Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Meeting of BNSSG ICB Board Meeting

Date: 1st December 2022
Time: 9:00
Location: MS Teams

Agenda Number:	6.1	
Title:	Clinical Commissioning Policies	
Confidential Papers	**Commercially Sensitive**	Yes/No
	Legally Sensitive	Yes/No
	Contains Patient Identifiable data	Yes/No
	Financially Sensitive	Yes/~~No~~
	Time Sensitive – not for public release at this time	Yes/No
	Other (Please state)	Yes/No

Purpose: Decision

Key Points for Discussion:

The paper provides an overview of proposed changes to the organisation's commissioning stance for the treatment of infertility and the provision of fertility preservation treatment. Changes include:

- Broadening the scope of fertility preservation.
- Providing assessment and treatment of infertility to single women.
- Reduce the number of independently funded cycles for Intrauterine Insemination (IUI) without conception
- Reduce the upper age limit of the prospective mother from 40 to 39 years.

The ICB Board is asked to consider and approve for adoption, the revised commissioning policies.

Recommendations:	Approve changes to the current commissioning policy for Fertility Assessment & Treatment and approve the proposed new policy for Fertility Preservation.
Previously Considered By and feedback:	Proposed policies have been reviewed by BNSSG ICB Commissioning Policy Review Group and the BNSSG ICB Clinical Review Group who have recommended it's adoption.
Management of Declared Interest:	There have been no conflicts declared by any individual involved in the review, nor any of the committees who have reviewed the proposed policies.
Risk and Assurance:	There is a risk that if the proposed policies are not adopted, the ICB will remain open to legal challenges under the Equality Act. The current commissioning policy for Fertility Assessment & Treatment, discriminates against single people, transgender people and those with a health issue that will prevent them conceiving. While some transgender patients have accessed funding for fertility preservation through the ICB's Exceptional

	Funding Panel, not adopting this policy would leave cohorts of patients who share a protected characteristic, disadvantaged. There is a risk that broadening the scope of criteria, could lead to an increase in activity that is not mitigated by other areas of the policy intended to limit expenditure. Work has been done to identify as far as possible the likely impact of changes. Activity will be monitored and should activity increase beyond current projections, a rapid policy review could be considered. There is a risk that lowering the upper age limit for prospective mothers will lead to some damage to the ICB's reputation and increase the number of complaints from MPs and members of the public. The rationale for lowering the upper age limit is backed by evidence and has been deemed a rational and legal position.
Financial / Resource Implications:	No net savings are anticipated because of the implementation of these policies. Due to the proposed approach to transition, it is likely that expenditure connected to Fertility Preservation will increase in the first year. Mitigations are proposed that should offset this risk moving forward.
Legal, Policy and Regulatory Requirements:	There are no known legal implications for either of the policies presented. They have been developed to comply with the Equality Act and utilise guidance from the HFEA (Human Fertilisation and Embryology Authority) and the National Institute for Health and Clinical Excellence (NICE).
How does this reduce Health Inequalities:	The policies presented address the current known issues around equitable access to fertility assessment and treatment. The criteria support changing unhealthy behaviours known to contribute to fertility problems, e.g., smoking and obesity.
How does this impact on Equality & diversity	An Equality Impact Assessment (EIA) has been completed and signed off by the ICB's Equalities Lead. Adjustments to the current policy address unfair discrimination against patient groups that share a protected characteristic. Mitigations within the policy to limit expenditure have also been deemed fair.
Patient and Public Involvement:	A three-month period of Patient and Public Engagement (PPE) was undertaken. Participants prioritised for change, the broadening the scope of people who can access Fertility Preservation, increasing the number of cycles of In Vitro Fertilisation (IVF) from 1 to 3 and removing relationship status as a barrier to funding.
Communications and Engagement:	Further engagement with clinicians and the general public will be required to successfully communicate the changes to the commissioning stance. A comms plan has been developed.
Author(s):	Chris Moloney (Commissioning Policy Development Manager) Peter Goyder (Clinical Lead for Policy Development and Exceptional Funding)
Sponsoring Director / Clinical Lead / Lay Member:	Joanne Medhurst (Chief Medical Officer)

Agenda item: 6.1

Report title: Clinical Commissioning Policies for Infertility Assessment & Treatment and Fertility Preservation.

1. Background

The ICB's Commissioning Policy Review Group (CPRG) requires that each commissioning policy is reviewed three years from the date of adoption. BNSSG ICB's current Fertility Assessment & Treatment commissioning policy has been reviewed in line with this requirement. The Commissioning Policy Development (CPD) team are responsible for initiating and leading the review of commissioning policies.

The review of the organisation's policy on Fertility Assessment & Treatment was due in December 2020. However, due to a range of issues including the impact of COVID-19 on provider's ability to engage and low staffing levels within the CPD team, the review began in March 2021.

In the development of these proposed policies, the CPD team have engaged with fertility specialists from the Bristol Centre of Reproductive Medicine (BCRM), North Bristol Trust (NBT) and University Hospitals Bristol and Weston (UHBW). The ICB's Medicines Management team were also involved in the development of these policies. Further information on the engagement process can be found in section 11.

Changes to the proposed policies were discussed at length by CPRG in January 2022. This discussion included consideration of proposed changes, using the previous organisation's Ethical Framework for Decision Making (minutes can be found in Appendix 1). The proposed policies were reviewed at CPRG in March 2022. This group recommended they be considered for adoption. Due to organisational transition from a CCG to an ICB, the proposed policies were taken to the Clinical Review Group (CRG) in September 2022. After some discussion, the group agreed to endorse the proposed policies and recommend their adoption to the ICB Board.

2. Scope of Review

The scope of the policy review was agreed by the then BNSSG CCG's Clinical Executive in February 2021. Due to the evidence of negative impact on fertility of smoking and unhealthy Body Mass Index (BMI) for the prospective mother, these points were not included in the scope of the review.

Where possible, the current policy commissions in line with NICE Clinical Guidelines. However, there are areas of non-compliance which have been included within the scope of the review. The below table sets out the agreed scope of the review, and the rationale for the inclusion of each element.

Aspect of Policy	Rationale
Purpose of policy	Clarify what the CCG wants to achieve with this policy
Relationship Status	Unclear why treatment is only offered to couples
Relationship length, stability, and joint legal responsibility criteria.	Unclear if this is reasonable assessment of welfare of the child
Fertility Preservation	Currently provided only in response to cancer
Number of IVF Cycles	Not been reviewed since 2006
Length of time person hasn't conceived to get an assessment	Currently stands at 2 years. Majority of south west CCGs require 1 year
Primary & secondary fertility	Relates to clarifying the purpose of the policy
Age of the prospective mother	Raising the age has not been reviewed as an option. Previous engagement work focused on lowering the age
Surrogacy	There is scope to part fund. Does this link in with what the policy wants to achieve
Any aspect where we are not in line with NICE guidance.	To help understand the reason for any deviation from NICE

Following a period of Public and Patient Engagement (PPE), further discussions with the then CCG's Commissioning Executive and Governing Body identified relationship status as a priority the review. The current policy allows access to fertility treatment for couples only. This discriminates access to treatment based on relationship status and therefore leaves the organisation open to legal challenge due to the tenets of the Equality Act 2020. Further detail on the PPE project can be found in section 11.

3. Considerations

Delays

As noted, the review of the organisation's policy for Fertility Assessment and Treatment was delayed due to the impact of COVID-19. The review began in March 2021.

As part of the review, a significant period of engagement was planned by the CPD team. This coincided with local elections across BNSSG. In accordance with the organisation's rules around engagement during elections, this engagement was delayed by three months. This caused further delay to the completion of this policy review.

Transition

The current commissioning policy for Fertility Assessment and Treatment includes provision for

couples only. The refreshed commissioning policy would support single women in the assessment and treatment of infertility where they met criteria. The practical implementation of this element is complicated by necessary changes to current contractual arrangements between the ICB and fertility services. Should the proposed policies be approved by the ICB Board, it is intended that the new policy is implemented from April 1st, 2023. This is considered the best time frame for making significant changes to the contract.

Significant changes to the ICB's current commissioning stance on infertility treatment and fertility preservation, have been proposed in the draft commissioning policies. Key changes include a lowering of the upper age limit of the prospective mother from 40 to 39 years. Under this criteria, prospective mother's must not be older than their 39th birthday at referral.

Most individuals seeking infertility assessment and treatment, must have undergone two years of regular unprotected sex without conceiving, before they can apply for NHS funded infertility treatment. In lowering the upper age limit of the prospective mother, some patients aged 39 years, who have been trying to conceive for a year, could be denied treatment if the new policy is implemented because of the proposed new policy's lower upper age limit. There is then, a need to consider how the ICB will transition from the current commissioning stance to the proposed new approach in a way that is rational and fair.

The proposed change may affect, on average, around 30 women per year. As it is a change that will ostensibly only have three months of warning the cohort of women disadvantaged by this should be allowed to transition, which would take 9 months. BNSSG ICB's Executive Team have indicated that for this nine-month period, women aged between 39 and 40 years, who are known to their clinician as having suspected infertility and have been trying to conceive for at least one year, could still be referred for the funding of investigations and treatment of infertility under this policy should they meet the rest of the criteria.

Cost Considerations

Elements of the current policy, particularly in relation to relationship status and fertility preservation, are discriminatory. This has been confirmed by the ICB's solicitors. This leaves the organisation at risk of a potential legal challenge under the Equality Act. There is then, a need to equalise opportunity of access to NHS funded fertility assessment and treatment.

The CPD team have been advised by the ICB's Chief Finance Officer (CFO) that any changes to the current policy, must not lead to increased expenditure for the ICB. Therefore, to equalise access within the proposed policies, criteria has been adapted to offset any increased activity. This has been done in a way that does not unlawfully or irrationally discriminate based on protected characteristics.

4. Policy Overview – Infertility Assessment & Treatment

The title of the policy has changed from Fertility Assessment & Treatment to clarify that the purpose of the policy is to find the causes of infertility and identify NHS commissioned treatments that are likely to help resolve infertility.

To maintain consistency in the scope and purpose of this policy, fertility preservation will now be managed under a separate policy. This is discussed in the following section.

To equalise access of opportunity and limit potential legal challenges for discrimination, the revised policy will not limit assessment and treatment of infertility to heterosexual and same sex couples.

Under the revised policy, single women will be eligible for assessment and treatment of infertility provided they meet the relevant criteria within the policy. This includes having regular unprotected sex for a period of two years or undergoing 6 independently funded unstimulated cycles of Human Fertilisation & Embryology Authority (HFEA) approved donor insemination.

There are limited treatment options for single men with infertility. Most of these treatments are funded by NHS England. BNSSG ICB does not currently fund, or part fund, any interventions to resolve infertility in single men. Assessment and treatment for single men is, therefore, outside the scope of this policy.

Under the proposed policy, the weight of the prospective father will no longer form part of the assessment. This is due to the challenges of consistently registering a BMI from the prospective father in primary care, and the lack of evidence for its adverse impact on conception.

Additional criteria have been proposed for the investigation, assessment, and advice on primary infertility for heterosexual couples and single people. These are conditions where there is good evidence that they have an adverse impact on fertility. Under the revised policy, patients could be funded for treatment if there are the following known conditions:

- Azoospermia
- Stage 4 Endometriosis
- A low sperm count, described as <1 million per 30ml taken on two occasions 3 months apart

Under the existing policy, the number of independently funded cycles of unstimulated Intrauterine Insemination (IUI) required before a same sex couple can be referred for NHS funded assessment and treatment is 10.

IUI is an expensive procedure that places significant financial pressure on a couple. Given the apparent lack of parity within the criteria for heterosexual couples and same sex couples, the ICB is open to complaints from the public, and legal challenges around unlawful discrimination. It should be noted that there is currently a legal challenge that has been brought against an NHS commissioner regarding what is being deemed a ‘gay tax’ on NHS funded fertility treatment. This challenge is broadly concerned with the number of independently funded IUI cycles same sex female couples require prior to referral under that commissioner’s fertility policy. The CPD team’s patient and public engagement work also emphasised a need to review the criteria for same sex couples to make the policy more equitable.

HFEA evidence indicates that approximately half of women who undergo this treatment will be successful within 6 cycles. Discussions between the CPD team and local consultants supported the evidence that women will very rarely proceed to 10 cycles of IUI without conceiving.

Therefore, it is proposed that the number of independently funded cycles of IUI required for the referral of same sex female couples be reduced from 10 to 6.

The proposed policy includes provision for patients who cannot have penetrative sex because of a psychosexual or andrological condition. This might include, for instance, vaginismus. Patients will need to have received assessment from a relevant service before referral to a fertility service could be made. The purpose of this provision is to broaden equity of access for people where there is clinical justification.

This policy has attempted to resolve, as far as possible, several issues that were discriminatory against some protected characteristics, including marital status and sexual orientation. This is likely to increase activity and therefore expenditure for the ICB.

Given the instructions around financial considerations, set out in Section 3, the policy has sought to mitigate the impact of equalising access in way that does not unlawfully or irrationally discriminate based on a protected characteristic. Therefore, in the revised policy, the upper age limit for prospective mothers has been lowered from 40 to 39 years.

Evidence indicates that the success rate of IVF for women over the age of 40 years is generally less than for women under 40 years.

One study – 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles' (Smith et al., 2015) aimed to determine the live-birth rate per initiated IVF cycle via a prospective study of 156,947 UK women who received 257,398 IVF ovarian stimulation cycles between 2003 and 2010 and were followed until June 2012. The study indicated that the chances of success for one cycle of IVF for a woman under 40 years was 32.3%, while the chances of conceiving for women aged 40-42 years was 12.3%.

Given the evidence of effectiveness of IVF for women under 40 years compared to women over aged 40 years and over. It has been determined that the upper age limit of the policy should lowered. This policy is intended to support those people with the best chance of conceiving with assistance and must not increase expenditure. Lowering the upper age limit should lead to a reduction in one area of activity that will release resource to support the broadening of the scope of the policy.

The upper age limit for prospective fathers remains 54 years old. Most treatments and interventions are related to the female member of the couple, or the individual. Many females are affected by the policy cut off, while very few men are. Lowering the upper age limit for men could be considered, however the impact would be marginal.

5. Policy Overview – Fertility Preservation

This policy is a development of existing provision that is part of the ICB's current commissioning policy for fertility.

NHS funded fertility preservation is often recommended for patients who are either undergoing, or likely to be prescribed, certain types of cancer treatments. There is provision within BNSSG ICB's current fertility policy for patients who are to receive oncology treatment that is likely to compromise their fertility.

NICE guidance refers to the HFEA's code of practice regarding the provision of fertility preservation to people undergoing cancer treatments. The HFEA's Code of Practice does not offer specific guidance on commissioning fertility preservation for conditions or treatments beyond cancer. However, it does state that 'access restrictions to fertility treatment should only be in place for clinical reasons which are supported by evidence, and any restrictions based on social value judgments should be in keeping with local policies on decision-making and ethical frameworks.'

Legal advice from the ICB's solicitors – Bevan Brittan LLP – indicates that because the current policy provides fertility preservation only for patients undergoing cancer treatment, it is potentially discriminatory. This leaves the ICB at risk of a potential legal challenge under the Equality Act 2010.

Given that HFEA guidance suggests fertility preservation could extend beyond cancer treatment, the ICB does have discretion to fund this intervention for clinical reasons supported by evidence.

The proposed policy for fertility preservation, would fund people who will receive treatment that is likely to have an adverse and irreversible impact on their fertility and where there are no clear alternatives to that course of treatment. Alongside certain cancer treatments, this includes a small group of medications and some surgical interventions on ovaries and testes.

There are several medications that can have a long-term adverse impact on fertility. However, for most patients there will be an alternative treatment option that will not impact fertility.

Medication that is most likely to impact fertility, as described in this policy, are those used in some cancer treatments, cyclophosphamide and testosterone when used in hormone therapy in the treatment of gender dysphoria.

The policy does not set out an exhaustive list of medication and invites funding applications should clinicians believe the medication their patient has been prescribed will have an adverse and irreversible impact on their fertility. The policy will be closely linked to the BNSSG Formulary.

Some surgical interventions will have a similar impact on a person's fertility as cancer treatments. These include surgery on, or removal of, a second ovary or testes. Given that these interventions are likely to have an adverse and irreversible impact on a person's fertility, it is proposed that people who will undergo these treatments should have access to fertility preservation.

6. Financial resource implications

As noted above, the CPD team have been directed to ensure that any changes to the ICB's commissioning stance on the treatment of infertility must not increase expenditure. This section describes the likely costs of making the policy more equitable and proposes mitigations.

During 2020/21, fertility services within BNSSG were closed for long periods due to the COVID-19 pandemic. Consequently, the number of referrals significantly reduced. While activity has increased for 2021/22, the number of referrals fer fertility treatment is expected to be considerably less than reported in 2019/20. Therefore, it is difficult to establish an accurate trend for local activity. For the purposes of this paper, local activity data for 2019/20 will be used as the baseline for any projection of financial impact. Activity connected to applications for assessment and treatment will also be referred to from the last three years. This data includes funding requests received by the ICB's EFR team, and expenditure reported by the ICB's Business Intelligence (BI) team regarding fertility treatment. The total cost of expenditure for fertility assessment and treatment for 2019/20 £993,177.

The proposed policy will enable single women to undergo assessment and treatment of infertility where they meet the relevant criteria. This is likely to have an impact on activity. BNSSG ICB does not fund single women for the assessment and treatment of infertility. Therefore, the number of single women with infertility within BNSSG is unknown. A small number of health systems may fund the treatment of single women through EFR; however, the majority do not have provision within their current policies. The CPD team have been unable to obtain referral data regarding single women from these organisations.

The most recent available data from the HFEA indicates that, in 2019, 2,138 cycles of IVF or Donor Insemination were funded by the NHS for single people. This accounted for 4% of the total number of NHS funded treatment cycles for England. This cohort constituted less than 1% (0.014%) of the total population of England registered as single or unmarried, according to the Office for National Statistics (ONS).

ONS data also indicates that 7% of the women, nationally, who describe their marital status as divorced, widowed or have never been never married or in a civil partnership, would meet the age criteria for the proposed policy on Infertility Assessment & Treatment.

Data from BNSSG county councils indicates that 170,375 of BNSSG's total female population would meet the age criteria in the proposed policy. However, this figure does not indicate what proportion of this cohort would register their marital status as single. Furthermore, this data does not account for the number of lone parent families, shared custody agreements, nor is there data to indicate the number of single women who have infertility.

Activity has been projected using national trends to propose a minimum and maximum number of single women who might meet the age criteria of the proposed policy.

The first projection presents a minimum number of single women who might seek funding for infertility treatment.

Assuming that BNSSG's population is aligned with national trends, 119,226 women within BNSSG could be within the age group of the proposed policy, and would describe their marital status as divorced, widowed or have never been never married or in a civil partnership. Again, this does not

account for lone parent families, shared custody agreements, nor is there data to indicate the number of single women who have infertility. Using HFEA data on demand for NHS funded treatment for infertility, and if BNSSG follows national trends and less than 1% (0.014%) of this cohort, the number of single women requesting funding for infertility assessment and treatment could be 1 per year. The ICB's EFR team have indicated that they have only seen 1 application for funding from a single woman over the last five years. It is believed by those involved with the review that the numbers are not likely to be significantly high.

A second means of projecting activity related to single women, would be to use national trends again, and use the percentage of single women receiving NHS funded treatment against the total number of funding applications.

For the financial year 2019/20, the number of heterosexual couples that applied for infertility assessment treatment was 238. Following HFEA trends, if the ICB were to assume that 4% of the total cohort would be single women, then it is likely that 9 additional single women each year could apply. It is worth noting that, although the number of referrals for infertility treatment were impacted by COVID-19, the number of funding applications received yearly from 2019/20 to 2021/22 are similar. Assuming 4% of the cohort would be single women, BNSSG ICB could expect to see up to 11 funding applications each year from single women.

Should the proposed policy be adopted, this could lead to an additional expenditure of £34,584.

Given the limitations of local data, it is difficult to make a reliable projection on the number of single people who may require assessment and treatment for infertility. Information that is unavailable includes the prevalence of infertility for single people and a breakdown of marital status by age.

If the proposed policies are adopted, the CPD team would work with the ICB's contracts and BI teams to establish a means of monitoring this data.

With regard to changes to the commissioning stance on fertility preservation there is reliable data already being collected that can inform projections.

The number of patients currently prescribed cyclophosphamide, and who are within the age criteria for this policy, is 5. Input from the medicine's optimisation team indicates that the number of patients prescribed cyclophosphamide is likely to remain at a similar level.

BI data indicates that the number of BNSSG patients on either a gender dysphoria, or transsexualism pathway is consistently low. In 2019/20, the number of BNSSG patients on one of these pathways was 8. These pathways are commissioned by NHSE, and each pathway works to different service specifications. Therefore, it is unclear what the overall impact might be.

It is also unclear how many patients would want to preserve the potential to conceive following their transition.

The ICB already funds fertility preservation for patients undergoing some cancer treatments. The proposed policy will not have an impact on activity for this cohort.

It is difficult to provide an accurate figure of the likely cost impact of this policy. What the CPD team cannot know is the number of patients within the cohort who believe their family is complete or would want to have children in the future.

The cost of gamete cryopreservation is £3,350. Assuming the number of patients on medication that would have a long-term adverse impact on fertility remains at current level, a gender dysphoria or transsexualism pathway remained at this level, and assuming they each wanted to preserve the potential to conceive, the ICB could expect a cost increase of £43,550. Activity would be regularly monitored by the CPD team using BI data.

There is a small cohort of patients who will require fertility preservation because of a planned surgical intervention that will have an adverse impact on their fertility. Local specialists estimate that approximately 5 patients per year might require funding on this basis. Activity data from providers does not indicate the exact activity.

The level of activity is not expected to increase, however the CPD team would monitor activity through BI reporting and, possibly, direct activity reports from the provider. Assuming activity remains at the current level for this cohort – as expected – the ICB could see an increase of £16,750 per year.

Due to the transition period proposed for the implementation of the new commissioning policy for Infertility Assessment & Treatment, it is likely that there be increased expenditure for the ICB in financial year 2022/23. The number of women aged over 39 years who applied for funding for fertility assessment in 2021/22 was 35. Should the proposed approach to the transition of from the current commissioning stance on infertility be approved, a proportion of this cohort could be eligible for treatment. There is no way to know from current available data what the number of women in this cohort would be.

It is unlikely that a significant number of single women would seek funding in the funding for infertility assessment and treatment in the first year. This is due to the policy's criteria which stipulates that single women must have first undergone two years of unprotected sex without conceiving, or 6 cycles of independently funded IUI. According to local consultants, six cycles of IUI can take up to a year to complete. Therefore, unless the patient has a known condition that could enable them to seek funding outside of this timeframe, it is not anticipated that a significant number of single women would be able to apply for funding of Infertility Assessment & Treatment in the first year.

It should be noted that, due to the proposed transition period, it is likely that there will be an increase in fertility expenditure for BNSSG ICB for 2023/24. This is due to the implementation of the proposed policy for Fertility Preservation. While there are mitigations to offset the increase in activity in the long term, these would ostensibly not be fully in place for 2023/24 due to the proposed transition period. That is to say, there would be greater equity of access for Fertility Preservation in 2023/24, which would lead to increased expenditure. However, the lowering of the upper age limit for prospective mothers, would not be implemented until 2024/25.

For 2019/20, the BNSSG CCG spent £117,250 on fertility preservation. The proposed policy could lead to an increase in this figure of £60,300. As the proposed mitigations to offset cost increase would not be fully implemented in 2023/24, there is a risk that fertility expenditure could be increased for BNSSG ICB by up to £60,300 in 2023/24. Accepting this risk and allocating

increased funding to the assessment and treatment of infertility, would ensure that women within the cohort appropriate for the proposed transition plan are not unfairly disadvantaged.

Adopting the proposed policies could lead to an increase in regular annual expenditure of £94,844 per annum.

Mitigations

There are two elements of policy that could be adjusted to 'fairly' offset the impact of equalising access. The first would be to remove the provision of fertility preservation completely. This would mean that no one could access fertility preservation which would be fair if a very difficult decision to make. Using activity data from 2019/20 as a guide, data from the ICB's contracts team indicates that removing fertility preservation could lead to a reduction in expenditure of £117,250 for the ICB.

However, feedback from the CPD team's PPE process suggests that this would not be in keeping with our population's priorities for the review of the ICB's commissioning stance.

The second potential mitigation is to reduce the upper age limit for the prospective mothers from 40 years of age to 39. Despite NICE guidance stipulating that the upper age limit for prospective mothers should be 42, thirty-three ICB's across the country currently have an upper age limit of 39 or less.

Data from the ICB's EFR team indicates that the number of applications from women aged 39 or over for 2019/20 was 32. This represents expenditure approximately £100,608. For the financial year 2021/22 this number was 35, an expenditure of £110,040. As noted, 2020/21 has not been referenced due to complications arising from the pandemic.

The HFEA have indicated that the number of people aged 40 and above, seeking treatment for infertility is increasing. While projections for savings and expenditure will require monitoring should the policies be approved, lowering the age limit of the prospective mother from 40 to 39 years, could release enough resource to broaden the scope of fertility preservation, and enable single women to access infertility treatment where they meet criteria.

7. Legal implications

Legal advice from the ICB's solicitor – Bevan Brittan LLP - has indicated that areas of the current policy are potentially discriminatory and open to legal challenge under the Equality Act.

There is a specific challenge around the equity of access for fertility preservation provided under the current policy. Currently, BNSSG ICB will only fund fertility preservation for patients undergoing some cancer treatments, which will have an adverse and irreversible impact on their fertility. It is recognised that there are number of NHS funded interventions that can have a similar impact on a person's ability to conceive.

The current commissioning stance only provides assessment and treatment of infertility for heterosexual and same sex couples. There are no clinical rationale why single people should not be assessed under this policy.

The proposed policies endeavour to address areas of non-compliance, making the commissioning stance more equitable and avoiding unlawful and irrational discrimination. The proposed policies broaden equity of access for people where there is clinical justification.

8. Risk implications

There is a risk that if the proposed policies are not adopted, the ICB will remain open to legal challenges under the Equality Act. The current commissioning policy for Fertility Assessment & Treatment, discriminates against single people, transgender people and those with a health issue that will prevent them conceiving. While some transgender patients have accessed funding for fertility preservation through the ICB's Exceptional Funding Panel, not adopting this policy would leave cohorts of patients who share a protected characteristic, disadvantaged. A small number of complaints and enquiries from MPs and the public have been received since the current policy was adopted. Therefore, it is likely that these complaints will continue should the current commissioning stance remain in place.

There is a risk that broadening the scope of criteria, could lead to an increase in activity that is not mitigated by other areas of the policy intended to limit expenditure. Work has been done to identify as far as possible the likely impact of changes. However, as noted the projections are based on national trends and do not directly reflect the health needs of BNSSG's population in relation to infertility.

The CPD team are confident in their projections around increased activity for fertility preservation. However, the number of single women who might seek infertility treatment is currently unknown and, due to limitations in the available data, there is a possibility that the projections presented are inaccurate. However, it is believed to be unlikely that the projections will be grossly inaccurate due to activity reported by the EFR team. Activity will be monitored and should activity increase beyond current projections, a rapid policy review could be considered.

There is a risk that lowering the upper age limit for prospective mothers will lead to some damage to the ICB's reputation and increase the number of complaints from MPs and members of the public. The rationale for lowering the upper age limit is backed by evidence and has been deemed a rational and legal position. While the severity of this defensible position is low, there is a high likelihood of challenges from MPs and members of the public. A key mitigation for this will be how the proposed policies are communicated, and the engagement the organisation has from local partners and stakeholders. The CPD team have worked with the ICB's Insights and Engagement team to undertake this work.

9. How does this reduce health inequalities

The policies presented address the current known issues around equitable access to fertility assessment and treatment. These are discussed in sections 4, 5 and 10.

The criteria support changing unhealthy behaviours known to contribute to fertility problems, e.g., smoking and obesity. There is some evidence that there is a higher level of prevalence of smoking among certain ethnic groups. As the policy stipulates that prospective mother's and, where appropriate, their partners must be non-smokers, it is recognised that the policy could be construed as having a negative impact on certain patient groups. However, there are a range of smoking cessation services that GPs can refer individuals to support their referral for assessment and treatment of infertility.

HFEA data indicates that people from BAME communities do not access fertility treatment as regularly as people of white-British ethnicity. We currently do not have enough information to fully understand this. It should also be noted that the outcomes of IVF for people from BAME communities are less positive than people of white-British ethnicity. We currently do not have enough information to fully understand this. However, there is a national programme of work to address this. For the purposes of future policy reviews, the CPD and the Clinical Effectiveness and Research team will monitor the progress of this work.

10. How does this impact on Equality and Diversity?

Infertility Assessment & Treatment

Equality impact assessment has been completed and signed off by the ICB's Equalities Lead. This can be found in appendix 2.

This policy has attempted to resolve, as far as possible, several issues that were discriminatory against some protected characteristics, including marital status and sexual orientation. The proposed policy does not negatively impact any patient group that shares a protected characteristic.

This policy uses clinical evidence and provides a clear rationale for people who will be considered for treatment and assessment. Focusing on primary infertility means that the policy is intended to support patients who have never conceived a child and have significant difficulty conceiving.

The criteria for this policy have been broadened based on clinical evidence to equalise access for people who share a protected characteristic. This has been done as far as possible, within the limitations of current funding resource. This includes reducing the number IUI cycles for same sex female couples and opening fertility assessment and treatment up to single and unmarried people.

Transgender patients are unlikely to fulfil certain evidence-based criteria that helps to identify patients with possible primary infertility. For instance, having regular unprotected sex for a period of two years prior to referral. Patients on a gender dysphoria pathway will be supported through a proposed new policy for fertility preservation that will preserve their potential to have children.

Fertility Preservation

Equality impact assessment has been completed and has been signed off and can be found in appendix in appendix 2. The proposed policy does not impact negatively on any group who share a protected characteristic. The policy develops on BNSSG ICB's current provision for fertility preservation that was discriminatory, by establishing a clear rationale based on clinical evidence.

11. Consultation and Communication including Public Involvement

The CPD team undertook a significant period of patient and public engagement (PPE). This included the development of three surveys that were each tailored to specific groups. These groups included healthcare professionals, the general public (referred to as stakeholder survey) and GPs. The survey was published on the then CCG's website and disseminated to the three BNSSG Local Authorities, fertility services, acute providers and a broad range of community groups. The purpose of these surveys was to give local communities the opportunity to inform what areas of the current policy should be a priority for review. Participants highlighted the following:

- Broadening the scope of people who can access Fertility Preservation.
- Increase the number of cycles of In Vitro Fertilisation (IVF) from 1 to 3.
- Length of time a person has not conceived should be considered more important that relationship status.

The survey was live for three months. Following this period, the responses were collated and passed to Dr Ilhem Berrou, Senior Lecturer at the University of the West of England to undertake independent analysis and write up the findings. The survey asked questions specific to areas within the scope of the review.

The CPD team discussed the policy with specialists from the BCRM, NBT and UHBW.

The policy has also been supported by the ICB's medicines optimisation team, who provided an overview of medication that can compromise fertility.

The CPD team presented an overview of the survey analysis, outcomes of discussions with consultants and the medication review performed by the medicine's optimisation team, to the CCG's GP clinical lead forum. The findings were also presented to the then BNSSG CCG's Clinical Executive for guidance on how to proceed with these priorities.

It was agreed that broadening the scope of fertility preservation and removing the requirement within policy that only couples could receive funding should be actioned. However, given the financial constraints, increasing the number of IVF was not considered a viable option. It should be noted that BNSSG ICB's current commissioning stance offers one fresh and one frozen cycle of IVF.

Data
The CPD team undertook an evidence review of disabilities that can impact fertility. It was deemed that the current policy adequately addresses disabilities and illnesses that are likely to require particular consideration with regard to conception. This includes the provision of sperm washing for patients with a positive HIV diagnosis.

The proposed policy also provides clarity on the support it can provide patients who cannot have penetrative sex because of a psychosexual or andrological condition. This might include, for instance, vaginismus. Patients will need to have received assessment from a relevant service before referral to a fertility service could be made.

Alongside data from the ICB's BI data, the CPD team has reviewed data from the HFEA, financial data from the CCG's contract lead for fertility and activity data from BCRM. Data sources will be cited as required.

The CPD team performed a comparison of BNSSG ICB's current fertility policy against its eleven other (then) CCGs. Each element from the scope of the current review (e.g., age of prospective mother, number of IVF cycles) was used as the means of comparison. BNSSG ICB's policy is predominantly in line with the majority of other ICBs.

Appendices

Appendix 1 – Proposed Commissioning Policies (Attached)

Appendix 2
Note: This work was undertaken prior to the CCG becoming an ICB, therefore the below refers to CCG rather than ICB.

Ethical Implications
In January 2022, the CPRG held a two-and-a-half-hour debate on the ethical implications on some of the proposed changes to the CCG's policies for commissioning fertility assessment, treatment, and preservation.

The group discussed the proposed changes considering the five principles of the CCG's ethical framework for decision making. From these discussions the group reached unanimous consensus regarding what changes to the policies should be taken forward to clinical executive for adoption.

The five principles of the CCG's ethical framework for decision making are:

Principle 1 – Rational
Decision-making is rational and based upon a process of reasoning which involves:
- Being logical in the way reason is applied to reach a decision

- Ensuring that the decision is based on available evidence of clinical effectiveness
- Ensuring that the decision is based on the available, different types of evidence of whether or not something 'works' and is safe. Types of evidence include research studies, case studies and service user and clinician insight.
- Making a realistic appraisal of the likely benefits and harms to the population of Bristol North Somerset and South Gloucestershire and patients and service users
- Weighing up all relevant factors, including risks and costs to all relevant organisations and also to the people that we serve
- Taking account of the wider political, legal and policy context
- Ensuring individuals involved in decision-making are appropriately skilled and trained

Principle 2 – Inclusive
Decisions should be arrived at through a fair and non-discriminatory process that:

- Reinforces the concept of equality of opportunity of access to healthcare
- Ensures patient and public insight is considered in decision-making
- Balances the rights of individuals with the rights of the wider community

Principle 3 – Take account of the value we will get
We have finite resources, and they must be managed responsibly. Investment in one area of healthcare will inevitably mean that resources will have to move away from other areas of healthcare.

Decisions should be based on careful consideration of the trade-offs between cost and benefit, both short and long term. These decisions will recognise that complex trade-offs cannot necessarily be reduced to simple cost benefit calculations. We need to balance the impact of cost against other factors such as the impact on the population's health.

Decisions will take account of the outcomes we will achieve (for example population health, quality of health, survival rate, extent of recovery, people's experience, safety) for the resources that we use (for example the amount we pay for a service, salaries, investment in equipment and buildings). This is what we call "value".

Principle 4 – Transparent and open to scrutiny
Decisions and the way they are made should be transparent and easily understood. The information provided to decision makers should be fully documented together with the process followed and the degree of consensus reached.

Principle 5 - Promote health for both individuals and the community
Decisions about things that promote health and avoid people becoming ill will be considered alongside things that will cure illness and other interventions. There may be times when it is appropriate to target specific demographic groups or health issues in order to reduce inequalities in health outcomes.

The below provides an overview of the group's responses to key discussion points within the proposed policies, against the principles of the CCG's ethical framework.

Assuming infertility is a health issue should BNSSG CCG fund assessment regardless of someone's relationship status?

Rational
It was proposed that traditional approaches to the family were the likely drivers behind the CCG's existing rationale for the funding of fertility assessment. The group further recognised that, since the development of IVF, the 'traditional family' is no longer the expectation among the population. This is reflected in legislation related to accessing fertility services, even if decisions around the public funding of fertility treatment do not reflect the broader changes.

From the perspective of intended outcome, there is no evidence to suggest that relationship status has an impact on an individual's physiological infertility, or a woman's ability to carry a child to live birth.

The concept of the 'traditional family' is further complicated by changing attitudes to sexual and gender identities. Public health specialists noted that more people are identifying as different genders, and more people are identifying as different sexualities. This means that traditional expectations of relationship status may no longer be appropriate.

Given these factors, the group agreed that any policy on the assessment of infertility should be based on the needs of the individual and not on their relationship status.

Inclusive
Implementing this proposal would increase the equality of opportunity of access to healthcare.

Value
The cost implications of adopting this recommendation have been described above. Within the context of the ethical debate, the challenge for CPRG was to develop a safe and equitable policy for clinical executive to consider. While affordability must be considered, this is believed to fall within the remit of clinical executive. This is partly because of the group's capability to carry out the required financial modelling. Moreover, it was recognised that this policy is a small part of the broader commissioning landscape, and that the group are unlikely to have an appropriate insight into the CCG's commitments in order to make an absolute judgement on value.

However, the group recognised the need to consider cost mitigations should Clinical Executive decide that the financial risk to the policy is too great. Such mitigations could include reducing the upper age limit of prospective mothers within the criteria. This would reflect evidence of reduced fertility for women from the age of 38 years and could offset the impact of additional activity.

Focusing on the ethics of the proposal, the group agreed that it was reasonable for the CCG to accept additional costs to increase equity of access. Given the extent to which the proposed policy could reduce inequity of access and limit the potential for accusations of unlawful discrimination, it was agreed that equity should take priority over cost impact. There was unanimous agreement that investment in equalising access to services was warranted.

Transparent & Open to Scrutiny
It was agreed that the discussions and decisions of the group satisfied this principle. It was further noted that the discussion had been recorded and, pending approval from the chair and in agreement with all information governance protocols, could be shared beyond the group.

Promote Health for Both Individuals and the Community
This principle was not considered relevant to the discussion of the policy.

Should single people be funded for treatment of infertility?

Rational
While there are a number of potential treatment single women with infertility, there are several conditions for single men that will be very difficult to treat – for instance a man with a zero sperm count. Where this is the case for heterosexual couples, the likely next step would be surgical sperm recovery for the purposes of surrogacy which is not funded by BNSSG CCG. Surrogacy and surgical sperm recovery can be funded by NHSE and therefore are outside the scope of this policy.

However, the assessment of patients with low sperm count – as defined within the policy – would be the responsibility of the CCG. Men within a heterosexual couple in this instance could be able to access IVF treatment. For single men, there is no CCG commissioned treatment.

Given that the treatment options for single men are limited to NHSE funded interventions, CPRG agreed that the CCG should only fund infertility treatment for single women. It was agreed that this was a rational decision based on the biological factors and the limited treatment options for single men. Furthermore, it was agreed that the policy would not fund treatment for people born without a womb.

Inclusive
While there is a degree of inequity in this decision, part of this is due to physiological difference between men and women. Not funding treatment for infertility at all, is the only decision that could be entirely equitable. Implementing the proposed policy would increase equity of opportunity for accessing infertility treatment, while limiting the potential for accusations of unlawful discrimination.

Value

Criteria set out within the policy is intended to ensure that people most in need of treatment, and with the best chance of conceiving, are funded. This would support the best use of the CCG's resource.

Changes to the current provision for fertility preservation, would lead to an increase in the number of people who might be eligible for funding, therefore positively impacting on outcomes that matter to people seeking fertility assessment and treatment.

Transparent & Open to Scrutiny
Recommendations agreed by CPRG were based on evidence rather than personal opinion. This supported a rational and transparent logic to decision making.

Promoting Health for Individuals and The Community
Broadening the scope of the policy will promote positive outcomes for a greater portion of the community.

Should the CCG fund fertility preservation for treatments other than cancer drug treatments?

Rational
Funding fertility preservation for treatments other than cancer drug treatments would have the same impact on a person's fertility. As the impact of some non-cancer treatments are the same as cancer treatments, it is rational to provide fertility preservation for patients undergoing these treatments.

Inclusive
Funding fertility preservation for patients undergoing treatments other than cancer is a more equitable approach that limits the potential for accusations of unlawful discrimination by the CCG. This approach would increase equality of opportunity of access to healthcare within BNSSG.

Value
As discussed in the previous section, there is likely to be a small cost increase to the CCG. The number of additional patients that are likely to require funding is low. There are no cost mitigations that can be factored into this policy to reduce cost without risking unlawful discrimination. The only equitable approach that would avoid cost increase would be to remove funding for fertility preservation completely.

Transparent & Open to Scrutiny
Recommendations agreed by CPRG were based on evidence rather than personal opinion. This supported a rational and transparent logic to decision making.

Promoting Health for Individuals and The Community

Broadening the scope of the policy will promote positive outcomes for a greater portion of the community.

Appendix 3 – Equality Impact Assessments (Attached)

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Fertility Preservation
Criteria Based Access

Funding approval for Fertility Preservation Treatment will only be provided by the CCG where an individual will receive NHS provided treatment that will have an adverse, long-term impact on fertility, where there is no clear alternative, and where the individual meets the rest of the criteria.

Patients who are to receive oncology treatments which are likely to compromise their fertility are eligible for fertility preservation, as will patients prescribed cyclophosphamide, and those prescribed testosterone for individuals on a gender dysphoria pathway.

Clinicians could apply if they feel the drug that they are working with fits the categorisation.

For guidance, please refer the medication's record within the BNSSG's Joint Formulary guidance at https://remedy.bnssgccg.nhs.uk/formulary-adult/bnssg-joint-formulary/about-the-bnssg-joint-formulary/

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Section A - Fertility Preservation Prior to NHS Commissioned Treatment

CRITERIA BASED ACCESS
For consideration by specialist services and referring clinicians when planning treatment.
In order to access services patients must meet all of the following criteria:

1. Either:
    a. The individual will be prescribed NHS commissioned medication that is likely to have an adverse and irreversible impact on their fertility.
    b. The individual will undergo an NHS provided intervention that is likely to have an adverse and irreversible impact on their fertility (this can include a second ovarian removal, or planned surgery on a remaining testis that could lead to removal).
2. Patients who meet the criteria for fertility preservation, are eligible for fertility preservation treatment including:
    a. for single individuals or those not in a stable relationship: sperm collection and storage, or oocyte harvesting and storage, or
    b. storage for couples in a stable relationship: oocyte harvesting, fertilisation and embryo Cryopreservation prior to treatment to allow subsequent In Vitro Fertilisation (IVF) treatment in line with this policy provided they meet the requirements for funding below.
3. Patients must have commenced puberty and not be older than the limits for treatment set out in the commissioning policy for Infertility Assessment & Treatment (the prospective mother's 39th birthday and the prospective father's 54th birthday).
4. At the time of fertility preservation treatment, patients do not need to be able to demonstrate that they comply with the requirements of this policy in respect of smoking and Body Mass Index (BMI), as delaying treatment until a patient could comply may compromise treatment.
5. Fertility preservation for the following patients is not commissioned and will not be funded by BNSSG where:
    a. the patient wishes to undergo a vasectomy or female sterilisation and wishes to preserve fertility, or
    b. the patient wishes to delay conception, or
    c. the patient has living offspring and therefore does not qualify for funding for fertility preservation treatment. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children.
    d. the patient has previously received an NHS funded cycle of fertility treatment either locally or elsewhere in the UK.

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Section B - Fertility Treatment including Assisted Conception and IVF following Fertility Preservation Treatment

PRIOR APPROVAL
For Fertility Service consideration when planning treatment.

1. Once the patient has completed treatment and been advised by clinicians that they may safely commence fertility treatment, they must meet all of the requirements of the CCG's commissioning policy for Infertility sections A & B to be eligible for treatment.
2. Sperm, oocyte and embryo storage will be handled in line with the BNSSG Cryopreservation policy in place at the time of collection as set out in this policy.
3. Individuals will not be required to demonstrate infertility by undergoing 6 cycles of independently funded Intrauterine Insemination (IUI) or having regular unprotected sex for two years.
4. Patients must meet the criteria set out in the general principles of BNSSG's policy for Infertility Assessment & Treatment.

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C - Cryopreservation of Sperm, Oocytes and Embryos – Criteria Based Access

Cryopreservation is term use to describe the freezing and storage of sperm, oocytes and embryos for patients.

1. Patients who have had sperm, oocyte or embryo cryopreserved prior to commencement of medication or following interventions that will have an irreversible and adverse impact on fertility will be funded for;
   - a maximum of 2 years after reaching the age of 21,
     OR
   - until 2 years after their condition is sufficiently stable to allow pregnancy,
     OR
   - a maximum of five years post collection, freezing and storage.
2. Funding for storage will cease six months following the death of the patient, or if the patient or their partner reaches the upper age limit.
3. Once the period of NHS funding ceases, patients or their family can elect to self-fund for a further period, not to exceed appropriate Human Fertilisation and Embryology Authority (HFEA) regulations on length of storage.
4. Patients with cryopreserved sperm, oocytes or embryos must comply with all requirements of the fertility services and the HFEA or NHS funding for these products will cease. This includes Consent, in a manner as set down by HFEA regulations, must be obtained at the outset and at regular intervals (usually annually) during the period of storage for storage to continue.
5. Commencement of Cryopreservation does not entitle patients to fertility treatments. There is the potential for patients to meet the access criteria for Cryopreservation and not to meet the criteria for fertility treatments at a later date. Patients in this category may elect to self-fund further fertility treatment using the cryopreserved sperm, oocytes or embryos.

Section D - Posthumous Assisted Reproduction – Exceptional Funding Request

BNSSG does not fund fertility treatments associated with posthumous assisted reproduction**.**

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form.

Patients who wish to use cryopreserved sperm, oocytes or embryos following the death of their partner, may only do so where appropriate consents have been obtained prior to the death of their partner, as set down in HFEA guidelines.

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For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

Fertility preservation can mitigate against the likely impact of some NHS prescribed treatments, on an individual's potential to have children in the future.

Fertility problems can lead to mental health issues, including suicidal ideation in the more extreme cases. Fertility preservation could limit the potential for these issues to develop.

Fertility preservation can reinforce equality of opportunity across a wide range of patient groups, by enabling patients who have undergone NHS prescribed treatment that removes fertility, the same level of opportunity as those who have not.

Risks

Fertility preservation is generally considered safe, carrying small risks to the patient. There are some risks and issues which may need to be considered.

The process for sperm storage involves masturbation and semen analysis. It should be noted that very unwell men may find masturbation and ejaculation difficult.

Fertility preservation is, potentially, physically more demanding for women than men as the process to collect oocytes (eggs) is more demanding than the collection of sperm in most cases.

There's no evidence that current fertility preservation methods can directly compromise the success of treatments. However, the success of treatment if it is delayed to pursue fertility preservation, could be compromised.

Alternatives

Without fertility preservation, a person who meets the criteria outlined in this policy is unlikely to become a biological parent. Individuals may wish to consider surrogacy arrangements or adoption, however the CCG does not routinely fund surrogacy.

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Do Nothing

Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes "not yet" is a good enough answer until you gather more information.

Fertility Preservation – Plain Language Summary

Fertility preservation is the freezing of a person's reproductive cells. Female reproductive cells are called ova, or egg cells, male reproductive cells are called sperm.

Cryopreservation is the process of freezing a person's reproductive cells, using liquid Nitrogen, without causing damage to the cells.

Certain types of NHS prescribed treatments can have an adverse long-term impact on a person's reproductive and, therefore, their ability to have children in the future. These include some cancer treatments, and hormone therapy which is commonly used in the medical treatment of gender dysphoria.

Freezing a person's reproductive cells, preserves the opportunity for that person to have family in the future.

Once a patient has completed their treatment, and their clinician believes it is safe for them to do so, their frozen reproductive cells may be used in In Vitro Fertilisation (IVF) or Intracytoplasmic Sperm Injection (ICSI).

In vitro fertilisation (IVF) is one of several techniques available to help people with fertility problems have a baby.

During IVF, an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory.

The fertilised egg, called an embryo, is then returned to the woman's womb to grow and develop.

It can be carried out using your eggs and your partner's sperm, or eggs and sperm from donors.

Intracytoplasmic sperm injection (ICSI) is a type of IVF treatment that involves drawing up a single sperm into a very fine glass needle and injecting it directly into the centre of the egg.

The fertilised egg (embryo) can then be transferred into the womb of the woman as in a normal IVF cycle. The live birth rates for ICSI and conventional IVF are similar.

The major development of ICSI means that as long as some sperm can be obtained fertilisation is possible.

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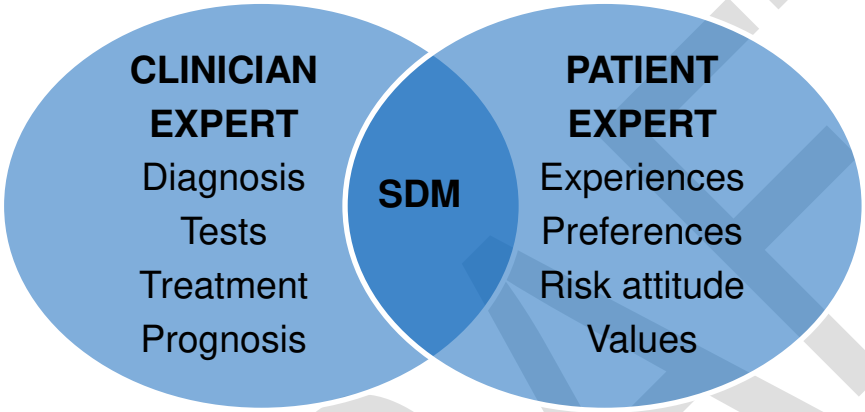
Intrauterine insemination (IUI), also known as artificial insemination, is a fertility treatment that IUI involves separating sluggish, non-moving or abnormally shaped sperm and injecting directly into the womb.

Shared Decision Making

If a person fulfils the criteria for Fertility Preservation, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. It means that people receiving care and clinicians delivering care can understand what is important to the other person.
The person and their clinician may find it helpful to use 'Ask 3 Questions':

1. What are my options? (see sections above)
2. What are the pros and cons of each option for **me**?
3. How can I make sure that I have made the right decision?

This policy has been developed with the aid of the following:

1. NICE (2017) Fertility Problems: Assessment & Treatment (Clinical Knowledge Summary) www.nice.org.uk
2. National Library of Medicine (2015) 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles'.

Due regard

In carrying out their functions, the Bristol, North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the CCGs are responsible, including policy development and review.

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OPCS Procedure codes

Must have any of (primary only):

Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net**.

Glossary

Cryopreservation	Cryopreservation is the process of freezing and storing sperm, oocytes and embryos so that they can potentially be used at a future date, typically in an attempt to achieve a pregnancy.
Embryo	Refers to a fertilised Oocyte It is called an embryo until about eight weeks after fertilisation and from then it is instead called a foetus.
Female Sterilisation	Female sterilisation is an operation to permanently prevent pregnancy. The fallopian tubes are blocked or sealed to prevent the eggs reaching the sperm and becoming fertilised
Gender Dysphoria	Gender dysphoria is a term that describes a sense of unease that a person may have because of a mismatch between their biological sex and their gender identity.
Intrauterine Insemination (IUI)	Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti-oestrogens or gonadotrophins (stimulated IUI).
In-Vitro Fertilisation	In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body.
Oocyte	Refers to a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell.
Ovary	The ovaries are small, oval-shaped glands located on either side of the uterus. They produce and store eggs and make

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	hormones that control the menstrual cycle and pregnancy.
Sperm	Refers to the male reproductive cells.
Testis	One of two egg-shaped glands inside the scrotum that produce sperm and male hormones.
Vasectomy	A vasectomy is a surgical procedure to cut or seal the tubes that carry a man's sperm to permanently prevent pregnancy.

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Infertility Assessment & Treatment

Criteria Based Access/Prior Approval

Assessment of Infertility – Criteria Based Access
Treatment of Infertility – Prior Approval

Funding for the assessment and treatment of infertility will only be granted by the ICB for:

- Heterosexual couples who have not conceived after two years of regular unprotected sex (exceptions apply in certain circumstances as described within the policy).
- Single women who have not conceived after two years of regular unprotected sex.
- Single women who have not conceived after 6 unstimulated cycles of independently funded Human Fertilisation and Embryology Authority (HFEA) approved Intrauterine Insemination (IUI)
- Same sex couples who have undergone 6 independently funded unstimulated cycles of HFEA approved IUI and have not conceived.
- Men who have been shown to have low or zero sperm counts can also be assessed.

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Section A - General Principles for all Patients

Points that should be noted when considering whether patients are eligible to access NHS funded infertility assessment and treatments:

1. Fertility treatment should be offered in the least invasive format appropriate, namely investigation and assessment, followed by assisted conception. All referrals for assessment and treatment should be made on the form published on the BNSSG websites and accompanied by a referral letter setting out detailed clinical information and background.
2. Individuals who do not meet the eligibility criteria set out in the relevant section of this policy or have received NHS funded In Vitro Fertilisation (IVF) treatment elsewhere are not eligible for treatment under this policy.
3. The prospective mother must not be older than their 39th birthday at referral and the prospective father should be not older than their 54th birthday at referral.
4. Where a prospective mother has previously received NHS funded treatment as part of another couple, they will not be barred from accessing NHS funded treatment under their current relationship where they meet all criteria. They will not be managed as single women within the scope of this referral.
5. The individual requiring assessment must have no living offspring/children to qualify for funding. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children. If the individual or couple adopts a child or becomes pregnant naturally during assessment or treatment, they are no longer eligible for fertility assessment or treatment.
6. Individuals who have had unsuccessful NHS funded fertility treatment, or have a child, will not be eligible to have NHS funded consultations with fertility services to assess their condition and secure treatment advice.
7. For the purposes of this policy, the commencement of IVF/ Intracytoplasmic Sperm Injection (ICSI) cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore, if a cycle is abandoned for clinical reasons this is still counted as the fresh cycle that the couple are entitled to. One frozen cycle using frozen embryos will follow a fresh cycle if deemed clinically appropriate. Patients will not be eligible for further NHS funded investigation and fertility treatment following completion of this cycle.
8. A full IVF/ICSI treatment cycle includes:
    - Diagnostic tests, scans and pharmacological therapy
    - Counselling for couples
    - Stimulation of prospective mother's ovaries to produce oocytes
    - Harvesting of the oocytes
    - Fertilisation using IVF or ICSI (assisted hatching is not provided)
    - One fresh embryo transfer
    - If unsuccessful, within twelve months of cryopreservation, one frozen embryo transfer from remaining frozen embryos [maximum of 2 embryos per cycle]

Continued below

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Section A - General Principles for all Patients (cont'd)

- A follow up consultation with fertility services post IVF treatment.
- Where patients have completed their NHS funded full cycle of IVF treatment but have frozen embryos remaining in storage, they can elect to self-fund further treatment with the fertility services.

9. The individual's GP must have given their positive recommendation to proceed to treatment. Account must be taken of additional factors such as active hepatitis,

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Section B - Investigation, Assessment and Advice on Infertility Issues
Criteria Based Access for Heterosexual Couples

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with infertility, individuals must meet all of the following criteria:

1 An individual maybe referred if:
   a. The individual has failed to conceive after two years of regular unprotected sexual intercourse
      Or
   b. If the individual has undergone 6 cycles of independently funded unstimulated IUI using sperm from an HFEA approved source.
      Or
   c. If there is a sexual health condition where the patient is unable to have penetrative sex. Individuals must have completed all relevant therapy provided by Psychosexual or Andrology services.

2 **Patients may be referred outside this timeframe if**:
   a. there is a known condition which is likely to affect fertility (e.g., severe oligomenorrhoea, low sperm count <1 million per ml taken on two occasions 3 months apart, bilaterally blocked fallopian tubes, azoospermia, stage 4 endometriosis or premature ovarian insufficiency)
      Or
   b. there is known premature ovarian insufficiency, defined as follicle-stimulating hormone (FSH) greater than 25, measured 2 months apart - coupled with oligomenorrhea or amenorrhea
      Or
   c. Alternatively, an anti-Müllerian hormone (AMH) marker of less than 1
      Or
   d. FSH > 25 on 2 occasions 3 months apart.

3 If the female being assessed will be older than their 39th birthday within the two year time frame, they can be referred after one year as long as they can still be referred before their 39th birthday.

4 Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.

5 Individuals, or if in a couple, both prospective parents must be registered with a BNSSG GP.

6 The individual must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.

7 Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.

Continued Below

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Section B - Investigation, Assessment and Advice on Primary Infertility Issues for Heterosexual Couples. Criteria Based Access (cont'd)

8 Individuals must be non-smokers as confirmed in their primary care records. This includes prospective fathers or partners. Individuals who are smokers can be referred to a fertility service but should also be referred to smoking cessation services and be able to demonstrate by compliance with that service that they are non-smokers prior to commencing assessment. Prospective fathers and partners who smoke should be informed that there is an association between smoking and reduced semen quality and, although the impact of this on male fertility is uncertain, they should cease smoking prior to treatment to improve sperm quality.

9 The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2 for a period of six months as evidenced from her primary care record. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services to reduce their weight prior to assessment and treatment by fertility services (see NICE Recommendations).

10 Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services to assist her to lose weight and aid fertility.

11 A prospective father is not older than their 54th birthday. Male fertility has been shown to decrease with age, with evidence of greater incidence of disability poor sperm function and DNA degradation.

12 Neither the prospective mother, nor any partner, has been sterilised in the past even if it has been reversed and the sterilisation is the cause of the fertility problems.

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Section C - Investigation, Assessment and Advice on Infertility Issues for Same Sex Couples. Criteria Based Access

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with fertility, couples must meet all of the following criteria:

1. Same sex couples may be assessed if self-funded insemination on at least 6 non-stimulated cycles from an HFEA approved clinic has failed to lead to a pregnancy. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy.
2. Same sex couples where either:
   a. both partners have fertility issues, i.e., blocked fallopian tubes or anovulation
   Or
   b. where only one partner is sub-fertile, where possible, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.
3. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
4. Both the individual being assessed, and their partner must be registered with a BNSSG GP.
5. The couple must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
6. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.
7. The prospective mother must be a non-smoker as confirmed in their primary care records. Patients who are smokers may still be referred to a fertility service, but should also be referred to smoking cessation services and be able to demonstrate that they are non-smokers prior to assessment. Partners of prospective mothers who smoke should also be offered a referral to smoking cessation services in order to improve their health and support their partner.
8. The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services.
9. Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.
10. The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle in line with heterosexual couples and will not be eligible for a further NHS funded treatment with their partner.

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Section C - Investigation, Assessment and Advice on Primary Infertility Issues for Same Sex Couples. Criteria Based Access (cont'd)

11. The prospective mother has not been sterilised in the past even if it has been reversed and the sterilisation is not the cause of the fertility problems.
12. Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

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Section D. Investigation, Assessment and Advice on Primary Infertility Issues for Single Women. Criteria Based Access

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with fertility, single women must meet all of the following criteria:

1. Single women may be assessed if:
    a. they have undergone 6 independently funded non-stimulated cycles of IUI from an HFEA approved source and have not conceived.
    b. The individual has failed to conceive after two years of regular unprotected sexual intercourse
2. Patients may be referred outside of the two-year timeframe if:
    a. there is a known condition which is likely to affect fertility (e.g., severe oligomenorrhoea, bilaterally blocked fallopian tubes, stage 4 endometriosis, premature ovarian insufficiency)
    Or
    b. there is a sexual health condition where the patient is unable to have penetrative sex. Individuals must have completed all relevant therapy provided by a Psychosexual or Andrology service
    Or
    c. there is known ovarian failure, defined as follicle-stimulating hormone (FSH) greater than 25, - measured 2 months apart - coupled with oligomenorrhea or amenorrhea
    Or
    d. they have an anti-Müllerian hormone (AMH) marker of less than 1
    Or
    e. their FSH > 25 on 2 occasions 3 months apart
3. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy.
4. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
5. The individual being assessed must be registered with a BNSSG GP.
6. The individual must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
7. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates
8. The prospective mother must be a non-smoker as confirmed in their primary care records. Patients who are smokers may still be referred to a fertility service, but should also be referred to smoking cessation services and be able to demonstrate that they are non-smokers prior to assessment.

Continued below

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Investigation, Assessment and Advice on Primary Infertility Issues for Single Women

Continued

9. The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services.

10. Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.

11. The individual who has undertaken NHS funded fertility treatment, regardless of previous relationship status, whether successful or not, will be deemed to

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Section E - Assisted Conception. Prior Approval
The Fertility Service is required to secure funding from the CCG following assessment and before treatment commences under Sections E, F and G.

If IVF has been unsuccessful, patients will not be eligible for further IUI.

Assisted conception services include Intrauterine Insemination (IUI), ovulation induction medication and donor insemination. In order to access assisted conception services following investigation and assessment, couples must be assessed against the following criteria:

1. Each prospective mother will be offered up to three treatment cycles of IUI and up to a total of six treatments of the three techniques.
2. The BMI of the prospective mother must remain between 19 and 29.9 kg/m2 whilst accessing fertility treatment. This is because the success of fertility treatment is significantly reduced where the prospective mother is outside of these limits.
3. An assessment of a prospective mother's overall chance of successful pregnancy through natural conception or with IVF should be made with one of the following measures to predict the likely ovarian response to gonadotrophin stimulation in women who are considering treatment:
   a. anti-Müllerian hormone [AMH]
   Or
   a) b. timed follicle-stimulating hormone [FSH] and Estrogen.
4. The prospective mother must have;
   a) an AMH of greater than or equal to 5.4 pmol/l
   Or
   b) a FSH level less than or equal to 15iu/l.

Where AMH/FSH levels are outside of this, donor eggs will be the expected pathway.

5. If donor sperm is used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

Section F - In-Vitro Fertilisation or Intracytoplasmic Sperm Injection
PRIOR APPROVAL
For Fertility Service consideration when planning treatment – see above.
1. One full treatment cycle of IVF or ICSI (with oocyte donation and/or surgical sperm recovery if required) in line with Section A Points 7 and 8, will be offered to individuals where other assisted conception techniques have failed or carry a very low chance of success

In addition to all the criteria above, the following criteria must also be satisfied at the time of treatment:
1. The prospective mother's serum, if using their own eggs, FSH must be less than or equal to 12iu/l at the time of treatment or an AMH of greater than or equal to 5.4 pmol/l.

Continued Below

Continued

2. The prospective father's serum FSH level must be less than 15 iu/l or testicular volume must be greater than 8ml (as assessed by a fertility specialist) for surgical sperm recovery and storage to be undertaken.
3. If donor sperm / oocytes are used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

Section F - Surgical Sperm Retrieval for Male Infertility - NHS England
This treatment is funded by NHS England please refer to the NHS England Clinical Commissioning Policy Surgical Sperm Retrieval for Male Infertility at:
https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16040_FINAL.pdf
Or contact NHS England for more information.

NB: Patients must meet the criteria to access treatment under this policy in order to access treatment under the NHS England policy.

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Section G - Sperm Washing – Exceptional Funding Request

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form.

In cases where suppression of viral load is not possible then sperm washing could be available but only on recommendation from a specialist in communicable disease based on U=U guidelines.

BNSSG will approve funding for sperm washing with one full cycle of fertility treatment in conjunction with this policy where:

a. the couple qualify for fertility treatment under this policy, and
b. the prospective father is HIV positive.

Sperm washing is a technique used to decrease the risk of Human Immunodeficiency Virus (HIV) transmission in HIV positive prospective fathers, because the HIV infection is carried by the seminal fluid rather than the sperm. Research has shown that it can reduce the risk of transmission by 96%. However, there may still be a small risk of HIV transmission which some couples may find unacceptable.

Patients can be seen, assessed and treated by local fertility services although a sperm-washing service is only available at the Chelsea & Westminster (C&W) Hospital in London, and at the time of drafting this policy, no other clinics in the UK offer a sperm-washing service.

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Section H - Pre-Implantation Genetic Diagnosis
This is funded by NHS England – please contact them for more information.

Section I - Funding of Surrogacy Arrangements and Treatments – Individual Funding Request
The CCG does not fund any element of surrogacy. Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form.

Maternity Care Arrangements
The Commissioner commissions maternity services to provide appropriate support, guidance and care to women during and after pregnancy and these services will continue to be available to surrogates.

BRAN

For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

The primary benefit of fertility treatment is to provide the opportunity for people who are unable to become pregnant naturally to become pregnant.

This assessment stage can support the development of treatment of plans that can help to reduce some of the adverse elements of pregnancy. This can also enable patients to adopt health lifestyle practices that can optimise them for treatment and increase the likelihood of conception.

Risks

Fertility treatments are generally considered safe, carrying small risks to the patient. Fertility treatment, and the conditions described within this policy to support said treatment, will not completely negate the impact of pregnancy.

The main risks of fertility treatment are multiple pregnancy and Ovarian Hyperstimulation Syndrome (OHSS), which can happen if the ovaries are over-stimulated. This can make some women very ill, and they may need to spend time in hospital and have intensive treatment.

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Women who receive IVF treatment are at a slightly higher risk of an ectopic pregnancy. The potential impact on the patient's mental health and wellbeing is likely to be impacted following ectopic pregnancy. Consequently, clinicians in primary care and those providing fertility treatment should recognise the potential risks and discuss with each patient as appropriate.

Similarly, IVF can become less successful with age. The risks of miscarriage and birth defects can increase with the age of the recipient.

It is likely that women may experience side effects to certain medications used during IVF. Due consideration should be given to the impact this might have on their general health and wellbeing, including the emotional impact of the process.

Alternatives

Studies exploring alternatives such as the use of Complementary and Alternative Medicine have concluded this is not associated with improved pregnancy rates. The National Institute for Health and Care Excellence (NICE) states further research is needed before such interventions can be recommended.

Adoption is a further alternative.

Do Nothing

Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes "not yet" is a good enough answer until you gather more information.

Shared Decision Making

If a person fulfils the criteria for Infertility, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:

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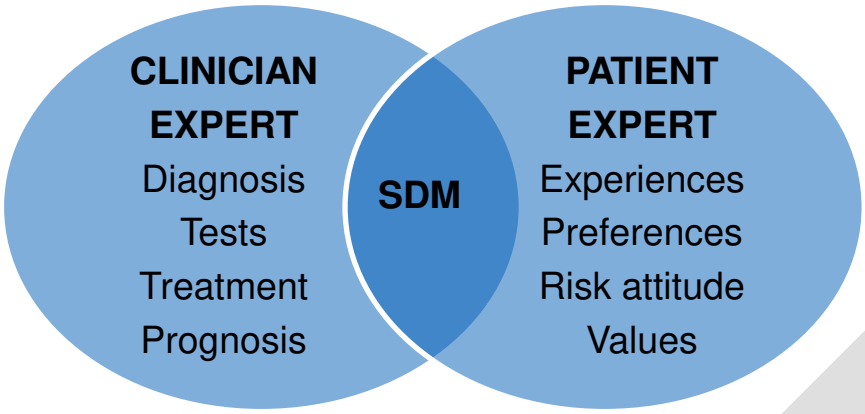

It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. It means that people receiving care and clinicians delivering care can understand what is important to the other person. The person and their clinician may find it helpful to use 'Ask 3 Questions':

1. What are my options? (see sections above)
2. What are the pros and cons of each option for **me**?
3. How can I make sure that I have made the right decision?

Infertility – Plain Language Summary

An estimated one in seven couples have difficulty conceiving. In the UK it is estimated that 84% of women would conceive within one year of regular unprotected sexual intercourse. This rises to 92% after two years and 93% after three years. This includes women with fertility problems.

In men, a fertility problem is usually because of low numbers or poor quality of sperm. Female fertility decreases with increasing age. For women aged 35, about 95% who have regular unprotected sexual intercourse will get pregnant after three years of trying. For women aged 38, only 75% will do so.

Other factors which affect fertility success rates include obesity and social factors such as alcohol and drug misuse and therefore this policy has criteria on these subjects.

In vitro fertilisation (IVF) is one of several techniques available to help people with fertility problems have a baby.

During IVF, an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory.

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The fertilised egg, called an embryo, is then returned to the woman's womb to grow and develop.

It can be carried out using your eggs and your partner's sperm, or eggs and sperm from donors.

Intracytoplasmic sperm injection (ICSI) is a type of IVF treatment that involves drawing up a single sperm into a very fine glass needle and injecting it directly into the centre of the egg. The fertilised egg (embryo) can then be transferred into the womb of the woman as in a normal IVF cycle. The live birth rates for ICSI and conventional IVF are similar.

The major development of ICSI means that as long as some sperm can be obtained fertilisation is possible.

Intrauterine insemination (IUI), also known as artificial insemination, is a fertility treatment that IUI involves separating sluggish, non-moving or abnormally shaped sperm and injecting directly into the womb.

This policy has been developed with the aid of the following:

1. NICE (2017) Fertility Problems: Assessment & Treatment (Clinical Knowledge Summary) www.nice.org.uk
2. National Library of Medicine (2015) 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles'.

Due regard

In carrying out their functions, the Bristol, North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the CCGs are responsible, including policy development and review.

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NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

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Patient and Public Involvement	TBA

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OPCS Procedure codes

Must have any of (primary only):

Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net.**

Glossary

AMH	Anti-Müllerian hormone (AMH) - Comparison of an individual's AMH level with respect to average levels is useful in fertility assessment, as it provides a guide to ovarian reserve and identifies women that may need to consider either egg freezing or trying for a pregnancy sooner rather than later if their long-term future fertility is poor.
Azoospermia	Azoospermia is where he testicles are either producing no sperm or very low numbers of sperm and sperm is not present in the ejaculate.
Embryos	Refers to a fertilised Oocyteoocyte. It is called an embryo until about eight weeks after fertilisation and from then it is instead called a foetus.
Endometriosis	Endometriosis is a condition where tissue similar to the lining of the womb starts to grow in other places, such as the ovaries and fallopian tube.
FSH	Follicle-Stimulating Hormone (FSH) regulates the development, growth, pubertal maturation, and reproductive processes of the human body.
ICSI	Intracytoplasmic Sperm Injection is a variation of in-vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.
Infertility	In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years.
IUI	Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti-oestrogens or gonadotrophins (stimulated IUI).
IVF	In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman

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	and fertilised with a man's sperm outside the body.
Ooctye (Eggs)	Refers to a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell.
Oligomenorrhoea	Oligomenorrhoea is infrequent menstruation defined by a cycle length between 6 weeks and 6 month
Regular Unprotected Sex	Unprotected sex is sex without any contraception or condom. The NHS recommends that people trying to get pregnant have sex every 2-3 days across the days mid cycle around the time of ovulation.
Sperm	Refers to the male reproductive cells
Sperm, Oocyte or Embryo Cryopreservation	Sperm, Oocyte or Embryo Cryopreservation is the freezing and storage of Sperm, Oocyte or Embryos that may be thawed for use in future in-vitro fertilisation treatment cycles.

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Overview

Project Code	STP001152
Title	Fertility Preservation
Aims and Objectives	The aim of this policy is to enable the preservation of gametes (reproductive cells) for patients who are due to receive NHS prescribed medication that will have an adverse and irreversible impact on their fertility. Fertility preservation will enable patients to have the opportunity to try and conceive (with assistance) once treatment has been completed and it is considered safe to do so.
Authors	Christopher Moloney
Last Modified Date	09/11/2022 12:31:47

Background & Evidence

What is the local and national evidence behind this work? Have you spoken to the Clinical Effectiveness team (bnssg.clinical.effectiveness@nhs.net) about reviewing existing evidence? If an evidence review has been undertaken, upload the documentation to the Plan Document Folder.

Savings Summary

Contract and Activity Implications - Which line of which contract will this intervention target?

Health Inequalities Impact Assessment (HEAT)

1. Your programme of work
2. Data and Evidence
3. Distribution of Health
4. Causes of Inequalities
5. Potential effects
6. Action plan
7. Evaluation and monitoring

Health Inequality Impact Assessment Approval

Equality Impact Screening & Full Assessment

What are the main aims, purpose and outcomes of the proposal?	The purpose of this policy is enable the preservation of reproductive cells for patients who will be prescribed NHS medication that will have an adverse and irreversible impact on their fertility and where there is no clear alternative to this treatment. The aim of the policy is to enable people to try to conceive (with assistance) once treatment that is likely to have compromised their fertility has been completed.
Does this Proposal relate to a new or existing programme, project, policy or service?	Existing
If existing, please provide more detail	This policy is an extension of the proposed policy for Primary Infertility - Assessment & Treatment. WIthin the existing commissioning policy for Fertility Assessment & Treatment, there is provision for fertiliy preservation where patients will undergo some cancer treatments. As this does not constitute primary infertility, the provision for fertility preservation has been removed from the proposed new policy for infertility. This is to support consistency within the definition of primary infertility and to reduce the potential for confusion among patients and referrers. The intention is to manage fertility preservation under a different commissioning policy with broader criteria to support equity of access.

Does this proposal affect service users, employees and/or the wider community?	Yes. This policy is a development of provision that is part of the CCG's existing fertility policy. There is provision within BNSSG CCG's current fertility policyonly for patients who are to receive oncology treatment that is likely to compromise their fertility. The Human Fertilisation and Embryology Association's (HFEA) Code of Practice does not offer specific guidance on commissioning fertility preservation for conditions or treatments beyond cancer. However, it does state that 'access restrictions to fertility treatment should only be in place for clinical reasons which are supported by evidence, and any restrictions based on social value judgments should be in keeping with local policies on decision-making and ethical frameworks. Legal advice indicates that because the current policy provides fertility preservation only for patients undergoing cancer treatment, it is potentially discriminatory against other patients undergoing treatments that will have a similar impact on their fertility. Therefore, the new policy supports patients who will be prescribed medication as part of NHS treatment that will have an adverse and irreversible impact on their fertility and where there is no clear alternative to this treatment. It is difficult to identify the exact number of people who are likely to be effected by this change. However, it is likely, that the cohort will be relatively small. There are a number of medications that can have and adverse impact on fertility. However, for the majority of patients there will be an alternative treatment option that will not impact fertility. Medication that is most likely to impact fertility are those used in some cancer treatments, cyclophosphamide and testosterone when used in hormone therapy in the treatment of gender dysphoria. The policy does not set out an exhaustive list, and invites funding applications should clinicians believe the medication prescribed their patient will have an adverse and irreversible impact on their fertility. The policy will be closely linked to the BNSSG Formulary. The number of patients currently prescribed cyclophosphamide, and are within the age criteria for this policy, is 5. Input from the medicines optimisation team indicates that the number of patients prescribed cyclophosphamide is likely to remain at a similar level. Business Intelligence data indicates that the number of BNSSG patients on either a gender dysphoria, or transsexualism pathway is consistently low. In 2019/20, the number of BNSSG patients on one of these pathways was 8. In 2020/21, the number of BNSSG patients to these pathways was also 8. The ratio of biological men to women is unknown from the available data. It is also unclear how many patients would want to preserve the potential to conceive following their transition.
Could the proposal impact differently in relation to different characteristics protected by the Equality Act 2010	Yes
Age	Neutral

Please provide reasons for your answer and any mitigation required	The proposed policy has an upper age criteria for women. Women must be referred before their 40th birthday. NICE guidance states that women between the ages of 40-42 should be offered one cycle of IVF, provided they meet other relevant criteria. There is no medicolegal requirement for the CCG to fully comply with NICE guidance. Evidence indicates that the success rate of IVF for women in this cohort is generally less than for women under 40 years. One study – 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles' (Smith et al., 2015) aimed to determine the live-birth rate per initiated IVF cycle via a prospective study of 156,947 UK women who received 257,398 IVF ovarian stimulation cycles between 2003 and 2010 and were followed until June 2012. The study indicated that the chances of success for one cycle of IVF for a woman under 40 years was 32.3%, while the chances of conceiving for women aged 40-42 years was 12.3%. It is also recognised that the chances of complications during pregnancy increase with age. There are a number of issues within the existing policy that have a negative impact on some protected characteristics. Certain of these leave the CCG open to legal challenge under the Equality Act. In order to address these issues, while recognising the limited resources available to the CCG, the CPD had to consider a variety of factors in order to prioritise changes within the policy. Given the relatively low success rate for IVF in women in over 40 years, the questionable legality of certain areas of the policy and the limited resources available to the CCG, it has been agreed that at this time increasing the upper age limit for prospective mothers is not a priority for change. This decision has been discussed with the CCG's clinical executive. There is an upper age limit for of 54 years for men in the proposed policy for Primary Infertility Assessment & Treatment, that this policy will adhere to. This is based on evidence that indicates that sperm motility reduces with age. This is in line with the intention of supporting patients with best chance of having children (with assistance). There is a lower age limit, which is that the patient must have commenced puberty.
Disability	Positive
Please provide reasons for your answer and any mitigation required	This policy is intended to support patients where medication will compromise fertility for the patient. There are a range of medications that can be used in a number of long term health conditions, that could have an adverse impact on a patient's fertility. However, for the majority of these medications there will be an appropriate alternative treatment pathway, should the patient to try and have a family. This would be treatment that does not have the same impact on the patient's potential to conceive, and would be prescribed by a relevant specialist after counselling the patient on their treatment options. However, where an alternative is not possible for a patient with a long term conditions (e.g. they cannot tolerate the proposed treatment) this policy would support the patient and enable them to preserve their reproductive cells.
Gender Reassignment	Positive
Please provide reasons for your answer and any mitigation required	This policy enables patients who on a gender dysphoria pathway where the likely outcome is transition, to preserve their reproductive cells. This means that, should they wish, the individual will be able to try and have children (with assistance) once they have completed their treatment. This is a development on the existing policy which has no provision for patients on a gender dysphoria pathway.
Race	Neutral
Please provide reasons for your answer and any mitigation required	The policy makes no mention of race or ethnicity.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	The policy makes no mention of religious belief. It is recognised that, due to their beliefs, members of some religious groups may not wish to pursue fertility preservation.
Sex	Neutral
Please provide reasons for your answer and any mitigation required	This policy includes provision for men and women who will be prescribed treatment that will impact their chances to conceive.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	The policy does not differentiate between heterosexual patients and those from an LGBTQ cohort.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	This policy does not provide provision for patients with living offspring, or patients or who are already pregnant. This is to ensure that the CCG can make the most effective and equitable use of it's resource for fertility treatment. In the rare instances where a patient might be pregnant when undergoing treatment, their options would most likely be discussed with them by their consultant and also discussed at a relevant MDT.
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	The policy makes no reference to marital status or civil partnership status

Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010.	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not?	Yes
Please provide reasons for your selection(s)	This policy broadens the scope of the CCG's provision for fertility preservation. This policy enables people with a variety of long term conditions to access fertility treatment. This policy also enables people with gender dysphoria, where the intention is to transition, to access treatment that would enable them to try and start a family later in life. This is a significant step forward for the CCG, and is a direc response to complaints and challenges from members of the public. While the policy holds an upper age limit, this is based on clinical evidence and is not a social value judgment. The upper age limit reflects evidence that will help identify patients who have the best chance of conceiving a child (with assistance) and carrying it to full term. The policy makes no further comment on any other protected characteristic.
Does the proposal relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this proposal to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
Based on your answers above, do you believe this should proceed to full EIA?	No
If no, then explain your reasons and evidence	The prinicple of this policy is to preserve the potential for patients to have children after a course of NHS prescribed medication has been completed that will remove the potential for them to subsequently start a family. The policy includes provision that is in line with the HFEA's code of conduct and adheres to the most relevant national and local guidance on fertility preservation. The criteria developed is based on the most relevant clinical evidence, and has been discused and agreed with fertility specialists and pharmacists. This policy equalises access to treatment for patients with long term health conditions and transgender patients. This change has been effectuated as a direct result of challenges from individuals and organisations across BNSSG and nationally. Therefore, this policy advances equality of opportunity between those who share a protected characteric and those who do not. This policy will not have a negative impact on any group who share a protected characteristic, nor does it volunteer an ethical or social value judgment on any groups or individuals.

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma

Comments from Equality Lead	22.12.21 In terms of risk, policy seems to be in line with national guidance, having reviewed similar EIAs from Coventry, NCL EIA (single fertility policy) also mentions the negative impact as a result of Covid, that might push some people over the age limit, because of extended waiting times, the mitigation noted is to follow national guidance to reduce waiting times; it was suggested BMI might be higher for some women in ethnic minority groups. Where potential negative impact is likely (age, BMI, parents, socio-economic factors [self-funding]) national guidance was followed as a mitigation. NCL also produced a recommendations report, I reviewed p30-38 to see how engagement shaped their EIA - recommendations include having clear pathways, following national guidance, include trigger points for regular review and comms and gp education is important. Hereford indicate higher prevelance of smoking in gay and lesbian communities and poorer socio-economic groups, this poses a risk of cancer - also "Socially deprived patients may be less likely to access cryopreservation due to later presentation of disease." BNSSG policy does not exclude patients based on BMI and smoking at the time of preservation. The BNSSG CCG policy also seems fair in this regard. In the policy "**Fertility Preservation Medication Criteria Based Access**" section C Cryopreservation point 2. I wondered if there were any concerns from engagement about the capping funding at age 25, is this NICE guidance? With regard to the "**Primary Infertility Assessment & Treatment**" policy, I am unable to comment on the equity in access between eligibility for 'prospective mothers, who have failed to conceive after regular unprotected sexual intercourse for more than one year but less than two years' and 'same sex couples who must fund insemination for at least 6 non-stimulated cycles.' I note under CCG00436, the number of attempts had been reduced from 10 to 6 in response to engagement. I am unable to comment on legality of this policy. It would be useful to include some of the feedback from BNSSG CCG engagement in this EIA to support sign off, but based on current review and practice in other CCGs the policy seems equitable. Trigger points for 'regular' review would help to mitigate risks of inequitable access, experience and outcomes.
Date Approved	23/12/2021

Quality Impact Screening & Full Assessment

Is there an impact on patient safety?	No
Is there an impact on delivery of national standards?	No
Is there an impact on the provider's duty to protect people?	No
Is there an impact on clinical workforce capability and skills?	No
Does the plan create an impact on the prevention of violence and aggression; or contribute to service users feeling less safe?	No
Is there an impact on partner organisations and any aspect of shared risk?	No
Provide a rationale for assessing the impact on Patient Safety	The policy proposed outlines the circumstances under which the CCG will fund the preservation of reproductive cells. Patients would be eligible where they will be given NHS prescribed medicatin that will have an irreversible and adverse impact on their fertility. This is already happening for patients undergoing some cancer treatments. The processes for freezing reproductive cells will not change. Patients will be counselled by their clinician about the potential risk of any treatment. This is a measure that is understood to be happening already and therefore this policy does not impact on the workforce's skills, capability nor does it neccesitate a significant change to the current clinical protocols when managing patients on medication that could impact fertility.
Does your plan comply with the best evidence guidance including NICE?	Yes
Does your plan impact on the delivery of services in line with national clinical and quality standards?	No
Does your plan lead to a change in care pathways?	Yes
Is there an impact on the delivery of clinical outcomes?	No
Provide a rationale for assessing the impact on Clinical Outcomes	The policy would neccesitate a small change in care pathways that is unlikely to impact any clinical outcome. Patients are already being counselled on the potential risks of certain medication. While patients would be referred to a fertility service prior to commencing treatment, this is unlikley to have an impact on treatment outcomes, provided referral is made in a timely manner that does not delay treatment.

Does your plan have an impact on service user experience?	Yes
Does your plan have an impact on carer experience?	No
Does your plan support the choice agenda?	No
Does your plan address concerns and issues identified through PALs, complaints, and national and local service user and carer surveys?	Yes
Provide a rationale for assessing the impact on Patient Experience	This policy broadens the scope of provision for fertility preservation to patients on a range of NHS prescribed drugs that will adversely effect their fertility. This includes patients on a gender dysphoria pathway where the plan is to transition. These individuals are not included within the current policy. This issue has been the cause of a number of patient complaints. Therefore, this policy addresses a significant inequity and is likely to improve the experience of a number of patients including those on a gender dysphoria pathway. The policy does not stipulate a provider, however it should be noted that there are a limited number of fertility services locally.

Risk Scoring

Quality Domain	Patient Outcome
Risk Description	Delay to commencement of treatment to enable harvesting of gametes
Probability	1
Impact	2
Total	2

Quality Domain	Patient Experience
Risk Description	The process for sperm storage involves masturbation and semen analysis. It should be noted that very unwell men may find masturbation and ejaculation difficult.
Probability	1
Impact	2
Total	2

Proceed to full QIA	No
Please explain your reasons	This policy represents a broadening of the criteria for fertility preservation. This policy does not impact directly on either services users or providers. Although there is a small risk that patient treatment might be delayed to enable the harvesting of reproductive cells, this is highly unlikely and there are no known instances locally of this happening.

PPI & Comms Impact Screening, Assessment and Plan

Are you planning a brand new service?	No
Are you planning to decommission a service?	No
Are you redesigning a service?	No
Are you relocating a service?	No
Are you redesigning a pathway?	No
Is it a policy change?	Yes
Is it a formulary change?	No
Is it a change in prescribing guidance?	No
An impact on the manner in which the services are delivered to the individuals at the point when they are received by users?	No
Explain why you have answered yes or no to the above:	This policy sets out the criteria under which an individual would be eligible for fertility preservation. It does nto represent a change to service provision. Where treatment is planned that could compromise fertility, patients are already being counselled with appropriate treatment plans developed.
An impact on the range of health services available to users?	Yes

Explain why you have answered yes or no to the above:	This policy is a development of provision that was previously a part of the CCG's fertility policy. NHS funded fertility preservation is often recommended for patients who are either undergoing, or likely to be prescribed, certain types of cancer treatments. NICE guidance refers to the HFEA's code of practice regarding the provision of fertility preservation to people undergoing cancer treatments. This guidance does not explicitly refer to people undergoing treatment for other conditions. There is only provision within BNSSG CCG's current fertility policy for patients who are to receive oncology treatment that is likely to compromise their fertility. The Human Fertilisation and Embryology Association's (HFEA) Code of Practice does not offer specific guidance on commissioning fertility preservation for conditions or treatments beyond cancer. However, it does state that 'access restrictions to fertility treatment should only be in place for clinical reasons which are supported by evidence, and any restrictions based on social value judgments should be in keeping with local policies on decision-making and ethical frameworks. Given that HFEA guidance suggests fertility preservation could extend beyond cancer treatment, the CCG does have discretion to fund gamete preservation for clinical reasons supported by evidence. This policy is a development on current provision to support patients who will be prescribed medication as part of NHS treatment that will have an adverse and irreversible impact on their fertility and where there is no clear alternative to this treatment. This is likely to be a very small number of patients per year (approximately 13). There are a number of medications that can have and adverse impact on fertility. However, for the majority of patients there will be an alternative treatment option that will not impact fertility. Medication that is most likely to impact fertility, as described in this policy, are those used in some cancer treatments, cyclophosphamide and testosterone when used in hormone therapy in the treatment of gender dysphoria. The policy does not set out an exhaustive list, and invites funding applications should clinicians believe the medication prescribed their patient will have an adverse and irreversible impact on their fertility. The policy will be closely linked to the BNSSG Formulary.
Is engagement required for this activity?	No
Is a Comms Plan required?	No
If you answered yes to either of the above, please complete part 2 below. If you answered no, please explain why.	A three month period of engagement has already been undertaken.

Named Communications Lead (ask Associate Director of Communications and Engagement for guidance)
Christopher Davies
Louise Fowler
Mary Adams
Bridget James
Niema Burns
Sharon Woma
Carol De Halle
Karen Bissix

Project Members
Project Members
Sharon Woma

Proposal Role	Equalities Support

Overview

Project Code	CCG000436
Title	Fertility Assessment and Treatment
Start Date	01/12/2017
Authors	Victoria Tucker
Last Modified Date	31/10/2022 09:13:59

Background & Evidence

What is the local and national evidence behind this work? Have you spoken to the Clinical Effectiveness team (bnssg.clinical.effectiveness@nhs.net) about reviewing existing evidence? If an evidence review has been undertaken, upload the documentation to the Plan Document Folder.

Health Inequalities Impact Assessment (HEAT)

1. Your programme of work
2. Data and evidence
3. Distribution of health
4. Causes of inequalities
5. Potential effects
6. Action plan
7. Evaluation and monitoring
8. Health Inequality Impact Assessment Approval

Equality Impact Screening & Full Assessment

What are the main aims, purpose and outcomes of the proposal?	The purpose of the policy is find the causes of primary infertility and identify NHS commissioned treatments that are likely to help resolve infertility. There is no provision within the revised commissioning policy for secondary infertility. There is no provision within the proposed policy for fertility preservation. This will be managed in a separate policy.
Does this Proposal relate to a new or existing programme, project, policy or service?	Existing
If existing, please provide more detail	The CCG's Commissioning Policy Development team are undertaking a refresh of the existing Fertility and Assessment Treatment policy. This refresh is in accordance with the agreed review schedule that is part of the organisations governance and commissioning protocols. The CCG is committed to making best use of resources for fertility assessment and treatment. The existing policy sets out the circumstances in which the CCG will fund assessemtn and treatment of primary infertility and preserve the opportunity for people to conceive.
Does this proposal affect service users, employees and/or the wider community?	The propsed policy will affect service users and the wider community. The proposed policy includes new and adapted criteria that seeks to equalise access to fertility assessment and treatment. This includes same sex couples and heterosexual single people. The proposed policy will enable single people to access fertility assessment and treatment provided they meet the relevant criteria. The existing policy stipulates that fertility treatment is for couples. Ammending this criteria will remove the negative impact the existing policy has on the protected characteristic of marriage/civil partnership. It is unknown how many people are likely to be affected by this change. According to data from the Human Fertilisation and Embryology Association (HFEA) HFEA data, the number of single women accessing IVF treatment has steadily increased. However, this data does not indicate if the decision to undergo IVF treatment was a result of a lifestyle choice or primary infertility. Therefore, the CPD team are unable to provide a reliable activity projection for this change to criteria. The current policy specifies that same sex couples must have undergone 10 independently funded unstimulated cycles of intrauterine insemination (IUI). Treatment is expensive and so is likely to place a significant cost pressure on couples. Evidence from the The Human Fertilisation and Embryology Authority (HFEA) indicates that the pregnancy rate for a stimulated cycle of IUI is 17%. The success rate for an unstimulated cycle is 16%. The HFEA indicate that approximately half of women who undergo this treatment will be successful within 6 cycles. Discussions with consultants also indicated that women will very rarely proceed to 10 cycles of IUI without conceiving. It is unclear how many patients this will impact, as the CPD are unable to collect data on the number of same sex couples who wish to have children. The proposed policy offers provision for patients who are unable to penetrative sex because of psychosexual and andrological issues. The policy does not provide an exhaustive list of conditions, but specifies that patients must have been reviewed by either a psychosexual or andrological service prior to referral for fertility assessment and treatment. One condition that is likley to have an impact is Vaginismus, which is an automatic reaction where vaginal muscles tighten up whenever penetration is attempted. As above, it is unclear how many patients will be affected by this measure. This is a new addition to the policy that will need to be monitored and reviewed.

Could the proposal impact differently in relation to different characteristics protected by the Equality Act 2010	Yes
Age	Negative
Please provide reasons for your answer and any mitigation required	The proposed policy has an upper age criteria for women. Women must be referred before their 39th birthday. NICE guidance states that women between the ages of 40-42 should be offered one cycle of IVF, provided they meet other relevant criteria. There is no medicolegal requirement for the CCG to fully comply with NICE guidance. Evidence indicates that the success rate of IVF for women in this cohort is generally lower for women over 40 years. One study – 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles' (Smith et al., 2015) aimed to determine the live-birth rate per initiated IVF cycle via a prospective study of 156,947 UK women who received 257,398 IVF ovarian stimulation cycles between 2003 and 2010 and were followed until June 2012. The study indicated that the chances of success for one cycle of IVF for a woman under 40 years was 32.3%, while the chances of conceiving for women aged 40-42 years was 12.3%. It is also recognised that the chances of complications during pregnancy increase with age. There are a number of issues within the existing policy that have a negative impact on some protected characteristics. Certain of these leave the CCG open to legal challenge under the Equality Act. In order to address these issues, while recognising the limited resources available to the CCG, the CPD had to consider a variety of factors in order to prioritise changes within the policy. Given the relatively low success rate for IVF in women in over 40 years, the questionable legality of certain areas of the policy and the limited resources available to the CCG, it has been agreed that at this time lowering the upper age limit for prospective is a more equitable of mitigating the costs of broadening access in other areas of the policy to remove unlawful discrimination. This decision has been discussed with the CCG's clinical executive.
Disability	Positive
Please provide reasons for your answer and any mitigation required	There is limited evidence that disabilites can cause primary infertility, The proposed policy does include provision for patients that cannot have penetrative sex, and therefore cannot conceive. The policy does not provide an exhaustive list of conditions that are within the scope of this criteria, however patients would first need to be reviewed by a relevant andrological or psychosexual service. Certain of these conditions could include Vaginismus or potentially an injury or disability that leads to paralysis and therefore means that the patient cannot have penetratvie sex. The proposed policy will equalise access to patients with conditions that can prevent or remove the potential for conception.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	The central aim of this for this policy is to identify physiological reasons for primary infertility and identify possible NHS funded treatments to resolve them. Therefore, patients on a dender dysphoria pathway are not included within the scope of this policy. However, a new policy has been developed to enable patients on a gender dysphoria pathway, where the intention is to transition, to preserve their reproductive cells (gametes) and have children once they have transitioned.
Race	Neutral
Please provide reasons for your answer and any mitigation required	The policy does not make any stipulation on race. During public and patient engagement, the CPD sought advice and involvement from a number of community and advocacy groups from across the BAME community. HFEA data indicates that people from BAME communities do not access fertility treatment as regularly as people of white-British ethnicity. We currently do not have enough information to fully understand this. It should also be noted that the outcomes of IVF for people from BAME communities are less positive than people of white-British ethnicity. We currently do not have enought information to fully understand this. However, there is a national programme of work to address this. For the purposes of future policy reviews, the CPD and the Clinical Effectiveness and Research team will monitor the progress of this work. There is some evidence that there is a higher level of prevalence of smoking among certain ethnic groups. As the policy stipulates that prospective mother's and, where appropriate, their partners must be non smokers, it is recognised that the policy could be construed as having a negative impact on certain patient groups. However, there are a range of smoking cessation services that GPs can refer individuals to in order to support their referral for assessment and treatment of infertility.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	The policy makes no stipulation on religion. It is recgonised that some religious groups may feel that fertility treatment for same sex couples and single people is in conflict with their personal beliefs.

Sex	Negative
Please provide reasons for your answer and any mitigation required	There is limited provision for single men within the policy. Thepolicy provides assessment for single men, however there are very treatments available for male infertility. BNSSG CCG does not currently commission any treatments for male infertility. These treatments are funded by NHS England. Surrogacy is not routinely funded by BNSSG CCG, however the policy invites excpetional funding applications in some circumstances.
Sexual Orientation	Positive
Please provide reasons for your answer and any mitigation required	Under the existing policy, the number of independently funded cycles of unstimulated Intrauterine Insemination (IUI) required before a same sex couple can be referred for NHS funded assessment and treatment is 10. IUI is an expensive procedure that can place significant financial pressure on a same couple. During the CPD team's engagement process and on the basis of legal challenges progressing against an NHS commissioner, the number of IUI cycles required before NHS funded assessment and treatment has been reviewed. The purpose is to make the policy fairer for same sex couples, while establishing criteria that can reasonably indicate primary infertility. Evidence from the The Human Fertilisation and Embryology Authority (HFEA) indicates that the pregnancy rate for a stimulated cycle of IUI is 17%. The success rate for an unstimulated cycle is 16%. The HFEA indicate that approximately half of women who undergo this treatment will be successful within 6 cycles. Discussions with consultants indicate that women will very rarely proceed to 10 cycles of IUI without conceiving. Therefore, the proposed criteria for this policy, is to reduce the number of independently funded cycles from 10 to 6. This is considered to be a fairer approach to managing access to treatment for infertility, that also recognise the need for an appropriate proxy. There is limited provision for same sex male couples within the policy. The policy is intended to identify patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth. Single men are unable to conceive (even with assistance) and carry a child to birth. Furthermore, while women can undergo donor insemination there is no corresponding treatment for single men that would enable them to demonstrate difficulty in having children with an otherwise 'healthy' mother. Surrogacy is not routinely funded by BNSSG CCG, however the policy invites excpetional funding applications in some circumstances.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	As the policy is concerned with primary infertility, individuals with living offspring are outside the scope of this policy. should a prospective mother who's funding application has been approved, conceives before fertility treatment starts, the application will be closed and funding withdrawn.
Marriage & Civil Partnership	Positive
Please provide reasons for your answer and any mitigation required	The policy makes no stipulation on marriage. The criteria of the policy has been broadened to include single people. The policy indicates that, where a couple are receiving treatment, they must both accept joint legal responsibility of any children.
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010.	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not. ?	Yes
Please provide reasons for your selection(s)	This policy uses clinical evidences and provides a clear rationale for people who will be considered for treatment and assessment. Focusing on primary infertility means that the policy is intended to support patients who have never conceived a child and have significant difficulty conceiving. The criteria for this policy has been broadened on the basis of clinical evidence to equalise access for people who share a protected characteristic. This has been done as far as possible, within the limitations of current funding resource. This includes reducing the number IUI cycles for same sex female couples and opening fertility assessment and treatment up to single and unmarried people. Transgender patients patients are unlikely to fulfil certain evience based criteria that helps to identify patients with possible primary infertility. For instance, having regular unprotected sex for a period of two years prior to referral. Patients on a gender dysphoria pathway will be supported through a proposed new policy for fertility preservation that will preserve their potential to have children.

Does the proposal relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this proposal to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
Based on your answers above, do you believe this should proceed to full EIA?	No
If no, then explain your reasons and evidence	There is a clear definition and rationale for the purpose of this policy. That is to support people who have never conceived a child and have difficulty conceiveng. This policy is intended to identify patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth. The criteria within the policy is based on clinical evidence, that is intended to support the assessment of patients by clinicians in primary and secondary care. This criteria will enable clinicians to identify patients with the greatest level of clinical need. There is a limited provision within the policy for single men and same sex male couples. This is based on the premise that neither a single man, nor same sex male couple, can conceive (even with assistance) and carry a child to birth. There is also limited potential to reliably demonstrate that these cohorts can demonstrate a failure in their reproducitve systems that stop them from having children.

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma
Comments from Equality Lead	On review of the EIA, and policies 'fertility preservation' and 'primary infertility and assessment & treatment', the policies appear to be fair. Adjustments have been made to mitigate against potential inequity for same sex couples who previously had to undergo 10 cycles before being eligible. Having reviewed other CCG EIAs/policies, where there is potential negative impact, the approach has been to follow national guidance, which has been done here. I am otherwise unable to comment on the legality of the policy. As recommended in STP001152, monitoring will help to identify issues and support gaps in our data.
Date Approved	23/12/2021

Quality Impact Screening & Full Assessment

Is there an impact on patient safety?	No
Is there an impact on delivery of national standards?	No
Is there an impact on the provider's duty to protect people?	No
Is there an impact on clinical workforce capability and skills?	No
Does the plan create an impact on the prevention of violence and aggression; or contribute to service users feeling less safe?	No
Is there an impact on partner organisations and any aspect of shared risk?	No
Provide a rationale for assessing the impact on Patient Safety	The fertility policy sets out the circumstances under which funding will be given for the assessment and treatment of patients with suspected subfertility. The policy does not directly impact on the delivery of patient facing services. Services who provide assessment and treatment of infertility will have undergone all appropiate dilligence during the commissioning and contracting stage. The policy ensures that people with the best clinical chance of conceiving are granted funding. This limits the potential for the development of psychologicial and physical conditions arising from failure to conceive. The policy sets out guidance on healthy BMI for prospective mothers alongside smoking status. This can help to limit the potential for a preterm birth, small gestational age or gestational diabetes. Where donor insemination is to be used as a means of demonstrating primary infertility, the policy will state that this must be from an source that has been approved by the Human Fertilisation and Embryology Authority (HFEA)
Does your plan comply with the best evidence guidance including NICE?	No
Does your plan impact on the delivery of services in line with national clinical and quality standards?	No

Does your plan lead to a change in care pathways?	No
Is there an impact on the delivery of clinical outcomes?	No
Provide a rationale for assessing the impact on Clinical Outcomes	The policy complies with the best evidence accrued through discussions with consultants, pharmacists and GPs. A number of evidence reviews have been conducted by the CPD team with the support of the CCG's Clinical Effectiveness & Research team. While the policy utilises NICE guidance, it differs from NICE on the age of the prospective mother. NICE guidance recommends that women between the ages of 40-42 years are offered one cycle of IVF provided they meet the relevant criteria. Evidence indicates that the success rate of IVF for women in this cohort is generally less than for women under 40 years. One study – 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles' (Smith et al., 2015) aimed to determine the live-birth rate per initiated IVF cycle via a prospective study of 156,947 UK women who received 257,398 IVF ovarian stimulation cycles between 2003 and 2010 and were followed until June 2012. The study indicated that the chances of success for one cycle of IVF for a woman under 40 years was 32.3%, while the chances of conceiving for women aged 40-42 years was 12.3%. t is also recognised that the chances of complications during pregnancy increase with age. This policy has attempted to resolve a number of issues that were potentially discriminatory against some protected characteristics including marital status and sexual orientation. The proposed policy has endeavoured to address these as far as possible. In addressing these issues, the CPD team have sought guidance from the general public, clinicians and the CCG's Clinical Executive, in order to prioritise areas for change within the policy. Given the clinical evidence that identifies the relatively low success rate per IVF cycle for women over 40 years, and the resource constraints, it has been determined that working to resolve elements of the policy where there is a possibility of discrimination, without clinical justification. It should be noted that the majority of BNSSG's peer CCG's do not provide IVF for women over the age of 40 years. Given the above, the CPD team believe that the policy complies with best evidence while recognising the resource limitations faced by the commissioner.
Does your plan have an impact on service user experience?	No
Does your plan have an impact on carer experience?	No
Does your plan support the choice agenda?	Yes
Does your plan address concerns and issues identified through PALs, complaints, and national and local service user and carer surveys?	Yes

Provide a rationale for assessing the impact on Patient Experience	Patients will be offered a choice of provider. This will be discussed at the referral stage with an appropriate clinician and does fall outside the scope of the policy. The proposed policy seeks to address complaints, raised locally and nationally, regarding the access to treatment for same sex female couples. Under the existing policy, the number of independently funded cycles of unstimulated Intrauterine Insemination (IUI) required before a same sex couple can be referred for NHS funded assessment and treatment is 10. IUI is an expensive procedure that can place significant financial pressure on a same couple. During the CPD team's engagement process and on the basis of legal challenges progressing against an NHS commissioner, the number of IUI cycles required before NHS funded assessment and treatment has been reviewed. The purpose is to make the policy fairer for same sex couples, while establishing criteria that can reasonably indicate primary infertility. Evidence from the The Human Fertilisation and Embryology Authority (HFEA) indicates that the pregnancy rate for a stimulated cycle of IUI is 17%. The success rate for an unstimulated cycle is 16%. The HFEA indicate that approximately half of women who undergo this treatment will be successful within 6 cycles. Discussions with consultants indicate that women will very rarely proceed to 10 cycles of IUI without conceiving. Therefore, the proposed criteria for this policy, is to reduce the number of independently funded cycles from 10 to 6. This is likely to reduce some of the financial burden on same sex female couples while addressing an issue that has been raised through public and patient engagement. The proposed policy includes provision for patients who cannot have penetrative sex because of a psychosexual or andrological condition. This might include, for instance, Vaginismus. Patients will need to have received assessment from a relevant service before referral for a fertility service could be made. The purpose of this provision is to broaden equity of access for people where there is clinical justification, and the potential of an adverse impact on a particular patient group. Given the above, the CPD team are confident that the new policy represents a fairer approach to treating infertility, that will enable patients to progress through the services with the appropriate support.

Risk Scoring

Quality Domain	Patient Experience
Risk Description	There is very limited provision for single men and same sex male couples. This could lead to complaints from this cohort.
Probability	1
Impact	1
Total	2
Proceed to full QIA?	No

Please explain your reasons	The proposed policy will not have an adverse impact on patient outcomes. In the development of criteria, the policy has utilised a range of evidence and has been informed at each stage of development by local fertility specialists and pharmacists. This policy is intended to identify the causes of primary infertility and any likely treatments that may resolve the issues. The criterion for this policy have been developed in order to support clinicians identify patients with the most need, and those with the most realistic chance of conceiving with assistance. This means that patients will be given advice and treatment that is best suited to their needs. The proposed policy is likely to improve patient experience, particularly for same sex couples. The criteria for assessment of same sex couples has been altered in line with the best evidence, to enable a fairer approach to commissioning services for this cohort, one that will reduce the financial pressures on said couples. The policy also enables single women to access fertility treatment, which is a forward step from the existing policy. This not only reflects certain societal changes in family formatin, as indicated by the HFEA, but relieves financial pressure for single women with primary infertility who will no longer have to access private IVF treatment. A small number of conditions have been added to the criteria for the assessment of infertility for hetersexual couples and single women. These include: • Azoospermia • Oligospermia. • Stage 4 Endometriosis • A low sperm count, described as <1 million per 30ml taken on two occasions 3 months apart These are conditions where there is good evidence to suggest that they can compromise and individual's fertility. Including these conditions within the proposed policy, provides great equality of opportunity by equalising access, but is likely to support patients obtain the most relevant and effective advice and treatment sooner.

QIA Approver(s)

Jenny Thompson

Heidi buck

Comments from QIA lead	I believe the changes indicated through research and engaging the general public has improved the policy provision to potentially an improved outcome for the patient involved. There are no concerns to note from a Quality perspective and no requirement for a full QIA process to be undertaken..
Date of Quality Assurance	31/10/2022

PPI & Comms Impact Screening, Assessment and Plan

Are you planning a brand new service?	No
Are you planning to decommission a service?	No
Are you redesigning a service?	No
Are you relocating a service?	No
Are you redesigning a pathway?	No
Is it a policy change?	Yes
Is it a formulary change?	No
Is it a change in prescribing guidance?	No
An impact on the manner in which the services are delivered to the individuals at the point when they are received by users?	No
Explain why you have answered yes or no to the above:	The CCG's commissioning policy for the assessment and treatment of Fertility is being revised, as per the organisation's agreed schedule for review. Any changes to the policy would reflect a change to the circumstances in which the CCG would fund treatment. It would not neccesitate a change to the delivery of assessment or treatment for fertility.
An impact on the range of health services available to users?	Yes

Explain why you have answered yes or no to the above:	The proposed policy will enable single hetersexual women access fertility assessment and treatment provided they meet the other relevant criteria. The proposed policy will include for provision for people with a psychosexual condition that prevents them from having penetrative sex and, therefore, prevents them from being able to conceive. The proposed policy does not have provision for fertility preservation. Under the existing policy, patients undergoing some cancer treatments would be able to freeze their reproductive cells prior to any treatment that will remove their potential to conceive. However, these patients will be managed under a separate policy that utilises the existing policy's critieria. These patients will continue to be able to access fertility preservation. This represents an administrative change to provide clarity around the purpose and definition of policies to clinicians and the public.
Is engagement required for this activity?	No
Explain why you have answered No to the above?	A three month period of patient and public engagement has already been undertaken. This included the publication of three sepearate surveys for healthcare professionsals, members of the public and GPs. The results were collated and analysed by a researcher at the University of the West of England. During this time, the CPD team spoke with a number of representatives from various community groups and organisations including those representing the LGBT+ and BAME communities. A considerable amount of desktop research has also been performed, including reviews of local JSNAs and investigations into complaints which included approaching and discussing policy development with members of the public who had raised complaints.

PPI Approver(s)

Mary Adams

Lessons Learned

Lessons Learned

Consideration for the future

Overseas patients

Description	see email saved in fertility feedback file
Recommended Action	for next policy review
Date Learned	31/07/2019

Consideration for policy

Description	Hope you are well. We have just had it raised that in cases where – for example – the male patient has proven azoospermia and frozen semen stored from prior to oncology treatment, the couple can be seen for fertility assessment without actively trying for/wanting a child at the moment. I've recently had one or two whereby the couple have been seen a few times over the past year or so for full investigations in preparation and consideration of the fact that they may hope to have a child in a year to 18 months, but do not wish to have treatment quite yet. After discuss this with Niall, we were hoping that something could be added into the Fertility policy that in cases whereby they meet the exclusion criteria of not needing to have been trying to conceive for two years (due to a known cause of infertility, such as azoospermia or both fallopian tubes being absent), they must be actively wanting treatment to have a child at present – not considering it for in the future. It essentially means that at the moment, partners of patients with known infertility are getting seen for full investigations at any point, whether or not they have any clinical history that could cause an issue with their own fertility. However, in this sort of example, a woman with known high risk of having damaged tubes - but who has a partner that does not have any known sperm issues - cannot have her tubal patency tested, despite any clinical risk/history.
Recommended Action	To be included in policy review
Date Learned	10/09/2019

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