London has a population of over 1.5m residents. The population is relatively young with Camden, Haringey and Islington having more adults under the age of 30 than other NCL areas. Haringey, Islington and Enfield have on average, higher rates of deprivation compared to London, although pockets of deprivation are dispersed across NCL¹. More than half of NCL residents are White, with around 20% Asian and 20% Black. Barnet and Camden have larger Asian communities, whereas Haringey and Enfield have larger Black communities.²

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

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

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

# **Engagement with patients and stakeholders**

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

Draft for engagement - North Central London CCG Fertility Policy Equality Impact Assessment

<sup>&</sup>lt;sup>1</sup> NCL CCG Diversity and inclusion strategy 2021-2023

<sup>&</sup>lt;sup>2</sup> GLA 2018, Housing led population projections

In developing this policy, NCL CCG has carried out engagement activities to support the review stage (consisting of pre-engagement, engagement and review recommendations) and to influence the policy development stage of the programme.

A pre-engagement stage was carried out ahead of the start of the engagement window for the Fertility Policies Review. We wrote to a core list of 75 key stakeholders, which included 38 groups representing protected characteristics, across North Central London offering the opportunity to discuss our approach and seek their early views. We also wrote to national special interest groups to collate views (for example, Fertility Network UK and The LGBT Mummies Tribe) as well as local Healthwatch leads and the Chairs of the Joint HOSC and HOSC committees. Responses received in the pre-engagement period were logged, and where relevant, used to inform our engagement approaches.

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

In addition to the groups that we engaged with, the Steering Group that led the policy review also included on member of Fertility Network UK to fulfil the Community Member 'expert' role and one of the CCG's existing Community Members, acting as the NCL 'citizen' Community member on the group. These members have also contributed to the development of the policy, and in particular to equality considerations, through the Steering Group itself.

NCL CCG was 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. The core engagement methods implemented by the CCG are detailed in Appendix 1.

Good and detailed qualitative insights and data were collected. For the information about the themes of the engagement, you can read the <a href="NCL CCG Fertility Policies Review: Engagement Report">NCL CCG Fertility Policies Review: Engagement Report</a> here. 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. NCL CCG has been committed to using these insights to support the development of this policy at local, borough and system level to improve service provision.

The views of specialist clinicians were obtained during the course of the NCL Fertility Policies Review in the following ways:

- Establishing a Clinical Reference Group (CRG) of fertility special ists 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.
- 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 fertility policies review.
- Considering findings of interviews with specialist clinicians who provide ovarian tissue cryopreservation<sup>3</sup>.

You can read the NCL CCG Fertility Policies Review: Engagement Report here. This document reports the findings from the stage 1 public engagement window (10 May to 9 July 2021)

Following on from Phase 1 of our engagement process, we then commenced the Policy Development Phase. With input from our Clinical Reference Group and expert clinicians on the CCG Governing Body, we have developed a draft Policy and we are now due to go out to 12 weeks of engagement on the draft policy from 22 November 2021 to 13 February 2022.

Input from governing body clinicians fed into the second stage of Policy Development with the formation of a Readers' Advisory Panel made up of six NCL Community members to provide advice and observations on the phrasing and 'readability' of the draft NCL fertility policy from the perspective of readers and local residents. The Policy Development engagement window for this work is anticipated to run from 22 November 2021 to 13 February 2022. During the engagement window, local residents will be able to contribute their views and experiences in the following ways:

- By attending one of our online public meetings (N=5)
- By attending a face-to-face public meeting
- By inviting CCG staff to attend a meeting or event, for example Fertility Support Groups, or GP Patient Participation Groups
- By completing the online questionnaire (hard copies will be available upon request (also in easy read))

Residents will be able to find out about the engagement opportunities via our <u>website</u> and the Fertility Policy Development team will be contactable by email <u>nclccg.fertility-development@nhs.net</u> and by telephone: 020 3688 2038

The communications and engagement team will be proactively raising awareness of the draft single policy and how to give feedback through our public website, social media and key stakeholder public-facing channels (e.g. The LGBT Mummies Tribe, Fertility Network UK, Healthwatch, NHS providers, local authority and local voluntary and community sector groups (focusing on seldom-heard communities).

The EQIA currently reflects that draft policy, and will be updated as and when the Policy itself is updated. We will collect responses from this second engagement phase and will then report back to the S&C Committee and will take this feedback into account in finalising the Policy. Once we have a finalised Policy, we will update the EQIA accordingly.

Draft for engagement - North Central London CCG Fertility Policy Equality Impact Assessment

<sup>&</sup>lt;sup>3</sup> Note, these interviews were undertaken as part of a different policy review for a group of CCGs based in the south east in October 2020.

# **Impact analysis**

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

									,
Protected Group/Strands	and d from I inform the ar	ribe how lisadvanta local/NHS nation. It's nalysis ar policy/se V/R'.	the policy aged gro S/national s importand refere	ups base sources nt that th nced for i	will impa d on the s + the lat he relevar robustnes	data avai est COV nt data is ss and re	ilable ID 19 used in levance.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
Age	The d conce aged have	data indic between 1 raft NCL ( eption trea under 43. NHS fund	18-45 in N CCG polic atments (A NCL wom ed ACT a	CL. y specifie CT) will be nen agede vailable to	s assisted e funded f 43 and ov o them.	d for eligible		Positive	<ul> <li>The NCL CCG draft policy specifies ACT will be funded for eligible women aged under 43 years. The rationale for this is:</li> <li>NICE Clinical Guideline (CG) 156 and Quality Standard (QS) 73 recommend funding of IVF for women aged up to 42 (inclusive).</li> <li>The NICE CG156 full guideline states that IVF is not cost effective for women aged 43 years or older.</li> </ul>
	Age	Barnet	Camden	Enfield	Haringey	Islington	Total		The NICE CG156 full guidelines states: 'The
	43	2,799.00	1,708.00	2,484.00	1,941.00	1,323.00	10,255.00		clinical and health economic evidence was overwhelming in indicating that IVF should not
	44	2,851.00	1,844.00	2,372.00	1,976.00	1,302.00	10,345.00		be offered to women aged 43 years or older'
	45	2,773.00	1,706.00	2,250.00	1,942.00	1,292.00	9,963.00		HFEA data on all fertility treatments undertaken in the UK shows the success rates decrease as
	46	2,709.00	1,912.00	2,185.00	1,770.00	1,430.00	10,006.00		the woman's age increases for IVF and other
	47	2,665.00	1,773.00	2,277.00	1,871.00	1,258.00	9,844.00		ACT including donor insemination, IUI and IVF using thawed eggs.
	48	2,787.00	1,653.00	2,304.00	1,820.00	1,282.00	9,846.00		using maweu eggs.

Protected Group/Strands	Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19						ilable ID 19 used in levance.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	A work Service	2,810.00 2,816.00 2,830.00 25,040.00 the above who may age age of man's age as through a ge. 5 Sen age (with the above a position ace.	details fer require fer menopautis is an initial in natural uccess rath the exception	male popularility trea lise for word al predictor conception tes for ferr eption of l'	ulation est tment. men in Uk or of her o n.4 Fertility tility treatr VF using women a	imates by (is 51. verall chay decreas nents dec donor egg	age not ance of es as crease as gs) <sup>6</sup>		The NCL CCG will promote the policy to all eligible age groups and ensure equity in access.  Recommendation / mitigating action (1)
	The d	Iraft NCL ( IVF is the	only treat	ment opti	on (in whi	ch case e	ligible	Positive	The rationale for requiring women to try to conceive for 2 years prior to accessing NHS funded intercourse is:

<sup>&</sup>lt;sup>4</sup> NICE <u>CG156</u> (2013) <sup>5</sup> <u>Infertility - NHS (www.nhs.uk)</u>

<sup>&</sup>lt;sup>6</sup> HFEA data

Protected Group/Strands	and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	demonstrate their infertility by trying to conceive for either 2 years of regular unprotected intercourse or 12 cycles of IUI in order to be eligible for NHS funded IVF.  Older women may be over the age threshold if they have to undergo 2 years of unprotected intercourse before they are eligible for IVF.		<ul> <li>This is recommended in NICE CG156 for all ages of women accessing IVF</li> <li>NICE noted data from Dunson (2004 – see Table below) when making their recommendations         <ul> <li>Age (years)</li> <li>Pregnant after 1 year</li> <li>19-26</li> <li>92%</li> <li>98%</li> <li>27-29</li> <li>87%</li> <li>95%</li> <li>30-34</li> <li>86%</li> <li>94%</li> <li>35-39</li> <li>Removing this criterion may mean woman who would have otherwise conceived naturally are treated with IVF</li> </ul> </li> <li>Where investigations show IVF is the only treatment option, patients can be referred directly for IVF</li> <li>Implementation planning and support will schedule engagement and guidance to primary care and secondary care to support implementation of the new policy. Our aim being that as people enquire, they can find info easily via our website and be well supported by their GP or other treating clinician.</li> </ul>

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	The draft NCL CCG policy requires women undergoing ACT to have a BMI within the range 19-30 kg/m².  Feedback from the engagement exercise was that older people and people with medical conditions may find it more difficult to lose weight than younger people.	Negative	<ul> <li>The BMI criteria are in place for the following reasons:         <ul> <li>NICE CG156 states that a female BMI outside this range is likely to reduce the success of assisted reproduction procedures</li> <li>NICE CG156 recommends women should be informed BMI should ideally be in the range 19-30 before commencing assisted reproduction</li> </ul> </li> <li>HFEA Commissioning Guide for Fertility Treatment states: Women should have a BMI of 19-30 kg/m² before commencing assisted reproduction.</li> </ul>
	The COVID-19 pandemic may have 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 to meet the age criteria).	Negative	<ul> <li>Ensure people can get support and information about the draft policy in a timely way to make informed decisions about when they want to attempt to have a baby.</li> <li>National response to Covid-19 pandemic in operation to reduce waiting times.</li> </ul>
Disability	Based on the 2011 Census, 8.6% of men and 9.3% of women in London have an illness or disability that limited a lot of their daily activities.	Positive	The draft NCL CCG policy is broadly consistent with NICE CG156 in funding ACT to eligible patients with physical disability/ psychosexual problems.

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	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.  The draft NCL CCG policy specifies that up to 6 cycles of IUI using partner sperm is funded for these patient groups if they have not conceived after 6 cycles of self-funded IUI. These patients may also be eligible for IVF if they undergo a total of 12 unsuccessful IUI cycles.		This group of patients have been covered in the policy.  Recommendation / mitigation (2)  Recommendation / mitigation (3)
	In 2018, Public Health England estimated that the prevalence rate for HIV was 5.7 per 1,000 people in London. This equates to an estimated 1,778 men aged 18-42 in NCL who are HIV+. The draft NCL CCG policy specifies sperm washing may be funded for eligible men who are HIV+ and have a HIV- female partner.	Positive	The draft NCL CCG policy is consistent with NICE CG156 in funding sperm washing to eligible patients who are HIV+.  This group of patients have been covered in the policy
	Data from Public Health England Cancer Registry indicates around 1,900 NCL women and 1,500 NCL men aged 15-44 are likely to be diagnosed each year with cancer which may be treated with a potentially gonadotoxic treatment.  The draft NCL CCG policy specifies that fertility preservation interventions (cryopreservation of sperm, eggs and embryos) is funded for eligible patients who are either due to undergo a	Positive	The draft NCL CCG policy is broadly consistent with NICE CG156 in funding fertility preservation for patients due to undergo a gonadotoxic treatment.

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	gonadotoxic treatment or have a medical condition which is likely to progress such that it will lead to infertility in the future. This applies to patients with conditions including cancer.		
	The draft NCL CCG policy indicates that IVF/ ICSI using donor eggs will be funded for eligible patients who have undergone bilateral oophorectomy or who have ovarian failure following chemotherapy or radiotherapy. This applies to patients with conditions including cancer.	Positive	The draft NCL CCG policy is consistent with NICE CG156 in funding IVF/ ICSU using donor eggs for eligible patients who have undergone bilateral oophorectomy or ovarian failure following chemotherapy or radiotherapy.
	People with HIV who require fertility treatment need to be referred to clinics licensed to treat them. <sup>7</sup>	Positive	The draft NCL CCG policy is inclusive of those with HIV.
	The draft NCL CCG policy states that assisted conception treatments involving surrogates are not routinely funded by NCL CCG for any patient group. This has potential an impact on people who would not be able carry a pregnancy to term due to a disability.	Negative	The rationale for this is: a surrogate is available only to those with means and, by parity of reasoning with the prohibition on mixing NHS and private care in one episode of care, ACT involving surrogates is not funded. NICE does not make recommendations on ACT involving surrogates.
Gender	NCL Demographics (April 2019/20) estimate population of 809,362 males (49%) and 838,675 females (51%)	Positive	"Gender" in itself is not the critical factor. The point of the policy is to deal with pathological issues to do with an individual's sexual reproductive system

<sup>&</sup>lt;sup>7</sup> HFEA

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	Some fertility treatments are specific to either men or women and as such require different considerations when developing policy (e.g. surgical sperm retrieval is specific to man and oocyte cryopreservation is specific to women).		Due to the nature of policies on assisted reproductive technologies, it is necessary to refer to the sex of patients on occasion. This document therefore refers to 'men' and 'women', and 'male' and 'female'. When these terms are used in this document, unless otherwise specified, this refers to sex defined by biological anatomy. It is acknowledged that this may not necessarily be the gender to which individual patients identify.
	NICE CG156 makes specific recommendations regarding the woman's age; no equivalent recommendations are made regarding the man's age.  The draft NCL CCG policy has retained the upper age limit for women but has removed the upper age limit for men.	Positive	The draft NCL CCG policy is consistent with NICE CG156 guidance with regard to the age of women undergoing IVF.  The upper age limit for women has been retained because of the strong evidence outlined above that IVF birth rates decrease as the women's age increases.  The upper age limit for men has been removed because this was based on previous HFEA regulations which have now been changed (previously sperm could not be stored after a man reached the age of 55 years; this has now been changed so sperm cannot be stored for more than 55 years duration).

Protected Group/Strands	and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
	The draft NCL CCG policy specifies IUI and IVF are funded for eligible single women and female same sex couples. No assisted conception treatments are funded for single men or male same sex couples because ACT involving surrogacy are not funded for any patient groups.	Negative	The draft NCL CCG policy specifies IUI and IVF are funded for eligible female same sex couples broadly consistent with NICE CG156 recommendations. NICE CG156 does not address surrogacy. The rationale for not funding ACT involving surrogacy for any patient groups is as follows: a surrogate is available only to those with means and, by parity of reasoning with the prohibition on mixing NHS and private care in one episode of care, ACT involving surrogates is not funded.
Gender reassignment	NHS admissions data indicates that in 2018/19, just under 100 NCL patients were admitted to secondary care with a primary diagnosis of gender dysphoria.  People undergoing gender reassignment interventions such as hormone therapy or surgery may wish to cryopreserve their genetic materials to preserve their fertility.  Although admissions data may give an indication of the numbers of patients undergoing gender reassignment interventions on the NHS, there is likely to be a significant number of transgender patients accessing gender reassignment interventions privately thereby underestimating the number who require fertility preservation.	Positive	The draft NCL CCG policy states that fertility preservation may be offered to eligible patients under the care of a specialist clinician who confirms they are due to undergo a gonadotoxic treatment, including those who are due to undergo interventions for gender reassignment

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected	Likely impact	Recommendation /mitigating action
Croup/otrailus	and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	See the keys at the end of the form	Please reference by entering the number from the list on the next page.
	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'	Positive	The draft NCL CCG policy states that fertility preservation may be offered to eligible patients under the care of a specialist clinician who confirms they are due to undergo a gonadotoxic treatment, including those who are due to undergo interventions for 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.	Positive	This has been acknowledged in the draft NCL CCG fertility policy.
Marriage and civil partnership8	Assisted Conception Treatment (ACT) for single women and those who are not married or in a civil partnership.	Positive	The draft NCL CCG policy specifies IUI and IVF is funded for eligible single women on the same basis as it is available for female same sex couples.
	Couples in a 'stable relationship' for a specified period of time.9	Positive	The draft NCL CCG policy does not stipulate this a requirement for service users to be in a "stable relationship" for a specified period of time.
	Access for single women compared to couples for fertility services.	Positive	The draft NCL CCG policy specifies IUI and IVF are funded for eligible single women on the same basis as it is available for female same sex couples.

 $<sup>\</sup>frac{\$_{https://www.ons.gov.uk/file?uri=\%2fpeople population and community\%2fbirths deaths and marriages\%2flive births\%2fd at a sets \%2fbirths by parents characteristics\%2f2019/parents characteristics 201912112020134413.xls\_$ 

<sup>&</sup>lt;sup>9</sup> NCL CCG Fertility Policy Review Recommendations report

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
Pregnancy and maternity	The NCL CCG Policy is to support those with a pathological issue to help them become pregnant.  Multiple births are the single greatest risk of fertility treatment. People entering fertility services with the aim of a single live birth may be impacted.	Positive / unknown	The policy states that embryo transfer strategies outlined in NICE CG156 should be followed in order to minimise the number of multiple births.
	The draft NCL CCG policy specifies that 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.	Negative	The CCG has a statutory duty to maintain financial balance. The CCG needs to focus resources on patients in most need. Investigations and other (medical/ surgical) treatments for infertility are not covered by the policy and may therefore be available for couples who already have a child together.  Recommendation / mitigation (1)
	Some CCGs do not fund fertility treatments for couples where one individual in a couple has a child from a previous relationship. <sup>11</sup>	Negative	The draft NCL CCG policy specifies that ACT will be funded for eligible patients where at least one partner does not have a living child.  Recommendation / mitigation (1)

HFEA
 NCL CCG Fertility Policy Review Recommendations report

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
Race/ethnicity <sup>12</sup>	Mid 2019 estimates NCL demography and diversity of have 63% White and 37% BAME. <sup>14</sup> Local specialists noted that age-related decline in fertility may occur sooner for Asian/ Chinese women compared to Caucasian and African women (Gleicher, 2012).	Positive / unknown	The NCL CCG policy on eligibility is inclusive of all race / ethnicities.  The age related criteria is not specific to race / ethnicity.
	It has been suggested by service users that ethnicity impacts on BMI and should be taken into account in relation to the BMI eligibility criterion for women.	Positive / unknown	The BMI criterion outlined in the proposed policy is consistent with NICE CG156 recommendations and the HFEA Commissioning Guide for Fertility Services.
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).	Positive	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). The NCL CCG draft policy states that up to six cycles of unstimulated IUI using partner sperm is funded for people with unexplained infertility, mild endometriosis or mild male factor infertility who have social, cultural or religious objections to IVF

<sup>12</sup> https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/parentscountryofbirthenglan dandwales/2019

<sup>13</sup> https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fbirthsdeathsandmarriages%2flivebirths%2fdatasets%2fparentscountryofbirth%2f2019/parentscountryofbirth2019 .xls x

14 https://intranet.northcentrallondonccg.nhs.uk/downloads/Governing%20Body/Meeting/Diversity%20%20Equality%20and%20Inclusion.pptx

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
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).  The draft NCL CCG policy specifies that assisted conception treatments involving surrogates are not funded for any patient groups. This excludes male same sex couples from accessing NHS funded fertility treatments.	Negative / unknown	The draft NCL CCG policy specifies IUI and IVF is funded for eligible female same sex couples broadly consistent with NICE CG156 recommendations. NICE CG156 does not address surrogacy. The rationale for not funding ACT involving surrogacy for any patient groups is as follows: a surrogate is available only to those with means and, by parity of reasoning with the prohibition on mixing NHS and private care in one episode of care, ACT involving surrogates is not funded.  NICE CG156 does not address surrogacy.
	NICE CG156 recommends IUI for eligible people in same sex relationships.	Positive	The draft NCL CCG policy specifies IUI and IVF is funded for eligible female same sex couples broadly consistent with NICE CG156 recommendations.
	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.	Positive	The draft NCL CCG policy criteria on demonstrating infertility for eligibility for IVF are broadly consistent with NICE CG156 recommendations. In determining their recommendations on this topic, the NICE GDG discussed ethical and practical issues relating to 'equivalence' including time, financial cost, availability of donor sperm and practical difficulties.

Protected Group/Strands	Level of impact  Describe how the policy/service will impact the protected and disadvantaged groups based on the data available from local/NHS/national sources + the latest COVID 19 information. It's important that the relevant data is used in the analysis and referenced for robustness and relevance. If the policy/service is not relevant to a group/strand then say 'N/R'.	Likely impact See the keys at the end of the form	Recommendation /mitigating action Please reference by entering the number from the list on the next page.
Disadvantaged groups [homeless, unemployed,	Some patients who have frozen embryos from NHS funded cycles available may not be able to afford treatment using these.	Negative	Investigations are outside of the scope of the draft policy.  Recommendation / mitigation (1)
single parents, asylum seekers, victim of domestic violence]	The draft policy states treatment will not be funded for women aged under 40 years if they have undergone 3 previous IVF cycles. For women aged 40-42 treatment is not funded if they have undergone any previous IVF cycles.  Patients who have previously undergone private treatment but can no longer afford this may therefore be ineligible for NHS funded treatment.	Negative / unknown	The draft policy is consistent with NICE CG156 recommendations.
Human Rights [how the policy/service will impact Human Rights of patients]	The development of the draft NCL Fertility policy builds on the opportunity for improving and promoting equality and human rights of our population.	Positive	The draft policy will have a positive impact on human rights, particularly Article 8: Right to respect for private and family life; Article 12: Right to marry and found a family.

# Recommendations/mitigating actions

No	Recommendation/mitigating action	Which protected group/ strand does this cover	Lead Person and Organisation	Deadline/ Review date
1	Across the country most, if not all, CCGs have a set of fertility policies addressing funding of assisted conception treatments such as in vitro fertilisation (IVF) and intrauterine insemination (IUI). The CCG has a statutory duty to maintain financial balance, which means that it must make judgements about the affordability of any proposed service for local patients. In developing this policy, the CCG has sought to adopt NICE guidance wherever feasible. However, the need to balance service access demands with affordability has meant that in some sections the policy may vary from the full recommendations made by NICE.	Age Pregnancy / maternity Disadvantaged groups	NCL CCG	October 2024
2	Other related speciality pathways (not specifically detailed in the policy), for example, where treatment is planned that might result in infertility (such as treatment for cancer) or where people are known to have chronic viral infections (e.g. HIV) and are concerned about their fertility are to be followed. Recommendations are that these services are aware of the new policy in order to reduce unwarranted variation.	Disability	NCL ICS	October 2024
3	This policy cannot anticipate every possible individual clinical presentation. Clinicians may submit Individual Funding Requests for patients who they consider to have exceptional clinical circumstances and whose needs are not fully addressed by this policy. The CCG will consider such requests in accordance with its policy on Individual Funding Requests.	All (where relevant as per case by case basis).	Individual Funding Request Panel	October 2024

Please send a copy of the EqIA with the original business case or policy for review to Emdad Haque at <a href="mailto:emdad.haque@nhs.net">emdad.haque@nhs.net</a>

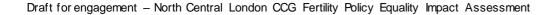
# Keys explaining the impact-

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

# Appendix 1: Core Engagement Methods

- Review Questionnaire (hard copy available upon request, easy read version also available on request).
- Online version hosted on our website
- Shared with our key stakeholder database, which included Healthwatches, VCS groups, special interest groups, local authorities and local hospital patient/membership groups.
- Distributed to the North Central London Residents Panel a group of nearly 1,000 local residents with an interest in health and care services
- Distributed via Next Door (online neighbourhood network) with close to 9,000 impressions across North Central London resident online timelines.
- Promoted via CCG public channels, notably social media, newsletters (to the wider NCL system and also our residents newsletter), news articles on our public-facing website and our intranet (recognising that our staff may wish to share their views).
- Information was shared by Provider organisations (not only those part of the North Central London system, but also those out of area who provide fertility services to our population), Healthwatches, local VCS, local authorities and other key partners through the Review period
- Shared with local general practice teams (both GPs and via Practice Managers and PPG Groups) across our boroughs via NCL CCG GP website
  and newsletter Public and service user-focused activity:
- Three open-access online events were run for members of the public. These events were spread throughout the engagement period and were run at different times of the day, with one held at the weekend in order to allow the greatest accessibility for attendees with differing responsibilities
- A service user focus group, supported by Fertility Network UK
- A resident focus group with LGBT men
- A resident focus group, hosted in collaboration with the Enfield Racial Equality Council, which particularly welcomed people from local ethnic minority communities and those with lived experience from across the five NCL boroughs
- A resident focus group held with residents whose country of origin was not the UK 12
- Outreach via fertility group social media channels, including a pre-recorded Instagram Live event with The LGBT Mummies Tribe, which had over 350 views
- A pre-recorded question and answer session with the Clinical Responsible Officer and Programme Director, which was shared on the CCG's YouTube channel and via social media platforms in collaboration with The LGBT Mummies Tribe
- In-depth interviews held with residents from local BAME and LGBT communities Wider stakeholder-focused activity:
- 1:1 briefings for key stakeholders and representative organisations
- Meetings with local organisations, including online groups, discussion sessions with groups
- In-depth interviews conducted with individuals with protected characteristics
- Attending/presenting at meetings organised by others, such as Healthwatch and local community groups, VCS organisations, PPG network meetings and local authorities
- Information shared with our communications counterparts in local authorities and Trusts General Practice-focused activity
- Presentation by CRO and Programme Director to webinar for all NCL Governing Body GPs and clinical leads. This webinar is held weekly and chaired by the Chair of the CCG's Governing Body.

- Presentations to Borough-based GP Forums in Barnet and Islington During the pre-engagement phase seventy eight organisations were contacted and invited to take part in the Review, as well as a wide range of stakeholders. During the engagement phase:
- 52 people completed the survey
- 44 people were involved in group discussions, public online sessions and interviews
- 350+ people viewing a Mummies' Tribe Instagram Q&A session
- From the FPR public website you can see the number of times documents were downloaded by visitors to the webpage.
  - o NCL Fertility Review Questionnaire 103 downloads
  - o Patient Leaflet 131 downloads
  - o NCL FPR Variations slide deck 149 downloads
  - o Barnet Fertility Policy 111 downloads
  - Camden Fertility Policy 106 downloads
  - Enfield Fertility Policy 89 downloads
  - Haringey Fertility Policy 113 downloads
  - o Islington Fertility Policy 84 downloads
  - o NCL CCG Fertility Policies Review FAQs 104 downloads
  - o North Central London Fertility Policies Review Easy Read Leaflet 122 downloads
- 31 Tweets were sent from the NCL CCG's account which had 27,954 impressions on local stakeholder and resident twitter accounts raising awareness of the Fertility Policies Review.





# North Central London Clinical Commissioning Group Fertility Policies Development

Joint Health Oversight and Scrutiny Committee (JHOSC)

Briefing Paper

Sarah Mansuralli
Executive Director for Strategic Commissioning

20 September 2021

V0.01

# Contents

1. Introduction	3
2. Setting the scene (public feedback)	3
3. Review Recommendations	6
4. Next Steps	6

# 1. Introduction

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, 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 the CCG, and so our Governing Body has commissioned a review into the five legacy fertility policies to make recommendations on the way forward.

Initial work began in September 2020, but elements of the project were paused as a result of the COVID-19 pandemic. Full work recommenced in April 2021 and is being done in two stages. The first stage was a Review, with the aim of producing a set of principles and recommendations to inform the development of the future single policy. No decisions on the future policy were made in the Review stage.

This briefing paper relates to the first stage, informing the JHOSC of the reasons for the review, the methodology undertaken, a summary of the public feedback, recommendations and next steps.

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 included the following key stages:

- 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.
- 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 focused 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.
- 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.

# 2. Setting the scene (public feedback)

A key strand of the Review stage has been to seek the views of our residents, service users, voluntary and community (VCS) organisations, fertility groups and wider stakeholder audiences, both on our currentfertility 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; this briefing paper highlights a summary of the findings from the feedback received.

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, an online questionnaire (also available as a hard copy (and easy read) on request), and articles featured in our stakeholder and residents newsletters. A range of approaches were taken to reach out to groups andindividuals 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 not only the challenges presented by the pandemic, but also the small numbers of people for whom this topic is relevant. Also important to note is 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 single policy is 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 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 below. NCL CCG is committed to using these insights, working collaboratively with our Providers and residents, to improve local commissioning decisions and service provision.

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 strong feeling the future policy should follow NICE guidance / level up, not down (for example, three 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 addins, and the treatment journey
- There should be equality of access for all, including same sex couples and single women
- The new policy should consider including surrogacy
- Questions were asked around 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 policy changes?

IUI should be offered for unexplained fertility before IVF, if women prefer

# Service experience:

- Fertility treatment is considered a luxury, distress is not fully taken into account
- Ad hoc approach to male investigations. 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 mental health is a concern for people even prior to their first engagement with a GP, and throughout the whole process.
- Feedback was also received on mental health support (counselling) for women from Black, Asian and minority ethnic communities could be improved, related to pressures (from extended family) to conceive
- Impact of the pandemic: delays to access treatment, inability of partners to attend appointments

# Other points:

- Improve training for GPs and others so they understand and communicate the new policy
- Are there ethnicity differences in fertility in women?
- A perceived lack of knowledge among 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 NHS 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)
- Fertility treatment is not a necessity and shouldn't 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 recommendations for the future policy, which can be found in the <u>Recommendations Report</u>. Please note that a detailed set of recommendations are outlined on page 33 of the report. Learnings from this stage will also be used to develop and refine the Communications and Engagement Strategy for the next stage, commencing later this year. We anticipate that the engagement period for the second phase will begin in the autumn 2021.

It is important to note that a key success of the engagement undertaken to date has been the establishment of relationships with both local communities across NCL and colleagues at NHS providers and local authorities who can assist us in promoting the draft single fertility policy.

# 3. Review Recommendations

In summary 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.

# 4. Next Steps

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, which are currently underway or in planning, are:

- Policy drafting
- Engagement on the single draft Policy
- Equality Impact Assessment
- Draft Single Policy to be presented at the November JHOSC meeting

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 in 2022.