Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Reference: FOI.ICB-2425/027

Subject: Equality Impact Assessment on Infertility Assessment & Treatment Policy - Criteria Based Access/Prior Approval

*I can confirm that the ICB **does hold some of the information requested**; please see responses below:*

QUESTION	RESPONSE
1. A copy of the Equality Impact Assessment (EIA) conducted by BNSSG on their policy for Infertility Assessment & Treatment, focusing on Criteria Based Access/Prior Approval. Any documentation related to the development, review, or amendments made to the policy, including minutes of meetings, reports, or correspondence.	A copy of the Equality Impact Assessments for the commissioning policies on Infertility Assessment & Treatment, and Fertility Preservation have been included. Minutes and briefing papers from meetings of the Commissioning Policy Review Group, the ICB Board and Health and Care Review Meeting have been included. Also included is a study on cumulative live birth rates and IVF which informed some decisions and is cited throughout. Please note, as the review took place throughout 2021 and 2022, not all correspondence is available. However, the documents provided capture discussions and decisions. Please note: FOI requests and responses are publicly available and therefore personal information has been redacted. The ICB considers the names included in the enclosed document(s) to be

	personal information and therefore has applied a section 40 (Personal Information) exemption to this information.

The information provided in this response is accurate as of 9 May 2024 and has been approved for release by Dr Joanne Medhurst, Chief Medical Officer for NHS Bristol, North Somerset and South Gloucestershire ICB.

Overview

Project Code	CCG000436
Title	Fertility Assessment and Treatment
Start Date	01/12/2017
Authors	[redacted]
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	[redacted]
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)

[redacted]

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)

[redacted]

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

Workstream Members

Proposal Members

[redacted]

Proposal Role	Clinical Lead

[redacted]

Proposal Role	Equalities Support
[redacted]	
Proposal Role	Project Manager
[redacted]	
Proposal Role	Project Support
[redacted]	
Proposal Role	Project Support
[redacted]	
Proposal Role	Project Team Member
[redacted]	
Proposal Role	Project Team Member
[redacted]	
Proposal Role	Quality & Assurance Lead
[redacted]	
Proposal Role	Quality & Assurance Lead

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	[redacted]
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	[redacted]

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)

[redacted]

Project Members

Project Members

[redacted]

Proposal Role	Equalities Support

NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Commissioning Policy Review Group

Minutes of the meeting held on 18th January at 1pm, via MS Teams.

Minutes

Present		
[redacted]	Chair, Independent GP for BNSSG CCG	[redacted]
[redacted]	Medical Director - Clinical Effectiveness for BNSSG CCG	[redacted]
[redacted]	Clinical Lead for Policy Development	[redacted]
[redacted]	Head of Clinical Effectiveness	[redacted]
[redacted]	Public Health (Observer)	[redacted]
[redacted]	Public Health (Observer)	[redacted]
[redacted]	Clinical Lead for BNSSG Referral Service and Remedy	[redacted]
[redacted]	Public Health Consultant	[redacted]
[redacted]	Head of Primary Care Strategy, NBT	[redacted]
[redacted]	Exceptional Funding Manager, BNSSG CCG	[redacted]
[redacted]	Commissioning & Planning Manager, UHBW	[redacted]
[redacted]	Commissioning Policy Development Manager, BNSSG CCG	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	Deputy Chair, GP Clinical Lead, BNSSG CCG	[redacted]
Apologies		
[redacted]	Medical Director, NBT	[redacted]
[redacted]	Senior Exceptional Funding Request Manager	[redacted]

	Item	Action
01	**Introductions and Welcome**	
02	[redacted]	
03	**Declarations of interest** [redacted]	
04	[redacted]	
05	[redacted]	
06	[redacted]	

	Item	Action
	[redacted]	
07	[redacted]	
09	[redacted]	

	Item	Action
	[redacted]	
10	[redacted]	

	Item	Action
	[redacted]	

	Item	Action
	[redacted]	
11	[redacted]	

	Item	Action
	[redacted]	

	Item	Action
12	[redacted]	
13	[redacted]	
14	**Fertility Policy** [redacted] gave a background on the discussion that the CCG's Governing Body had asked the group to undertake. The purpose of the discussion was to address some of the ethical issues around the proposed policy and come to some recommendations that can inform decisions made by Clinical Exec and, ultimately, Governing Body who will be responsible for signing off this policy. [redacted] confirmed that group had been asked to look specifically at the two proposed policies through the lens of the CCG's Ethical Framework. The plan therefore, was to use the framework to guide discussions. [redacted] then provided an overview of the guidance outlined in the CCG's ethical framework around building consensus in decision making. [redacted] was also clear that the discussion was open to each member of the group, and that	

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	everyone's opinion or comments were invited. [redacted] introduced [redacted] who noted that decisions or recommendations against this policy should not be based on personal preference. [redacted] noted that the purpose of the framework is to support commissioners make decisions based on what is right for our population, rather than our own individual values or beliefs. [redacted] echoed [redacted] comments that this discussion was part of a broader process, and that Governing Body had asked CPRG to have a healthy debate that could provide assurance that any recommendations for this policy were made using the principles of the ethical framework. [redacted] noted that an output from discussion will be a paper for Clinical Exec that describes the reasoning behind the recommendations of this group. [redacted] gave an overview of the policy review to date, including the outcomes of the 3 month period of patient and public involvement that took place. This engagement posed a number of questions around areas of the policy that were within the scope of the review, as agreed by CCG Clinical Exec. The responses helped the CPD team to prioritise areas the review, and further informed discussions with fertility services. [redacted] introduced the questions that the group would be asked to discuss. [redacted] noted that although the policy utilises NICE guidance, there are areas of the policy that are potentially discriminatory. Areas of the policy that are open to challenge on this basis, is the current stance to use relationship status as a barrier to assessment and treatment – i.e. only people on a couple are currently able to access treatment. Therefore, one of the questions the group will be asked is whether a person should be given assessment and treatment for infertility on regardless of relationship status. NICE guidance still recommends that assessment and treatment should be for couples, and not single people, Another area of policy [redacted] noted that uses NICE guidance is around fertility preservation. Historically, the CCG has only provided preservation for people undergoing some cancer treatments. The current proposed policy would provide assessment and treatment for patients receiving any NHS prescribed medication that could remove the potential to conceive. However, there is still a question of whether other interventions should be included within the scope of the policy. [redacted] suggested that the group go through the policy first and then consider the questions posed and their ethical considerations. This was to ensure that the nuances of the policy were addressed. [redacted] asked whether transgender people would be covered within the scope of the policy. [redacted] indicated that this was part of the broader discussion for this policies, in terms of fertility preservation and when it is appropriate for a transgender person to access assessment or treatment.	

	Item	Action
	The group proceeded to review the policy. [redacted] noted that the policy has been renamed, including the word 'Primary', to be clear that the policy is concerned with the assessment and treatment of primary infertility. [redacted] noted that the CCG only funds assessment for primary infertility. The question is whether it should be opened up to secondary infertility. It is recognised that general practice and primary care support a lot of patients with secondary infertility, however there is no support from secondary care for this. [redacted] reflected on discussions with Clinical Exec where, following recognition of resource implications, the greater need, and need for investment was around primary infertility rather than secondary. [redacted] asked how secondary infertility was being defined by this policy. [redacted] noted that the difference is around having a viable pregnancy. [redacted] provided clarification on the purpose of the policy. The purpose of the policy isn't to lead to a live birth, the purpose of the policy is to assess issues with infertility and provide support or treatment for that. [redacted] proposed definition of secondary infertility is where a person has conceived, regardless of whether or not that conception lead to a live birth, and has issues conceiving again. [redacted] reflected that the decision from Clinical Exec was that the best use of resource was to support people who had never conceived. [redacted] asked whether conceived was being used synonymously with inseminated. [redacted] suggested she was not. Using a lay explanation, conception could be simplified as having a positive pregnancy test. [redacted] challenged that sub fertility can be due to male factors, in the conventional sense of that term. [redacted] noted that care was needed to avoid a bias towards the mother or father. Particularly when discussing donor insemination, or same sex couples. [redacted] notes that the policy creates within itself proxies for primary infertility. For instance, the policy states that 'patients should have no live children.' [redacted] agreed that the proxies within the criteria should be well aligned to each other. The proxy for heterosexual couples for instance, is that the haven't been able to conceive after 2 years of regular unprotected sex. The proxy for a same sex female couple is currently 10 cycles of HFEA approved donor insemination. The latter is more onerous and less affordable. There is work being done to address the number of cycles. However, [redacted] reiterated that the policy needs to be about individuals and not relationships. Therefore, discussions need to be supportive of individual infertility rather than traditional models of the family. [redacted] asked patient could have demonstrated secondary infertility, but subsequently be diagnosed with primary infertility. [redacted] gave an example of a heterosexual person who had conceived previously, and that conception	

	Item	Action
	had not proceeded to a live birth. [redacted] asked that if that person had not conceived for two years after regular unprotected sex whether they would start to be eligible again, for treatment of primary infertility. [redacted] noted that the definitions needed to be laid out better. [redacted] noted that if a person has had a number of pregnancies that haven't lead to viable pregnancies then they would be eligible. [redacted] further noted that if someone is having recurrent miscarriages, assessment can be made at any time through the recurrent miscarriage clinic. However, this does not mean that the individual needs a fertility assessment. [redacted] noted that the criteria for the recurrent miscarriage clinic is to have had 3 or more miscarriages. This means that a patient may have conceived once and then not been able to conceive for a period of two years, or 10 cycles of donor insemination. [redacted] clarified that this person would then be able to access treatment under the policy. [redacted] noted that making definitions along the lines of primary and secondary infertility could become confusing. [redacted] indicated that there needs to be some marker in the title that doesn't raise the hopes of individuals who won't be able to access services. The question is what do we put in our title to guide people and describe the policy. [redacted] raised further complications with using 'primary' in the policy. [redacted] noted that when going through the markers and proxies, it becomes very challenging. For instance, the burden of proof is inconsistent between heterosexual and same sex couples. That is to say, a heterosexual couple simply need to say they've been having sex for two years, while a same sex couple or an individual would need to pay a great deal of money to access assessment. **Action – 'Primary' to be removed from the title of the policy.** [redacted] challenged the rationale for using the word infertility rather than fertility, particularly when thinking about equity between groups. [redacted] then challenged that if, same sex couples and individuals required 6 cycles of donor insemination – as proposed in the revised policy – if the team knew how long that might take. [redacted] noted that it could take six months to fulfil 6 cycles, and therefore could be quicker than the process for heterosexual couples. [redacted] suggested that in looking at use of resources, we cannot afford and it's not clinically appropriate to have some form of marker that gives a proxy for infertility. There needs to be a way of getting the best gain for the population. [redacted] note that individuals will need different markers to couples. The challenge then is identifying the most appropriate markers. [redacted] asked if either a definition for primary infertility, or appropriate wording needed to agreed in the meeting. [redacted] suggested that there are some good	

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	definitions for primary and secondary infertility, and what the policy does not do is lay them out well. [redacted] suggested that the CPD team will work on this. [redacted] echoed [redacted] point and clarified his understanding of the definition of secondary infertility, which is where an individual has had one or more pregnancies in the past but is having difficulty conceiving again. [redacted] gave the scenario of an individual who had an unsuccessful pregnancy at 18, has not been pregnant since, and at the age of 36 decides to try and have children. Under the policy, the individual could be eligible for assessment. [redacted] recognised the need to limit activity as appropriate, but felt that the markers within the policy do contradict the definition of primary as understood by the group. [redacted] reiterated the policy should be for primary and secondary under these definitions. [redacted] also read the policy that if a patient had conceived once, regardless of timeframe, they would be ineligible. The fact that [redacted] had indicated that the patient would be has contradicted that, and so the policy is not clear on this point. [redacted] confirmed that miscarriage is not a block to assessment. [redacted] agreed that a much clearer definition was needed. [redacted] noted that although CPRG is not responsible for funding allocation per se, any recommendations for Clinical Exec will need to recognise the resource implications. Therefore, when the group suggest that the policy should cover primary and secondary infertility, they need to be mindful of the cost implications of doing that, in order to make a thorough recommendation to Clinical Exec. [redacted] first noted the World Health Organisation's (WHO's) definition of infertility. [redacted] then responded to [redacted] challenge around resource implications, and indicated that he cannot see the justification for not including an individual who had conceived at a young age, where the pregnancy didn't proceed. [redacted] noted that any decisions made by the group need to be perceived as fair. [redacted] recognised that some decisions may be open to legal challenge. [redacted] responded that role of the group, for this discussion, was to consider the policy through the lens of the ethical framework which may or may not remove the risk of legal challenge. However, it will demonstrate a transparent and thorough process for decision making. [redacted] noted that it is unlikely that there would be a legal challenge, as the CCG has the option to not fund fertility assessment and treatment at all. [redacted] indicated that while this was an important discussion, the group needed to move forward with the discussion. [redacted] indicated that the group needed to make a decision on how to move forward. [redacted] suggested he would be happy to remove the word 'primary' from the policy's title. [redacted] reflected that the term was contradictory to the criteria	

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	within policy, and so it should be removed. [redacted] noted that 'secondary' remains within the body of the policy. It was agreed that, if primary is being removed, secondary should be removed also. [redacted] asked [redacted] how he would like to continue with the review. [redacted] suggested the group review the general principles for all patients and move through the policy from there. [redacted] suggested points 4 & 5 were contradictory. [redacted] noted that point 4 states people who have received NHS treatment as part of another couple won't be barred from treatment on their current relationship. Point 5 states the individual must have no living offspring. [redacted] confirmed the issue was around relationship status, and whether the policy is looking at the individual or the relationship status. [redacted] questioned whether point 4 could be removed as it is relevant only to relationships. If so then point 5 would need to be reworded to reflect changes in relationship and familial status. For instance, if a divorcee entered a relationship and had problems conceiving, would the child from the previous marriage preclude the possibility of fertility treatment. [redacted] recognised the various complexities were not addressed within the policy yet. [redacted] questioned whether it was possible to do that, and further recognised that within the meeting it would not be possible to check every scenario. [redacted] responded that these are the scenarios that GPs will encounter in practice. [redacted] suggested that the only way to develop a fair and equitable approach to commissioning fertility assessment and treatment is not commission it at all. [redacted] advised that the CCG has no appetite for this decision. [redacted] asked whether, because point 5 talks about individuals, whether that made a difference to the policy. [redacted] commented on [redacted] point that to simplify this point would be to say that if any member of the couple have a child they would be excluded from treatment. [redacted] noted that if this was to be the case, we could be discriminating against female divorcees as they would be unable to have fertility treatment while single women who had never been married and had children, could. [redacted] suggested that the group move away from this part of the discussion and consider the questions originally brought to the group. Partly, because many of the issues considered by the group are relevant to a the question on relationship status. [redacted] agreed and directed the discussion towards the two questions the group were tasked with considering, through the lens of the ethical framework.	

	Item	Action
	[redacted] introduced the first question around whether single people should be eligible for assessment of infertility and secondly treatment. The group were then directed to address, firstly, the question of whether single people should be eligible for assessment of infertility. [redacted] provided context to this point, drawing on discussions with local fertility services. [redacted] indicated that a significant number of single women are accessing donor insemination. The proxy proposed around donor insemination for same sex couples, could also be a proxy for infertility for this cohort. [redacted] opened the floor for discussion. [redacted] acknowledged that the decisions made should not reflect personal values. However, [redacted] asked for guidance on how the group could decide on the subject that wasn't personal, or a reflection on personal values. [redacted] recognised the issues and advised that the ethical framework is the team's guide for navigating this discussion. [redacted] reiterated the need for the perception fairness among all patients. [redacted] introduced the principles of the framework, and emphasised that each has equal weighting in decision making. [redacted] suggested that the group consider the questions and run through the ethical framework in order. The group agreed, [redacted] re-stated the **first question which was; assuming infertility is a health issue should we fund assessment regardless of someone's relationship status.** [redacted] further clarified that currently the CCG only funds assessment for heterosexual and same sex couples. [redacted] then asked the team to provide the rational basis for a decision. **Rational** [redacted] noted that the world has changed considerably, and that since the development of IVF, the 'traditional' family is no longer the expectation among the population. However, treatment on the basis of relationship status could exclude 50% of the population. For instance, someone who was biologically born a man cannot carry a child and there is no likelihood of the CCG funding surrogacy. However, the most equitable approach would not be to look at relationship status but to look at individuals. [redacted] echoed [redacted] points around changes to the perception of the traditional family. [redacted] noted that more traditional approaches to the family were likely the rationale behind the CCG's approach to commissioning fertility treatment. [redacted] noted that, for them, the important factor was the outcome, i.e. a live birth. Therefore, the policy should be about the outcome, rather than the	

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	relationship status. [redacted] further noted that relationship status has been further complicated as more people are identifying as different genders and more people identifying as different sexualities. Therefore, the policy should be based on the individual [redacted] noted that scientifically, biologically and clinically research, relationship status has no impact on the outcome either of live birth or conception. [redacted] reiterated this point, noting that the policy can give criteria that will help with the success of treatment, but that the policy should still look at the individual and not the relationship. [redacted] agreed that the effectiveness of treatment is the same regardless of relationship status and indicated that there appeared to be clear consensus across the group that providing fertility assessment for single people was logical and rational. There was no challenge to the unanimous consensus. **Inclusive** [redacted] suggested that the decision to fund single people for assessment is clearly inclusive. The group agreed. [redacted] raised a query about how increasing investment in fertility treatment would affect other interventions, particularly with regard to balancing the rights of the individual against the rights of the community. [redacted] queried how this could be rationalised under the banner of an inclusive approach. [redacted] agreed this was a relevant point, but suggested discussion could be better placed during consideration of value. **Value** [redacted] noted that fertility is part of a broader system. The challenge for the group is to develop a safe and equitable policy, and it will be for Clinical Exec to decide whether it is affordable and for this group to work the challenge following their review. [redacted] recognised this was a prudent way forward. However, [redacted] believed the group should comment on the proposed cost implications and also any reasonable mitigations to limit cost. [redacted] agreed that affordability is massive consideration, however the group cannot reasonably carry out the financial modelling and projections. [redacted] suggested the group focused on ethical considerations. [redacted] explained that the proposed policy would go some way in increasing the equity of access and that the CCG would have to accept additional costs in order to do that. [redacted] proposed that equity should take priority over finances in this instance. [redacted] did not believe that consideration of resource was within the scope of the debate and that the focus should remain with the ethical issues of whether to treat single people. The question of affordability [redacted] considered	

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	to be a separate question. [redacted] disagreed with [redacted] view and echoed [redacted] earlier comment that the group need to take into consideration the financial implications. [redacted] further indicated that this could inform an ethical policy that can mitigate the financial impact through criteria, such as lowering the upper age limit from 40 to 38. [redacted] understood [redacted] position, but pointed to issues around inclusivity that this might raise. In particular for patients in their 30's, or choose to have children later in life. [redacted] noted the points made, and suggested that within the paper for Clinical Exec to accompany the policy, we provide some potential mitigations to go along with cost projections. [redacted] further noted that, while it was not within the group's remit to make a decision on finances, the group should consider resource implications. [redacted] suggested that one approach would be to provide Clinical Exec with the proposed cost pressures of a policy and ask if they are acceptable to said group. If the cost pressures are not acceptable, CPRG should get clarity from Clinical Exec that they are being given a mandate to seek mitigations to limit expenditure. [redacted] provided two potential options for the group. The first was to remain within the financial envelope for fertility treatment. This would not enable the group to equalise access. The second would be to closely monitor activity to inform a review of the policy. The group unanimously agreed that the cost implications should be taken into consideration, but that Clinical Exec would have to make a the decision on affordability. There was agreement that investment in equalising access to services was warranted. **Transparent & Open to Scrutiny** [redacted] noted that this had been an open discussion, with minutes available to members of the public if needed. The group agreed that the decision satisfied this principle **Promote Health for Both Individuals and the Community** The group did not feel this was relevant to this policy. **Unanimous Decision – recommend to Clinical Exec that single people should be funded for assessment of infertility.** The group moved to the second part of the question. **Should single people be funded for treatment of infertility?** [redacted] suggested that one decision would follow through into the other.	

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	However, [redacted] also noted that there are some conditions that will be very difficult to treat, for instance a man with a zero sperm count. [redacted] believed that the second question warranted further discussion. [redacted] provided an example scenario of an unmarried man who has an arrangement with woman who will carry a child for them. If they have failed to conceive and the man is assessed and found to have zero sperm count, [redacted] asked what the next steps would be. [redacted] noted that for a heterosexual couple there would be the potential for surgical sperm recovery. The question then is whether the CCG should part fund surrogacy. [redacted] asked how many other scenarios the team might need to consider. [redacted] suggested the only other scenario would be for female patients using donor sperm who cannot conceive and another issue is discovered during assessment. [redacted] noted that surgical sperm retrieval is an NHSE commissioned intervention and therefore is it outside of the scope of this policy. [redacted] clarified that we're making a decision on the funding for assessment rather than treatment. [redacted] noted that there are a considerable spectrum of conditions that could warrant discussion, however CPRG will not be able to cover them in the scope of this discussion. [redacted] discussed single men and indicated that there is no assessment or definition for an infertile single man within the current policy. It could be that as there is no clear definition for an infertile single man, this is a rational reason for not including them within the treatment element of this policy. [redacted] provided a definition of an individual who in the work up for surrogacy, for example, had semen analysis that had shown the individual had oligospermia or azoospermia, which could mean that they need assessment and would fit within the NHSE policy. The challenge again, is what the proxy for infertility is. [redacted] agreed with [redacted] point, but noted that there is a potential proxy that the CPD team can work up for the policy in partnership with the fertility services. [redacted] asked [redacted] what decision needed to be made by the group. [redacted] suggested that the issue was around what treatments may or may not be funded. [redacted] noted that at some point the group need to look at the core policies and the criteria within once the ethical questions have been resolved. [redacted] reviewed the NHSE sperm retrieval policy and confirmed that NHSE	

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	will only fund if the person has funding for the next stages of treatment. [redacted] recognised the example of sperm retrieval was not the most expedient, and suggested conditions where the patient has low levels of sperm, in which case responsibility for assessment and treatment would rest with the CCG. The challenge remains whether the CCG would provide treatment following assessment. [redacted] challenged that azoospermia and oligospermia does not necessarily mean that the patient is infertile. [redacted] responded that the chance of conception with less than 5,000,000 sperm per ml is very low, and below 1,000,000 per ml, exceptionally low. During the review of the policy, fertility services have confirmed this would be the marker for oligospermia and also to allow patients to be seen outside of the usual 2-year timeframe. This marker is considered a strong indication that an individual presenting with this sperm count would not be able to have children without assistance. Given that responsibility for the patient's assessment would be the responsibility of the CCG, this marker is within the policy. [redacted] asked what the treatment would be in these circumstances. [redacted] confirmed that in a couple it would be IVF. [redacted] asked for clarity from [redacted] and [redacted] on how the group should proceed in tackling this question. [redacted] understanding that single females would be funded for treatment and assessment whether they are in a relationship or not. This is guided by the group's principle to not take relationship status into account. [redacted] further suggested that assessment for single born males is something we should fund, however there are no treatments commissioned by the CCG for this cohort. [redacted] noted that there is inequity in this decision, however part of that inequity is physiological – i.e. men are not born with wombs and so are never going to be able to carry a pregnancy. [redacted] raised the question of whether the group felt that this was a reasonable and rational decision in regard to the treatment of single born males and females. [redacted] agreed with [redacted] argument, adding that because the CCG cannot part fund, and because the CCG does not fund surrogacy, there is an inequity in terms of treatment for single born males. [redacted] provided a brief summary of this approach. [redacted] felt that, due to biological facts, the approach to not fund treatment for single born males is rational, even if it is not completely inclusive. [redacted] noted that care was needed with language throughout the policy, noting that the policy should focus on an individual's biology rather than gender. [redacted] suggested that the group run through the ethical framework to think	

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	through the question and provide the CPD team with the appropriate level of scrutiny can be described to the Clinical Exec. [redacted] agreed and clarified the decision being discussed. [redacted] began by confirmed that there are a number of treatment's for infertility for women that are commissioned. However, there aren't many treatment options for men, and the ones that the group have discussed are funded by NHS England. However, the CCG's Exceptional Funding process could be another possible avenue for patient's to apply for funding. The team then reviewed the ethical framework, against the proposal to fund treatment for single born females, but not for men. **Rational** The team agreed that the decision was rational given the biological factors, and the fact that treatments for single men are funded by NHS England. **Inclusive** It was recognised that the decision was not completely inclusive as a result of biological factors. [redacted] asked if this move meant that the policy would exclude people who do not have a womb. [redacted] indicated that this was his understanding and asked the group if there was a counter opinion. No counter was proposed. **Value** The group did not believe that funding single born females for treatment, but not single born males, would have a significant impact on value. **Transparent & Open to Scrutiny** The group agreed that there had been an open and transparent about the logia and rationality around this decision. The group agreed that they had been lead by evidence rather than personal opinion. **Promoting Health for Individuals and The Community** The group agreed that this would promote health for individuals and communities by broadening the scope of access to treatment. [redacted] provided a summary of the group's recommendation for Clinical Exec. CPRG recommends that the CCG funds single born females for treatment of infertility. However, the group are not recommending funding for treatment of single born males, because the interventions that can be done are not commissioned by the CCG. **Unanimous Decision – Recommend to Clinical Exec, that the CCG funds single born females for treatment of infertility.** [redacted] noted that, in redrafting the policy and background information, care needed to be taken in the language used and that it was consistent throughout all the documents.	

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	[redacted] agreed with [redacted] point and reiterated the point of using appropriate language when discussing gender. [redacted] noted that with policies of this complexity, it is useful to provide and easy to understand version for GPs and members of the public. This will help GPs explain to people why they may not be eligible for assessment and treatment. [redacted] noted that there is an easy read guide, as well a commissioning guide, available. [redacted] asked if a member of CPRG could volunteer to read through the policy again, once it is written, just to provide a fresh pair of eyes. [redacted] also asked that, when a paper is written up for clinical exec, that we note the amount of time that has been taken to discuss the policy. [redacted] raised a query about the upper age limit for women. The proposed policy states that 'prospective mother must not be older than 40 years of age at referral.' [redacted] asked if further clarification could be added to state that women aged 40 years or older cannot be referred. [redacted] noted that occasionally patients do present seeking referral after their 40th birthday. [redacted] agreed this was a reasonable approach, but noted that the group had not gone through the policy in any detail yet, which was still needed before it could proceed through Clinical Exec. [redacted] raised a query about age discrimination given that referral male patients is higher than female patients. [redacted] noted that this was due to evidence that fertility levels diminish in men later than women. [redacted] noted that age criteria came from previous NICE guidance. [redacted] advised that despite improvements in IVF and better outcomes for women trying to conceive later in life, evidence indicates that best use of resources remains in funding assessment and treatment for women up to 40 years. NICE guidance on the male has not changed. [redacted] asked whether a decision needed to be made on age cut offs immediately. [redacted] reminded the group that debate would be needed in order to come to a meaningful consensus. [redacted] noted there are lots of points within the policy that need to be addressed. [redacted] suggested that more thorough review of the policy was required. The group agreed to bring the policies back at a later date, and discuss the ethical considerations around fertility preservation for the remainder of this meeting. [redacted] introduced the question for debate which was, **'Should the CCG fund fertility preservation for treatments other than cancer drug treatments**?'	

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	[redacted] provided an outline to the CCG's current approach for fertility preservation, and the proposal for fertility preservation in the new policy. [redacted] noted that, as laid out by NICE and NHSE, within the existing policy, fertility preservation is provided for patients undergoing some cancer treatments. [redacted] proposed that this is an inequitable position. [redacted] then provided an overview of some of the proposed changes, which would provide fertility preservation for patients prescribed NHS medication that is likely to remove fertility, and where there is no clear alternative. This would cover patients on a range of pathways such as renal, where cyclophosphamide may be needed. [redacted] related discussions with clinicians and pharmacists and noted that there are likely to be other drugs that could remove fertility. In particular, NHS prescribed testosterone for patients on a gender dysphoria pathway. [redacted] noted that while a review of the medication was the initial approach to reducing inequity between patient groups, it has since become clear that there are other NHS interventions that are non-drug related, but could also remove a person's fertility. [redacted] gave the example of a surgical procedure which may remove fertility either partially or completely, by removing a second ovary. [redacted] provided background on the discussions from Governing Body on this policy. It was recognised that there are lots of surgical treatments with different levels of risk to a person's fertility. [redacted] asked that the group take into consideration the level of risk that the CCG should be prepared to take, because this could open the floodgates to a very high level of activity. [redacted] noted that the policy states that cryopreservation will funded for one year, and suggested that this was unfair for a teenager with cancer. [redacted] suggested that this was more to do with the detail of the policy rather than the ethical considerations. [redacted] provided an overview of the background to this element of policy, which is currently based on cancer treatments, but urged the group to, for this discussion, consider the principles rather than the details of the policy. [redacted] opened up the discussion, noting that legal guidance on this issue is that the CCG is open to discrimination on this element of policy. On this, [redacted] argued that the current policy is unfair to exclude patients on the basis that they do not have cancer, but are receiving treatments that could remove their fertility. This was balanced with a reminder of the potential resource implications. [redacted] asked if there was any relevant guidance from cancer services that could be used. [redacted] noted that there is a lot of commissioning guidance behind the current policy. [redacted] then indicated, from discussions with specialists, there are very likely to be a very small group of drugs that should be within the scope of the policy. It was further noted that gynaecologists believe that there will	

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	only be a small number of women where a surgical element will cause concern around loss of fertility, and it will largely be where there is likelihood of surgery requiring removal of the second ovary. Again these numbers are likely to be low. [redacted] concluded that the policy for fertility preservation, would be for very high risk procedures. [redacted] challenged that if the numbers are small, perhaps funding should be sought through the exceptional funding panel. [redacted] indicated that the process for obtaining exceptional funding would generally not fit with the patient's treatment pathway due to time delays caused by the EFR process. [redacted] noted that the examples [redacted] had provided for interventions where there is a high risk of removal of fertility. Given concerns around the impact this policy may have on activity, it was questioned what other types of surgery might need to be considered that carry a high risk of increasing activity. [redacted] noted that potentially pelvic surgery, cancer surgery or high risk abdominal surgery could be high risk for women. It was recognised that there weren't many interventions for men of a similar risk. [redacted] suggested that one possible way forward would be to fund fertility preservation for ovarian surgery only at this point. [redacted] agreed that provided there aren't a reasonable number of other patient groups that could be affected, limiting access to fertility preservation for patients where surgery is likely to remove fertility, to patients undergoing ovarian surgery, would be a sensible starting point. In terms of mitigating concerns around impact, [redacted] asked that the CPD team provide an estimate around the number of patients undergoing the treatments discussed. This would provide assurance to Clinical Exec. **Action – [redacted] to include activity data around the above surgical interventions, within the next briefing paper for this policy.** [redacted] responded to [redacted] concerns around some of the surgical interventions that could lead to high volume of activity if the decision to fund fertility preservation for these patients was made. [redacted] suggested mitigations including the age of the patient cohort, noting that they would most likely meet the criteria for assessment and treatment of infertility post surgery. [redacted] also noted that certain of the presentations [redacted] had raised, would not give clinicians the time or opportunity to perform any fertility preservation treatments. There were no further comments on this issue. [redacted] therefore reminded the group of the question, which was 'should the CCG fund fertility preservation for treatments other than cancer drug treatments?' [redacted] asked if, as a principle, the group agree that the CCG should fund this, and for the group to once again use the principles of the ethical framework.	

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	Rational It was agreed that funding fertility preservation for both cancer and non-cancer treatments, would have the same impact on an individual's fertility. **Inclusive** The group agreed that this was an equitable approach. This approach would increase equality of opportunity of access to healthcare. **Value** The group noted that the size of the patient cohort that would be able to access funding was likely to be low. It was accepted that more work needed to be done on identifying actual activity. [redacted] noted that the group of patients specialists are looking to fund, are like to be less than 5 per year. [redacted] noted that there would be an increase in resource and asked if there were any mitigations that could be factored into the policy. [redacted] stated that the only mitigation that would be equitable, would be to not fund fertility preservation at all. The question was then asked of the group whether fertility preservation should not be funded. There was unanimous consensus that removing the policy was not an option. **Transparent & Open to Scrutiny** The group acknowledged that this had been an open discussion, that is minuted and can be circulated beyond the group if required. **Promoting Health for Individuals and The Community** The group were unsure how this point related to the policy being discussed. [redacted] asked for clarity around what interventions would be within the scope of this policy. [redacted] advised that, within the surgical sphere, the area for priority identified with specialists was around the probable of definite removal of the second ovary. There might be equivalents, and these could be managed through exceptionality. However, there have not been any groups suggested by the specialists who should be within the scope of the policy. [redacted] clarified that the policy would be for people undergoing a second ovary surgical interventions. The group discussed drug treatments that might be covered within this policy. [redacted] asked if the group needed to be more explicit about what would be covered at this point. [redacted] noted that the CPD team are working with the medicines management to decide how a drug is documented to be appropriate within the fertility preservation policy. The policy will use an example in the policy. [redacted] stated that in most situations, where a drug could be prescribed that will remove fertility, there are alternative drugs that can be prescribed which don't affect fertility. Cyclophosphamide is the only drug where there is no real alternative. [redacted] sought clarity on the pathway for fertility preservation, and the likely level of involvement of GPs. [redacted] confirmed that there was a direct pathway	

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	for patients and, therefore, GPs would not need to be involved. [redacted] asked that, before we formally recommend this Clinical Exec, that estimates around the likely financial impact are collected. Furthermore, there would need to be some way to provide monitoring of activity with some kind of thresholds, so that any unexpected increase can be flagged. [redacted] also asked that, as a principle, it could be useful to ask Clinical Exec whether CPRG needs to undertake a commitment to stick within the existing expenditure, or to move outside of the current financial envelope. [redacted] asked the group if a recommendation should be taken to Clinical Exec that we don't increase expenditure. It was noted that such a recommendation would mean that the current proposed criteria may need to be adapted to limit or mitigate for increases in activity. [redacted] proposed that trying to keep expenditure within current limits is a secondary element of the discussion. [redacted] indicated that Clinical Exec should comment on whether a policy is affordable. Should that group decide a policy is not affordable, and that there is appetite for further restriction, then it should come back to CPRG. [redacted] suggested that the simplest way forward would be to highlight to Clinical Exec the potential resource implications and ask for a decision. **Unanimous Decision – Recommend to clinical executive, that the CCG funds fertility preservations for patients who will be prescribed medication that is very likely to remove fertility, or will undergo surgical procedure on a second ovary that has a high risk of leading to ovarian failure.** [redacted] proposed next steps. The first was to explore with the executive team the extent to which the group should consider the financial implications of policies. [redacted] also proposed that a separate meeting is require to go through the policies, based on the discussions of the meeting. From there a redrafted policy could be presented either at an interim CPRG or the next CPRG. [redacted] was concerned that the correct level of scrutiny has been given to the policy, to take it through the approval pathway within the current timeframe. [redacted] proposed that this should be discussed outside of the meeting, and that a decision on how to proceed would be circulated among the group. [redacted] noted that, moving forward, the timeframe has will need to change. It was suggested that the policy needs to be given the time it needs in order to get the right level of scrutiny. [redacted] also reflected that the timescales had been put in place to enable the policy to be approved before the CCG is abolished. [redacted] concluded that the group should feel comfortable in extending the timelines to make the policy as good as it can be.	

	Item	Action
15	[redacted]	

Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Briefing Paper for Commissioning Policy Review Group (CPRG) Meeting

Date: **18th January 2022**

Title: **Commissioning Policy Review Group (CPRG) Briefing Paper**

Purpose

The aim of this paper is to provide an overview of the outcomes and outputs of the policy review process. This paper aims to support the CPRG to:

- Review the commissioning policies that have been reviewed
- Make decisions on whether to recommend a reviewed commissioning policy to BNSSG CCG's Clinical Executive Committee for adoption or removal

The outputs described in this paper include an Equality Impact Assessment (EIA), a Quality Impact Assessment (QIA), Public & Patient Involvement plan (PPI) and the likely financial impact of adopting the recommendations of the Commissioning Policy Development (CPD) team.

Reasons for commissioning policy review

There are five reasons that policies are reviewed:

- **Three year review** – Each commissioning policy has a review date which is set at three years from the date of adoption.

- **NHS England's Evidence Based Intervention Guidance for CCGs (NHSE EBI)** The aim of this program is to prevent avoidable harm to patients, avoid unnecessary operations, and free up clinical time by only offering interventions on the NHS that are evidence-based and appropriate. CCG's are required to pay due regard to this work in the formatting of commissioning policies.

- **Removal of criteria considered to be a Significant Functional Impairment (SFI)** – The CCG's Governing body has advised that, for exceptional funding requests, exceptionality should be based on clinical factors only, in line with other CCGs and NHS England. Non clinical factors, frequently referred to as 'Significant Functional Impairment', affecting a person will not be considered. This ensures that decisions are objectively and avoids judgement of an individual's relative worth.

- **New information –** A policy will be reviewed if the CCG receives new and relevant information or significant feedback on a policy once it has been adopted that would

necessitate a review.

- **Admin Changes -** Policies can be updated when clerical details need updating in line with organisational changes. This does not constitute a formal policy review but requires sign off from CPRG in line with the CCG's governance protocols.

The policies described in this paper will have been reviewed for at least one of the above reasons.

Our approach to health inequalities

The CCG defines health inequalities as unjust and avoidable differences in people's health across the population and between specific population groups.

Health inequalities are socially determined by circumstances largely beyond an individual's control. Health inequalities are not random and do not happen by chance.

The CCG recognises the importance of understanding and recognising the impact of its commissioning policies on health inequalities.

There is a developing CCG health inequalities plan that describes actions to improve the quality of equality impact assessments and undertake more robust consideration of their results in decision-making. The plan also recommends embedding health inequalities champions within committees and programme boards. There is also an action to provide further support for staff to ensure that health inequalities are consistently covered in their work.

Recommendations made to CPRG by the Commissioning Policy Development (CPD) team.

This section gives further detail about each policy's review including the date a policy was adopted, the reason for the review, the clinical teams involved in the review and an overview of equality and quality assessments. An assessment of likely commissioner spend as a result of policy adoption, is also provided.

Table 1 summarises the policies that have been reviewed and the recommendation being made by the CPD team to CPRG.

Changes in wording to policies are highlighted yellow in the policy document.

Table 1

Policy	Reason for review	Recommendation to CPRG
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
Primary Infertility – Assessment & Treatment	Three Year Review	Recommend adoption to Clinical Executive Committee
Fertility Preservation	New Policy	Recommend adoption to Clinical Executive Committee

[redacted]

[redacted]

Due to the Covid 19 pandemic the clinicians did not have capacity to fully engage. A

[redacted]

Primary Infertility – Assessment & Treatment

Adopted 1st December 2017

The CPD team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), North Bristol Trust (NBT) and University Hospitals of Bristol and Weston (UHBW) in the development of this policy.

The revised policy is clear that its purpose is to 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. The policy has been renamed Primary Infertility – Assessment & Treatment to reflect this.

To maintain consistency in the scope and purpose of this policy, fertility preservation will be managed under a separate policy. This is discussed further 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 to heterosexual and same sex couples. Under the revised policy, single people will be eligible for assessment and treatment, provided they meet the relevant criteria within the policy, and therefore opening access to single women. This includes having

regular unprotected sex for a period of two years, or undergoing donor insemination for an equivalent period.

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

Additional criteria have been proposed for the investigation, assessment and advice on primary infertility for heterosexuals. There are conditions where there is good evidence that they have an adverse impact on fertility, and where it is likely that there will be a significant number of patients who are diagnosed with these conditions. Under the revised policy, patients could be funded for treatment if there are the following known conditions:

- Azoospermia
- Oligospermia.
- 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 can place significant financial pressure on a same sex couple. Given the apparent lack of parity with the criteria for heterosexuals, this leaves the CCG open to complaints from the public and, potentially, legal challenge around unlawful discrimination. It should be noted that there is currently a legal challenge 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 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.

It was also indicated that there was clinical evidence to compel a review of this criteria, to develop a more equitable policy.

Evidence from 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, 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 for same sex female couples

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.

EIA

Equality impact assessment has been completed and is awaiting sign off.

As this policy deals with primary infertility, fertility preservation for patients undergoing some cancer treatments is not included within this policy. A separate policy has been developed for fertility preservation.

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%.

It 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.

QIA

Quality impact assessment has been completed and is awaiting sign off.

PPI

PPI assessment has been completed and is awaiting sign off.

Financial Impact

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.

The proposed policy will enable single people to undergo assessment and treatment of infertility where they meet the relevant criteria. This is likely to have an impact on activity. According HFEA data, the number of single women accessing IVF treatment has steadily increased over the last 5 years. However, this data does not indicate if the decision to undergo IVF treatment was a result of a lifestyle choice or primary infertility. It is therefore difficult to make an accurate projection of the likely financial impact.

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. This accounted for 4% of the total number of NHS funded treatment cycles for England. This cohort constituted less than 1% of the total population of England registered as single or unmarried.

Data from the Office of National Statistics (ONS) indicates that, across BNSSG, there are 273,448 people who register their marital status as single. While this is not broken down by age, 170,375 of BNSSG's total female population would meet the age criteria in the proposed policy. Assuming local activity follows national trends, and that 0.014% of the total female population of BNSSG who meet the proposed age criteria seek referral, proposed changes to the policy could lead to an increase in fertility activity of up to 30 referrals per year, and an overall increase in fertility spend of £94,320. Fertility expenditure for the CCG in 19/20 was £993,177.

It is worth noting that in 2019/20, the number of heterosexual couples who received fertility treatment in was 290. This also constitutes less than 1% of BNSSG's total population of couples in either a marriage or civil partnership.

It should be noted that HFEA research indicates that the majority of single women access fertility treatment in their 30's. Given this, it is possible that the number of single women seeking treatment for infertility could be less than estimated above.

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

It is also unclear how many lone parent families there are across BNSSG. In 2020, there were estimated to be 197 lone parent families across BNSSG. However, this

data is likely to have changed in the interim. The number of lone parent families is likely to have an impact on the number of people seeking infertility treatment.

While the number of single women in BNSSG is unknown, 45% of the total population are registered as single or unmarried. Assuming the 45% of the total number of women in BNSSG who would meet the proposed policy's age range are single, would give a potential population of single women as 76,668.

NHS data suggests around 14% of couples (1 in 7) require treatment for infertility. However, there is no data on primary infertility in single people. Assuming solely that 14% of single women across BNSSG, within the policy's criteria for age, required treatment for primary infertility, activity could increase by 10,700. However, this is highly unlikely to be the total number of women with primary infertility across BNSSG This does not take into consideration factors in the male partner that can cause infertility. NICE indicates that that in 30% of cases, male factors cause infertility. Therefore, the above figure is unlikely to reflect actual need.

Given the limitations in the data, it is reasonable to take national data as a guide for understanding local demand. The CPD team, however, will work with the CCG's contracts team and BI to establish a means of monitoring this data.

As noted, there are several conditions that have been added to the criteria for heterosexual couples. There is currently no data to indicate how this might impact activity, the consensus among clinicians involved in this review is that the cohort will be small, however the CPD team will work the CCG's BI team to establish a means of monitoring this data.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Fertility Preservation

New Policy

The commissioning policy team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), North Bristol Trust (NBT), University Hospitals of Bristol and Weston (UHBW) and pharmacists from the CCG's medicines optimisation team.

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 that might compromise fertility.

There is provision within BNSSG CCG's current fertility policy for patients who are to receive oncology treatment that is likely to compromise their fertility.

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 CCG'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 CCG 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 CCG does have discretion to fund gamete preservation for clinical reasons supported by evidence.

The policy for fertility preservation supports patients who will be prescribed medication as part of their NHS treatment that will have an adverse and irreversible impact on their fertility and where there is no clear alternative to this treatment.

There are a number of medications that can have such an 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 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.

EIA

Equality impact assessment has been completed and is awaiting sign off

This policy preserves the potential for transgender people, who are in the process of transitioning, to conceive later in life. This policy addresses an element of existing CCG provision for fertility preservation that was discriminatory, by establishing a clear rationale based on clinical evidence.

QIA

Quality impact assessment has been completed and is awaiting sign off.

PPI

PPI assessment has been completed and is awaiting sign off.

Financial Impact

The number of patients currently prescribed cyclophosphamide, and who 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.

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. 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.

The CCG 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. Assuming that the cohort remains a similar size and that each patients wants to pursue fertility preservation, the CCG could see an increase in expenditure of £43,350 per year. The CPD team will liaise with both the CCG's Acute Contracts and BI team to establish monitoring for these costs.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Glossary

Clinical Policy Review Group (CPRG)	Clinical Policy Review Group (CPRG) - quarterly meeting coordinated by the Commissioning Policy Development Team in order to clinical review / update existing policies against new NICE guidelines and other developments. CPRG also clinically evaluates new policies identified. The of this group is to make recommendations to the Commissioning Executive in regard to Commissioning Policies to adopt on behalf of BNSSG.
Evidence Based Interventions Programme (EBI)	The Evidence-Based Interventions Programme was established and developed as a joint enterprise between five national partners: the Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence as well as NHS England and Improvement. The programme focuses on 17 interventions that fall into this category. Four interventions that should not be routinely offered to patients unless there are clinically exceptional circumstances, and 13 interventions that should only be offered to patients when certain clinical criteria are met.
Due Regard	NHS England has advised that each CCG must evidence it has paid Due Regard to the recommendations made through the EBI Programme, and details of this recorded.
Exceptional Funding Request [EFR]	Where a CCG has published a policy stating that certain treatments are not routinely funded, or no commissioning policy exists. Treatment will only be funded via agreement from commissioners in exceptional circumstance.
Criteria Based Access [CBA]	Where a CCG has published a policy setting out eligibility criteria. If clinicians are content that the patient meets the criteria, they may proceed to treat without seeking funding approval. Funding cases are audited by members of the EFR / CPD team to ensure that the policy has been adhered to and reduce in appropriate activity.

Prior Approval [PA]	Where a CCG has published a policy setting out eligibility criteria. Clinicians, where they feel patients meet the criteria, must seek funding approval from the commissioners prior to treating. Applications are submitted by Clinicians and reviewed by administrators from the EFR / Referral Management team, where criteria is evidenced in full the CCG issued a reference code giving funding approval. Where funding approval is given, it is usually given for a term of 1 year and / or 1 intervention only. Repeated treatments require repeated applications.
Significant Functional Impairment	Significant functional impairment is defined by the BNSSG Health Community as - Symptoms preventing the patient fulfilling routine work or educational responsibilities - Symptoms preventing the patient carrying out routine domestic or carer activities This is a subjective criterion.

NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Commissioning Policy Review Group

Minutes of the meeting held on 8th March at 10am, via MS Teams.

Minutes

Present		
[redacted]	Chair, Independent GP for BNSSG CCG	[redacted]
[redacted]	Medical Director - Clinical Effectiveness for BNSSG CCG	[redacted]
[redacted]	Clinical Lead for BNSSG Referral Service and Remedy	[redacted]
[redacted]	Public Health Consultant	[redacted]
[redacted]	Commissioning & Planning Manager, UHBW	[redacted]
[redacted]	Commissioning Policy Development Manager, BNSSG CCG	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	Senior Clinical Effectiveness Programme Manager	[redacted]
[redacted]	Medical Director, UHBW	[redacted]
[redacted]	Senior Exceptional Funding Request Manager	[redacted]
[redacted]	Exceptional Funding Request Manager	[redacted]
Apologies		
[redacted]	Deputy Chair, GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	Clinical Lead for EFR and Policy Development	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	
[redacted]	Head of Primary Care Strategy, NB	[redacted]

	Item	Action
01	**Introductions and Welcome**	
02	**Apologies received from:** [redacted] noted that [redacted] is unwell and unable to attend the meeting. [redacted] noted that the intention for the meeting was for the group to go through the proposed policies for Infertility and Fertility Preservation. [redacted] noted that a	

	Item	Action
	discussion had taken place with the CPD team to decide whether the meeting should go ahead, given how instrumental [redacted] has been in the development of the policy. It was agreed that the discussion around the content of the policy should not proceed without [redacted]. However, [redacted] noted that there were issues around the financial implications of the policy that could be discussed by the group which could lead to recommendations to support and inform discussions at clinical exec. [redacted] indicated that, alongside a forensic review of the proposed policy, a period of discussion with providers would be required as proposed changes to the policies that could impact on tariff the CCG pays for fertility services. [redacted] suggested that the financial discussion cannot happen without an in-depth review of the policies. [redacted] suggested it was likely that in the process of reviewing the policies, changes could be proposed that would impact on the finances. [redacted] agreed and noted that there are two elements to financial discussions. The first would be the absolute impact on activity the proposed policies would have, the second would be how activity caused by a more equitable policy could be offset by other criterion within the policy. [redacted] suggested that, as a group, we could consider the mitigations at this point as the choice of mitigations outlined in the briefing appears to be quite straightforward. Any changes proposed during this discussion could be factored into the forensic review of the policy.	
03	[redacted]	
04	**Financial Implications** [redacted] provided an overview of conversations with the CCG's Chief Finance Officer, [redacted] made it clear that fertility expenditure had to remain with the current financial parameters. [redacted] noted that the proposed policies go a long way to equalising access to fertility services, and that there would be a cost to this. The policies would	

	Item	Action
	open fertility preservation to patients on non-cancer pathways, who were due to undergo treatment that is likely to have an adverse and irreversible impact on their fertility levels. The policy would also enable assessment and treatment for single women. Broadening the scope of the policy could lead to a cost increase of approximately £154,300. £60,300 of this would come from changes to fertility preservation, and the remaining £94k, would come from enabling single women to access assessment and treatment. Given [redacted] steer on financial thresholds, this increase in activity would need to be offset through the criteria of each policy. [redacted] noted that there are two equitable ways to limit activity and keep fertility expenditure within the current parameters. The first would be to remove fertility preservation for all patients, which could lead to an overall cost reduction of £117,250. The second would be to reduce the upper age limit of prospective mothers from 40 to 39 years of age. This could lead to a reduction in expenditure of £198k. [redacted] noted that the projected activity for single women were not likely to be completely reliable, as there are several variables which the CPD team will not be able to find out. These include the number of women with primary infertility, or those who do not want children. [redacted] also noted that number of women who would be impacted by a reduction in the upper age limit is also a projection based on recent activity levels. [redacted] noted that, in considering these changes, the policy would need to go back out for a period of Patient & Public Engagement which could last up to 12 weeks. [redacted] also noted that several CCG's already have reduced their upper age limit from 40 years for prospective mothers. [redacted] asked how [redacted] was able to get the projected activity data for single women. [redacted] advised that the Human Fertilisation and Embryology Authority (HFEA) provided figures on the number of single people who had received fertility treatment for 2019/20. [redacted] used these figures as a starting to point to get a proportion of the UK's population who register their marital status as single. [redacted] then took this figure and used local ONS and JSNA data to calculate the number of women who might be eligible based on age and relationship status. [redacted] noted a discrepancy between the briefing paper and [redacted] presentation. The briefing paper gave figures for women aged 38-40, while [redacted] discussed women aged 39-40. [redacted] apologised and confirmed that there was an error in the briefing paper, and that activity discussed related to women aged 39-40 years. [redacted] asked whether lowering the upper age limit would be enough to cover the cost of equalising access. [redacted] suggested it could be, however there was still a risk that activity for single women could be higher than the	

	Item	Action
	projections. [redacted] indicated that removing fertility preservation, while equitable, would be an unpopular and hard decision for the CCG to make. Given that lowering the age limit is in line with what certain other CCGs are doing, this move could be the preferred option. [redacted] noted that very few CCGs fund single people. [redacted] requested that CPD, IFR and RSS should meet to discuss the potential impact of allowing single people to access fertility assessment and treatment. **Action – [redacted] and [redacted] to discuss and arrange a meeting between the three teams.** [redacted] noted that local tariffs for fertility treatment are based on the management of couples. This would include assessment of male patients. The price of this tariff is agreed to ensure all provider costs of treatment are covered. Changing the policy would require a review of the tariff and could lead to a new pricing structure. [redacted] asked [redacted] for clarity around the cost implications, and whether fertility treatment would become more expensive for BNSSG CCG. [redacted] stated that a conversation with providers was needed to better understand the impact. [redacted] suggested that lowering the prospective age of the mother would be a backward step. [redacted] asked what proportion of CCG's had an upper age limit for prospective mothers lower than 40. [redacted] was concerned that BNSSG may become an outlier in this regard. [redacted] noted that the majority of CCG's still have an upper limit of 40. However, there are a significant minority of CCG's, many of whom are within BNSSG's peer group, who's upper age limit is under 40 years. **Action – [redacted] to provide the exact number of CCGs with an upper age limit younger than 40.** [redacted] questioned whether BNSSG would be a leader in healthcare, in terms of funding single people for fertility treatment, or would BNSSG be an outlier. [redacted] noted it would be positive if BNSSG were on the 'crest of a wave,' however being an outlier could have an impact on decision making. [redacted] noted that very few CCG's fund single people, and that in the review only 1 other CCG had been noted as funding single people for fertility treatment. **Action – [redacted] to provide the exact number of CCGs who fund single people for fertility treatment.** [redacted] not that there is an inequity between same sex couples and single people. Under the proposed policy, single people would meet criteria if they have not conceived after 2 years of regular unprotected sex – which does	

	Item	Action
	not sit right within a public health setting – or after 6 cycles of intrauterine insemination (IUI). Same sex couples would have to go through 6 cycles of IUI. Given cost pressures on same sex couples in this regard, there is a level inequity. [redacted] noted that [redacted] has suggested changing the proposed policy, to remove the criteria that single women can qualify for funding if they have had 2 years of regular unprotected sex without conceiving. This would equalise, to some extent, the criteria for single women and same sex couples. The group agreed that this issue should be discussed during the policy review at April's CPRG. [redacted] suggested that the CPD team ask CCGs around the country, whether their position on funding for fertility treatment for single people is likely to change. **Action – [redacted] to raise the question of future funding for single people for fertility treatment among other CCGs.** [redacted] noted that introducing single people, and single sex people into the policy was a way of respecting the individual. However, [redacted] noted that the policy could put heterosexual couples at a disadvantage as they are being asked to wait for two years before seeking funding for fertility treatment, while same sex couples and single people could be construed as 'jumping the queue.' [redacted] questioned whether single people and same sex couples should undergo 6 cycles and wait 2 years to bring them in line with heterosexual couples. [redacted] noted that this was considered and discussed by the CPD team during the review. This issue was discussed with fertility providers. The consensus was that the significant financial burdens of independently funded fertility treatment were deemed commensurate with the 2-year wait set out in policy for heterosexual couples. [redacted] questioned whether the criteria for single people and same sex couples, should be 6 cycles of IUI over 2 years to equalise access. [redacted] recognised that several points had been raised which needed to be discussed as part of the in-depth policy review. [redacted] noted that, regarding the financial implications of the policy, [redacted] had introduced issues around tariffs for fertility services that had not been factored into cost projections which could impact the decision making of the group. [redacted] suggested two approaches to moving forward with decision making around how the group should mitigate potential increases in cost for the CCG due to broadening the scope of the policy. The first was for the group to use the numbers provided by the CPD team, and propose an approach to 'balance the books'. [redacted] suggested that not making a decision because exact numbers were not available, was not a prudent course of action. This is because it is unlikely that the numbers for potential activity that the	

	Item	Action
	CPD team can collate will be completely accurate information. [redacted] suggested that the group uses the available data to propose a way forward, noting that ultimate decision around financial risk lay with clinical exec. [redacted] noted that different CCG's have different policies, and this will have been influenced to some degree by cost considerations. It was further noted that ST has given a clear steer that, in developing the new policies, the CCG must stay within the current budget. Therefore, the group needed to be mindful of that and work towards that goal. [redacted] asked the group whether it was sensible to use the data available to make a recommendation with caveats around the financial implications. [redacted] was uncomfortable making a decision based on the available data. [redacted] noted that he was uncomfortable reducing the upper age limit for prospective mothers from 40 to 39 years of age. [redacted] asked for more clarity on where CCGs around the country sit in terms of their upper age limit. [redacted] also expressed concern over the potential for BNSSG to be an outlier in the commissioning of fertility treatment for single women. [redacted] asked for clarity around existing commissioning arrangements for single women from CCGs around the country **Action – [redacted] to provide an overview of the number of CCGs currently funding single people.** **Action – [redacted] to reach out to CCGs to find out whether their position for the funding of single people is likely to change, and how.** [redacted] asked whether we should look at the question of lowering the upper age limit for prospective mothers from a value perspective. [redacted] noted that the success rate of fertility treatment for women aged 40 was much lower than women aged under 40. [redacted] emphasised that fertility levels do not suddenly diminish when a woman reaches 40, rather they drop off from the age of 38. One could argue that, as the success rates reduce from the age of 38, the decision to reduce the upper age limit should be made on the basis of value, rather than a decision based purely on equity. [redacted] asked if the group had data on the success rates for fertility treatment based on age. [redacted] noted that a study had been cited previously with this data. The group agreed it would be useful to have this data circulated again. **Action – [redacted] to circulate research paper with data on success rates of fertility treatment by age.** [redacted] agreed that framing the discussion around lowering the upper age limit within the sphere of value was a sensible approach. [redacted] noted that there were three options in terms of balancing the books.	

	Item	Action
	The first was to not fund fertility preservation, the second was to not fund single people for assessment and treatment of infertility which would be inequitable, or to reduce the age of the prospective mother. Based on the available data, which [redacted] recognised could be tightened up, [redacted] proposal was that the upper age limit should be reduced to 39 years, noting that this should cover the cost of including single women within the fertility policy. [redacted] further proposed that close monitoring of activity should continue for up to a year until a true sense of activity is clear. [redacted] agreed that this was likely to be a rational solution. [redacted] noted that the IFR team have a good tranche of data around the number of women applying for funding of fertility treatment by age. [redacted] asked if [redacted] could share this with the CPD team. **Action – [redacted] to share data on the number of women applying for NHS funded fertility treatment with the CPD team.** [redacted] also noted that fertility consultants are reluctant to offer IUI to patients over the age of 38 due to the low success rate. [redacted] asked whether this should be factored into the policy. [redacted] agreed this was a good idea that should be further explored; however, this would increase the complexity of the issue. [redacted] asked whether the CCG would be open to challenge given NICE guidance states that women up to 40 years of age should be offered IVF. [redacted] responded that this was guidance and not law. [redacted] reflected on his experience in develop NICE guidance and noted that it is up to commissioning organisations to decide how they implement the guidance. Therefore, it is unlikely BNSSG CCG would be challenged on this basis. [redacted] asked if the CPD team received challenges or complaints around the upper age limit. [redacted] noted that there are subtle differences in success rates for fertility treatment across women over the age of 38. On the basis of value, [redacted] challenged whether the emotive nature of the fertility policy had overtaken the value discussion. [redacted] wanted to know whether the team had access to complaints about the fertility policy across various age groups. [redacted] noted that the team did not have this information currently, and that complaints around the fertility policy – received by the CPD team – pertained to fertility preservation. [redacted] suggested he work with [redacted] and providers to better understand the complaints they receive. [redacted] suggested that group make a decision, and that the group try to come to a consensus on the proposal. [redacted] clarified that the proposal is that the CCG reduces the upper age limit for prospective mothers from 40 to 39 years of age. Based on the numbers currently proposed by the CPD team, this reduction in activity should cover the costs of changes to the fertility policy and the fertility preservation policy.	

	Item	Action
	[redacted] recognised that there are several financial issues that could not be quantified presently. [redacted] reiterated [redacted] point that we will not have a true picture of activity until we implement the policy. [redacted] agreed that lowering the age would on of the least controversial ways of mitigating costs related to broadening the scope of the policy. [redacted] asked if the group felt that lowering the upper age limit would be equitable. [redacted] raised a concern that there would be a transition period required, given that patients and GPs are used to the current age limit of 40 years. [redacted] warned that this could lead to people being refused funding for treatment, where they had expected to qualify for funding. [redacted] noted that around 25% of applications for fertility funding came from patients who were 38 years or over. [redacted] noted that the number of patients this translated to, was close to the projections given in the briefing paper. [redacted] noted that the group were being asked to balance different equities. For instance, lowering the upper age limit would be unfair to patients who were 40 years of age. Limiting treatment to an age group is ostensibly unfair. However, the value argument could help the CCG make a difficult choice. [redacted] asked the group to consider the proposal in light of the CCG's ethical framework for decision making. The group agreed it was a rational decision. [redacted] asked that up-to-date evidence is circulated ahead of the next meeting. This is unlikely to change the proposal and decision. [redacted] asked if the decision was inclusive, and whether the group agreed it was being made following a non-discriminatory process. The group were happy that this was an inclusive policy. The group agreed that the decision was based on value, and that this element of the ethical framework had been central to the discussion of the policy. [redacted] noted that the discussion had been open and honest, with minutes that would be published. Therefore the group agreed the decision was transparent and open to scrutiny. [redacted] noted that this would need to go out to consultation again, however the scale of this consultation has yet to be agreed with the CCG's PPI lead. The group agreed that the principle of promoting health for individuals and the community was not relevant to this policy. [redacted] recognised that certain members of the group had significant reservation around the proposal but asked that the group now try and	

	Item	Action
	reach a consensus. [redacted] asked if the group agreed with the proposal and encouraged people who do not agree to raise their concerns. [redacted] further clarified the proposal for the group. [redacted] asked that people register their decision to agree or disagree with the proposal in the meeting chat to enable a formal count. The decision to support the proposal was unanimously agreed. [redacted] thanks the group for their engagement and noted that the full review of the proposed fertility policies will need to be deferred until April's CPRG meeting. [redacted] noted that the April is likely to be quite long, as there are several commissioning policies that will require discussion at that meeting. [redacted] reminded the group of the question of equity around same sex couples and single people requiring 6 cycles of IUI, and how this could enable them to get have fertility treatment quicker than heterosexual couples who need to wait 2 years for fertility treatment. [redacted] asked that the CPD team try and clarify the timeframe for completing 6 cycles of IUI. **Action – [redacted] to discuss timeframes for IUI with fertility specialists.** [redacted] noted the issue of patient and public involvement and asked that the terms of reference for this engagement were brought to April's CPRG. [redacted] noted he was in discussions with the PPI lead and comms and work to have a briefing on this by the next meeting. **Action – [redacted] to clarify the process for engagement.**	
	[redacted] [redacted]	

Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Briefing Paper for Commissioning Policy Review Group (CPRG) Meeting

Date: 8th March 2022

Title: Commissioning Policy Review Group (CPRG) Briefing Paper

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Purpose

The aim of this paper is to provide an overview of the outcomes and outputs of the policy review process for the CCG's commissioning policies on Fertility Preservation and Infertility – Assessment & Treatment. This paper aims to support the CPRG to:

- Review the commissioning policies that have been reviewed
- Make decisions on whether to recommend a reviewed commissioning policy to BNSSG CCG's Clinical Executive Committee for adoption or removal

The outputs described in this paper include an Equality Impact Assessment (EIA), a Quality Impact Assessment (QIA), Public & Patient Involvement plan (PPI) and the likely financial impact of adopting the recommendations of the Commissioning Policy Development (CPD) team.

The paper also provides an overview of CPRG's previous discussions on some of the ethical implications of key changes to the CCG's commissioning policies for infertility and fertility preservation.

Reasons for commissioning policy review

There are five reasons that policies are reviewed:

- **Three year review** – Each commissioning policy has a review date which is set at three years from the date of adoption.

- **NHS England's Evidence Based Intervention Guidance for CCGs (NHSE EBI)** The aim of this program is to prevent avoidable harm to patients, avoid unnecessary operations, and free up clinical time by only offering interventions on the NHS that are evidence-based and appropriate. CCG's are required to pay due regard to this work in the formatting of commissioning policies.

- **Removal of criteria considered to be a Significant Functional Impairment (SFI)** – The CCG's Governing body has advised that, for exceptional funding requests, exceptionality should be based on clinical factors only, in line with other CCGs and NHS England. Non clinical factors, frequently referred to as 'Significant Functional Impairment', affecting a person will not be considered. This ensures

that decisions are objectively and avoids judgement of an individual's relative worth.

- **New information –** A policy will be reviewed if the CCG receives new and relevant information or significant feedback on a policy once it has been adopted that would necessitate a review.

- **Admin Changes -** Policies can be updated when clerical details need updating in line with organisational changes. This does not constitute a formal policy review but requires sign off from CPRG in line with the CCG's governance protocols.

The policies described in this paper will have been reviewed for at least one of the above reasons.

Our approach to health inequalities

The CCG defines health inequalities as unjust and avoidable differences in people's health across the population and between specific population groups.

Health inequalities are socially determined by circumstances largely beyond an individual's control. Health inequalities are not random and do not happen by chance.

The CCG recognises the importance of understanding and recognising the impact of its commissioning policies on health inequalities.

Recommendations made to CPRG by the Commissioning Policy Development (CPD) team.

This section gives further detail about each policy's review including the date a policy was adopted, the reason for the review, the clinical teams involved in the review and an overview of equality and quality assessments. An assessment of likely commissioner spend because of policy adoption, is also provided.

Table 1 summarises the policies that have been reviewed and the recommendation being made by the CPD team to CPRG.

Table 1. Policy, review reason and the recommendation

Policy	Reason for review	Recommendation to CPRG
Infertility – Assessment & Treatment	Three Year Review	Recommend adoption to Clinical Executive Committee
Fertility Preservation	New Policy	Recommend adoption to Clinical Executive Committee

Cost Considerations

The CPD team have been advised that CCG expenditure for fertility preservation and infertility assessment and treatment, must not lead to increased costs for the CCG.

The proposed policy would, if adopted, broaden the scope of the policy to include single people could cost around £72,312. This is the maximum amount of expected expenditure.

The proposed Fertility Preservation policy would also broaden access and lead to a smaller increase in activity and expenditure.

To equalise access within the proposed policies, criteria will need to be adapted to offset any increased activity, and in a way that does not unlawfully or irrationally discriminate on the basis of protected characteristics.

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. Using activity data from 2019/20 as a guide, data from the CCG's contracts team indicates that removing fertility preservation could lead to a reduction in expenditure of £123,950 for the CCG.

The second potential mitigation is to reduce the upper age limit for the prospective mothers from 40 years of age to 39. Currently thr

ee of BNSSG's peer CCGs have an upper age limit of 39.

Lowering the upper age limit of the prospective mother to 38 years of age could lead to a reduction in expenditure of £198,400. To fully understand the financial impact, more work needs to be done to understand the breakdown of current BNSSG activity by age and gender.

The CPD already have a good understanding of the likely cost savings associated with removing fertility preservation. However, until further work is completed projections for savings connected to a reduction in patient age will not be as preces as Clinical Executive may require to make an informed decision.

Infertility – Assessment & Treatment

Adopted 1st December 2017

The CPD team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), North Bristol Trust (NBT) and University Hospitals of Bristol and Weston (UHBW) in the development of this policy.

The revised policy is clear that its purpose 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 be managed under a separate policy. This is discussed further 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 to heterosexual and same sex couples.

Under the revised policy, single people will be eligible for assessment 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 unstimulated cycles of HFEA approved donor insemination.

Under this policy, single women will be able to access fertility assessment treatment provided they satisfy the criteria set out within policy.

Single men will be able to receive assessment for infertility. There are limited treatment options for single men with infertility. Most of these treatments are funded by NHS England. BNSSG CCG does not currently fund, or part fund, any interventions to resolve infertility in single men. Treatment for single men is 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 partly due to the challenges of consistently registering a Body Mass Index (BMI) from the prospective father, and the lack of evidence for its adverse impact on the 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 can place significant financial pressure on a couple. Given the apparent lack of parity within the criteria for heterosexual couples and same sex couples, the CCG is open to complaints from the public and legal challenge 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 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. This was

further echoed in clinical evidence which indicated that very few women would require more than 6 cycles of unstimulated IUI in order to conceive.

Evidence from The Human Fertilisation and Embryology Authority (HFEA) indicates pregnancy rate for a stimulated cycle of IUI is 17%. The success rate for an unstimulated cycle is 16%. The HFEA indicate 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, 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 for same sex female couples

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.

EIA

Equality impact assessment has been completed and signed off.

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. The proposed policy has an upper age limit for women of 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%.

Due to the evidence of effectiveness of IVF for women over 40 years, it has been determined that the upper age limit of the policy should not be increased. To make best use of resources, this policy is intended to support those people with the best chance of conceiving with assistance.

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.

QIA

Quality impact assessment has been completed and is awaiting sign off.

PPI

PPI assessment has been completed and is awaiting sign off.

Financial Impact

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.

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. According HFEA data, the number of single women accessing IVF treatment has steadily increased over the last 5 years. However, this data does not indicate if the decision to undergo IVF treatment was a result of a lifestyle choice or infertility. It is therefore difficult to make an accurate projection of the likely financial impact.

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).

It is worth noting that in 2019/20, the number of heterosexual couples that were funded for fertility treatment by BNSSG CCG, was 290. This constitutes less than 1% of BNSSG's total population of couples in either a marriage or civil partnership.

ONS data indicates that, across BNSSG, there are 273,448 people who register their marital status as single. While this is not broken down by age, data from local councils indicates that 170,375 of BNSSG's total female population would meet the age criteria in the proposed policy. Assuming local activity follows national trends, and that less than 1% of the total female population of BNSSG who meet the proposed age criteria seek referral, proposed changes to the policy could lead to an increase in fertility activity of up to 30 referrals per year, and an overall increase in fertility spend of at least £94,320. Fertility expenditure for the CCG in 19/20 was £993,177.

HFEA research indicates that most single people access fertility treatment in their 30's. Given this, it is possible that the number of single women seeking treatment for infertility could be less than estimated above.

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.

It is also unclear how many lone parent families there are across BNSSG. In 2020, there were estimated to be 197 lone parent families across BNSSG. However, this data is likely to have changed in the interim. The number of lone parent families is likely to have an impact on the number of people seeking infertility treatment.

Given the limitations in the data, it is reasonable to take national data as a guide for understanding local demand. The CPD team, however, will work with the CCG's contracts team and BI to establish a means of monitoring this data.

As noted, there are several conditions that have been added to the criteria for heterosexual couples. There is currently no data to indicate how this might impact activity, the consensus among clinicians involved in this review is that the cohort will be small, however the CPD team will work the CCG's BI team to establish a means of monitoring this data.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Fertility Preservation

New Policy

The commissioning policy team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), North Bristol Trust (NBT), University Hospitals of Bristol and Weston (UHBW) and pharmacists from the CCG's medicines optimisation team.

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 that might compromise fertility.

There is provision within BNSSG CCG's current fertility policy for patients who are to receive oncology treatment that is likely to compromise their fertility.

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 CCG'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 CCG 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 CCG does have discretion to fund gamete preservation for clinical reasons supported by evidence.

The proposed policy for fertility preservation, will 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 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.

It is recognized that there are some surgical interventions that 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.

EIA

Equality impact assessment has been completed and has been signed off.

This policy preserves the potential for transgender people, who are in the process of transitioning, to conceive later in life. This goes some in way in addressing an element of existing CCG provision for fertility preservation that was discriminatory, by establishing a clear rationale based on clinical evidence.

QIA

Quality impact assessment has been completed and is awaiting sign off.

PPI

PPI assessment has been completed and is awaiting sign off.

Financial Impact

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. 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.

The CCG 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 CCG 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 – as expected – the CCG could see an increase of £16,750 per year.

For 2019/20, the CCG spent £117,250 on fertility preservation. The proposed policy could lead to an increase in this figure of £60,300.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Appendices

Appendix 1 – Ethical Implications of Proposed Policy
Appendix 2 – Cost Mitigations

Appendix 1
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 2 – Cost Implications

The policies presented have been drafted to equalise access to infertility assessment and treatment. Single men and women could be eligible for assessment of infertility within the new policy, and single women could be eligible for treatment of infertility provided they meet the rest of the criteria.

The proposed policy for Fertility Preservation provides support for patients who will undergo NHS commissioned treatments that will remove their potential to conceive. This will address elements of the existing policy that are discriminatory.

The CPD team have been advised that CCG expenditure for fertility preservation and

infertility assessment and treatment, must remain within the current financial envelope. That is to say, the policy must not lead to increased costs for the CCG.

Noted in the following sections are the potential financial implications for adopting the policy with these proposed changes.

Broadening the scope of the policy to include single people could cost around £94,000. It should be noted that this is the maximum amount of expected expenditure. It should further be noted that, due to a lack of certain patient level information, the CPD team cannot make an accurate projection for the likely increase in activity.

Given the direction from the CCG's executives, in order to equalise access certain areas of the proposed policies will need to be adapted to offset increased activity. This will have to be done in a way that does not unlawfully or irrationally discriminate on the basis of protected characteristics. There are two elements of policy that could be adjusted to 'fairly' offset the impact of equalising access.

CPRG are asked to consider these mitigations and indicate a preferred approach to cost containment.

Age of Prospective Mother

There is clinical and commissioning precedent for lowering the age of the prospective mother. Lowering the age of the prospective mother would recognise the reduction in fertility levels for women associated with age.

The upper age limit within the CCG's existing fertility policy is 40 years. Currently three of BNSSG's peer CCGs have an upper age limit of 39. Another of BNSSG's peer CCGs has an upper age limit of 35. It should also be noted that this age limit reflected in the commissioning policies of a number of CCGs across England. The HFEA are clear that, from the age of 38, women are more likely to require fertility treatment.

According to data from the Office of National Statistics (ONS), across BNSSG there will be approximately 12922 aged 38-40 years in the region from March 2022. In 2019/20, the number of heterosexual couples that were funded for fertility treatment by BNSSG CCG, was 290. This constitutes less than 1% (roughly 0.5%) of BNSSG's total population of couples in either a marriage or civil partnership.

Assuming activity follows these levels and less 1% of women require assessment for infertility, lowering the age limit to women aged 38 years could mean that 64 fewer women would seek referral for assessment.

BNSSG CCG currently pays £3,100 per cycle of IVF. Lowering the upper age limit of the prospective mother to 38 years of age could lead to a reduction in expenditure of £198,400. In order to fully understand the financial impact, more work needs to be done by the CPD team to understand the breakdown of activity by age and gender. These data sets are not currently available to the CPD team, however progress is being made to build them.

Fertility Preservation
There is no legal requirement for the CCG to fund fertility preservation. The central requirement is that, should fertility preservation be funded for one cohort of patients, it commissions fertility preservation fairly, basing its decision to fund on clinical evidence and in line with local ethical framework.

Removing fertility preservation from the policy would mean that the CCG effectively removes the potential for any patient undergoing treatment that can compromise fertility to receive NHS funded assisted conception.

The CCG's fertility spend would reduce slightly. The number of patients funded for fertility preservation in 19/20 was 37. Data from 2020/21 is unlikely to provide an accurate account of need across BNSSG due to the impact of Covid-19 on referrals to fertility services. Therefore, the assumption should be that the CCG could save £123,950 in 22/3 should it remove fertility preservation from its policy.

Glossary

Clinical Policy Review Group (CPRG)	Clinical Policy Review Group (CPRG) - quarterly meeting coordinated by the Commissioning Policy Development Team in order to clinical review / update existing policies against new NICE guidelines and other developments. CPRG also clinically evaluates new policies identified. The of this group is to make recommendations to the Commissioning Executive in regard to Commissioning Policies to adopt on behalf of BNSSG.
Evidence Based Interventions Programme (EBI)	The Evidence-Based Interventions Programme was established and developed as a joint enterprise between five national partners: the Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence as well as NHS England and Improvement. The programme focuses on 17 interventions that fall into this category. Four interventions that should not be routinely offered to patients unless there are clinically exceptional circumstances, and 13 interventions that should only be offered to patients when certain clinical criteria are met.

Due Regard	NHS England has advised that each CCG must evidence it has paid Due Regard to the recommendations made through the EBI Programme, and details of this recorded.
Exceptional Funding Request [EFR]	Where a CCG has published a policy stating that certain treatments are not routinely funded, or no commissioning policy exists. Treatment will only be funded via agreement from commissioners in exceptional circumstance.
Criteria Based Access [CBA]	Where a CCG has published a policy setting out eligibility criteria. If clinicians are content that the patient meets the criteria, they may proceed to treat without seeking funding approval. Funding cases are audited by members of the EFR / CPD team to ensure that the policy has been adhered to and reduce in appropriate activity.
Prior Approval [PA]	Where a CCG has published a policy setting out eligibility criteria. Clinicians, where they feel patients meet the criteria, must seek funding approval from the commissioners prior to treating. Applications are submitted by Clinicians and reviewed by administrators from the EFR / Referral Management team, where criteria is evidenced in full the CCG issued a reference code giving funding approval. Where funding approval is given, it is usually given for a term of 1 year and / or 1 intervention only. Repeated treatments require repeated applications.
Significant Functional Impairment	Significant functional impairment is defined by the BNSSG Health Community as - Symptoms preventing the patient fulfilling routine work or educational responsibilities - Symptoms preventing the patient carrying out routine domestic or carer activities This is a subjective criterion.

NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Commissioning Policy Review Group

Minutes of the meeting held on 17th May at 9am, via MS Teams.

Minutes

Present		
[redacted]	Chair, Independent Clinician for BNSSG CCG	[redacted]
[redacted]	Clinical Lead for Policy Development	[redacted]
[redacted]	Clinical Lead for BNSSG Referral Service and Remedy	[redacted]
[redacted]	Public Health Consultant	[redacted]
[redacted]	Exceptional Funding Manager, BNSSG CCG	[redacted]
[redacted]	Commissioning & Planning Manager, UHBW	[redacted]
[redacted]	Commissioning Policy Development Manager, BNSSG CCG	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	[redacted]
[redacted]	Commissioning Policy Development Support Officer, BNSSGCCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	GP Clinical Lead, BNSSG CCG	[redacted]
[redacted]	Medical Director, UHBW	[redacted]
[redacted]	Senior Referral Service Administrator (Observing)	[redacted]
Apologies		
[redacted]	Medical Director - Clinical Effectiveness for BNSSG CCG	[redacted]
[redacted]	Senior Exceptional Funding Request Manager	[redacted]
[redacted]	Deputy Chief Medical Officer, NBT	[redacted]

	Item	Action
01	**Introductions and Welcome**	
02	**Apologies received from:** [redacted]	
03	**Declarations of interest** None noted.	
04	[redacted]	
05	[redacted]	
06	[redacted]	
07	[redacted]	

	Item	Action
	[redacted]	
09	[redacted]	
10	[redacted]	
11	[redacted]	

	Item	Action
12	[redacted]	

	Item	Action
	[redacted]	
13	[redacted]	

	Item	Action
	[redacted]	
14	[redacted]	
15	[redacted]	
16	[redacted]	

	Item	Action
	[redacted]	
17	[redacted]	
18	[redacted]	

	Item	Action
	[redacted]	
19	[redacted]	
20	[redacted]	
21	**Item: Infertility – Assessment & Treatment** [redacted] gave a brief background on development of this policy, with particular focus on previous discussions held by the group. [redacted] stated that, if needed, the BNSSG CCG ethical framework could be used to assist with decision making. [redacted] then explained the review had started 2 years ago when the Chief Executive was keen that a full review was carried out due to some areas of inequity and consistency within the policy which needed to be addressed. [redacted] noted that there were areas of the current policy that were inequitable, in particular the provision for fertility preservation [redacted] emphasised, that the intention of the new policies was to fund assessment and treatment for	

	Item	Action
	infertility based on need. [redacted] noted that, although commissioning as per the NICE guidance could be the ideal scenario, this would not be realistic in terms of what is affordable for BNSSGG. Following discussions with the CCG's chief finance officer, it was clear that the any changes to the policy must not increase expenditure. Therefore, any changes to the policy that would broaden access and increase activity, would need to be mitigated within the policy. [redacted] noted the considerable amount of patient and public consultation consultation that has taken place around this policy. The outcomes have helped the CPD team identify areas within the current policy that are a priority for change. Providers have also been engaged throughout the policy and understand the challenges faced by the CCG in developing a more equitable policy that is cost neutral. They have been helpful in making adjustments to the policy, and ensuring the appropriate compromises are made. [redacted] recognised the work that CPRG has done to guide the development of the policy. With regard to the current draft of the policy, [redacted] noted that the biggest change from the previous CPRG meeting, was that the upper age limit for prospective mothers has been lowered from 40 to 39 years. This has been done to offset the potential increase in activity, broadening access to fertility treatment will have. This will cause some inequity for current patients who are being managed under the current policy. [redacted] suggested that a transition period would be appropriate to ensure patients currently being managed under the policy will not be barred from treatment when the policy changes. [redacted] explained the intended outcome for the meeting is to sign off on both policies, and recommend them for clinical executive. [redacted] then asked the group to start by going through page at a time. [redacted] agreed with this approach. **<u>Infertility & Treatment Policy Discussion</u>** [redacted] asked for feedback on the first page, no issues were raised by the group. [redacted] stated that the document did not flow through well in her opinion and that there were issues with consistency. [redacted] requested we dealt with this as we go through the pages, [redacted] agreed.	

	Item	Action
	General Principles [redacted] asked for any comments on Page 2 and 3, Section 8, the general principles for all patients. There were no comments from the group. **Section B** [redacted] asked for comments on section B of the policy. [redacted] discussed, whether this section only covered heterosexuals and asked the group if this needed more clarity. [redacted] explained it was initially drafted to cover heterosexual couples, however much of the criteria would also cover single women. [redacted] stated that it is wider than that as this covers the six cycles of Intrauterine insemination (IUI). [redacted] asked if the criteria for not conceiving after 2 years of regular unprotected sex would apply to single women. [redacted] noted that this could apply. [redacted] indicated that at the previous meeting the group had provisionally expressed their desire to remove criteria for single women due to the issues around sexual health. [redacted] agreed but stated that there were issues around relationships status that could make this criteria too complex for clinicians and patients. [redacted] asked [redacted] about other CCG criteria on this with single women. [redacted] stated that the criteria for 6 cycles did match the majority of other CCGs where single women were funded, but the criteria for unprotected sex part did not. The group were asked to vote on whether the criteria of not conceiving after 2 years of regular unprotected sex, should apply to single women as well as heterosexual women. [redacted] raised the issue of IUI, and whether single sex couples or single women. [redacted] questioned whether 6 cycles of IUI could be completed before the 2 year period that heterosexual couples would need to complete under the proposed policy. [redacted] stated that local fertility specialists had indicated that 6 cycles of IUI could, on average, take 18 months. [redacted] was satisfied that the timeframes were similar, noting that the 2-year period can be a distressing time for patients as they wait for specialist assessment. [redacted] asked for clarity around the criteria for heterosexual couples and same couples. [redacted] asked whether same sex couples would need to undergo 6 cycles of IUI before seeking referral. [redacted] confirmed they would. [redacted] asked	

	Item	Action
	if the policy was stating that heterosexual couples would need to access 6 cycles of independently funded IUI and/2 years of regular unprotected sex as a criteria for assessment. [redacted] explained that very few heterosexual couples are likely to use IUI and stated, however it could be used as part of a treatment which may be NHS funded, but not as a demonstration of infertility. Therefore, heterosexual couples would not need satisfy both elements of the criteria, and the likely proxy is 2 years of unprotected sex without conceiving. [redacted] suggested that wording of the policy is amended to reflect that independently funded IUI must be tried before referral for assessment can be sought. [redacted] state that there was more clarity for heterosexual couples, given that if the male partner has oligospermia or azoospermia, they don't have to go through privately funded IUI. [redacted] asked whether this constituted a definition it is infertility at that point? [redacted] said it was and that this criteria had been better defined. Previously, azoospermia was defined as no sperm. It is now agreed that when the sperm count is the less than 1,000,000 per ml the likelihood of fertility is incredibly low. [redacted] asked if that was the only parameter that the fertility services think is relevant in terms of male fertility, and whether within semen analysis, issues such as motility are considered more or less important. [redacted] stated that these issues are much harder to define, however, there might be an exceptional funding request, if there was a different combination that wanted to be looked at. [redacted] asked if that would be considered in individual circumstances if there was, for example, a count that was above 1,000,000 but very low poor motility or poor levels of normal forms or something like that. Then asked if there was any guidance around what levels would significantly affect fertility. [redacted] indicated that each case must be taken on merit. [redacted] returned to [redacted] point, and asked the group to vote on proposed changes to criteria for single individuals. The group were asked to vote on whether the criteria for single women should include unprotected sex for two years.	

	Item	Action
	[redacted] asked if that could that be viewed as discrimination because a person might be making a moral judgment upon single women. [redacted] indicated that there are potential inequities in the criteria. A person cannot prove that they are having regular unprotected sex. This could be discriminatory against same sex couples where there is no male partner but they must have 6 cycles of independently funded IUI. [redacted] asked how this inequity could be balanced. [redacted] also discussed the complexities of different relationship status. For instance, a woman who is in a relationship with another woman but is also having sex with a man because she's in a Poly relationship. [redacted] noted that this could become a very complicated process for primary care, who will need to understand and explore the nuances of sexuality and relationships. [redacted] added that the criteria of the policy encourages some women to then go out and have unprotected sex. This is a concern from a sexual health perspective. [redacted] moved the group to vote on [redacted] amendment. The amendment to the policy would be to remove the proxy of 2 years regular unprotected sex without conceiving, from the criteria for single women. The group voted as follows: 2 For the proposed change 4 To keep the same criteria 2 Abstained [redacted] Asked this was recorded properly in the minutes. [redacted] then reminded the group that male BMI has come out of policy. [redacted] raised the point in the policy that states prospective parents must be registered with a BNSSG GP. [redacted] noted there may be circumstances where patients live on the boundaries of BNSSG CCG who may be registered in GP practices that those cross boundaries. [redacted] explained patients must decide the commissioner to which they are applying for funding. Presently, BNSSG CCG is one of the few CCG's which has the option for only one of the parents to be registered with a BNSSG practice within the policy. As a result, the CCG has had to pick up commissioning costs for patients in the situation [redacted] has described. For instance, where the male partner is registered with BNSSG CCG GP but the prospective mother is not. This is about resolving a commissioning	

	Item	Action
	inequity. [redacted] explained that there are situations where couples don't necessarily live together and live in different parts of the country. [redacted] agreed but noted that if GP's believe their patients when they tell them they are having regular unprotected sex, they must believe them on that issue too. [redacted] enquired about situations where a GP doesn't want to take the patient, because they are out of area for example 80 miles. [redacted] explained that out of area is not an issue in the current climate. However, [redacted] recognised there might be situations of reasonableness which can be looked at. [redacted] asked for clarity on whether someone who is 39 but smokes can be referred. [redacted] said that patients can be referred, and should also be referred to a smoking cessation service. If the individual who smokes has not stopped smoking by the time they are seen by the fertility service, they maybe refused assessment or treatment [redacted] Asked if it should be worth clarifying on the policy to make it clear as it seems ambiguous to me. **Action –[redacted] to update the wording around smoking cessation.** **<u>Section C</u>** [redacted] asked the group for comments [redacted] stated that the criteria in this section is worded is very differently from those dealing with single women and heterosexual couples. In particular around the phrase 'NHS funding is not available for access to donor insemination facilities for fertile women.' [redacted] asked for clarity on this point. [redacted] noted that this was to stress that both individuals must have fertility issues, and that should one partner be fertile they should try to conceive before accessing the service. [redacted] explained that this was to clarify if one partner has received assessment and treatment, including a fresh and frozen cycle, which fails the other partner does not become eligible and they can't be considered as a single individual. [redacted] discussed miscarriage, noting his concern would likely apply to heterosexual and same sex couples. [redacted] noted that the Referral Service see referrals for couples who have been trying to conceive for two years, but have had a miscarriage within that period. [redacted] indicated that there is	

	Item	Action
	confusion whether that's infertility because, if they've conceived, that's not infertility, that's a miscarriage. However, [redacted] believes it can be very distressing for those for those individuals or couples who have had a miscarriage and otherwise failed to conceive over 2 year period are told that they must return to the start of the 2 year period. This puts GPs in difficult positions [redacted] Explained that the point was covered in that way as part of the NICE guidance. [redacted] stated the need to manage that expectation, and make it clear within Remedy. **Action – [redacted] to ensure guidance for GPs over the clock restarting following miscarriage is added to Remedy.** **<u>Single Women Criteria Based Section</u>** The group had no further comments. **<u>Assisted Conception Prior Approval</u>** [redacted] noted that this section moves on from the GP to the fertility service and covers section D and Section E. [redacted] asked if this section had been changed from the current policy. [redacted] advised that there small minute changes had been made, but this was purely to ensure the guidance fits with the latest from HFEA. The group had no further comments. **<u>Section F and G</u>** [redacted] explained that sections F and G, where the criteria for sperm washing for patients with a positive HIV diagnosis is set out, were discussed with [redacted] from NBT. [redacted] is the local lead HIV specialist and is very supportive of this wording. The group had no further comments. **<u>Section H and I</u>** [redacted] noted the discussions within CPRG around surrogacy. [redacted] noted the complexities in trying to part fund a pathway, and the group's decision that part funding a pathway was not a viable option. Currently, funding any part of a surrogacy pathway isn't supported by the CCG. This does leave	

	Item	Action
	some causes of infertility, so a woman born without a womb will have no options. [redacted] asked if a patient in that circumstance would get funding through exceptional funding. [redacted] indicated that there are multiple situations where surrogacy could be appropriate, so the likelihood of having exceptionality to fund surrogacy unlikely. [redacted]Asked if anywhere else in the country funds surrogacy. [redacted] indicated that only one CCG funds some elements of the surrogacy pathway, but it's only one, so we're not out of step. [redacted] asked where exceptional funding request in that basis would be considered. [redacted] explained that there's a significant cohort of women who could benefit from surrogacy. So, an individual being exceptional within that cohort is extremely unlikely. [redacted] noted that the proposed policy says the 'the CCG does not routinely fund surrogacy.' This is likely to cause confusion. [redacted] asked if this should be removed. [redacted] asked the group to show any objections to removing the word 'routinely' from the statement on surrogacy. The group had no objections. **Action – [redacted] remove the word routinely from this section.** [redacted] asked for any further comments. [redacted] noted that the group had made some decisions without needing to useh the ethical framework in great detail, and asked [redacted] if we now ask the group to approve this policy with the agreed changes. [redacted] agreed that this was appropriate. [redacted] asked the eligible to voters of the group to raise their hand if they were happy to recommend this policy to clinical exec? [redacted] noted there were five votes to recommend which was a majority among the voting members. . [redacted] asked if anyone was not happy to recommend the policy to clinical	

	Item	Action
	exec. [redacted] stated that within the ethical framework sets out a means for building consensus. [redacted] noted that there are different ways to register one's position on the policy which may not be to completely agree with the decision of the group, but to go along with the majority. [redacted] agreed this was the case and asked the group if people that hadn't voted could acknowledge they're happy to go along with the majority. [redacted] stated that she was happy with it, but emphasised her reservations made earlier. [redacted] asked if this would go out to consultation. [redacted] explained that consultation had already happened, and that the final policy was the CCG's response to it. [redacted] returned to [redacted] point about building consensus within the ethical framework. The framework notes that in building consensus there are several ways a person can register their decision. Essentially these are: • Agreement • Agree with reservations but still support the decision • Stand aside because you can't support the proposal, but you don't want to stop the group • Block the proposal with a fundamental disagreement. [redacted] confirmed that no one was intending to black the decision to reccoment the policy to clinical or, nor was anyone standing aside. [redacted] noted that some members of the group had reservations but asked if they will support the decision. No members of the group blocked the decision to progress the policy to clinical exec. One member of the group agreed with reservations. **Decision – Recommend approval of policy, with revised wording, to Clinical Exec.**	
22	**Item: Fertility Preservation** [redacted] gave a brief background of the review of this policy. [redacted] stated the current policy was not fit for purpose and was discriminatory. The inequity comes from the position to only funded treatment for patients receiving oncology treatments, that are likely to compromise their fertility. It's clear	

	Item	Action
	that there are several other treatments, either using the same drugs, other drugs or some procedures which lead to individuals being in the same situation. Through consultation it was clear that that we needed to widen the net, to include patients undergoing surgical treatments and medical treatments, which were very like to compromise fertility. [redacted] note that this issue was discussed by the group previously, and it was clear that there was support for broadening the scope of the policy. The question to consider is whether the current draft, addresses the issues. [redacted] noted that during the review, the team had engaged with dermatology, rheumatology, renal, liver particularly transplantation, gastroenterology, and respiratory around the issue of medication they use, where there is no clear alternative, and will have an adverse long term impact on an individual's fertility. The main drug that seem to apply is cyclophosphamide. However, the draft policy notes that if clinicians feel there is a different drug they are working with which is likely to compromise fertility, the CCG would consider it and take it based on the evidence available. The CCG's medicines management team are very supportive of this approach and have also been involved in those discussions the whole way along. [redacted] asked for further clarity. [redacted] explained that during the review, the team had identified certain drugs which are commonly used and would likely, if prescribed significantly give adverse long term affects to fertility. These drugs are used in a range of specialties including dermatology, renal and respiratory. Prior to treatment, patients will be advised by their clinician of the risks of the medication. Patients are given a choice of a drug which they are told does affect fertility or another drug that does not affect fertility. The individual would then be advised that if they chose the former, they could have their eggs or your sperm collected. However, most people would elect for the latter option. However, there are some drugs where there's no choice. The main medication where is there is no clear alternative is cyclophosphamide. There may be others used by physicians along the way where disease modification is required and there aren't other alternative. Therefore people can apply around those, through the specialist services. This would also include and cover the gender dysphoria pathway. [redacted] asked whether if somebody wanted to use a drug that was an alternative but isn't normally prescribed, they could apply for funding under the proposed policy. [redacted] stated that if the effect was equivalent to cyclophosphamide then treatment would most likely be funded.	

	Item	Action
	[redacted] noted that on the on the first page of the policy, there is a statement saying clinicians could apply if they feel the drug, they are working with fits the categorization they should see the formulary for guidance. [redacted] said that the link to the formulary provided send the user to the home page, and asked if there was a specific guidance paper around or whether clinicians would need to look for the individual medications. PG stated that they need to look to the individual medications. [redacted] suggested that this should be clearer. [redacted] Agreed with this and said that the policy team will discuss with the medicines management team. **Action – [redacted] to update the wording and discuss with the medicines management team.** **Section A** [redacted] asked the group for comments on section A. The group had no comments. **Section B** [redacted] asked the group for comments. The group had no comments. **Section C** [redacted] asked the group for comments. [redacted] referred to section C 1, noting it says individuals will be funded for cryopreservation for two years after the conditions is sufficiently stable or a maximum of five years post collection. [redacted] gave the example, of a 14 year old who'd had cancer treatment. There would be no expectation for them to have a baby by the time they are 19. If they can't afford to fund cryopreservation themselves this policy is unfair to those patients. [redacted] asked if this criteria was to do with the maximum length of time gametes can be stored. [redacted] stated that there is no maximum length of time but there is guidance of how effective the use is after a certain amount of time. [redacted] suggested that	

	Item	Action
	the wording is changed to 'for a maximum two years after reaching age 21.' [redacted] agreed with this approach, and suggested up to the age of 25 would be more appropriate. [redacted] agreed with [redacted], but noted that it was difficult to know when to draw the line in terms of cut off age. [redacted] noted that people may want to have children later in life, and that we shouldn't pressurise people to think about having families, when they're not ready to. [redacted] noted that if the length of time is significantly extended, there will be an increased cost which will then need to be recouped in some way by the policy. [redacted] suggested that the cohort who are having preservation before the age of 21 is going to be relatively small. [redacted] noted it's importance and suggested that the policy is amended to fund cryopreservation for people for two years beyond the age of 21. [redacted] Asked what the maximum storage time was. [redacted] indicated that techniques are improving all the time and, the real question is about the process of freezing and thawing, rather than how long gametes are store. [redacted] stated that the policy stated not to exceed the appropriate human fertilization authority regulations on length of storage, and asked for clarity on what the guidance was. [redacted] stated that this is gradually changing. Currently there is a 10-year recommendation at the moment, but [redacted] does not believe this is an absolute cut off point. [redacted] asked the group for more comments. [redacted] asked how much it would cost to for an individual to self-fund per year if they wanted to extend it. [redacted] Stated that from memory it was in the region of £200 per year. [redacted] reitterated [redacted] point about keeping within the allocated budget, and that any changes to the policy which would lead to increased cost, would need to be offset by other changes to the policy that could limit activity. [redacted] explained that the changes to the policy will increase the cohort of patients who can access this treatment. This is putting the biggest pressure on the whole budget, and is why the age of the prospective mother has been reduced from 40 to 39 years. [redacted] noted that the cost of treatment per individual is close £5000. [redacted] did not believe that increasing	

	Item	Action
	the age for adolescents to use within two years of reaching 21 would have a significant cost increase. [redacted] asked the group if they had any objections. The group had no objections. **Action [redacted] to raise the agreed limit of preservation within the policy** [redacted] Asked that this was reflected in the minutes. [redacted] Stated that this will also cover a significant number of patients on the gender dysphoria pathway as well. [redacted] Stated that should also be reflected in the minutes as well. **<u>Section D</u>** [redacted] explained this section was unchanged from the previous version. This section supports fertility services who receive requests to from individuals to use cryopreserved gametes of deceased partners. However, where there is no consent from the patient, services cannot do this. [redacted] asked [redacted] if submission of an IFR would then allow this to happen. [redacted] stated that the CCG cannot ever say there is no circumstance where this would not be funded. However, the exceptional funding process must look to see whether there's clinical exceptionality around a specific case. That's why all policies have an EFR clause. [redacted] Asked the group, if there were any other points on Section D? The group had no comments. [redacted] Does anyone object or have any other concerns with the policy. [redacted] Stated this has been approved for recommendation to clinical exec by everybody. [redacted] Thanked the group by saying it's been a long and complex process, but the input from this committee, through previous meetings and this has been nearly valuable to getting us to where we are. **Decision – Recommend approval of policy, with revised wording, to Clinical Exec.**	

	Item	Action
23	[redacted]	

Briefing Paper for Commissioning Policy Review Group (CPRG) Meeting

Date: **17th May 2022**

Title: **Commissioning Policy Review Group (CPRG) Briefing Paper**

Purpose

The aim of this paper is to provide an overview of the outcomes and outputs of the policy review process. This paper aims to support the CPRG to:

- Review the commissioning policies that have been reviewed
- Make decisions on whether to recommend a reviewed commissioning policy to BNSSG CCG's Clinical Executive Committee for adoption or removal

The outputs described in this paper include an Equality Impact Assessment (EIA), a Quality Impact Assessment (QIA), Public & Patient Involvement plan (PPI) and the likely financial impact of adopting the recommendations of the Commissioning Policy Development (CPD) team.

Reasons for commissioning policy review

There are five reasons that policies are reviewed:

- **Three year review** – Each commissioning policy has a review date which is set at three years from the date of adoption.

- **NHS England's Evidence Based Intervention Guidance for CCGs (NHSE EBI)** The aim of this program is to prevent avoidable harm to patients, avoid unnecessary operations, and free up clinical time by only offering interventions on the NHS that are evidence-based and appropriate. CCG's are required to pay due regard to this work in the formatting of commissioning policies.

- **Removal of criteria considered to be a Significant Functional Impairment (SFI)** – The CCG's Governing body has advised that, for exceptional funding requests, exceptionality should be based on clinical factors only, in line with other CCGs and NHS England. Non clinical factors, frequently referred to as 'Significant Functional Impairment', affecting a person will not be considered. This ensures that decisions are objectively and avoids judgement of an individual's relative worth.

- **New information –** A policy will be reviewed if the CCG receives new and relevant information or significant feedback on a policy once it has been adopted that would

necessitate a review.

- **Admin Changes -** Policies can be updated when clerical details need updating in line with organisational changes. This does not constitute a formal policy review but requires sign off from CPRG in line with the CCG's governance protocols.

The policies described in this paper will have been reviewed for at least one of the above reasons.

Our approach to health inequalities

The CCG defines health inequalities as unjust and avoidable differences in people's health across the population and between specific population groups.

Health inequalities are socially determined by circumstances largely beyond an individual's control. Health inequalities are not random and do not happen by chance.

The CCG recognises the importance of understanding and recognising the impact of its commissioning policies on health inequalities.

There is a developing CCG health inequalities plan that describes actions to improve the quality of equality impact assessments and undertake more robust consideration of their results in decision-making. The plan also recommends embedding health inequalities champions within committees and programme boards. There is also an action to provide further support for staff to ensure that health inequalities are consistently covered in their work.

Recommendations made to CPRG by the Commissioning Policy Development (CPD) team.

This section gives further detail about each policy's review including the date a policy was adopted, the reason for the review, the clinical teams involved in the review and an overview of equality and quality assessments. An assessment of likely commissioner spend as a result of policy adoption, is also provided.

Table 1 summarises the policies that have been reviewed and the recommendation being made by the CPD team to CPRG.

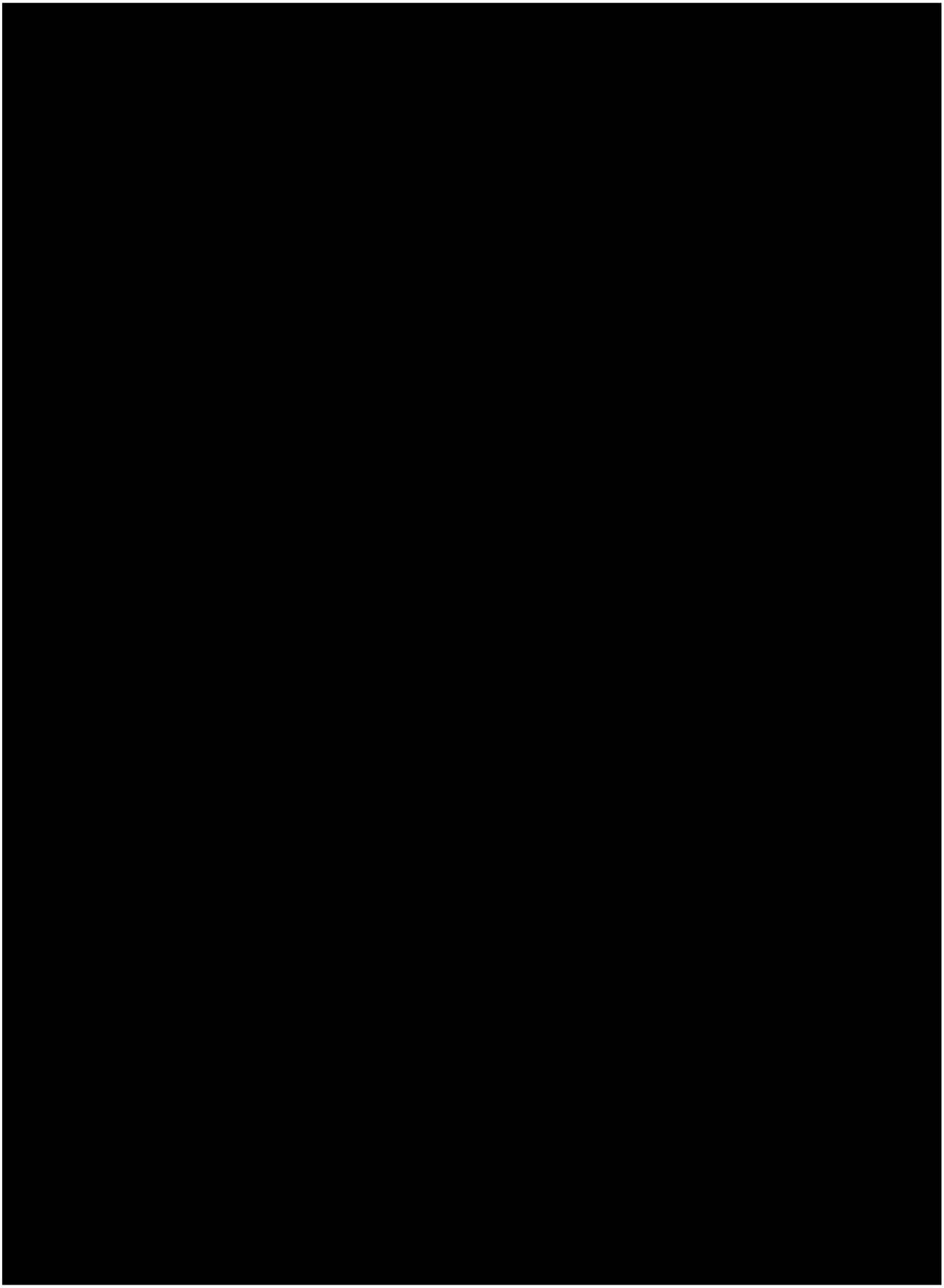
Changes in wording to policies are highlighted yellow in the policy document.

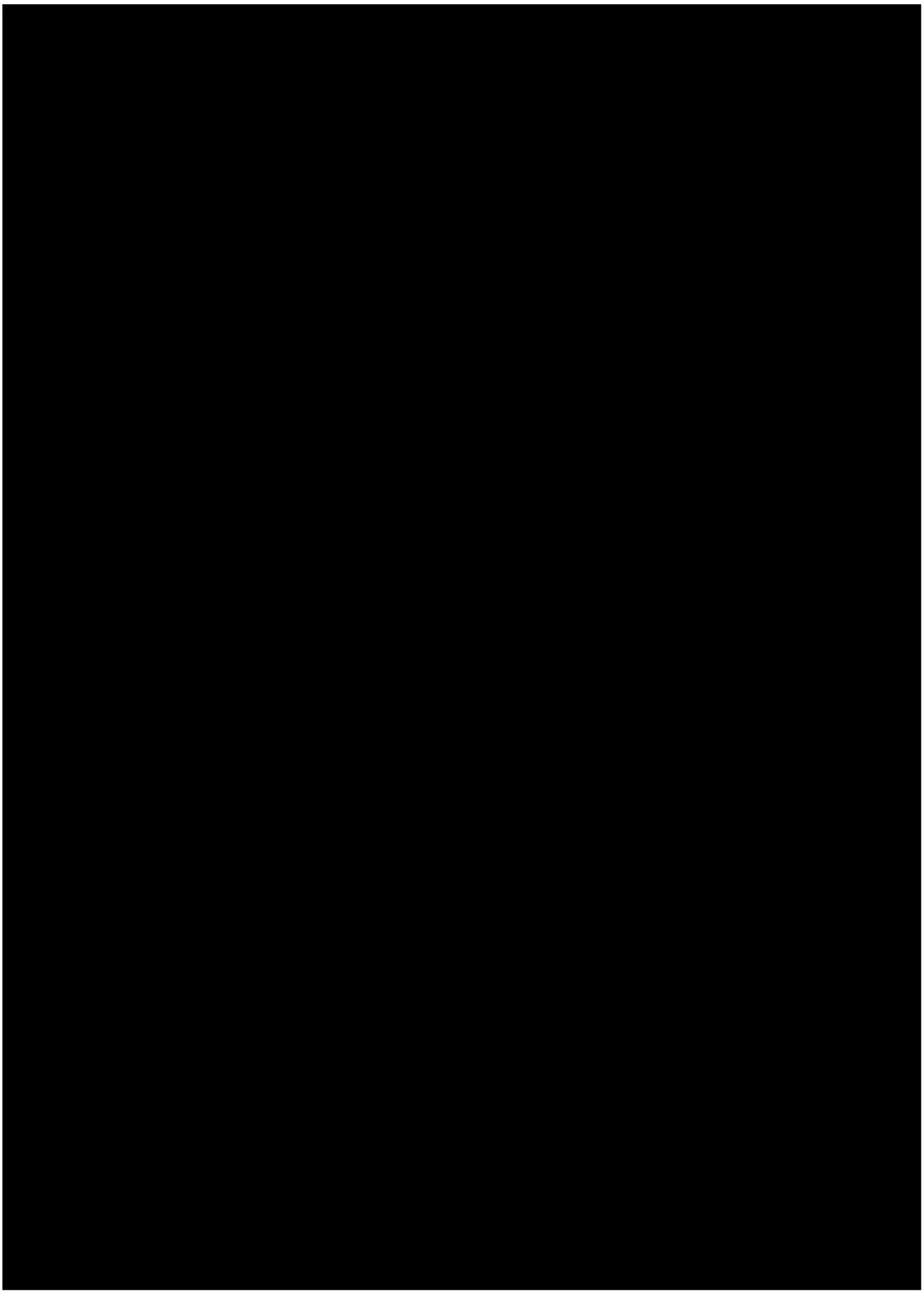
Table 1

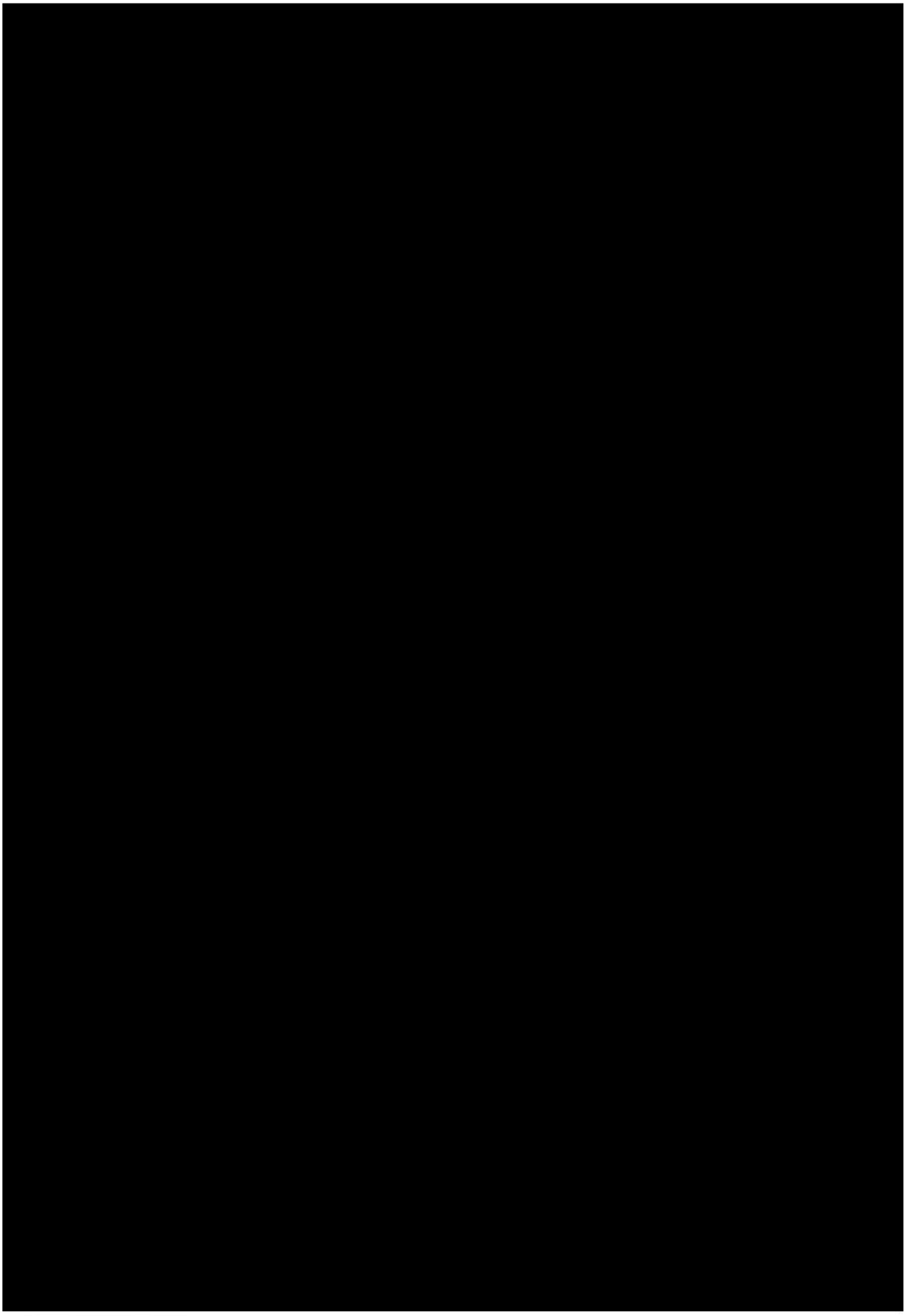
Policy	Reason for review	Recommendation to CPRG
[redacted]	[redacted]	[redacted]

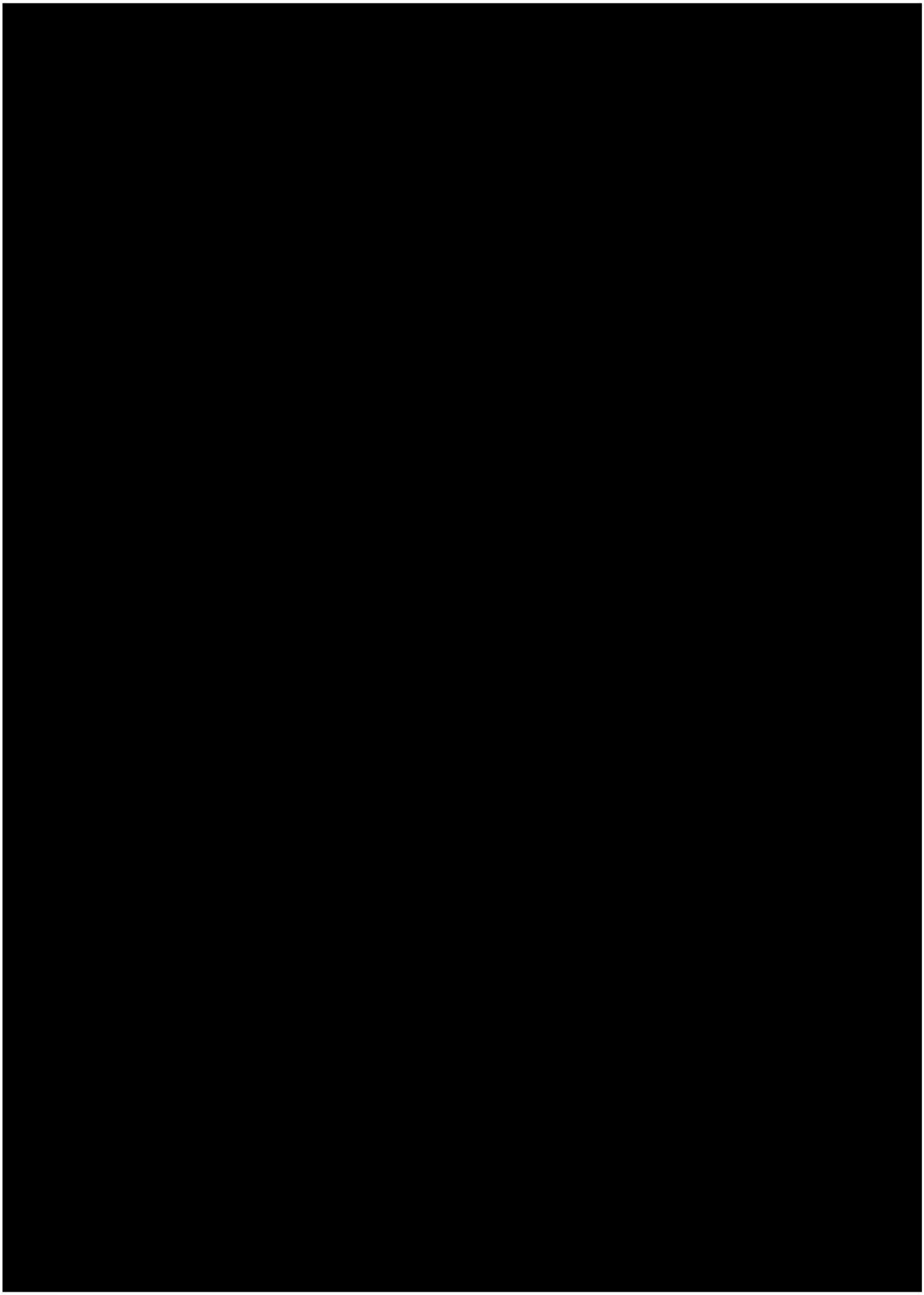
Policy	Reason for review	Recommendation to CPRG
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
Infertility Assessment & Treatment	Three Year Review	For Discussion
Fertility Preservation	New Policy.	For Discussion

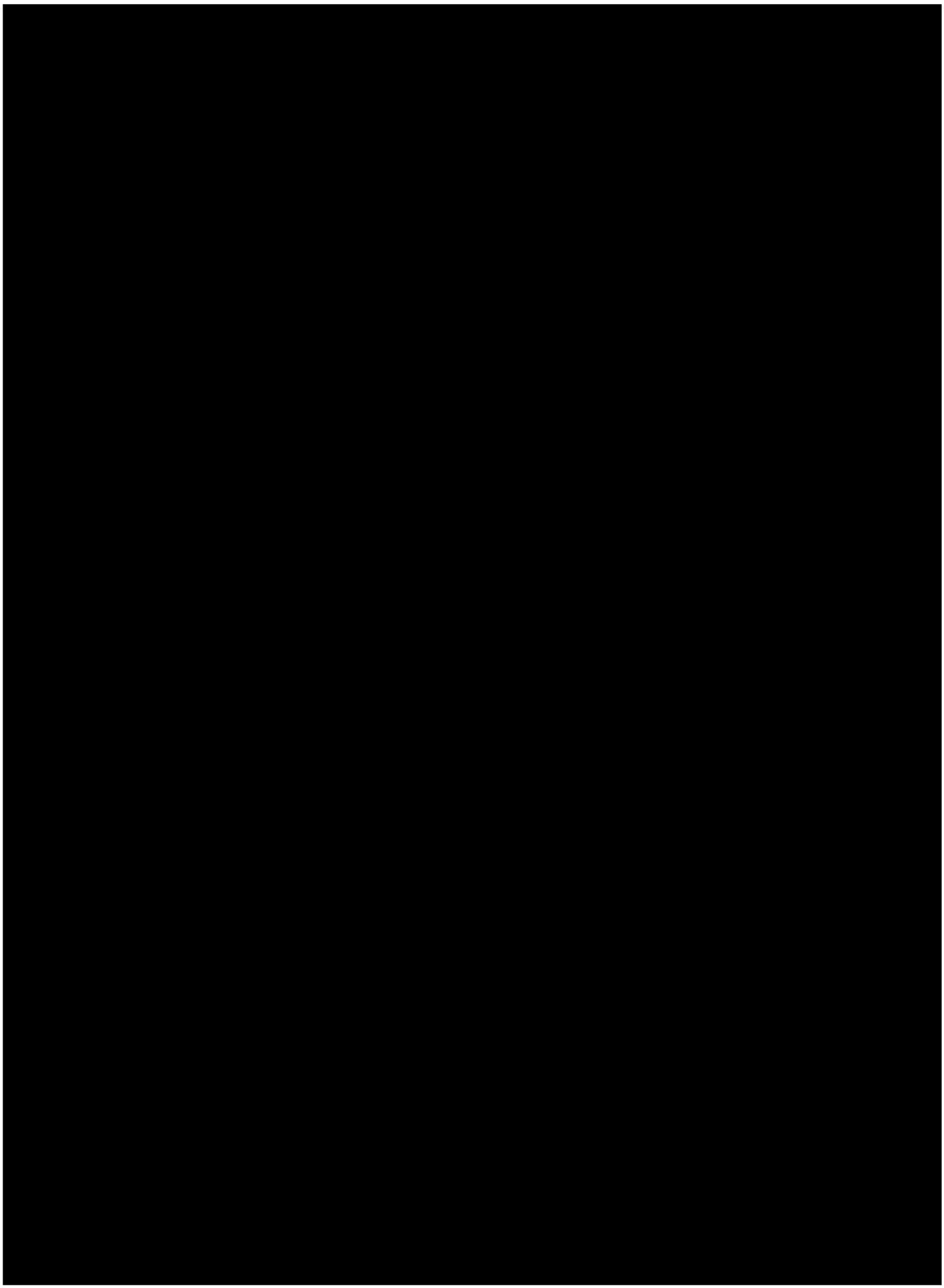
[redacted]

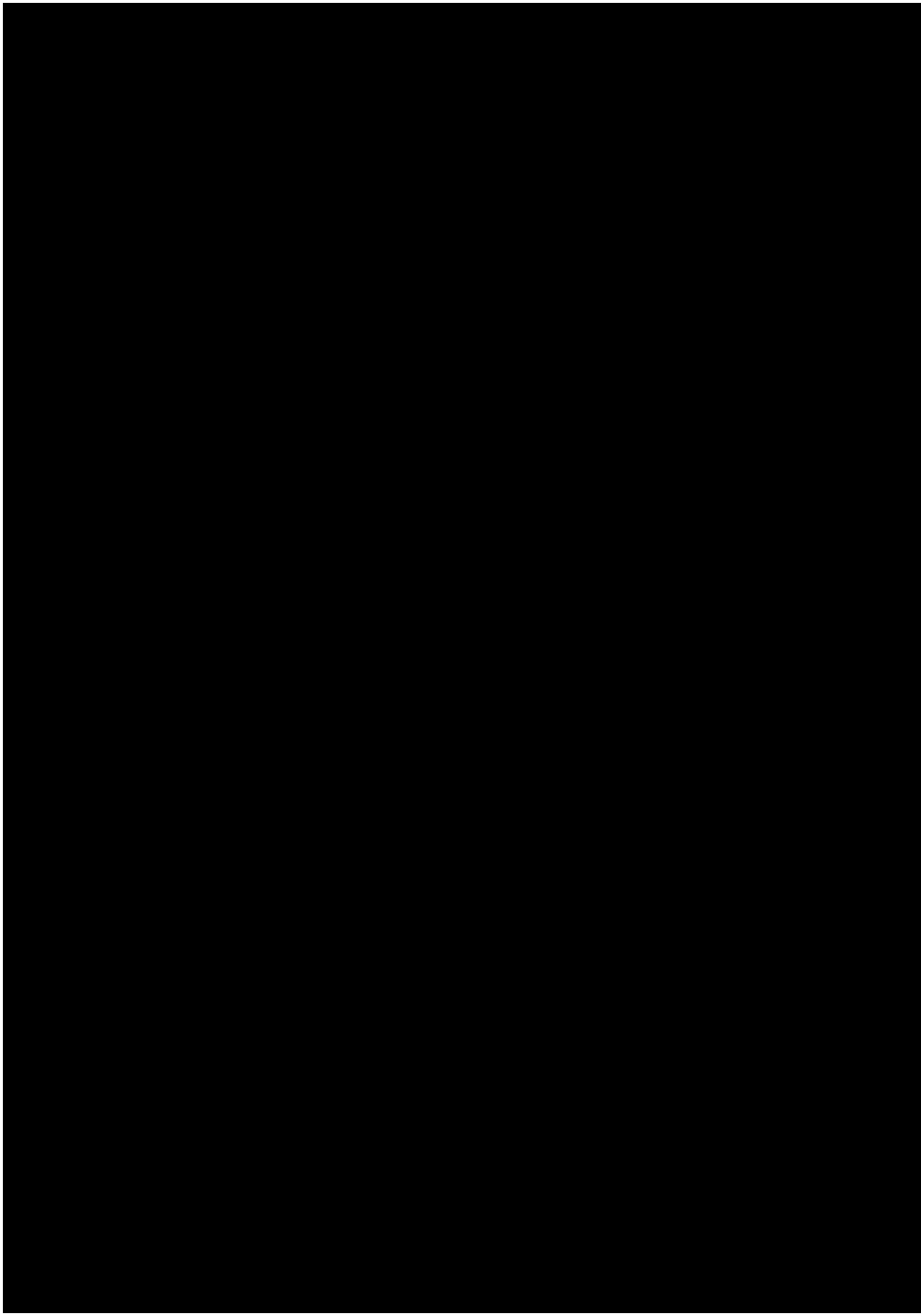


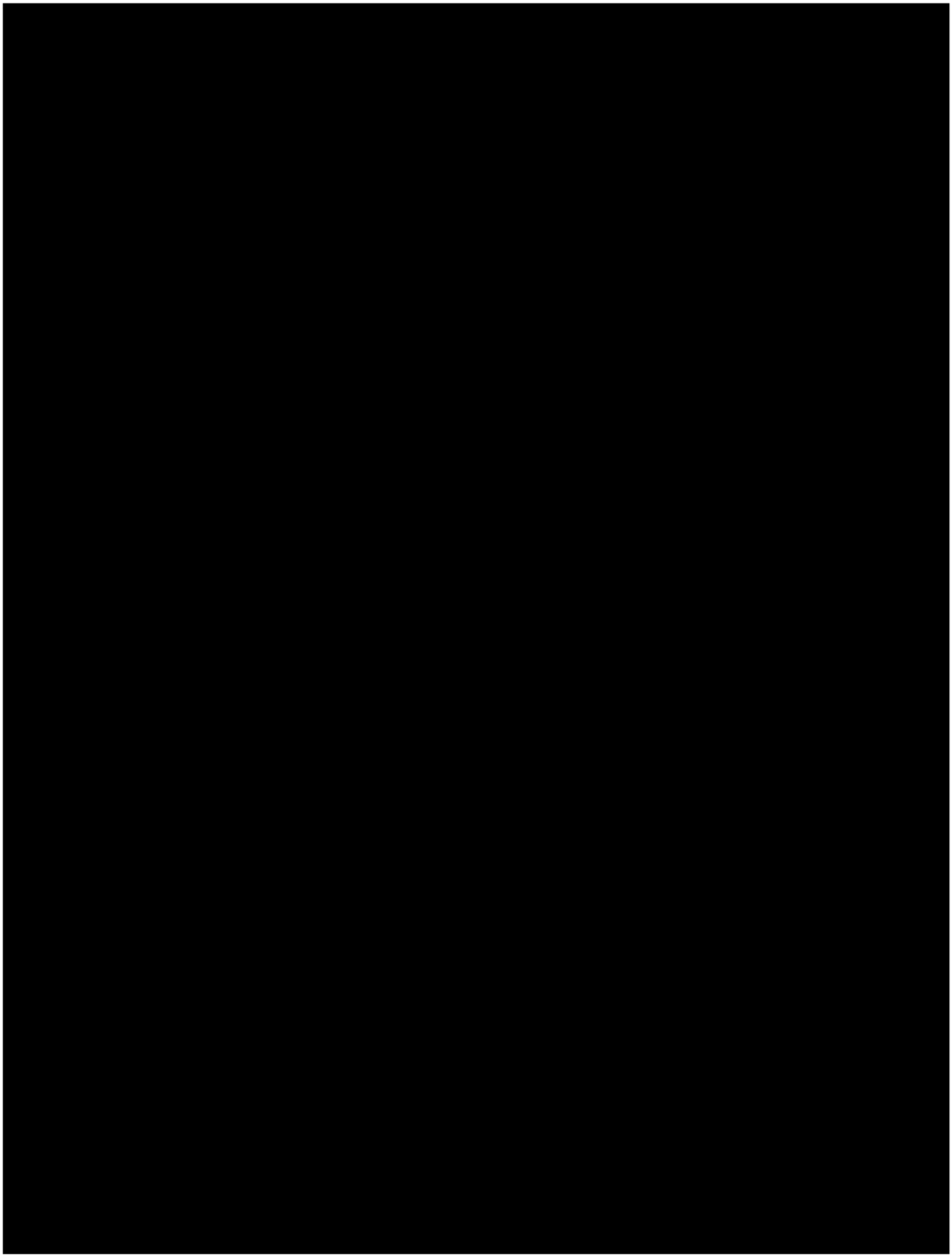


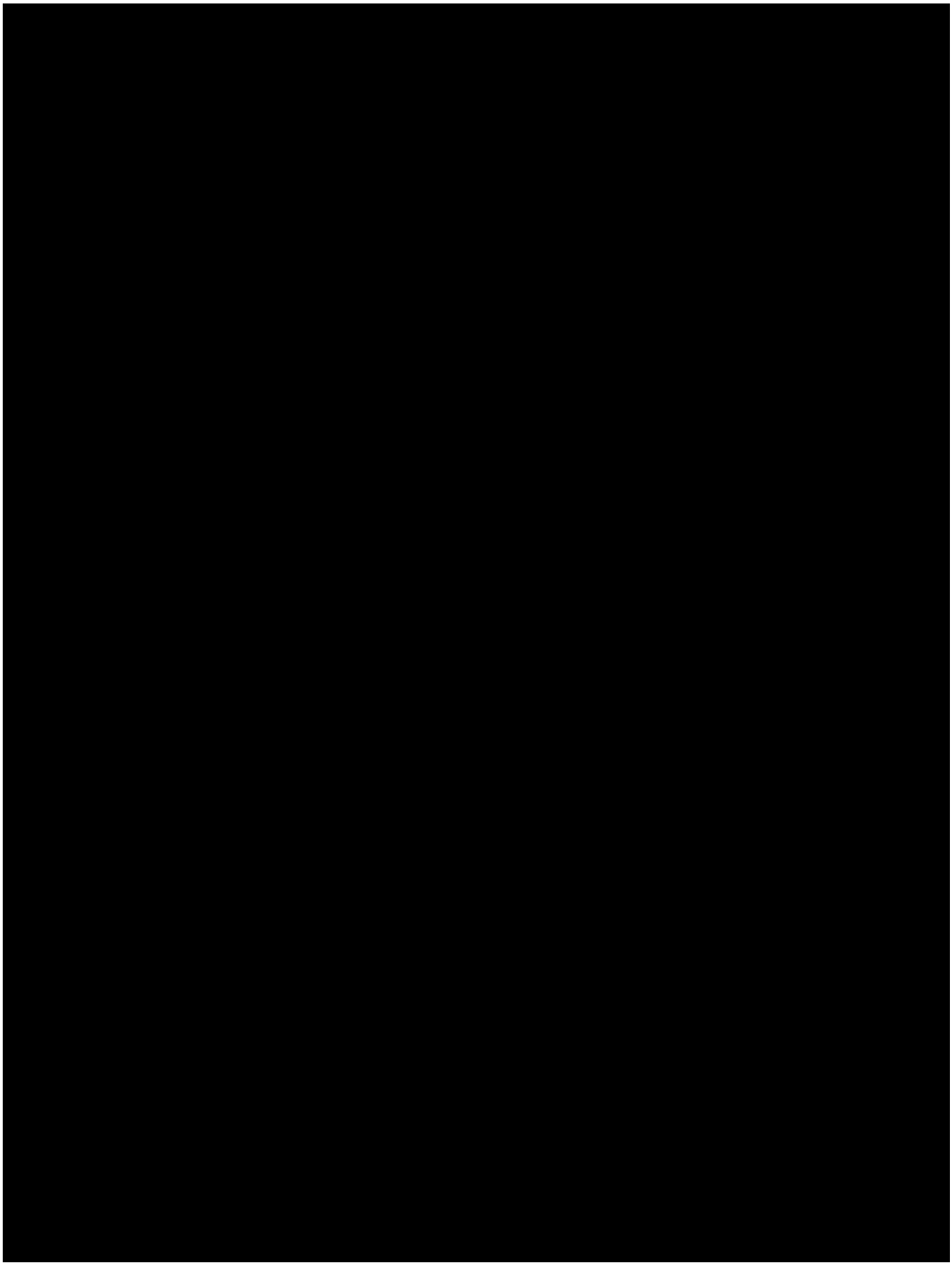


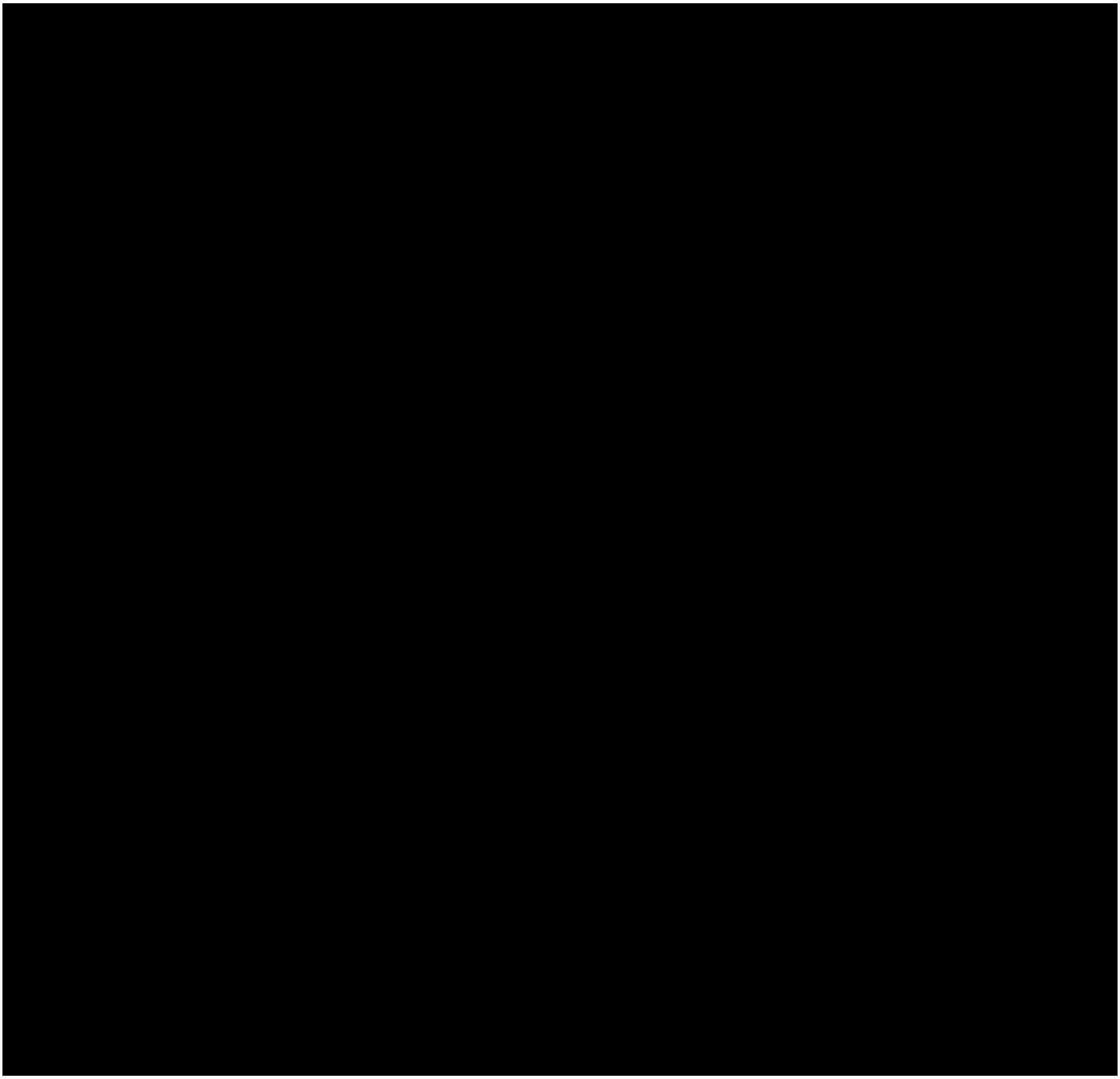












Infertility – Assessment & Treatment

The CPD team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), NBT and UHBW in the development of this policy.

The revised policy is clear that its purpose 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 be managed under a separate policy. This is discussed further 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 to heterosexual and same sex couples.

Under the revised policy, single people will be eligible for assessment 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 unstimulated cycles of Human Fertilisation and Embryology Authority (HFEA) approved donor insemination.

Under this policy, single women will be able to access fertility assessment treatment provided they satisfy the criteria set out within policy. Across England, there are 6 other CCGs who currently fund infertility treatment for single women.

Single men will be able to receive assessment for infertility. There are limited treatment options for single men with infertility. Most of these treatments are funded by NHS England. BNSSG CCG does not currently fund, or part fund, any interventions to resolve infertility in single men. Treatment for single men is outside the scope of this policy.

In order to offset the cost of broadening the scope of the policy's criteria, the upper age limit of the prospective mother has been lowered from 40 to 39 years of age. This reflects the gradual decline in fertility levels for women. While this move is ostensibly inequitable, it is worth noting that there this is some clinical evidence to justify this move.

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. Findings indicated that in women younger than 40, the cumulative live-birth rate for:

- the first cycle was 32.3%
- 48.7% for the second cycle
- 58.0% for the third cycle

For women aged 40-42, the cumulative live-birth rate for

- the first cycle was 12.3%
- 19.8% for the second cycle
- and 24.7% for the third cycle

It is also worth noting that 25% of the CCGs in England have an upper age limit of 39 or under. BNSSG CCG would not be a significant outlier in this regard.

Under the proposed policy, the weight of the prospective father will no longer form part of the assessment. This is partly due to the challenges of consistently registering a Body Mass Index (BMI) from the prospective father, and the lack of evidence for its adverse impact on the 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 can place significant financial pressure on a couple. Given the apparent lack of parity within the criteria for heterosexual couples and same sex couples, the CCG is open to complaints from the public and legal challenge 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 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. This was further echoed in clinical evidence which indicated that very few women would require more than 6 cycles of unstimulated IUI in order to conceive.

Evidence from the HFEA indicates pregnancy rate for a stimulated cycle of IUI is 17%. The success rate for an unstimulated cycle is 16%. The HFEA indicate 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, 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 for same sex female couples.

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.

EIA

Equality impact assessment has been completed and signed off.

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. The proposed policy has an upper age limit for women of 39 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%.

Due to the evidence of effectiveness of IVF for women over 40 years, it has been determined that the upper age limit of the policy should not be increased. To make best use of resources, this policy is intended to support those people with the best chance of conceiving with assistance.

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.

QIA
Quality impact assessment has been completed and is awaiting sign off.

PPI
A significant period of patient and public engagement was undertaken between May and August 2021. This engagement included a survey which asked for people to prioritise changes to the current fertility policy. This included whether the new policy should broaden the scope of fertility preservation, and whether the upper age limit for prospective mothers, of 40 years should remain. Following analysis of the data, fertility preservation was assigned a higher priority for review among respondents, than the age of the prospective mother. Therefore, it is proposed that no further proactive engagement is required on this issue.

The CPD team, in collaboration with colleagues from comms and the CCG's PPI leads, will draft a statement that describes how the CPD team used the data accrued through engagement. Patients, providers and other stakeholders will be informed of how the CCG plans to use the data to influence policy review. Given that the policy will be reviewed at open sessions of the Clinical Executive and Governing Body, this will give the public a further opportunity to express their thoughts and concerns.

Financial Impact
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 most projections of financial impact.

The CPD team have been advised that CCG expenditure for fertility preservation and infertility assessment and treatment, must not lead to increased costs for the CCG.

The proposed policy would, if adopted, broaden the scope of the policy to include single people could cost around £94,000 described below. This is the maximum amount of expected expenditure.

To equalise access within the proposed policies, criteria will need to be adapted to offset any increased activity, and in a way that does not unlawfully or irrationally discriminate on the basis of protected characteristics.

As discussed previously by the CPRG, the preferred mitigation within criteria would be to reduce the upper age limit for the prospective mothers from 40 years of age to 39. For the financial year 2021-22, the CCG received 35 funding applications for fertility treatment for women aged 39 or over. Assuming this activity remains consistent, lowering the upper age limit could generate a cost saving of £108,500. This would ostensibly cover the costs of broadening the scope of the policy to single women.

It is difficult to make an accurate projection of the likely financial impact broadening the scope of the criteria to single people will have. It should be noted that BNSSG CCG's EFR have received one funding application for fertility treatment of a single woman.

Projections for the number of single women who may seek funding for fertility treatment are based on the most recent available data from the HFEA regarding NHS funded fertility treatment for single people.

HFEA data 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).

It is worth noting that in 2019/20, the number of heterosexual couples that were funded for fertility treatment by BNSSG CCG, was 290. This constitutes less than 1% of BNSSG's total population of couples in either a marriage or civil partnership.

ONS data indicates that, across BNSSG, there are 273,448 people who register their marital status as single. While this is not broken down by age, data from local councils indicates that 170,375 of BNSSG's total female population would meet the age criteria in the proposed policy. Assuming local activity follows national trends, and that less than 1% of the total female population of BNSSG who meet the proposed age criteria seek referral, proposed changes to the policy could lead to an increase in fertility activity of up to 30 referrals per year, and an overall increase in fertility spend of at least £94,320. Fertility expenditure for the CCG in 19/20 was £993,177.

HFEA research indicates that most single people access fertility treatment in their 30's. Given this, it is possible that the number of single women seeking treatment for infertility could be less than estimated above.

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.

It is also unclear how many lone parent families there are across BNSSG. In 2020, there were estimated to be 197 lone parent families across BNSSG. However, this data is likely to have changed in the interim. The number of lone parent families is likely to have an impact on the number of people seeking infertility treatment.

Given the limitations in the data, it is reasonable to take national data as a guide for understanding maximum local demand. The CPD team, however, will work with the CCG's contracts team and BI to establish a means of monitoring this data.

It should also be noted that costs are based on the current local tariffs for fertility treatment.

Current tariffs are designed to balance the cost of providing treatment to couples, rather than single people. Changes to the laws around sperm donation, have led to a dramatic reduction in the number of sperm donors. Consequently, fertility providers are having trouble getting sperm for single patients, and so the cost of HFEA approved sperm is going up. Therefore, it is likely that to offset the cost of not having men in the equation, the cost of providing fertility treatment, and ultimately the tariff, will increase. The impact of this is still being determined.

As noted, there are several conditions that have been added to the criteria for heterosexual couples. There is currently no data to indicate how this might impact activity, the consensus among clinicians involved in this review is that the cohort will be small, however the CPD team will work the CCG's BI team to establish a means of monitoring this data.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Fertility Preservation

New Policy

The commissioning policy team engaged with clinicians at the Bristol Centre for Reproductive Medicine (BCRM), NBT, UHBW and pharmacists from the CCG's Medicines Optimisation team.

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 that might compromise fertility.

There is provision within BNSSG CCG's current fertility policy for patients who are to receive oncology treatment that is likely to compromise their fertility.

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 CCG'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 CCG 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 CCG does have discretion to fund gamete preservation for clinical reasons supported by evidence.

The proposed policy for fertility preservation, will 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 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.

It is recognized that there are some surgical interventions that 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.

EIA

Equality impact assessment has been completed and has been signed off.

This policy preserves the potential for transgender people, who are in the process of transitioning, to conceive later in life. This goes some in way in addressing an element of existing CCG provision for fertility preservation that was discriminatory, by establishing a clear rationale based on clinical evidence.

QIA

Quality impact assessment has been completed and is awaiting sign off.

PPI

PPI assessment has been completed and is awaiting sign off.

Financial Impact

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. 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.

The CCG 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 CCG 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 – as expected – the CCG could see an increase of £16,750 per year.

For 2019/20, the CCG spent £117,250 on fertility preservation. The proposed policy could lead to an increase in this figure of £60,300.

Recommendation to CPRG – Recommend revised policy to Clinical Executive for adoption.

Glossary

Clinical Policy Review Group (CPRG)	Clinical Policy Review Group (CPRG) - quarterly meeting coordinated by the Commissioning Policy Development Team in order to clinical review / update existing policies against new NICE guidelines and other developments. CPRG also clinically evaluates new policies identified. The of this group is to make recommendations to the Commissioning Executive in regard to Commissioning Policies to adopt on behalf of BNSSG.
Evidence Based Interventions Programme (EBI)	The Evidence-Based Interventions Programme was established and developed as a joint enterprise between five national partners: the Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence as well as NHS England and Improvement. The programme focuses on 17 interventions that fall into this category. Four interventions that should not be routinely offered to patients unless there are clinically exceptional circumstances, and 13 interventions that should only be offered to patients when certain clinical criteria are met.

Due Regard	NHS England has advised that each CCG must evidence it has paid Due Regard to the recommendations made through the EBI Programme, and details of this recorded.
Exceptional Funding Request [EFR]	Where a CCG has published a policy stating that certain treatments are not routinely funded, or no commissioning policy exists. Treatment will only be funded via agreement from commissioners in exceptional circumstance.
Criteria Based Access [CBA]	Where a CCG has published a policy setting out eligibility criteria. If clinicians are content that the patient meets the criteria, they may proceed to treat without seeking funding approval. Funding cases are audited by members of the EFR / CPD team to ensure that the policy has been adhered to and reduce in appropriate activity.
Prior Approval [PA]	Where a CCG has published a policy setting out eligibility criteria. Clinicians, where they feel patients meet the criteria, must seek funding approval from the commissioners prior to treating. Applications are submitted by Clinicians and reviewed by administrators from the EFR / Referral Management team, where criteria is evidenced in full the CCG issued a reference code giving funding approval. Where funding approval is given, it is usually given for a term of 1 year and / or 1 intervention only. Repeated treatments require repeated applications.
Significant Functional Impairment	Significant functional impairment is defined by the BNSSG Health Community as - Symptoms preventing the patient fulfilling routine work or educational responsibilities - Symptoms preventing the patient carrying out routine domestic or carer activities This is a subjective criterion.

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

BNSSG Integrated Care Board (ICB) Board Meeting

Minutes of the meeting held on 1st December 2022 at 12.15pm, held virtually through Microsoft Teams

Minutes

Present		
[redacted]	Chair of BNSSG Integrated Care Board	[redacted]
[redacted]	Interim Chief People Officer, BNSSG ICB	
[redacted]	Non-Executive Member – Audit	
[redacted]	Non-Executive Member – People	
[redacted]	Chief Executive Officer, BNSSG ICB	
[redacted]	Non-Executive Member – Quality and Performance	
[redacted]	Executive Director Adults and Communities, Bristol City Council	
[redacted]	Director of Digital Delivery and Development, Sirona care & health	
[redacted]	Chief Executive Officer, Avon and Wiltshire Mental Health Partnership NHS Trust	
[redacted]	Chair of the GP Collaborative Board	
[redacted]	Non-Executive Member – Primary Care	
[redacted]	Chief Executive Officer, South Gloucestershire Council	
[redacted]	Chief Nursing Officer, BNSSG ICB	
[redacted]	Chief Financial Officer and Deputy Chief Executive, BNSSG ICB	
[redacted]	Chief Executive Officer, North Somerset Council	
[redacted]	Non-Executive Member – Finance, Estates and Digital	
[redacted]	Chief Executive Officer, University Hospitals Bristol and Weston NHS Foundation Trust	
Apologies		
[redacted]	Chief Executive Officer, North Bristol Trust	[redacted]
	Chief Medical Officer, BNSSG ICB	
	Interim Chief Executive Officer, Sirona care & health	
	Chief Executive Officer, Bristol City Council	
	Chief Executive Officer, South Western Ambulance Service NHS Foundation Trust	

In attendance		
[redacted]	Director of Strategy, Partnerships and Population, BNSSG ICB	[redacted]
	Corporate Secretary, BNSSG ICB	
	Director of Transformation and Chief Digital Information Officer, BNSSG ICB	
	Clinical Lead Exceptional Funding Review & Commissioning Policies, BNSSG ICB	
	Director of Primary and Integrated Care, BNSSG ICB	
	Director of Performance and Delivery, BNSSG ICB	
	Healthwatch Bristol, North Somerset and South Gloucestershire	
	Commissioning Policy Development Manager, BNSSG ICB	
	Corporate Support Officer (Minute Taker), BNSSG ICB	
	Chief Executive Officer, One Care	

	Item	Action
1	**Welcome and Apologies** [redacted]	
2	**Declarations of Interest** There were no new declarations of interest and no declarations pertinent to the agenda.	
3	[redacted]	
4	[redacted]	

	Item	Action
	[redacted]	
5	[redacted]	

	Item	Action
	[redacted]	
6.1	**Clinical Commissioning Policies** [redacted] and [redacted] were welcomed to the meeting. [redacted] explained that the Fertility Assessment and Treatment policy had been reviewed in line with the review dates and the reviewed policy was agreed by the then CCG Clinical Executive. Following this the policy underwent 3 months of patient and public engagement which further informed its development. [redacted] noted that two additional factors had been considered during the review. The first was that although the policy reflected NICE guidance and best practice, it was recognised that more was needed around fertility preservation to provide greater equality of opportunity for people to access this treatment who were undergoing NHS care which would have a negative impact on fertility. Secondly, the ICB needed to review the policy's position to only fund assessment and treatment for couples as this stance could be challenged under the Equality Act. It had been recognised that the revised policy should not lead to an increase in the overall fertility spend and therefore any changes which would increase activity should be mitigated through other areas of the policy. [redacted] reported that the engagement exercise had identified that the public supported broadening the scope of fertility preservation and prioritising the length of time someone has tried to conceive. [redacted] noted that an additional policy regarding Fertility Preservation had been developed. [redacted] highlighted that the key aim of the Fertility Assessment and Treatment policy was to enable investigation and treatment for individuals or couples where infertility was likely to be present. [redacted] noted that NICE guidance had not been updated for several years and therefore the proposed changes had been the result of the consultation and to support equality. [redacted] confirmed that access to services continued to be based on not being able to become pregnant despite unprotected intercourse over a two-year period. The previous requirement for at least 10 cycles of self funded cycles has been reduced to six. This change was based on specialist advice and considered more achievable by couples and individuals. [redacted] explained that the current policy allowed early referral in instances where there was no ovulation due to blocked fallopian tubes and where there was zero sperm count. These conditions had been updated to include individuals with severe endometriosis and where sperm count was less than 1 million per ml. [redacted] noted that to remain within the	

	Item	Action
	allocated financial envelope the top age had been reduced from 40 to 39 which was in line with other areas in the country. [redacted] explained that the Fertility Preservation policy was based on NHS England guidance to provide gamete preservation for patients on cancer pathways where fertility may be affected. This was not an equitable position and therefore the policy had been amended to include gamete preservation for individuals whose fertility was likely to be significantly affected by any NHS commissioned treatment. [redacted] highlighted the lowering of age to 39 and noted that there was no change to the range or approach to services that would be delivered although access would be broadened. The key risk associated with the policy was financial and around the inclusion of single individuals. There was no local data to indicate whether this inclusion would significantly increase activity, although previous Exceptional Funding Request data had indicated that it would be unlikely that activity would exceed the levels outlined in the paper. [redacted] also highlighted a risk related to the transition period for the policy and the lowering of the upper age to 39. In order to ensure that women aged 39 were not unfairly disadvantaged by the policy, the ICB would not stop funding for women aged 39 for 9 months to a year after policy implementation. [redacted] explained that this meant that costs connected to fertility preservation would not be fully mitigated within the first year however some of the costs associated with the new policy would be mitigated through other elements covered through the Exceptional Funding Request route. [redacted] confirmed that the policy had been reviewed and recommended by the Commissioning Policy Review Group and by the Clinical Review Group, which was a sub-committee of the Health and Care Professional Executive. [redacted] highlighted the risk section within the paper and was pleased that the proposed changes had been supported with evidence. [redacted] noted the mitigations and asked whether there were likely to be any legal challenge or reputational damage. [redacted] explained that the evidence supported the approach and that the proposals would ensure that policy was legally safe and provided equitable access for the local population. [redacted] confirmed that any women already receiving treatment who was between 39 and 40 would complete their treatment. [redacted] asked how the policy would be communicated to primary care. [redacted] confirmed that following approval primary care and other providers would be informed of the changes through already agreed communications. [redacted] also noted the importance of patient communications which included communications in patient waiting rooms and updating websites. [redacted]	

	Item	Action
	[redacted] highlighted the importance that the upper age limit for treatment was emphasised in communications to support people to plan. [redacted] agreed and noted that people were making the decision to have babies later and therefore it was important that people were aware of the limits of the policy. **The BNSSG ICB Board approved the changes to the current commissioning policy for Fertility Assessment and Treatment and approved the proposed new policy for fertility Preservation**	
6.2	[redacted]	

	Item	Action
	[redacted]	
6.3	[redacted]	

	Item	Action
	[redacted]	

	Item	Action
	[redacted]	

	Item	Action
	[redacted]	
6.4	[redacted]	

	Item	Action
	[redacted]	
7.1	[redacted]	
7.2	[redacted]	

	Item	Action
	[redacted]	
7.3	[redacted]	

	Item	Action
	[redacted]	ICB Execs
7.4	[redacted]	

	Item	Action
	[redacted]	

	Item	Action
	[redacted]	
7.5	[redacted]	
8	[redacted]	

	Item	Action
	[redacted]	
9	[redacted]	
10	[redacted]	
11	[redacted]	

[redacted], Corporate Support Officer, December 2022

Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Meeting of BNSSG ICB Board Meeting

Date: 1st December 2022
Time: 12:35
Location: MS Teams

Agenda Number:	6.1
Title:	Clinical Commissioning Policies
Confidential Papers Does this paper contain information that should not be in the public domain? (This box will be removed from Governing Body Open papers by the Corporate Team when the paper is received)	

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):	[redacted] (Commissioning Policy Development Manager) [redacted] (Clinical Lead for Policy Development and Exceptional Funding)

Sponsoring Director / Clinical Lead / Lay Member:	[redacted] (Chief Medical Officer)

Please Keep these front pages to a maximum of two

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)

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Health and Care Review Group Meeting (Interim)

Minutes of the meeting held on 15 September 2022 at 14:00, on Microsoft Teams.

Minutes

Present		
[redacted] (Chair)	Chief Medical Officer, NHS BNSSG ICB	[redacted]
[redacted]	DPH, Bristol City Council	[redacted]
[redacted]	Chief AHP, NHS England	[redacted]
Apologies		
[redacted]	Clinical Lead for Primary Care Development, NHS BNSSG ICB	[redacted]
[redacted]	DPH, North Somerset Council	[redacted]
[redacted]	Interim Medical Director, Sirona	[redacted]
In attendance		
[redacted]	Commissioning Policy Development Manager, NHS BNSSG ICB	[redacted]
[redacted]	Clinical Lead, NHS BNSSG ICB	[redacted]
[redacted] (Minutes)	Programme Support Officer, NHS BNSSG ICB	[redacted]

	Item	Action
01	**Welcomes and Introductions.** [redacted]	
02	[redacted]	

	Item	Action
03	[redacted]	
04	**Commissioning Policies for Infertility Assessment & Treatment and Fertility Preservation** Discussion on comments received and feedback from papers introduced at previous meeting. • [redacted] question on equity of ages of mother and father cut off. [redacted]- Issue around this one is member of couple able to bare child. Reducing age for man penalises whole couple. Not good data for men at top end, quantifying if this would reduce cost. Does not feel like an equity issue when only one member of couple able to carry baby. [redacted]- make sure it is clear if this was picked up by chief nurse in last meeting. [redacted]– adds complexity to sentence but no material difference. [redacted]– can provide briefing note or refer to minutes of this discussion. Wording amended to same format for both mother and father. • What is criteria for pregnancy but no live child? Set out in section A5 of policy. **Agreed.** • What is definition of regular unprotected sex? [redacted] - Clinicians should use judgment – not stated in paper. Intercourse twice across most fertile period used to be the case; this has implications for single women. There is definition in policy – exceptions apply in certain circumstances. **Agreed.** • HFEA needs to be written out in full the first time. **Done.** • Why aren't men with low sperm counts written as bullet as bullet point with other bullet points? **Done.**	

	Item	Action
	• Shouldn't the cessation of funding begin only after natural birth rather than natural pregnancy? [redacted] - If we get to point of funding fertility treatment, if someone becomes pregnant, they are no longer infertile. If pregnancy is not successful clock restarts (2 years) as per NICE guidance. New cycle is a fresh and frozen cycle. At first intervention we collect as many eggs as possible, if first isn't successful and cannot be successful then can move to frozen cycle. [redacted]– could go as exception if miscarriage or stillbirth? [redacted]– there are complexities if under miscarriage clinic. If recommendation is that this looks to be more than current miscarriage, due to belief of underlying problem, this may then be taken forward to infertility setting. **Approved.** • Premature ovarian failure is repeated in both 2a and 2b. [redacted]– correct term premature ovarian insufficiency **Amended.** • Why is there a higher BMI cut-off with female age 37-39? [redacted]- Based on NICE guidance, should support women to lose weight, however once in final age period NICE view is that they should be given advice but not be so tight on criteria. **Approved as NICE compliant.** • In same sex couples section, the wording for BMI cut-off changes to "up to her fortieth birthday" so not consistent with same advice for heterosexuals **Corrected inconsistency.** • For assisted conception, FSH cut off is 15 for IUI and 12 for ICSI – is it supposed to be different? [redacted]- Gone to TAME consultant, no answer yet. Permission requested to amend on advice. **Approved.** • In SDM section, alternatives include adoption	

	Item	Action
	Amened. [redacted] suggests approval – note to group. All comments reviewed considered/adopted, discussed, and noted. Would like everyone else to approve within next working week. Need to adopt quoracy of at least 5. **ACTION ALL approval for paper given offline to reach quoracy.** [redacted] – could get policy adopted whilst awaiting approval? [redacted] – it needs implementation plan with staggered change. [redacted] – will not change at board, this is good governance. Implementation plans and processes can begin to be considered. Act as though ratified policy. [redacted] – more risk averse, as we are lowering upper age limit. Ethical question and threats. Risky if not going through top level of governance? [redacted] – you can do all the prep work before; we do not want to compromise clinical care and processes. Governance can be bended a little bit. Could discuss with Shane/Jeff. [redacted] – who owns this policy? Is it ICB as organisation and purchaser? If just ICB then fine to proceed as Jo identified, as about purchasing as narrow ICB definition of commissioning. **ACTION [redacted] to brief Executive Team for next week.** **ACTION [redacted] and [redacted] to create final fertility policies paper.**	**ALL** [redacted] [redacted]
05	[redacted]	
	[redacted]	

[redacted]
Programme Support Officer
15 September 2022

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Live-birth rate associated with repeat in vitro fertilisation treatment cycles

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Abstract

Importance—The likelihood of achieving a live-birth with repeat in-vitro fertilisation (IVF) is unclear, yet treatment is commonly limited to three or four embryo transfers.

Objective—To determine the live-birth rate per initiated IVF cycle and with repeated cycles.

Design, Setting and Participants—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.

Main exposure—IVF, with a cycle defined as an episode of ovarian stimulation and all subsequent separate fresh and frozen embryo transfers.

Main Outcome(s)—Live-birth rate per IVF cycle and the cumulative live-birth rates across all cycles in all women and by age and treatment type. Optimal, prognosis-adjusted and conservative cumulative live-birth rates were estimated, reflecting 0%, 30% and 100% of women discontinuing due to poor prognosis and having a live-birth rate of zero had they continued.

Results—In all women the live-birth rate for the first cycle was 29.5% (95%CI: 29.3, 29.7). This remained above 20% up to and including the fourth cycle. The cumulative prognosis-adjusted live-birth rate across all cycles continued to increase up to the ninth, with 65.3% (64.8, 65.8) of women achieving a live-birth by the sixth cycle. In women younger than 40 using their own oocytes, the live-birth rate for the first cycle was 32.3% (32.0, 32.5), and remained above 20% up to and including the fourth cycle. Six cycles achieved a cumulative prognosis-adjusted live-birth rate of 68.4% (67.8, 68.9). For women aged 40-42, the live-birth rate for the first cycle was 12.3% (95%CI: 11.8, 12.8), with six cycles achieving a cumulative prognosis-adjusted live-birth rate of 31.5% (29.7, 33.3). For women older than 42 years all rates within each cycle were less than 4%.

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Author contributions: DAL and SMN designed the study, developed the aims and obtained data. All authors contributed to developing the statistical analysis plan. ADACS completed all statistical analyses. DAL and ADACS wrote the first draft of the paper and all authors contributed to interpreting results and making critical comments on subsequent paper drafts. DAL and ADACS had full access to all the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis.

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No age differential was observed among women using donor oocytes. Rates were lower in those with untreated male factor infertility compared to those with any other cause, but treatment with either intra-cytoplasmic sperm injection or sperm donation removed this difference.

Conclusions and relevance—Among women in the UK undergoing IVF, the cumulative prognosis-adjusted live-birth rate after six cycles was 65.3%, with variations by age and treatment type. These findings support the efficacy of extending the number of IVF cycles beyond three or four.

Introduction

In-vitro fertilization (IVF) is commonly stopped after three or four unsuccessful embryo transfers,1,2 with three unsuccessful transfers labelled ‘repeat implantation failure’.3 This practice has been influenced by a study of 1,328 embryo transfers undertaken twenty-years ago, without use of intra-cytoplasmic sperm injection (ICSI), which reported a decline in live-birth rates after the fourth cycle.4 With one exception,5 previous studies of cumulative pregnancy or live-birth rates have been relatively small, with limited ability to precisely estimate cumulative success beyond four transfers.4,6–9 Previous studies have defined a cycle of IVF as an embryo transfer.5–9 Thus, each initiation of IVF with ovarian stimulation has been treated as several separate cycles whenever there has been a series of repeated embryo transfers. Given the promotion of single embryo transfer and the effective freezing of embryos have increased markedly over the last 10-15 years,10–15 it has been suggested that IVF success should be calculated as the live-birth rate per initiated ovarian stimulation, including all subsequent separate fresh and frozen embryo transfers.5,10–13

The aim of this study was to determine the extent to which repeat IVF cycles continue to increase the likelihood of a live-birth, defining an IVF cycle as the initiation of treatment with ovarian stimulation and all resulting separate fresh or frozen embryo transfers; hereafter we use the term “cycle” for this. Specific objectives were to determine: (i) the live-birth rate within each cycle, and the cumulative rate across all cycles; (ii) how these varied by age and treatment types (use of donor oocyte, ICSI or sperm donation); and (iii) the association between oocyte yield in one cycle and live-birth rate in subsequent cycles.

Methods

Ethical approval for this study was provided by the UK Human Fertilisation and Embryology Authority (HFEA) who have statutory obligations to prospectively collect information on all assisted reproductive treatment (ART) in the UK. Women provided written consent for this information to be used in analyses, audit and publications. The HFEA provided us with data on all ART events occurring in the UK between 1st January 2003 and 30th June 2012, with linkage of cycles to individual women and data on birth outcomes. Because all UK clinics, whether private or public, must provide information on any patients treated with ART, together with the outcomes of that treatment, to the HFEA, they are able to link cycles to individual women for all UK ART. We chose the 2003 start date in order to obtain a large cohort representative of contemporary treatment, and June 2012 was the latest date for which the HFEA could provide validated data. Because the live-birth outcome data were incomplete for cycles commencing between January 2011 and June

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2012 (as many of these cycles were still continuing and births from them could occur after June 2012) we limited our potentially eligible cohort to ovarian stimulation cycles initiated between 1st January 2003 and 31st December 2010, with live-birth outcome data collected up to June 2012.

We excluded ART that was not IVF or was undertaken for the purpose of storage, donation or surrogacy. We excluded women who had started IVF before 2003. As in other studies,5–9 once a live-birth occurred women were censored from further analysis. To reflect clinical practice and allow comparisons with other studies,4,5,7,9 we included all embryo transfers, whether the individual transfer was of one or more embryos.

Live-birth was defined as an infant born alive after 24 weeks gestation surviving more than one month. The World Health Organisation (WHO) define live-birth as a birth showing any sign of life irrespective of gestational age. As in other studies,5, 15,16 we modified this to capture births that were likely to be viable. We defined an IVF cycle as the initiation of ovarian stimulation and all resulting separate fresh or frozen embryo transfers. The live-birth rate within a cycle was defined as the probability of a live-birth from an ovarian stimulation encompassing all subsequent fresh and frozen embryo transfers from that stimulation. Thus, for those embarking on IVF the live-birth rate within one cycle answers the question '*What is my chance of a live-birth with one stimulation and retrieval of oocytes followed by as many subsequent separate embryo transfers as possible from that retrieval*?' The cumulative live-birth rate at a given cycle was defined as the probability of a live-birth from all cycles up to and including that cycle. This answers the question '*What is my total chance of a live-birth with repeat ovarian stimulation and oocyte retrievals, together with the subsequent embryo transfers from each cycle, up to a given cycle number*?'.

Information on age, types of treatment (oocyte donation, sperm donation and ICSI), oocyte yield and other couple characteristics were obtained from the HFEA dataset.

Statistical methods

We calculated the live-birth rates within the first and subsequent cycles up to the ninth, as the proportion of cycles resulting in a live-birth, using a normal approximation to construct confidence intervals. We calculated estimates of cumulative live-birth rates using different assumptions of women who discontinue IVF without a live birth (see below), up to the ninth cycle, using the Kaplan-Meier method with Greenwood's approximation to calculate confidence intervals (see online supplementary material for full details).17,18 We used a log-rank test19 to compare the live-birth rate within each cycle and cumulatively across all cycles. The first set of comparisons was between woman's age and oocyte source category and the second was between no male cause of infertility and male cause of infertility with and without treatment by ICSI or sperm donation. We assessed the relationship of oocyte yield in one cycle to live-birth rates in subsequent cycles in women younger than 40 years using their own oocytes, by calculating the within live-birth rate in the first, second, and third cycles by oocytes retrieved in the first cycle, and also calculating the within live-birth rate up to the fifth cycle by oocytes retrieved in the immediately preceding cycle.

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Dealing with discontinuation of IVF

Infertile couples discontinue IVF for a number of reasons, with a systematic review of patient perceptions concluding that the commonest reasons were the physical and/or psychological burden of treatment, relationship or personal problems.20 In any study estimating cumulative live-birth rates assumptions have to be made about what the rate in those who discontinue would have been had they continued. To account for this we calculated 'optimal' and 'conservative' estimates, which are the have been assessed in previous studies. In addition we calculated a prognostic-adjusted estimate. The optimal estimate, is based on the observed data, and whilst not always explicit in previous publications, this assumes that the cumulative live-birth rate in women who discontinue IVF without a live-birth, if they had continued would be equal to the rate in those who continue to have further cycles.5 The conservative estimate assumes those who discontinue IVF would have had a subsequent live-birth rate of zero.5 The true rate is thought to lie between these two.7 The prognostic-adjusted estimate aims to obtain this more realistic value. It assumes a fixed proportion of those who discontinue do so because of poor prognosis and that the live-birth rate in that proportion would have been zero, whereas for those who discontinue for other reasons, such as inability to pay, emotional distress or (in our dataset) emigration from the UK, it would have been similar to those who continue with treatment.

For the prognosis-adjusted estimate we considered the woman's age at her first cycle and oocyte yield in the previous cycle to be the strongest prognostic factors, because these have been shown to be strongly related to live-birth success.5,7,9,21,22 We checked that these were indicators of live-birth and of discontinuation of treatment in our own data, as well as comparing other available characteristics between those who discontinued and continued treatment after one unsuccessful cycle. To obtain age-adjusted and oocyte yield-adjusted estimates we calculated results for each age strata (18-34, 35-37, 38-39, 40-42, 43-44, 45-50, 50+ years) and for each possible oocyte-yield in the previous cycle and then obtained an average, weighted by the numbers within each category in the first cycle. It was not possible to calculate an age-adjusted estimates for the age stratified analyses as there is too little age variation within the age strata. For any analyses that include women using donor oocytes it is not possible to calculate rates adjusted for oocyte yield in the previous cycle as women using donor oocytes will not have an oocyte yield.

The age and previous oocyte yield adjusted results suggested that 3% of those who discontinued IVF did so because of poor prognosis. However, to calculate a prognostic-adjusted cumulative live-birth rate we assumed 30% of those who discontinued did so because of poor prognosis. We chose a value of ten-times that suggested by our data to obtain a conservative prognostic-adjusted estimate. Full details of how these estimates were calculated are provided in online supplementary material.

As the average population live-birth success rate for a single embryo transfer is between 20-30% in high income countries,10–13 we considered 20% to be a benchmark for a good live-birth rate within a cycle. All analyses were undertaken in Stata version 13 MP2. Two-sided p-values < 0.05 were considered to provide evidence against the null hypothesis.

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Comparison with live-birth rates in those not receiving ART

We used data on pregnancy and pregnancy loss rates from published literature to estimate live-birth rates in women who conceive naturally.23-254 Two prospective cohort studies of couples actively trying to conceive provided age specific pregnancy rates attained within twelve menstrual cycles.23,24 Live birth rates were calculated assuming 20% of natural conceptions result in a pregnancy loss.25

Results

Following planned exclusions the eligible cohort included 257,665 cycles in 157,475 women. For all analyses we excluded women with missing linkage information or implausible linkage (i.e. first IVF transfer being a frozen embryo transfer without preceding ovarian stimulation). This resulted in an analysis cohort of 257,398 cycles by 156,947 women (more than 99% of the eligible cohort; Figure 1). Table 1 shows the characteristics of the cohort. eTable 1 shows characteristics by year of treatment. Because of the large sample size there was statistical evidence of differences in all characteristics, but for most these were small and unlikely to be clinically important. For example, median age of the women differed by one-year and median oocyte retrieval differed by one across the study period. Use of ICSI increased by 11%, and transfer of single embryos by 17%, though the live-birth rate increased by just two-percent across the study period.

Table 2 shows the live-birth rate within each cycle for the whole cohort. In all women the live-birth rate for the first cycle was 29.5% (95%CI: 29.3, 29.7). The live-birth rate within cycles remained above 20% for each cycle up to and including the fourth. After their first cycle there were 110,614 women (70.5% of the analysis cohort) who did not have a live-birth. Of these, 37,704 (34.1%) discontinued treatment and 72,910 (65.9%) had at least one more cycle. eTable 2 compares characteristics between these two groups. Although there was statistical evidence of differences for all characteristics the actual differences were small.

The cumulative live-birth rate continued to increase up to the ninth cycle, with a cumulative prognosis-adjusted live-birth rate of 65.3% (64.8, 65.8) by the sixth cycle (Table 2). The equivalent optimal (78.0% (77.3, 78.8)) and age-adjusted (76.7% (76.0, 77.5)) estimates for six cycles were similar, while the conservative estimate was 46.8% (46.5, 47.0) (Table 2 and eFigure 1).

Results varied by age and oocyte source (Figure 2, Table 3, eTables 3 and 4). In women who were younger than 40 years and using their own oocytes (133,379 women, 85% of the cohort), the live-birth rate for the first cycle was 32.3% (32.0, 32.5). This remained above 20% up to and including the fourth cycle. The previous cycle oocyte-yield adjusted and optimal estimates were similar. Six cycles achieved cumulative live-birth rates of 68.4%, (67.8, 68.9), 80.3% (79.5 to 81.0) and 50.7% (50.5, 51.0), for the prognostic-adjusted, optimal and conservative estimates, respectively. For women aged 40-42, the live-birth rate for the first cycle was 12.3% (11.8, 12.8), with six cycles achieving a cumulative live-birth rates of 31.5% (29.7, 33.3), 41.5% (38.0, 44.9), and 19.2% (18.5, 19.8) for prognostic-adjusted, optimal and conservative estimates, respectively. For women older than 42 years

all rates within each cycle were less than 4% or based on too few live-births to calculate confidence intervals.

Use of donor oocytes removed this age differential, as the log-rank test showed no evidence for different cumulative live-birth rates between age categories (eTable 3). Irrespective of age, women using donor oocytes achieved live-birth rates within each cycle of 29.6% or greater for all cycles up to and including the ninth and a cumulative live-birth rate after six cycles of 86.7% (85.2, 88.3), 91.7% (90.3, 93.1) and 75.5% (74.0, 77.1) for the prognostic-adjusted, optimal and conservative estimates, respectively (eTable 4).

Live-birth rates varied by male cause infertility and its treatment (Figure 3 and eTables 5 to 7). Women whose infertility was due to a male related cause and who were not treated with either ICSI or donor sperm had lower live-birth rates than those with a non-male cause of infertility (eTables 3 and 5). Those with a male cause of infertility who were treated with ICSI had cumulative live-birth rates, after six cycles, of 71.3% (70.5, 72.1), 82.2% (81.1,83.4) and 54.7% (54.3, 55.2) using the prognostic-adjusted, optimal and conservative, estimates, respectively (eTable 6). Equivalent results for those with male infertility treated with donor sperm were 81.2% (78.6, 83.9), 90.2% (87.2, 93.1) and 65.9% (63.9, 67.9) respectively (eTable 7). Live-birth rates in both of these groups were greater than in those with a non-male cause of infertility (eTables 3 and 8).

Figure 4 shows the live-birth rate within the first, second and third cycles plotted against the number of oocytes retrieved in the first cycle in women under 40 years of age using their own oocytes. For those in whom no oocytes were retrieved in the first cycle the live-birth rates in the second and third cycles were greater than 20%. The live-birth rates in the first, second and third cycles continued to increase with increasing oocytes retrieved in the first cycle up to around 15 oocytes; thereafter the curves flatten. Plotting the live-birth rate within any cycle against the number of oocytes retrieved in the previous cycle gave a similar pattern (eFigure 2).

Using published data23–25 we estimated that the live-birth rate for women conceiving naturally, who had been trying for 12 menstrual cycles, varied between 58% and 74% depending on the woman’s age and frequency of intercourse (eTable 9). These estimates are based on studies that only included women younger than 40. Similar cumulative live-birth rates were achieved by the fifth or sixth cycle of IVF treatment in women of this age (Table 3), though, in these women, five cycles took a median of 2 years (1st, 3rd quartile: 2, 3).

Discussion

To our knowledge this is the first study to have linked fresh and frozen embryo transfers to obtain estimates of live-birth rate within each IVF ovarian stimulation cycle and cumulative live-birth rates across repeated stimulation cycles. Despite a decline in the success rate within each cycle as the number of these increased, the cumulative rate across cycles increased up to the ninth in the whole cohort, those younger than 40 (using their own oocytes) and those using donor oocytes (irrespective of age). They also increased up to the eighth or ninth in women aged 40-42, though for women older than 42 (using their own

oocytes) the likelihood of success was low and the cumulative live-birth rate did not appear to clearly increase beyond the fourth or fifth cycle. For those women able to use donor oocytes, age was unrelated to success. In those for whom the cause of infertility was related to a male partner problem, treatment with ICSI or donor sperm made a marked difference in the likelihood of success, with cumulative rates increasing up to the eighth or ninth cycle, whereas without treatment rates were lower than in those with other causes of infertility. In women under 40 years with a low oocyte yield in a previous cycle there was benefit in continuing with further cycles. We also found women under 40 years could achieve cumulative live-birth rates after five or six cycles that were similar to published live-birth rates achieved naturally within 12 menstrual cycles.23–25 It should be noted, however, that, in these women, five cycles took a median of 2 years.

Widespread adoption of single embryo transfer has reduced multiple pregnancies and adverse perinatal outcomes, but has meant that the chance of a live-birth from a single ovarian stimulation cycle is spread across multiple embryo transfers, which we have assessed here. Since this method of assessing IVF success combines all embryo transfer events following an ovulation stimulation into one analysis unit, we were unable to examine the effect of the number of embryos transferred per event. However, this method of assessing IVF success is increasingly recommended.5,10–13 Our results show how success rates per embryo transfer event are misleadingly lower, compared with the rate within each ovarian stimulation cycle. Furthermore, we have previously shown, using unlinked data from the same population, that the number of embryos transferred in one event has a relatively modest effect on live-birth rate, with a difference of 9% in women younger than 40 years and 16% in those aged 40 years or older, comparing double to single embryo transfer.15

Despite the differences in the definition of cumulative success between our study and the previous largest study (from the US), in which cumulative live-birth rates were estimated on the basis of each embryo transfer,5 and differences in health systems between the US and UK, both studies found age differences in rates and that these were removed with the use of donor oocytes. In the US study, those with a male cause of infertility had one of the highest cumulative live-birth rates per embryo transfer, but that study did not examine the effect of different treatments (ICSI or sperm donation) and it may be that all of those with male cause infertility in the US receive one of these treatments.

The key limitation of all studies looking at cumulative outcomes with repeat IVF is how one treats those who discontinue treatment. As seen in our data, and in previous studies,5,7 the extremes of the optimal and conservative estimates often vary markedly, for example in our data the optimal and conservative estimates were 78.0% and 46.8%, respectively, for the whole cohort. This is because of the differences between these two, in what they assume would have been the live-birth rate in those who discontinued IVF, had they continued; for the optimal estimate this is assumed to be the same as those who did continue, whereas the conservative estimate it is assumed to be zero. We examined the likelihood that such discontinuation was due to poor prognosis based on age and previous cycle oocyte retrieval. These analyses suggested approximately 3% of those who discontinued did so because of poor prognosis. This small proportion was because although these two were important predictors of live-birth, few women receiving IVF are older than 40 years (only 15% in our

national population cohort) and most women have a high oocyte yield (median 9 per cycle in our cohort). However, to account for other factors, for example pre-treatment reproductive hormone levels, smoking and body mass index (BMI), which have been linked to live-birth success, 7,22 but that were not available in this study, we assumed a 30% discontinuation due to poor prognosis. Because of the legal requirement for all UK clinicians to provide data on all ART patients, the HFEA were able to link cycles to individual women even if they moved between clinics within the UK. However, treatment abroad would be absent from our data. A European study, conducted 6 years ago, found very few UK couples travelled for ART to 49 clinics in six (non-UK) European countries with high rates of cross-border patients.26 We were only able to assess live-birth as an outcome: future studies should also consider potential adverse effects of continued treatment, including ovarian hyper-stimulation syndrome and possible increased risk of preterm birth, low birth weight or congenital anomalies.16,27,28

We acknowledge that for some couples the emotional stress of repeat treatments may be undesirable and the cost of a prolonged treatment course, with several repeat oocyte stimulation cycles, may be unsustainable for health services, insurers or couples. However, we think the potential for success with further cycles should be discussed with couples. A cost-effectiveness analysis is beyond the scope of this study, and the difficulties of undertaking such analyses for IVF, in which decisions related to how one values a new life and whether ‘benefits’ and ‘costs’ for both parents and the child should be included, are well-documented.29 The costs of IVF treatment vary between countries, whether publicly or privately funded, and the treatment type used, but are in the range of $14,000 (£9,000, €12,000) to $17,000 (£11,000, €15,000) per cycle.1,29,30 These costs exclude assessment prior to starting IVF and are based on transfer of one fresh embryo. Assuming each addition frozen embryo transfer costs $4000 to $5000,30 the cost per couple of continuing to six, rather than having just three cycles, could be as much as $132,000 compared to $66,000 (assuming one fresh and one frozen transfer per cycle).

Conclusions

Among women in the UK undergoing IVF, the cumulative prognosis-adjusted live-birth rate after six cycles was 65.3%, with variations by age and treatment type. These findings support the efficacy of extending the number of IVF cycles beyond three or four.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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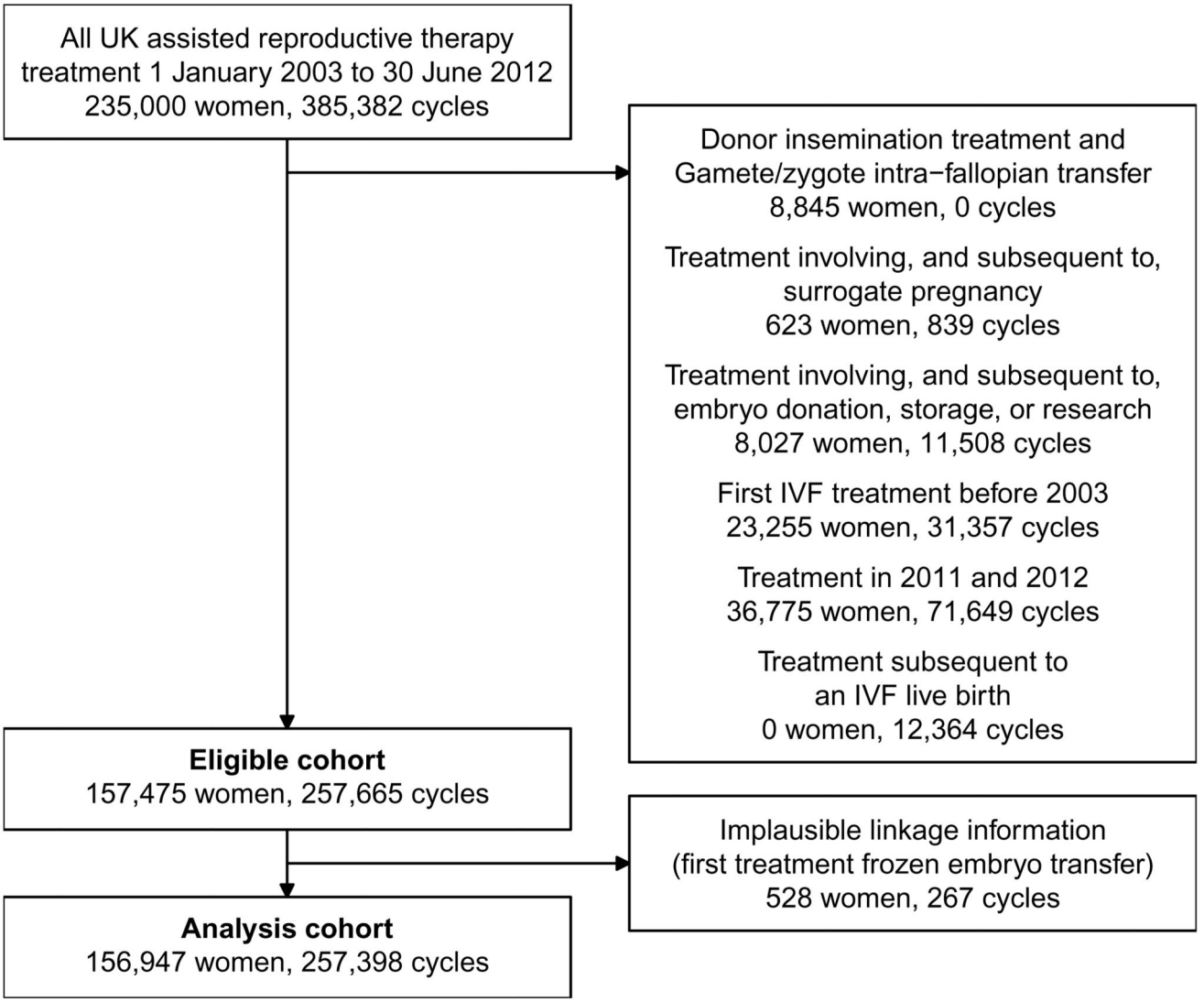
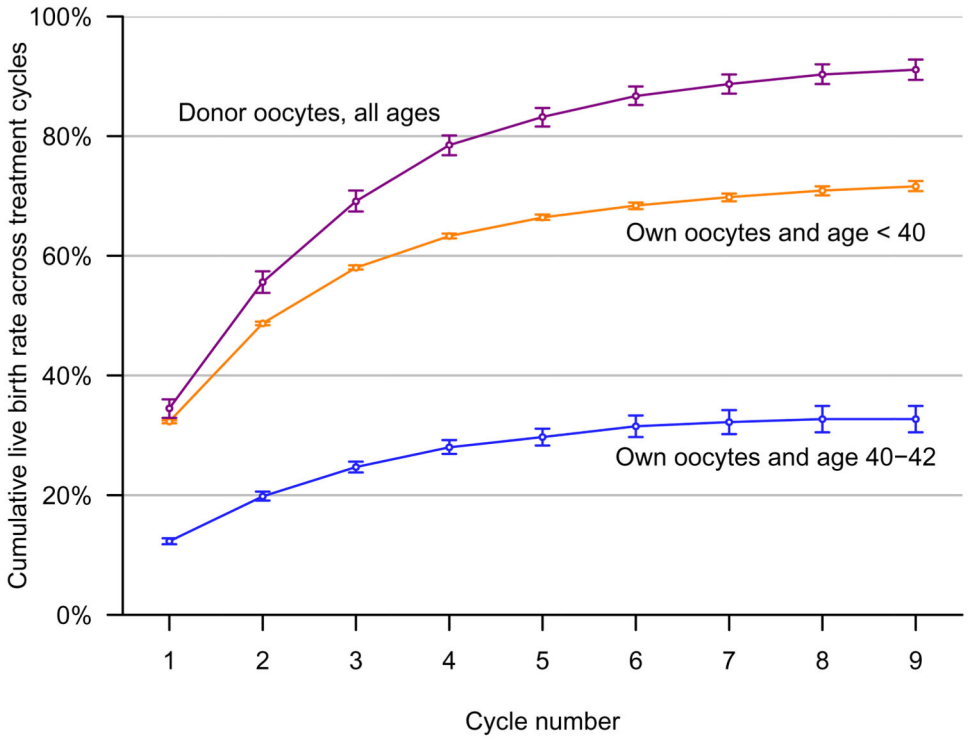


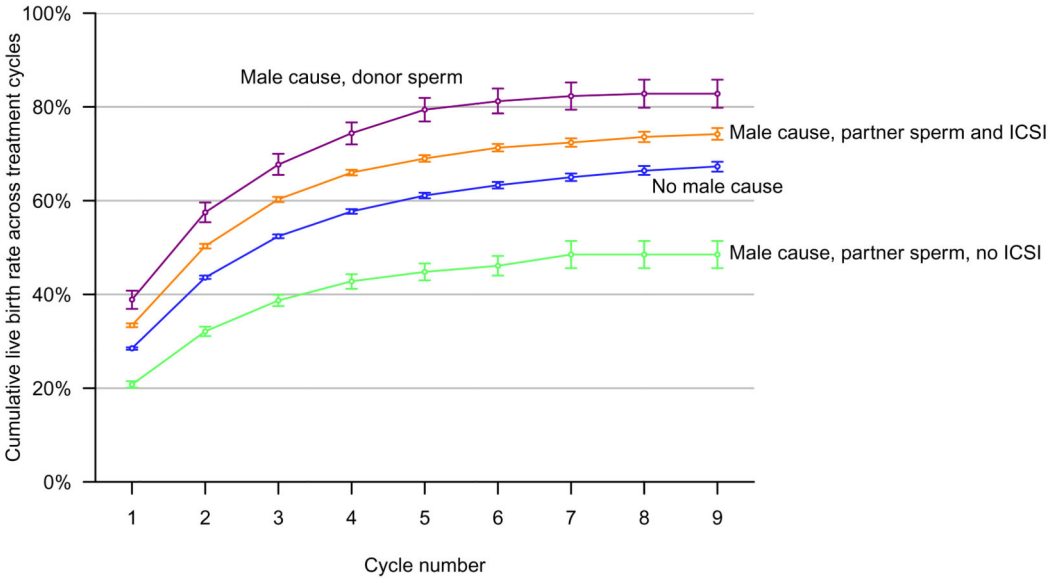
Figure 1. Definition of eligible and analysis cohort.



Number of women									
Own oocytes and age < 40	133,379	53,568	19,719	6,641	2,357	882	335	131	51
Own oocytes and age 40−42	15,561	6,671	2,579	884	301	130	60	36	20
Own oocytes and age > 42	4,420	1,578	509	160	67	24	10	5	4
Donor oocytes, all ages	3,587	1,636	939	554	287	126	53	27	8

Figure 2. Cumulative live-birth rate across all initiated IVF cycles by age and oocyte source.

The figure shows the prognosis-adjusted estimates of cumulative live-birth rates (i.e. the rate (shown on the y-axis) is the likelihood of a live-birth across all initiated cycles up to and including the numbers on the x-axis), with 95% confidence intervals. These are presented for women in two different age categories at the start of their first IVF treatment cycle (< 40 years and 40-42 years; women in both of these categories used their own oocytes) and also in women who used donor oocytes (these women cover the full age range). Data for women aged over 42 at their first treatment cycle are not shown because rates were so low it would have been difficult to represent them on this same graph (full results for these women are shown in Table 3). The prognostic-adjusted estimate assumes that 30% of those who discontinued IVF did so because of poor prognosis and that the live-birth rate in that 30% would have been zero had they continued. Analyses were completed in 156,947 women undergoing 257,398 cycles. Log-rank tests indicated a difference between the cumulative live-births rates for all groups ($p < 0.001$ for all comparisons).



Number of women									
No male cause	93,924	37,161	13,645	4,680	1,765	690	277	119	51
Male cause, partner sperm, no ICSI	12,536	4,207	1,478	471	148	70	30	15	3
Male cause, partner sperm and ICSI	48,016	21,006	8,203	2,911	1,015	377	141	57	24
Male cause, donor sperm	2,471	1,079	420	177	84	25	10	8	5

Figure 3. Cumulative live-birth rate across all initiated IVF cycles by ICSI and sperm donation.

The figure shows the prognosis-adjusted estimates of cumulative live-birth rates (i.e. the rate (shown on the y-axis) is the likelihood of a live-birth across all initiated cycles up to and including the numbers on the x-axis), with 95% confidence intervals. These are shown for couples without a male cause of infertility, couples with a male cause who were not treated with ICSI or sperm donation, those with a male cause who were treated with ICSI and those with a male cause who used sperm donation. The prognostic-adjusted estimate assumes that 30% of those who discontinued IVF did so because of poor prognosis and that the live-birth rate in that 30% would have been zero had they continued. Analyses were completed in 156,947 women undergoing 257,398 cycles. Log-rank tests indicated a difference between the cumulative live-births rates for all groups ($p < 0.001$ for all comparisons).

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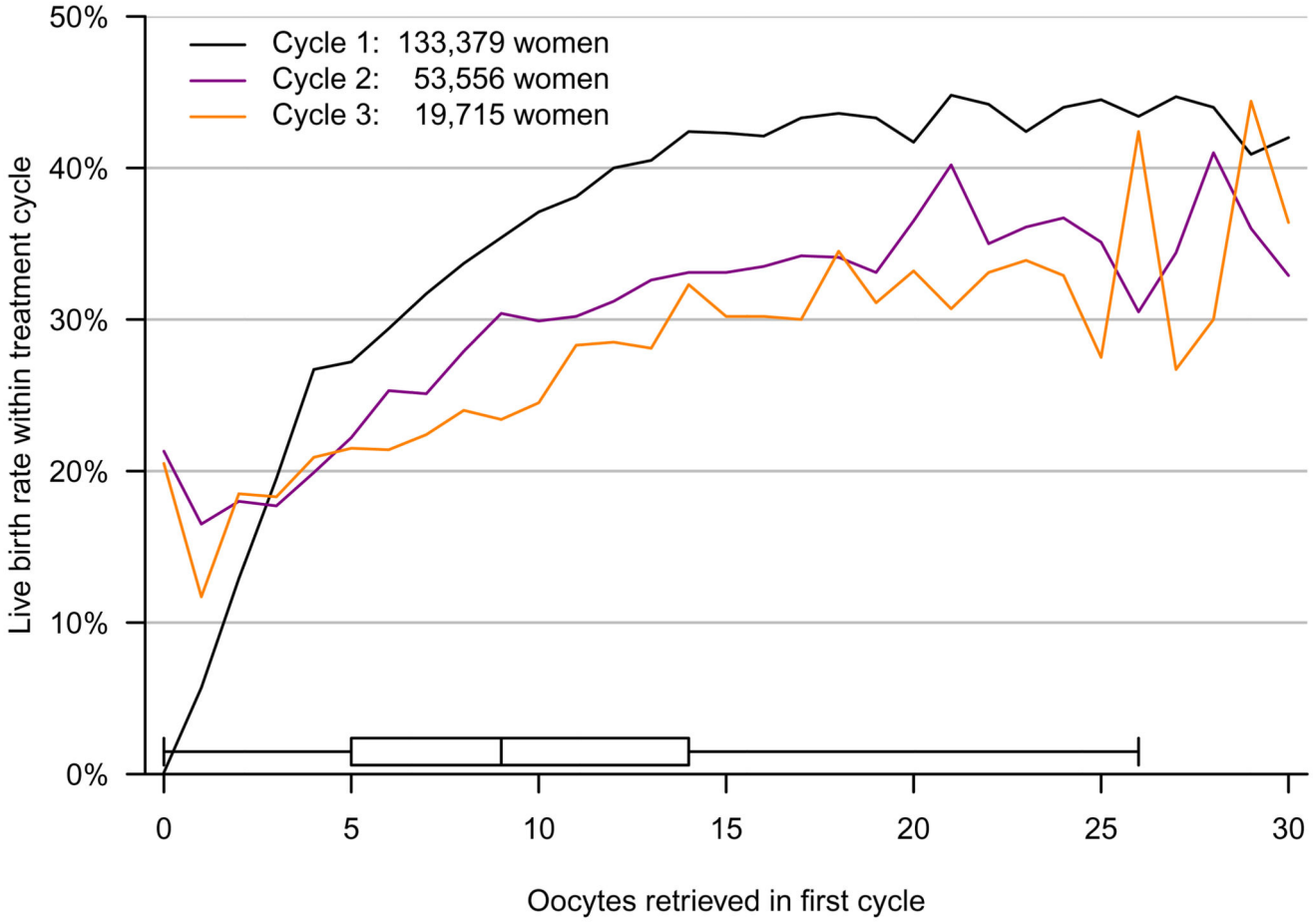

Figure 4. Live-birth rate within each single IVF treatment cycle by oocyte retrieval in first cycle.
The figure shows the live-birth rate within each individual first, second and third treatment cycle (i.e. for each line the rate on the y-axis is the rate for just that one treatment cycle), against the number of oocytes retrieved in the first treatment cycle (shown on the x-axis). Analyses are in 134,903 women aged less than 40 years and using their own oocytes. Box and whiskers show the central 95% of the distribution of oocytes retrieved in the first cycle, as well as the median and lower and upper quartiles.

Table 1

Characteristics of the analysis cohort of 156,947 women commencing IVF treatment for infertility in the UK in 2003-2010 (with outcomes assessed up to June 2012).

Characteristic	For all cycles combined[a]	For first cycle[b]
Number of women	156,947	156,947
Total number of cycles 1 2 3 More than 3	93,494 (59.6%) 39,707 (25.3%) 15,507 (9.9%) 8,239 (5.2%)	
Number of cycles	257,398	156,947
Live-births (% per cycle)	70,093 (27.2%)	46,333 (29.5%)
Woman's age (years) Median (1st quartile, 3rd quartile)	35 (32, 38)	35 (32, 38)
Duration of infertility (years) Median (1st quartile, 3rd quartile) Missing	4 (2, 6) 11,165 (4.3%)	3 (2, 5) 6,586 (4.0%)
Causes of infertility (non-exclusive) Tubal Ovulatory Endometriosis Male cause	46,535 (18.1%) 34,473 (13.4%) 15,889 (6.2%) 105,014 (40.8%)	28,181 (18.0%) 21,582 (13.8%) 9,654 (6.1%) 63,023 (40.2%)
Treated with ICSI	123,009 (47.8%)	68,608 (43.7%)
Treated with sperm donation	8,067 (3.1%)	4,781 (3.05%)
Treated with oocyte donation	7,223 (2.8%)	3,587 (2.3%)
Oocytes retrieved (own) Median (1st quartile, 3rd quartile)	9 (5, 13)	9 (5, 13)
Embryo transfer events per cycle No embryos transferred Fresh embryo transfer only Fresh and frozen embryo transfer	31,738 (12.3%) 199,713 (77.6%) 25,947 (10.1%)	20,794 (13.3%) 119,462 (76.1%) 16,691 (10.6%)
Number of embryo transfer events	257,581	157,043
Number of embryos transferred per embryo transfer event[c] 1 2 3-4	44,330 (17.2%) 201,888 (78.4%) 11,363 (4.4%)	29,942 (19.1%) 122,483 (78.0%) 4,618 (3.0%)

[a] The unit of analysis here is cycle (with results the average across all cycles per woman)

[b] As this is just one cycle the unit of analysis is the women at their first treatment cycle

[c] As there are a variable number of transfer events per treatment cycle (which includes all subsequent fresh and frozen transfer events) the % is per the number of transfer events (not per cycle)

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Table 2

Within initiated treatment cycle live-birth rates and cumulative live-birth rate across all cycles in 156,947 women undergoing 257,398 cycles of IVF

Cycle number	N Cycles	N live-births	Live-birth rate within each cycle % (95%CI)	Cumulative live-birth across all cycles using different estimates % (95%CI)			
				Optimal estimate[a]	Age adjusted estimate[b]	Prognostic-adjusted estimate[c]	Conservative estimate[d]
1st	156,947	46,333	29.5 (29.3, 29.7)	29.5 (29.3, 29.7)	29.5 (29.3, 29.7)	29.5 (29.3, 29.7)	29.5 (29.3, 29.7)
2nd	63,453	15,825	24.9 (24.6, 25.3)	47.1 (46.8, 47.4)	46.7 (46.4, 47.0)	45.1 (44.9, 45.4)	40.5 (40.3, 40.8)
3rd	23,746	5,358	22.6 (22.0, 23.1)	59.0 (58.7, 59.4)	58.3 (57.9, 58.6)	54.3 (54.0, 54.6)	44.6 (44.4, 44.9)
4th	8,239	1,690	20.5 (19.6, 21.4)	67.4 (67.0, 67.9)	66.4 (66.0, 66.9)	59.8 (59.4, 60.1)	46.1 (45.8, 46.3)
5th	3,012	553	18.4 (17.0, 19.7)	73.4 (72.8, 74.0)	72.2 (71.6, 72.7)	63.1 (62.6, 63.5)	46.6 (46.3, 46.8)
6th	1,162	202	17.4 (15.2, 19.6)	78.0 (77.3, 78.8)	76.7 (76.0, 77.5)	65.3 (64.8, 65.8)	46.8 (46.5, 47.0)
7th	458	79	17.2 (13.8, 20.7)	81.8 (80.8, 82.8)	80.5 (79.5, 81.5)	66.8 (66.2, 67.4)	46.9 (46.7, 47.2)
8th	199	37	18.6 (13.2, 24.0)	85.2 (83.9, 86.5)	83.7 (82.4, 85.0)	68.0 (67.3, 68.7)	46.9 (46.7, 47.2)
9th	83	13	15.7 (7.8, 23.5)	87.5 (85.9, 89.1)	86.3 (84.7, 87.9)	68.7 (68.0, 69.5)	46.9 (46.7, 47.2)

[a]The optimal estimate assumes that the cumulative live-birth rate in women who discontinue IVF without a live-birth, if they had continued, would have been equal to the rate in women who continued to have further IVF. That is it assumes that 0% of women who discontinued IVF did so because of poor prognosis that would have affected their live-birth success had they continued.

[b]The age-adjusted estimate assumes that the cumulative live-birth rate in women who discontinued IVF, if they had continued, would have been equal to the rate in women who were the same age at the start of treatment, and who continued to have further IVF. These results suggested approximately 3% of women who discontinued did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

[c]The prognostic-adjusted estimate assumes that 30% of women who discontinued IVF did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

[d]The conservative estimate assumes that the cumulative live-birth rate in all women who discontinued IVF would have been zero, had they continued. That is it assumes that 100% of women who discontinued did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

Note it is not possible to calculate an oocyte-adjusted estimate for the whole cohort due to the presence of women using donor oocytes.

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Table 3

Within initiated treatment cycle live-birth rates and cumulative live-birth rate across all cycles in 153,360 women, undergoing 250,175 cycles of IVF using their own oocytes, stratified by age at first ovarian stimulation cycle.

Cycle number	N Cycles	N live-births	Live-birth rate within each cycle % (95%CI)	Cumulative live-birth across all cycles using different estimates % (95%CI)			
				Optimal estimate[a]	Previous oocyte yield-adjusted estimate[b]	Prognostic-adjusted estimate[c]	Conservative estimate[d]
Aged less than 40 years							
1st	133,379	43,019	32.3 (32.0, 32.5)	32.3 (32.0, 32.5)	32.3 (32.0, 32.5)	32.3 (32.0, 32.5)	32.3 (32.0, 32.5)
2nd	53,568	14,532	27.1 (26.8, 27.5)	50.6 (50.3, 50.9)	50.7 (50.4, 51.1)	48.7 (48.4, 49.0)	44.3 (44.0, 44.5)
3rd	19,719	4,793	24.3 (23.7, 24.9)	62.6 (62.3, 63.0)	62.7 (62.3, 63.1)	58.0 (57.7, 58.4)	48.6 (48.4, 48.9)
4th	6,641	1,419	21.4 (20.4, 22.4)	70.6 (70.1, 71.1)	70.5 (70.1, 71.0)	63.3 (62.9, 63.7)	50.1 (49.8, 50.3)
5th	2,357	449	19.0 (17.5, 20.6)	76.2 (75.6, 76.8)	76.0 (75.4, 76.6)	66.4 (66.0, 66.9)	50.6 (50.3, 50.8)
6th	882	150	17.0 (14.5, 19.5)	80.3 (79.5, 81.0)	80.1 (79.3, 80.8)	68.4 (67.8, 68.9)	50.7 (50.5, 51.0)
7th	335	58	17.3 (13.3, 21.4)	83.7 (82.7, 84.7)	83.4 (82.4, 84.4)	69.8 (69.1, 70.4)	50.8 (50.5, 51.1)
8th	131	25	19.1 (12.4, 25.8)	86.8 (85.4, 88.2)	86.5 (85.1, 87.9)	70.9 (70.1, 71.6)	50.9 (50.6, 51.1)
9th	51	10	19.6 (8.7, 30.5)	89.4 (87.6, 91.2)	88.8 (87.2, 90.3)	71.6 (70.8, 72.5)	50.9 (50.6, 51.2)
Aged 40 to 42 years							
1st	15,561	1,914	12.3 (11.8, 12.8)	12.3 (11.8, 12.8)	12.3 (11.8, 12.8)	12.3 (11.8, 12.8)	12.3 (11.8, 12.8)
2nd	6,671	671	10.1 (9.3, 10.8)	21.1 (20.3, 21.9)	20.8 (20.0, 21.6)	19.8 (19.1, 20.6)	16.8 (16.3, 17.4)
3rd	2,579	223	8.6 (7.6, 9.7)	27.9 (26.8, 29.1)	27.6 (26.5, 28.7)	24.7 (23.8, 25.6)	18.5 (17.8, 19.1)
4th	884	69	7.8 (6.0, 9.6)	33.6 (31.9, 35.2)	33.0 (31.4, 34.7)	28.0 (26.9, 29.2)	19.0 (18.4, 19.6)
5th	301	16	5.3 (2.8, 7.9)	37.4 (34.8, 39.4)	36.5 (34.3, 38.8)	29.7 (28.3, 31.1)	19.1 (18.5, 19.8)
6th	130	9	6.9 (2.6, 11.3)	41.5 (38.0, 44.9)	40.5 (37.3, 43.8)	31.5 (29.7, 33.3)	19.2 (18.6, 19.8)
7th	60	2	3.3[†]	43.4 (39.1, 47.7)	42.4 (38.4, 46.3)	32.2 (30.2, 34.2)	19.2 (18.6, 19.9)
8th	36	1	2.8[†]	45.0 (39.8, 50.1)	43.4 (39.1, 47.6)	32.7 (30.5, 34.9)	19.2 (18.6, 19.9)
9th	20	0	0.0[†]	45.0 (39.8, 50.1)	43.4 (39.1, 47.6)	32.7 (30.5, 34.9)	19.2 (18.6, 19.9)
Aged more than 42 years							
1st	4,420	164	3.7 (3.2, 4.3)	3.7 (3.2, 4.3)	3.7 (3.2, 4.3)	3.7 (3.2, 4.3)	3.7(3.2, 4.3)
2nd	1,578	52	3.3 (2.4, 4.2)	6.9 (5.9, 7.9)	6.9 (5.9, 7.9)	6.3 (5.4, 7.2)	4.9 (4.3, 5.6)

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Cycle number	N Cycles	N live-births	Live-birth rate within each cycle % (95%CI)	Cumulative live-birth across all cycles using different estimates % (95%CI)			
				Optimal estimate[a]	Previous oocyte yield-adjusted estimate[b]	Prognostic-adjusted estimate[c]	Conservative estimate[d]
3rd	509	17	3.3 (1.8, 4.9)	10.0 (8.2, 11.7)	9.8 (8.1, 11.5)	8.3 (7.1, 9.6)	5.4 (4.7, 6.0)
4th	160	2	1.3†	11.1 (8.8, 13.4)	10.1 (8.5, 11.8)	8.9 (7.4, 10.5)	5.5 (4.8, 6.2)
5th	67	3	4.5†	15.1 (10.2, 20.0)	14.2 (10.7, 17.7)	10.7 (8.2, 13.2)	5.5 (4.8, 6.2)
6th	24	0	0.0†	15.1 (10.2, 20.0)	14.2 (10.7, 17.7)	10.7 (8.2, 13.2)	5.6 (4.9, 6.3)
7th	10	2	20.0†	32.1 (10.7, 53.5)	22.3 (14.0, 30.5)	15.9 (8.5, 23.2)	5.6 (4.9, 6.3)
8th	5	0	0.0†	32.1 (10.7, 53.5)	22.3 (14.0, 30.5)	15.9 (8.5, 23.2)	5.6 (4.9, 6.3)
9th	4	0	0.0†	32.1 (10.7, 53.5)	22.3 (14.0, 30.5)	15.9 (8.5, 23.2)	5.6 (4.9, 6.3)

Note it is not possible to calculate an age-adjusted estimate these age stratified analyses and there is too little age variation within the ages stratified groups to further adjust for age.

[a]The optimal estimate assumes that the cumulative live-birth rate in women who discontinue IVF without a live-birth, if they had continued, would have been equal to the rate in women who continued to have further IVF. That is it assumes that 0% of women who discontinued IVF did so because of poor prognosis that would have affected their live-birth success had they continued.

[b]The previous oocyte yeild-adjusted estimate assumes that the cumulative live-birth rate in women who discontinued IVF, if they had continued, would have been equal to the rate in women who had the same oocyte yield in the immediately previous ovarian stimulation treatment, and who continued to have further IVF. These results suggested approximately 3% of women who discontinued did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

[c]The prognostic-adjusted estimate assumes that 30% of women who discontinued IVF did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

[d]The conservative estimate assumes that the cumulative live-birth rate in all women who discontinued IVF would have been zero, had they continued. That is it assumes that 100% of women who discontinued did so because of poor prognosis and would have had a live-birth rate of zero, had they continued.

†These are cycles for which there was fewer than six live births and for these standard errors and hence confidence intervals could not be calculated