NHS
Wiltshire
Clinical Commissioning Group

Clinical Commissioning Group Governing Body
Paper Summary Sheet
Date of Meeting:

For: PUBLIC session ☒ **PRIVATE Session** ☐

For: Decision ☒ **Discussion** ☐ **Noting** ☐

Agenda Item and title:	**GOV/16/09/10 NHS Wiltshire Fertility Assessment And Treatment Policy**
Author:	Nadine Fox, Head of Medicines Management
Lead Director/GP from CCG:	Mark Harris, Director of Acute Commissioning Dr Helen Osborn, Medical Advisor
Executive summary:	The policy sets out the limits within which WCCG will fund treatment with either Intrauterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment. The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child. The CCG has reviewed its policy for fertility treatment funding and is proposing to make the following changes to the current criteria: • move from offering a maximum of 6 embryo transfers to a maximum of 3 embryo transfers (of which a maximum of 1 is fresh). • amend the time trying to conceive by reducing from 3 to 2 years for women who are 35-40 years of age. This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline • allow couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, (i.e. Azoospermia, or bilateral tubal blockage) and who meet other eligibility criteria, immediate access to NHS funded assisted reproduction services as long as all other eligibility criteria are met. • stipulate that couples must have been in a stable relationship for at least 2 years. This requirement supports the welfare of the child assessment as per HFEA Code of Practice. • stipulate that both partners must be registered with a GP practice in Wiltshire Clinical Commissioning Groups for at least 12 months prior to

	referral from primary care to secondary care and be eligible for NHS care (unless transferring whilst already on a treatment pathway where continuation of care will follow.) Clarification has also been made in areas where the previous policy was ambiguous and causing problems of interpretation between commissioner and provider: • Definition of cancelled and abandoned cycles • Embryo storage • Surrogacy This proposal has been discussed and supported at the Clinical Executive and agreed at Clinical Advisory Group and Quality and Clinical Governance Committee. NHS organisations are entitled to take decisions which do not follow NICE Clinical Guidance if they have a good reason to do so. The availability of resources and competing priorities can be a good reason.
Evidence in support of arguments:	NICE Clinical Guideline 156 – Fertility (https://www.nice.org.uk/guidance/cg156/resources/guidance-fertility-pdf) The Human Fertilisation Embryology Authority (HFEA) report 2014
Who has been involved/contributed:	Salisbury Fertility Centre Bath Fertility Centre
Cross Reference to Strategic Objectives:	
Engagement and Involvement:	Public Engagement via HealthWatch
Communications Issues:	
Financial Implications:	None in year
Review arrangements:	Review in line with STP Clinical policy workstream
Risk Management:	
National Policy/ Legislation:	NICE Clinical Guideline 156 – Fertility
Public Health Implications:	

Equality & Diversity:	
Other External Assessment:	
What specific action re. the paper do you wish the Governing Body to take at the meeting?	The Governing Body is asked to approve the revised policy which would come into effect for all new referrals from 28th October 2016.

NHS WILTSHIRE
FERTILITY ASSESSMENT AND TREATMENT POLICY

Introduction

In [Feb 2013] NICE published national guidance for Clinical Guideline 156 – Fertility (https://www.nice.org.uk/guidance/cg156/resources/guidance-fertility-pdf).

NICE clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on best available evidence. NHS organisations are entitled to take decisions which do not follow Guidance (other than NICE TAs) if they have a good reason to do so. The availability of resources and competing priorities can be considered as in this context.

In view of the continuing financial pressures upon the local health economy and most particularly in light of the CCG's requirement for financial recovery, Wiltshire CCG Clinical Advisory Group proposed that a review be undertaken of the CCG policy in relation to funding fertility treatment, suggesting that the CCG may not be able to continue to prioritise resources to fully implement all of the recommendations in NICE clinical guideline 156. The CCG has also taken the opportunity in reviewing the policy to clarify a number of other areas that have been raised by current service providers.

Wiltshire CCG currently offers three full cycles of IVF to couples. The CCG is one of two CCGs in the South West (the other being Swindon - where a policy review has been proposed) offering 3 cycles. The CCG has experienced patients who, in spite of living outside of the Wiltshire boundary, register with Wiltshire GPs specifically to access the service. Wiltshire CCG has reviewed the existing policy for fertility assessment and treatment in line with best clinical outcomes for patients within the existing financial resources.

Wiltshire CCG acknowledges that locally and nationally, the public and clinicians have very diverse views about access to fertility treatment and the funding of the provision of the treatment. Views range from whether the treatment is something that the NHS should fund at all; to all infertile patients receiving NHS funded full access to all recommended interventions made in NICE clinical guideline 156.

Background and current situation

The NHS fertility assessment and treatment Policy in Wiltshire was produced following NICE guidance issued in 2004 and the merger of PCTs to form Wiltshire Primary Care Trust. Wiltshire PCT's guidance ceased to exist when NHS Wiltshire Clinical Commissioning Group (CCG) was established in April 2014. All policies transferred to the CCG.

The CCG's current policy defines what fertility assessment and treatment is commissioned by the NHS in Wiltshire and sets out eligibility criteria for patients wishing to access these services.

Comparison with Bath & North East Somerset CCG (BaNES) and Somerset CCG Policies

BaNEs	Wiltshire	Somerset
Criteria Based Access (CBA) – One cycle of PGD will be considered for couples who meet the following criteria: One partner has had a positive test for a life-limiting condition. Female is aged between 23-40 Female has BMI between 19 and 30 Women with polycystic ovaries BMI between 19 and 33 At least one partner must have no living children. There are no concerns for the welfare of existing children within the relationship.	No Criteria Based access, Prior approval required for all Fertility treatment.	No Criteria Based access, Prior approval required for all Fertility treatment.

Criteria	BaNEs	Wiltshire	Somerset
Age of prospective mother at start of cycle.	After females 23rd birthday and before the females 40th birthday. CBA	After females 30th birthday and before the females 40th birthday.	After females 23rd birthday and before 40th birthday.
Age of male partner	No upper age limit.	Male partner before 55th birthday.	Male partner before 55th birthday.
Number of cycles	One full cycle of IVF/ICSI (Maximum of 1 fresh &1 Frozen embryo transfers).	Three full cycles of IVF/ICSI (Maximum of 3 fresh and 3 frozen embryo transfers).	One full cycle of IVF/ICSI (Maximum of 1 fresh and 1frozen embryo transfers).

	3 IUI = 1 Cycle IVF/ICSI	3 IUI = 1 Cycle IVF/ICSI 2nd or a 3rd fresh cycle should not be attempted until there is only one frozen embryo left available.	3 IUI = 1 Cycle IVF/ICSI
Time period trying to conceive	3 Years	3 Years	2 Years
Residency	Individuals must be registered with a GP in Bath or North East Somerset.	Female partner should be registered with an NHS Wiltshire GP or, if unregistered, live in Wiltshire on a permanent basis.	Couples must both be registered with a GP in Swindon CCG.
BMI	19 – 30 19 – 33 for women with Polycystic ovaries.	19 - 30	19 - 30
Previous infertility treatment – NHS and privately funded.	Couples who have already had 3 or more cycles of IVF / ICSI (privately or NHS funded elsewhere) will not be eligible for further NHS funding. Funding will not be available retrospectively for any couples who would have been eligible but self- funded their treatment.	Individuals who have undergone three or more previous IVF/ICSI cycles either NHS or privately funded, in any relationship, will be ineligible for further NHS funding	Previous privately funded treatment will not preclude patients from being eligible to NHS Somerset CCG funded fertility treatment. However previous cycles, privately funded, will be taken into account by the responsible clinician in determining the clinical appropriateness of commencing further cycles. In line with current clinical evidence, couples should undergo no more than five cycles in total. Where a member of the couple has previously received NHS funded treatment as part of another couple, they will not be barred from accessing NHS funded treatment under their current relationship where they meet all

			criteria
Surrogacy	None stated	Fertility treatment will be funded for women with a non-functioning uterus as long as the eligibility criteria are met for transfer to a surrogate mother. NHS Wiltshire will not fund the pre-treatment screening which the patient needs to arrange and self-fund.	Somerset Clinical Commissioning Group does not commission any clinical services associated with surrogacy.
Smoking status	Couples who smoke will not be eligible.	Couples who smoke will not be eligible.	Neither partner should smoke (Partners who smoke can be referred to the smoking cessation service.
Childlessness	At least one partner must have no living offspring/children. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children. If the couple adopt a child or conceive naturally during assessment or treatment, they are no longer eligible for fertility assessment or treatment.	Treatments for sub-fertility will be funded if the couple has no living children (including adopted children) from the partnership and one of the partners has no living children. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be eligible for treatment.	There should be no living children from the current relationship including adopted children but excluding fostered children. There should be no children from previous relationships for either partner.

Evidence and Guidance

National evidence based research and NICE guidance advises that although most women fall pregnant within two years of unprotected sexual intercourse, around 10% of couples are unsuccessful. This is called infertility and there are a range of reasons why couples do not conceive, including various clinical factors in the man or the women, such as age, obesity and/or lifestyle factors such as smoking or drinking.

There are a number of potential treatments for infertility in heterosexual and same sex couples, including medical and surgical interventions. However some couples can only conceive with the help of complex treatments such as in-vitro fertilisation (IVF) Intracytoplasmic sperm injections (ICSI) Intrauterine insemination (IUI) – assisted conception.

IVF involves drug treatments, ultrasound-guided egg collection from the woman, mixing of eggs and sperm in the laboratory and implantation of a fertilised egg(s) into the woman's womb. Any suitable embryo(s) not used in the initial treatment, can also be frozen for future use.

In February 2013 the NICE Clinical Guidance was updated and republished (NICE CG 156, February 2013). This guidance is not statutory but offers best practice advice on assisting people of reproductive age who have problems conceiving. The new NICE clinical guideline 156 made many recommendations, three of which were significantly different from the previous policy:

- Women under 40 (who meet certain criteria) be offered 3 full cycles of IVF.
- Women aged 40 – 42 (who meet certain criteria) be offered 1 full cycle of IVF.
- Access to fertility assessment and treatment should be after a two year period of infertility with the same partner.

The Equality Act 2010 means that people should not be discriminated against, directly or indirectly based on age, sex, sexual orientation, gender reassignment, race, religion and belief, marital status, disability and whether they are pregnant.

Clinical effectiveness metrics

The effectiveness and cost-effectiveness, of IVF falls rapidly as age increases and female fertility declines.

The Human Fertilisation Embryology Authority (HFEA) publishes evidence of effectiveness of assisted conception; the latest published evidence is set out below.

Live Birth rate, per treatment cycle started using patients' fresh eggs as reported by HFEA 2014.

	Year of treatment	2010	2011
AGE	18-34	32.2%	32.2%
	35-37	27.8%	27.4%
	38-39	20.8%	19.9%
	40-42	13.6%	13.4%
	43-44	5.0%	5.1%
	45+	1.9%	0.8%

Live birth rate per cycle started, after frozen embryo transfer using women's own eggs

	Year of treatment	2011	2012
AGE	18-34	21.4%	22.1%
	35-37	20.7%	20.7%
	38-39	17.1%	18.2%
	40-42	13.1%	15.0%
	43-45+	13.1%	7.2%

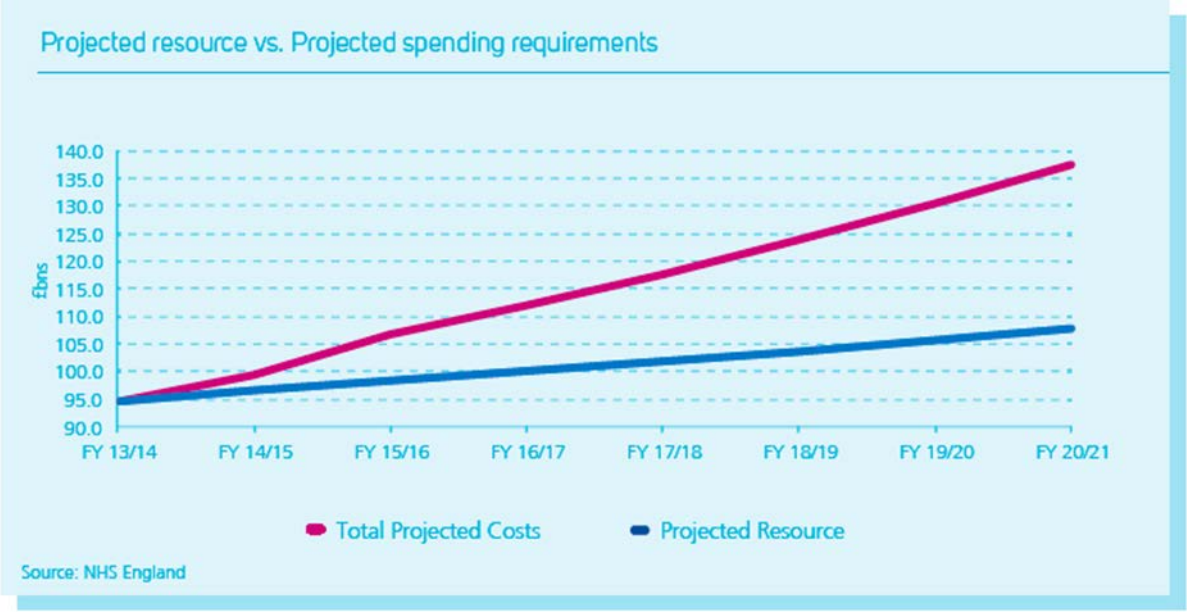
Financial considerations

The financial and demographic pressures facing the NHS mean that health and social care services must change. Continuing with the current model of care will result in the NHS facing a funding gap of around £30 billion (approximately 22% of projected costs), between 2013/14 and 2020/21(Table 1.)

NHS Wiltshire CCG must rationalise service delivery ensuring high-quality services in Wiltshire that are consistent with safe standards of care which are clinically and financially sustainable.

NHS Wiltshire CCG has finite resources to fund a whole range of health services and treatments. IVF is an expensive treatment which can often be unsuccessful. There is a need to balance funding for this treatment with all other treatments/services across the whole NHS.

Table 1.



Cost and clinical Modelling

- Cost modelling has been carried out to review the implications of :-widening the age range;
- giving consideration to the number of full IVF cycles commissioned;
- and reducing the period of infertility with the same partner before access to fertility assessment and treatment.

The cost modelling was calculated using the NICE 156 (2013) costing template. Where possible local assumptions and costs have been built into the model, however

it is recognised that any model has limitations and as such it is not possible to define an exact cost/risk analysis.

The current assisted conception contract annual value is £850,000, based on funding three cycles from which NICE assumes that on average 2.2 cycles are actually used.

Widening the age rate to those recommended by NICE would result in an additional cost pressure which is difficult to model as the numbers of women between 40 & 42 who would request treatment is unknown at this time.

Estimated additional recurrent costs of IVF treatment by increasing the age range of the female partner from 30-40years to 18-40years for the population of Wiltshire (using the NICE cost calculator).

Recommendation area	Year 1	Year 2	Year 3	Year 4
Increased recurrent costs of increasing the age range to 18-40years	£150,000	£297,000	£356,000	£356,000

Reducing the period of infertility with the same partner from 3 years to 2 years before access to fertility assessment and treatment would increase the costs by an estimated non-recurring amount over up to three years (using the NICE cost calculator). See below.

Recommendation area	Year 1	Year 2	Year 3	Year 4
Increased cost by reducing time in the wait for IVF from 3 to 2 years	£250,000	£336,000	£379,000	£0

The combination of the increased age range and reduced time trying to conceive would create an additional cost to Wiltshire as shown below:

Recommendation area	Year 1	Year 2	Year 3	Year 4
Combined increased costs of increased age range and reducing waiting time for IVF	£400,000	£633,000	£735,000	£356,000

Reducing the number of cycles to 2 with the same current criteria would reduce the number of average cycles actually used to 1.7 cycles at an annual cost saving of £193,182.

Reducing the number of cycles to 1 with the same current criteria would reduce the number of cycles actually used to 1 cycle at an annual cost saving of £463,637.

Both of the above savings to existing spend levels are the full year effect with any chance to current policy realising a part year impact in the first year of implementation as existing patients complete their cycles.

Public engagement

In May 2016 the CCG discussed with Healthwatch how it might seek the representative views of the public to help determine what future CCG policy regarding IVF provision across Wiltshire might look like. It was agreed that a public consultation was not required, and the approach taken was to present to the Healthwatch Volunteers forum made up of a mixed demographic of 35-40 people. The presentation took people through the CCG's existing policy and the implications of applying full NICE guidelines (as set out in CG 156) as well as the options to reduce the number of funded cycles; and people were asked to share their views about the level to which the CCG should fund IVF treatment. The National picture of diverse views was borne out at a local level, with a 50:50 split on the issues of:

- Implementing a male BMI
- Immediate funding with a known cause of infertility
- Access to treatment with children from one partner from a previous relationship

The average number of cycles suggested was 1.7 with a fifth of responders suggesting no funding at all.

The feedback from the meeting has helped to shape our thinking on the proposed new policy for Wiltshire.

Proposed New Policy - Differences between old and new policies

	Old Policy	**New Policy**
Embryo Transfers:	Maximum of 6 Embryo transfers of which a maximum of 3 will be Fresh Embryo transfers.	Maximum of 3 Embryo transfers of which a maximum of 1 will be a Fresh Embryo transfer.
Time trying to conceive:	Minimum of 3 years.	Minimum of 3 years for women under 35 years of age. Minimum of 2 years for women aged between 35 and 40.

Stable Relationship:	No Criteria set	Couples must have been in a stable relationship for at least 2 years.
Residency:	Patient should be registered with a Wiltshire GP	Patient should be registered with a Wiltshire GP
Age of woman at time of treatment:	Prospective mother must be under 40 years of age.	Prospective mother must commence treatment no later than 18 weeks before their 40th birthday.
Surgical Sperm Retrieval:	No Criteria Set	Where the male has obstructive azoospermia one surgical sperm retrieval procedure.
Sperm Donation:	No Criteria Set	Sperm donation will only be funded if altruistically donated without charge or from an NHS Sperm bank or equivalent.
Egg Donation.	No Criteria Set	Egg donation will only be funded if altruistically donated without charge or after a donation becomes available via the NHS Waiting list.
Same sex couples:	IUI – No criteria set Time trying to conceive: Donor Sperm:	Minimum of 10 self-funded, verified and documented cycles of IUI before eligible for NHS funded fertility assessment and treatment. Couples with unexplained infertility must wait a total of 3 years if under 35 years of age and 2 years if between 35 & 40 years of age. Wiltshire CCG will not routinely fund donor sperm.
IVF Definition of Cancelled and Abandoned Cycles:	No Criteria set	A full fresh cycle of IVF/ICSI comprises; ovulation induction, egg retrieval, fertilisation and implantation, and include appropriate diagnostic tests, scans and pharmacological therapy. Up to two frozen cycles using frozen embryos will follow a fresh cycle if deemed clinically appropriate.

Number of Transferred Embryos:	No Criteria set	A single embryo transfer per procedure will be undertaken (whether fresh or frozen) unless there is a clear clinical justification for not doing so (e.g. a single top quality embryo is not available). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).
Embryo Storage:	No Criteria set	The CCG will fund storage of good quality embryos from NHS funded IVF for up to 2 years or 18 weeks prior to the female partners 40th birthday if it is sooner.
Surrogacy:		Wiltshire CCG Will not fund

<u>Conclusion</u>

The policy sets out the limits within which WCCG will fund treatment with either Intra-uterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child

Due to a combination of financial position and procedure success rate we propose to make the following changes to our current criteria:

- move from offering a maximum of 6 embryo transfers to a maximum of 3 embryo transfers (of which a maximum of 1 is fresh).
- amend the time trying to conceive by reducing from 3 to 2 years for women who are 35-40 years of age. This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline
- allow couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, (i.e. Azoospermia, or bilateral tubal blockage) and who meet other eligibility criteria, immediate access to NHS funded assisted reproduction services as long as all other eligibility criteria are met.
- stipulate that couples must have been in a stable relationship for at least 2 years. This requirement supports the welfare of the child assessment as per HFEA Code of Practice.
- stipulate that both partners must be registered with a GP practice in Wiltshire Clinical Commissioning Groups

Clarification has also been made in areas where the previous policy was ambiguous and causing problems of interpretation between commissioner and provider:

- Definition of cancelled and abandoned cycles
- Embryo storage
- Surrogacy

The proposal has been to Clinical Executive and agreed at Clinical Advisory Group.

NHS organisations are entitled to take decisions which do not follow NICE Clinical Guidance if they have a good reason to do so. The availability of resources and competing priorities is accepted as a satisfactory reason.

Recommendation

The Governing Body is asked to approve the revised policy which would come into effect for all new referrals from 28th October 2016.

If agreed, this policy will be varied into existing contracts with existing service providers in line with the national NHS standard contract variation process.

NHS
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Clinical Commissioning Group

Wiltshire CCG Fertility Policy- DRAFT

Introduction

This policy sets out the limits within which WCCG will fund treatment with either Intrauterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment
The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child.

This document lists all policies related to assisted reproductive technologies (ART), i.e. the policy statements for:

- In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)
- Intra-uterine insemination (IUI) using Donor Insemination (DI)
- Surgical sperm retrieval
- Sperm washing
- Fertility preservation for patients who are to undergo therapy with oncology treatments which are likely to compromise their future fertility
- Sperm donation, oocyte donation, in-vitro maturation (IVM), and Surrogacy/Gestational Carriers
- Same sex couple and single women

In order to access NHS funded IVF, with or without ICSI; patients will be required to fulfil relevant eligibility criteria

These eligibility criteria are only applicable to policies set out in this document. They do not apply to:

- Investigations for general fertility problems and the primary treatment of conditions found during such investigation
- Medical treatment to restore fertility (for example, the use of drugs for ovulation induction)
- Surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis)
- Pre-implantation genetic diagnosis and services for members of the armed forces and some veterans, commissioning of which fall under the remit of NHS England

Wiltshire CCG does not partially fund treatments for patients who do not meet the criteria within this policy

Eligible couples requiring IVF, with or without ICSI, will have available to them a maximum of THREE embryo transfers including no more than ONE transfer from fresh cycles

A full cycle of IVF treatment, with or without ICSI, should comprise one episode of ovarian stimulation and the transfer of resultant fresh and frozen embryo(s), in line with the relevant policy to a maximum of three embryo transfers.

Other forms of assisted reproductive technologies are not included. Any new treatments or research trial treatments are not included – patients taking part in trials of new treatments will be considered separately and will be within the governance arrangements of that research trial. New developments in assisted reproductive technologies will be dealt with through the agreed local processes and would need to be proposed via a business case.

Eligibility Criteria

Duration of Infertility/Waiting Time

Couples with unexplained fertility must have infertility of at least three years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse with the partner seeking treatment or 12 cycles of artificial insemination over a period of at least:

- Three years duration for women under 35 years of age
- Two years duration for women who are 35 - 40 years of age

(I.e. All women with unexplained infertility who reach their 35th birthday will be referred after 2 years of trying to become pregnant)

In both of the above time scales this includes one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted conception services.

If the woman has a miscarriage, the couple will wait for a further

- Three years duration for women under 35 years of age
- Two years duration for women who are 35 - 40 years of age

Of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF.

Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, (i.e. Azoospermia, or bilateral tubal blockage) and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services as long as all other eligibility criteria are met.

Rationale
This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline.

Stable Relationship

All couples seeking NHS funded assisted reproduction services must have been in a stable relationship for a period of at least two years. This requirement supports the welfare of the child assessment as per HFEA Code of Practice.

Residency

Both partners must be registered with a GP practice in Wiltshire Clinical Commissioning Groups.
Where a patient moves during the course of treatment, every effort should be made to ensure continuity of care.

Age of Woman at Time of Treatment

Funding is available where the woman is aged between 30 years and 40 years of age. No treatment will be offered beyond these dates.
Fertility **treatment** for a prospective mother must commence no later than 18 weeks before the patients 40th birthday.

Comments:
NICE CG156 concludes that treatment with IVF is cost effective for women aged less than 39 years. There is considerable uncertainty about whether IVF is cost effective in any sub-groups of women aged between 40 and 42. The clinical and health economic evidence is overwhelming in indicating that IVF should not be offered to women aged 43 years or older.
This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline

Age of Male Partner at Time of Treatment

The age of the male partner must be before the 55th birthday.

Comments:
NICE CG156 does not provide guidance on the age of the male partner.
HFEA guidance recommends that the upper age limit for sperm donors should be 45 years; by contrast the professional guidance recommends 40 years or younger. In discussion with providers Wiltshire CCG has concluded that 55 years is a suitable age limit.

Previous Cycles
Couples will not be funded if either partner has already had three previous fresh cycles of IVF, with or without ICSI, irrespective of how these were funded.
This means that eligible couples will be funded: One fresh cycle of IVF, with or without ICSI, if no previous fresh cycles have been funded by the NHS, or if they have already received up to two non-NHS funded fresh cycles.

Comments:
NICE CG156 states that there is an inverse relationship between IVF success and the number of prior unsuccessful attempts. A maximum of three NHS funded IVF cycles is recommended by NICE CG156.There is a reduced likelihood of a live birth for the 4th cycle for women who have had 3 previous IVF cycles.

Definition of Childlessness

Funding will be made available to patients who do not have a living child from their current relationship and where either of the partners does not have a living child from a previous relationship (i.e. one of the partners may have a child, the other must not).

- A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.
- Once a patient is accepted for treatment they will no longer be eligible for treatment if a pregnancy leading to a live birth occurs or the patient adopts a child.

Female Body Mass Index (BMI)

Women will be required to achieve a BMI of 19-30kg/m2 documented in the clinical notes for a period of 6 months or more before each period of treatment begins. They should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary and secondary care.

Comments:
NICE CG156 states that low body weight is recognised as an important cause of hypo-oestrogenic amenorrhoea. In women, weight loss of over 15% of ideal body weight is associated with menstrual dysfunction and secondary amenorrhoea when over 30% of body fat is lost. Restoration of body weight may help to resume ovulation and restore fertility.

Smoking

Couples who smoke will not be eligible for NHS funded specialist assisted reproduction assessment or treatment, and should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. Couples presenting with fertility problems in primary care should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of maternal and passive smoking on the foetus, and the adverse health impacts of passive smoking on any children; and smoking cessation support should be provided as necessary.
Patients and their partner must be non-smoking and smoke free for a period of 6 months in order to access any fertility treatment and maintained during treatment.
Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking will result either in cessation of treatment or treatment costs being applied.
Providers should seek evidence of smoke free status. Non-smoking status should continue throughout treatment as confirmed by a CO reading of <6ppm.

Comments:
NICE CG156 states that smoking is likely to reduce women's' fertility. In addition, maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment.

Drugs and Alcohol

Patients will be asked to give an assurance that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs. Any evidence to the contrary will result in either non referral or the cessation of treatment.

Reversal of Sterilisation and Treatment Following Reversal

Subfertility treatment will not be provided where this is the result of a sterilisation procedure in either partner. The surgical reversal of either male or female sterilisation will not be funded.

Comments:
Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are made aware of this at the time of the procedure. Since the majority of requests arise for non-medical reasons, CCGs consider that it is inappropriate that NHS funds are used in reversing these procedures.

Policy Statements

In vitro fertilisation (IVF) with or without intra-cytoplasmic sperm injection (ICSI)

- Eligible couples requiring IVF, with or without ICSI, will have available to them a maximum of THREE embryo transfers including no more than ONE transfer from fresh cycles
- In order to access NHS funded IVF, with or without ICSI, patients will be required to fulfil relevant eligibility criteria

Comments:

Eligible couples are funded for one full cycle of IVF with or without ICSI rather than three – as recommended by NICE Clinical Guideline 156 – because NHS Wiltshire CCG has concluded that provision of three full cycles of IVF/ICSI for eligible couples is currently unaffordable in the context of local priorities. When making resource allocation decisions in this context, CCGs need to take into account the needs of the populations suitable for fertility treatment, as well as their wider population.

Intra–Uterine Insemination (IUI) / Donor Insemination (DI)

Unstimulated intrauterine insemination is offered as a treatment option in the following groups as an alternative to vaginal sexual intercourse.

- Patients with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
- Women in same-sex relationships
- Single women who have no live birth following self-funded artificial insemination (AI) of up to 10 cycles.

Patients who are receiving self-funded IUI who have not conceived after 10 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, should be offered a further 3 cycles of NHS funded unstimulated intrauterine insemination before IVF is considered.

- Procedures involving donor genetic materials are not funded within the local NHS for any patient group
- Sperm donation will be funded only where the sperm are altruistically donated without charge or can be accessed from an NHS sperm bank or equivalent

Rationale

When making resource allocation decisions in this context, CCGs need to take into account the needs of the populations suitable for assisted reproductive technologies, as well as their wider population. The decision not to fund assisted conception treatments using donated genetic materials was taken on the basis of the relative clinical- and cost-efficacy of different interventions and absolute affordability following consideration of the established principles and prioritisation agreed by the CCGs.

In the UK, donated genetic materials are in short supply, with demand commonly exceeding supply. An unintended consequence of any policy making ACT using donated genetic materials available on the NHS locally may be that patients could seek NHS funded treatments abroad. This is undesirable as clinics may be unregulated and treatments undertaken could pose significant health risks to patients.

Surgical Sperm Retrieval

- Eligible couples where the male has obstructive azoospermia will have **one** surgical sperm retrieval procedure funded
- In order to access NHS funded surgical sperm retrieval, couples will be required to fulfil eligibility criteria
- Surgical sperm retrieval will not be available if sub-fertility is the result of sterilisation (Where patients have consented to sterilisation)
- Where the procedure is successful, couples can access IVF with ICSI, in line with the relevant policy
- Cryopreservation of surgically retrieved sperm will be funded for a maximum of two years or a live birth, whichever is sooner.

Rationale
Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non- motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.

Sperm Washing

One sperm washing procedure will be funded within the local NHS for couples where the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater and where the female partner is HIV negative
Where the procedure is successful, couples may access IUI or IVF, with or without ICSI, depending on their clinical circumstances, in line with the relevant policy
In order to access NHS funded sperm washing and subsequent assisted conception treatments, patients will be required to fulfil relevant eligibility criteria

Rationale
According to NICE CG156, the evidence showed that sperm washing appears to be very effective in reducing viral transmission; no cases of seroconversion of the woman or the baby have been documented. In comparison with pregnancy outcomes following ACT without sperm washing, higher live full-term singleton birth rates are seen with IVF following sperm washing. This is likely to be because couples undergoing sperm washing were having ACT to avoid HIV transmission rather than for fertility problems. A comparison of pregnancy outcomes for different ACT methods using washed sperm was also undertaken. Consistent with other studies, IUI cycles had fewer singleton live births than both IVF cycles with and without ICSI, but it also had fewer multiple births. This may reflect the transfer of more than one embryo in IVF cycles.

Sperm washing is unavailable on the NHS for couples where the male is hepatitis C positive, because NICE CG156 recommends that couples who want to conceive and where the man has hepatitis C should be advised that the risk of transmission through unprotected sexual intercourse is thought to be low.

Fertility preservation for patients who are to undergo therapy with oncology treatments which are likely to compromise their future fertility

Wiltshire CCG will fund the collection and storage of eggs, embryos and sperm for individuals who are to be treated with oncology treatments which are likely to compromise their future fertility with the following conditions:

- Wiltshire CCG will fund the storage for first ten years only (in addition to the age criteria below being applied)
- Wiltshire CCG will not fund for the continued storage of eggs/embryos for a woman aged over 40
- Wiltshire CCG will not fund for the continued storage of sperm for a man aged over 55.
- Patients must have commenced puberty and not be older than the limits for treatment set out above.

At the time of fertility preservation, patients do not need to be able to demonstrate that they comply with the requirements of the Wiltshire CCG Fertility Policy in respect to BMI and smoking status, as delaying treatment until a patient could comply may compromise oncology treatment.

Women should be offered egg or embryo cryostorage as appropriate only if they are well enough to undergo ovarian stimulation and egg collection, provided that this will not worsen their condition and that sufficient time is available

Cryopreservation of ovarian tissue preservation is still an early stage of development and will not be funded

The eligibility criteria set out in the Wiltshire CCG Fertility Treatment Policy must be applied to any subsequent use of the stored material.

NHS funding of cryopreservation of materials will cease where:

- Fertility is established through tests or conception
- A live birth has occurred
- The patient dies and no written consent has been left permitting posthumous use

The CCG considers that the cryopreservation of gametes for patients who are about to undergo gender reassignment is not appropriate for commissioning as the patient is considered to be consenting to sterilisation as part of gender reassignment treatment. This treatment may be available via the NHSE treatment pathway.

Rationale
NICE CG156 recommends offering sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. For women of reproductive age who are preparing for medical treatment for cancer that is likely to make them infertile, CG156 recommends offering oocyte or embryo cryopreservation as appropriate if:

- they are well enough to undergo ovarian stimulation and egg collection, and this will not worsen their condition, and
- Enough time is available before the start of their cancer treatment.

Storage of cryopreserved material is recommended for an initial period of 10 years.

Sperm donation, oocyte donation, in-vitro maturation (IVM), and Surrogacy/Gestational Carriers

- Sperm donation will be funded only where the sperm are altruistically donated without charge or can be accessed from an NHS sperm bank or equivalent
- Egg donation where no other treatment is available. This will be available to women who have undergone premature ovarian failure (longer than six months amenorrhoea and FSH greater than 25IU/L) due to an identifiable pathological or iatrogenic cause, before the age of 40 years, or to avoid transmission of inherited disorders to a child where the couple meets the other eligibility criteria. The patient may be able to provide an egg donor; alternatively the patient can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.
- IVM will not be funded, due to limited evidence of effectiveness
- Wiltshire CCG will not commission any form of fertility treatment to those in surrogacy arrangements (i.e. the use of a third party to bear a child for another couple).

Rationale

Surrogacy was not included within the scope of NICE CG156. There are significant medico-legal issues involved in surrogacy arrangements that would pose risks to an NHS organisation funding this intervention.

The Surrogacy Arrangements Act 1985 states that commercial surrogacy is illegal in the UK. However, the surrogate can be paid reasonable expenses such as travel expenses and loss of earnings. The HFEA states that fertility clinics cannot identify surrogates for their patients.

Surrogacy arrangements are not legally enforceable, even if a contract has been signed and the expenses of the surrogate have been paid. The surrogate will be the legal mother of the child unless or until parenthood is transferred to the intended mother through a parental order or adoption after the birth of the child. This is because, in law, the woman who gives birth is always treated as the mother.

There is an absence of evidence on the long-term psychological impact or social consequences for commissioning couples, surrogates or children born to surrogates.

The donation of eggs, sperm and embryos is subject to strict UK regulations. Donors may be family, friends or strangers. In 2005, the law was changed so that donors can no longer remain anonymous. Now children born as a result of using donor gametes or embryos can, once they reach 18, discover their donor's identity (HFEA, 2007b). The regulation of donors in other countries is different to that in the UK.

Same sex couple and single women

Same Sex Couples (female)

- Same sex couples will be required to demonstrate infertility prior to commencing any investigations in line with the policy for heterosexual couples.
- Same sex couples must have undergone a minimum of self-funded 10 verified and documented cycles of artificial insemination before being eligible to access NHS funded fertility assessment and treatment. . All must be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations
- Couples are encouraged to maximise opportunities within these cycles by exploring the option of both partners undergoing artificial insemination. Where one partner is sub-fertile with fertility issues i.e. blocked fallopian tubes or anovulation, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.
- In line with the policy for heterosexual couples, same sex couples with unexplained infertility must wait a total of three years if aged less than 35 years or two years if aged between 35-40 years before becoming eligible for IVF treatment. Couples are encouraged to continue to try and conceive during this waiting period by safe methods.
- Couples with a diagnosed cause of absolute infertility which precludes any possibility of a natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.
- CCGs will not routinely fund donor sperm, but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy, providing the sperm meet the criteria set out by the treating provider unit.
- The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle, in line with the criteria for heterosexual couples, and will not be eligible for additional cycles with their partner or any future partners.
- Same sex fertile couples will not be funded for assisted conception methods under this policy.
- Couples will be required to fit all other criteria within this policy in line with heterosexual couples.
- Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

Additional Information

IVF Definition and Cancelled and Abandoned Cycles

A full fresh cycle of IVF/ICSI comprises; ovulation induction, egg retrieval, fertilisation and implantation, and include appropriate diagnostic tests, scans and pharmacological therapy. Up to two frozen cycles using frozen embryos will follow a fresh cycle if deemed clinically appropriate.

For the purposes of this policy, the commencement of IVF/ICSI cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore if a cycle is abandoned for clinical reasons this is still counted as a full cycle.

Number of Transferred Embryos

In keeping with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy patients will be counselled about the risks associated with multiple pregnancies and advised that they will receive a single embryo transfer (whether fresh or frozen) unless there is a clear clinical justification for not doing so (e.g. a single top quality embryo is not available). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).

Previously Infertility Treatment - NHS and Privately Funded

Couples, where either partner in current or previous relationship has undergone three or more previous IVF/ICSI cycles (either NHS or privately funded) will be ineligible for NHS funding within Wiltshire.
Couples who have previously self-funded treatment may be considered for further NHS funded embryo transfers to bring the total number of cycles to three embryo transfers in line with Wiltshire IVF policy statement.
The outcome of previous self-funded IVF treatment will be taken into account when Couples who have previously self-funded treatment may be considered for further NHS funded cycle(s) to bring the total number of cycles to three (as defined above).

Embryo storage

The CCG will fund storage of good quality embryos from NHS funded IVF for up to 2 years or 18 weeks prior to the female partners 40th birthday if it is sooner.
Patients must be counselled by the clinician and infertility counsellor to this effect. Any costs relating to the continued storage of the embryos beyond the second calendar year of the retrieval date is the responsibility of the couple

NHS Wiltshire Clinical Commissioning Group

Equality Impact Analysis – the EIA form

Title of the paper or Scheme:

For the record	
Name of person leading this EIA: Nadine Fox	Date completed 16/09/2016
Names of people involved in consideration of impact	
Name of director signing EIA: Mark Harris	Date signed 16/09/2016

What is the proposal? What outcomes/benefits are you hoping to achieve?

The policy sets out the limits within which WCCG will fund treatment with either Intrauterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment
The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child

Due to a combination of financial position and procedure success rate we propose to make the following changes to our current criteria:

- move from offering a maximum of 6 embryo transfers to a maximum of 3 embryo transfers (of which a maximum of 1 is fresh).
- amend the time trying to conceive by reducing from 3 to 2 years for women who are 35-40 years of age. This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline
- allow couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, (i.e. Azoospermia, or bilateral tubal blockage) and who meet other eligibility criteria, immediate access to NHS funded assisted reproduction services as long as all other eligibility criteria are met.
- stipulate that couples must have been in a stable relationship for at least 2 years. This requirement supports the welfare of the child assessment as per HFEA Code of Practice.
- stipulate that both partners must be registered with a GP practice in Wiltshire Clinical Commissioning Groups for at least 12 months prior to referral from primary care to secondary care and be eligible for NHS care (unless transferring whilst already on a treatment pathway where continuation of care will follow.)

Clarification has also been made in areas where the previous policy was ambiguous and causing problems of interpretation between commissioner and provider:

- Definition of cancelled and abandoned cycles
- Embryo storage
- Surrogacy

The proposal has been to Clinical Executive and agreed at Clinical Advisory Group.

NHS organisations are entitled to take decisions which do not follow NICE Clinical Guidance if they have a good reason to do so. The availability of resources and competing priorities can be a good

reason.

Who's it for? Wiltshire residents seeking treatment for infertility

How will this proposal meet the equality duties?
This policy will contribute to ensuring that all users and potential users of services are treated fairly and respectfully with regard to the protected characteristics of age, disability, gender, reassignment, marriage or civil partnership, pregnancy and maternity, race, religion, sex and sexual orientation.

What are the barriers to meeting this potential?
None

2 Who's using it? Refer to equality groups

What data/evidence do you have about who is or could be affected (e.g. equality monitoring, customer feedback, current service use, national/regional/local trends)?
Patients seeking treatment for infertility

How can you involve your customers in developing the proposal? HealthWatch involvement in decision making in gaining Public Engagement

Who is missing? Do you need to fill any gaps in your data? (pause EIA if necessary)

3 Impact Refer to dimensions of equality and equality groups
Show consideration of: age, disability, sex, transgender, marriage/civil partnership, maternity/pregnancy, race, religion/belief, sexual orientation
and if appropriate: financial economic status, homelessness, political view

Using the information in parts 1 & 2 does the proposal:

a) Create an adverse impact which may affect some groups or individuals. Is it clear what this is? How can this be mitigated or justified?

The review of the IVF and ICSI policy has a high equality impact on the protected characteristics defined in the Equality Act 2010 of age, disability, gender, pregnancy and maternity, and sexual orientation. For women over the age of 40 years NHS funded fertility treatment is not available locally, and this may have a negative equality impact on them and their partner, especially if they are unable to afford to pay for infertility treatment privately.

It was also noted that same sex female couples find it more difficult in practice to access treatment because they cannot demonstrate having 'tried' to get pregnant for a certain amount of time, unless they have already paid for IUI privately. The committee noted that income and ability to pay for treatment may provide a limitation for women and couples who seek self-funded treatment when NHS treatment is not available at the level that NICE recommends.

What can be done to change this impact?
This is mitigated to some extent by the fact that people who do not meet the criteria set out in the local policy, can – in exceptional circumstances – make an Individual Funding Request via their clinician, to have their case looked at again.

b) Create benefit for a particular group. Is it clear what this is? Can you maximise the benefits for

other groups?
The eligibility criteria for access to NHS-funded IVF have a positive equality impact for women between the age 30-40 years (including single women and women in same sex couples), as well as for men up to an age of 55years, who have confirmed infertility problems. People with disabilities and health conditions that do or may impact on their fertility can also access NHS treatment under the policy. The policy also has a positive impact for partners and close relatives of people who are unable to conceive

Does further consultation need to be done? How will assumptions made in this Analysis be tested? No further consultation at this stage

4 So what? Link to business planning process

What changes have you made in the course of this EIA?
None

What will you do now and what will be included in future planning?

When will this be reviewed?
Within the rolling programme of Clinical policies

How will success be measured?