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NHS DORSET CLINICAL COMMISSIONING GROUP

GOVERNING BODY

FERTILTY ASSISTED CONCEPTION POLICY REVIEW

Date of the meeting	17/03/2021
Author	H Nettle, Principal Programme Lead
Lead Director	P Richardson, Chief System Integration Officer
Clinical Lead	K Kirkham, Integrated Care System Clinical Lead Dorset and Assistant Clinical Chair, Dorset CCG
Purpose of Report	To advise the Governing Body of the fertility assisted conception policy review and seek approval to the proposed changes.
Recommendation	The Governing Body is asked to:- (a) consider whether it is satisfied and assured that the policy review has been undertaken with due care and process; (b) support the Clinical Reference Group (CRG) recommendation that changes made to the policy, set out in paragraphs 3.1.1 to 3.1.8 of this paper be adopted; (c) support the recommendation that the CCG adopt a move towards 3 cycles to align with NICE guidance whilst recognising that further discussions will take place in respect of financial consequence (prioritisation) and Governing Body approval.

Monitoring and Assurance Summary

Conflicts of Interest	N/A
Involvement and Consultation	The policy review group consisted of Dorset secondary care clinical leads and Dorset CCG contracted assisted conception service providers (consultants and business manager). Public engagement and consultation were considered not required in proportion to the proposed changes.
Equality, Diversity and Inclusion	QIA completed, see Appendix 2.
Financial and Resource Implications	In 2015 the fertility budget was £1.4 million; this budget was in place to accommodate a change in policy that was expected to increase activity level significantly due to aligning with the Equality Act (2010-2012); opening access to more couples across wider age range. The financial budget for Dorset Assisted Conception Services is now £740k due to underperformance year on year against original budget of £1.4 million, the budget was reduced to £740k in 2017. This policy

	review proposes increased investment to align with NICE guidance and offer increased cycles of treatment.
Legal/governance	The policies of other CCGs have been considered in the proposed policy changes set out in the paper.
Risk description/rating	As is the case with all eligibility policies there is the potential for the policy to be challenged. Potential resource/budget pressures considered as part of the review.

1. Introduction

1.1 The Criteria Based Access Protocol (CBAP) for Fertility - Assisted Conception, Appendix 1, went live on the 1st April 2017 following approval by Dorset CCG to align with best practice and National Institute of Clinical Excellence (NICE) guidance. Key changes included:

a) Pathway for recurrent miscarriage.
b) Reduced self-funded Donor Insemination (DI) from 12 to 6 to demonstrate infertility for same sex couples.
c) Both people of the couple have to be registered with a Dorset GP.
d) Offer 6 cycles of intrauterine insemination (IUI**)** as a treatment option in the relevant groups as an alternative to vaginal intercourse.
e) Access to 1 more attempt (cycle of in vitro fertilization (IVF)/ Intracytoplasmic sperm injection **(**ICSI)) for abandoned cycle of treatment and failed fertilisation. (ICSI is an enhanced procedure to IVF where the sperm is injected into the egg – this occurs in instances such as poor sperm quality).
f) Clarified delays in treatment once started the IVF cycle.
g) Added criteria to oocyte and embryo cryostorage criteria.

1.2 The financial impact resulting from changes in the Fertility - Assisted Conception CBAP has required close monitoring so the CCG could monitor the overall spend against the budget.

1.3 This paper details the review of the current CBAP for Fertility - Assisted Conception policy (that went live on the 1st January 2018) and sets out 14 proposed changes, found in Appendix 1 (Fertility Policy Review Issues). Of the proposed changes half of them are based on ethical grounds. Others relate to latest guidelines and evidence as well as feedback from patients and fertility providers on behalf of patients and their clinicians.

2. Report

2.1 The policy review group included a Dorset CCG GP lead, CCG programme lead, secondary care and tertiary care consultants, manager, and nurse. This group provided consistency and subject matter expertise which helped develop a response to a very challenging and complex policy area.

2.2 The review considered the whole policy from which emerged 14 specific areas of focus, resulting in 8 areas where changes are being proposed. A summary of these policy areas can be found in below in para 3, and in greater detail in Appendix 1 (Fertility Policy Review Issues). The associated Quality Impact Assessment for the suggested changes can be found in Appendix 2.

3. Summary Proposed changes

3.1 Eight areas are believed to warrant specific amendment.

3.3.1 Including access for IVF/ICSI where the couple have living children (including adopted children and offspring who are adults) from the current relationship.

3.3.2 Remove the criterion of 3 years trying to conceive and also remove couple being in the same stable relationship, and instead maintain criterion of 'Having regular unprotected intercourse for the 2 years prior to referral'.

3.3.3 In instances when couples having been trying to conceive over 2-3 years and are already referred/about to start IVF/ICSI treatment, then conceive naturally but miscarry, then then couples can continue with IVF/ICSI after a period of 6 months trying, providing there is no further natural conception.

3.3.4 Funding for egg/embryo and sperm cryopreservation to include couples who have living offspring already.

3.3.5 Policy to include fertility preservation for defined disease groups that impact on fertility e.g. Mayer-Rokitansky-Kuster-Hauser syndrome (MRKH) but cases will still be assessed on a case by case basis.

3.3.6 Fertility preservation for transgender/ gender dysphoria patients will include the freezing and storage of sperm and eggs only.

3.3.7 Male Sperm storage age cut off to be set at age 50. Anything outside of this will be considered via Individual Patient Treatment (IPT). Female egg/ embryo age cut off to align with the current IVF policy which is up to the age of 43.

3.3.8 In the event a patient dies then sperm, eggs and embryos can continue to be stored as per policy (up to 10 years). The fertility centre will manage ongoing storage decisions based on patient consent and wishes (as per HFEA guidance), and with any living partner (and/or family).

3.4 Single female access has been discussed but not changed in the policy; however, cases will be considered on a case by case basis through the Individual Patient Treatment Panel process.

4 Proposed Change to the Number of IVF cycles

4.1 In 2015 the CCG made the difficult financial decision to reduce the number of cycles from 2 cycles to 1 cycle. The decision was taken because the female age range was changed from age 30-35 to having no lower age limit, but an upper age limit of up to age 43.

4.2 The policy working group considered the benefits of moving towards or achieving full compliance with HFEA and NICE guidelines (which recommend 3 full cycles). This includes transfer of resultant Fresh and Frozen Embryos. After 3 cycles of treatment the success rates and cost effectiveness start to reduce. HFEA recommends women under 40 should be offered three full cycles of IVF treatment and women aged 40-42 should be offered one full cycle of IVF treatment if they have normal ovarian reserve for their age.

4.3 Prevalence information has been requested from Public Health Dorset; however, the data available was limited. Therefore, basing the modelling on the highest activity year (2019-20) that the Dorset contract has seen seemed reasonable, alongside the HFEA success rates.

4.3.1 Less than half of all IVF cycles in the South West are NHS funded (41%)- compared to North East and North West which see 55-60% of cycles are funded by the NHS.

4.3.2 With potential for COVID impacting on disposable income this may mean more people looking to the NHS over the next few years, so Dorset may need to build in contingency/review.

4.4 Three options in relation to IVF cycles are considered and detailed in Table 3 of Appendix 1. These are summarised below.

Option	**A**	**B**	**C**
Description	No change	Move to 2 cycles of treatment	Move to 3 cycles of treatment
Additional Cost (over £740k budget)	£0	£254k	£510k
Relationship to HFEA and NICE guidance	Maintain divergence	Move closer	Fully implement
Impact- percentage achieving pregnancy and the birth of a child	36%	54%	65%

4.5 The review recommends adopting option C. The additional funding (of £510k) will need to be sought in context of multiple requests being made to a system wide budget.

5 Financial Issues

5.1 In 2015 the assisted conception fertility budget was £1.4 million. The budget had been increased to accommodate aligning with the Equality Act (2010-2012) which had widened the age range of women eligible for IVF. Simultaneously CCG also took the difficult decision to reduce the number of cycles from 2 cycles to 1 cycle due to the expected increase in activity and spend because of this policy change.

5.2 However, Dorset did not see the anticipated growth in activity. As a result, the budget was reduced from £1.4 million to £740k and the rest of the budget was redistributed elsewhere across the Dorset ICS system. Even against this reduced budget, expenditure was around £150k less than planned until 2019/20 which saw spend of around £700k. This may have been as a result of awarding contracts to three tertiary providers where previously there was only one.

5.3 The financial implications of the proposed policy changes (3.1.1-3.1.8) have been considered within the review and are not assessed as causing significant impact except for the proposed increase in the number of cycles to 3, as outlined in Appendix 1 and described further in section 4.4 above.

6 Conclusions

6.1 There are several proposed changes that will improve the CCG's policy's clarity, as well as supporting better application of the criteria by the fertility centre and aid patient understanding. In some cases, it will reduce the need for requests to be raised through the IPT panel, for example, having clear criteria for fertility preservation will provide a more seamless pathway.

6.2 By adopting the recommended policy changes there is an opportunity to provide a more equitable and fair policy, adopting HFEA and NICE guidance and to support more people in Dorset to achieve a successful outcome and birth of a child. This has a cost implication of £510k.

6.3 The Dorset Clinical Reference Group (CRG) has considered and supported the proposed changes set out in 3.1.1 to 3.1.8 of this paper.

6.4 The Clinical Reference Group recommended a move towards 3 cycles to align with NICE guidance whilst recognising that further discussions will take place in respect of financial consequence (prioritisation) and Governing Body approval.

6.5 The QIA (Appendix 2) was approved but acknowledged that would need further review pending final decision from prioritisation and Governing Body decision.

7 **Recommendations.**

7.1 The Governing Body is asked to:-

7.1.1 consider whether it is satisfied and assured that the policy review has been undertaken with due care and process;

7.1.2 support the CRG recommendation and changes made to the to the policy, set out in point 3.1.1 to 3.1.8 of this paper be adopted

7.1.3 Support the recommendation that the CCG adopt a move towards 3 cycles to align with NICE guidance whilst recognising that further discussions will take place in respect of financial consequence (prioritisation) and Governing Body approval.

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Date : 5th March 2021

APPENDICES	
Appendix 1	**Fertility Policy Review Issues**
Appendix 2	**Quality Impact Assessment**

Dorset Fertility Assisted Conception Policy Review 2020-21

Issues identified with current policy

The below policy issues are set out in three parts.

Table 1 - Includes the policy issues that the fertility policy review group recommend proposed changes
Table 2 - Includes other policy issues that the fertility policy review group considered with no change
Table 3 - Cost modelling for increased cycles

Table 1: Policy Issues and proposed changes

No.	**Issue:**	**Current CCG criteria**	**NICE guidance / HFEA guidance / local information to consider**	**Recommendation to CRG and GB**	**Rationale**
1	Should the CCG fund IVF/ICSI for couples when one partner of the couple has a living child/children already (including adopted children, but excluding fostered children)?	There should be no living children from this relationship, including adopted children but excluding fostered children. There should be no children from previous relationships.	Other CCGs with policies that fund IVF/ICSI where the couple have no living children (including adopted children) from the current relationship / at least one of the partners must have no living children. (This includes biological and legally adopted children and offspring who are adults): • Bath and north east Somerset • Swindon • Kernow CCG (updated Nov 2019)	Include access for IVF/ICSI where the couple have living children (including adopted children and offspring who are adults) from the current relationship.	Based on other neighbouring CCGs' policies and ethical considerations. Unfair on the partner who does not have a genetic child, even if their partner has a child/children from a previous relationship, as some couples may have a genetically related child, but no involvement in upbringing.

			• Devon CCG (Jan 2019) Hampshire CCG and Wiltshire CCG policy are the same as Dorset CCG.		Considered issues of being fair, managing resources and being consistent. This could increase the gap between patients/couples that do not already have a child if you do fund couples to have a genetically related child/children from a previous relationship. It is hard to see how having conceived in the past is a compelling reason for refusing effective treatment to ameliorate the effects of disease in the present.
2	Issues raised about how the CCG define and evidence couples having to be in a stable 3 year relationship; do they have to be cohabiting? Why 3 years?	Couples must be in a stable on-going relationship for more than 3 years (evidenced by a GP) before referral.	NICE guidance does not stipulate as to the relationship status of the person planning to have treatment. **2. NICE Guidance CG156 (2103) recommendations** **https://www.nice.org.uk/guidance/cg156/chapter/Recommendations#intrauterine-insemination** : **1.2.1 Chance of conception** 1.2.1.1 People who are concerned about their fertility should be informed that over 80% of couples in the general population will conceive within 1 year if:	Remove the criterion of 3 years trying to conceive, and remove couple being in the same stable relationship, and instead maintain criterion of 'Having regular unprotected intercourse for the 2 years prior to referral'.	The 3-year period should not continue to be policy criteria and changed to the 2 years trying in line with NICE guidance, and if welfare of the potential child is not in question. Recognise that the fertility units complete the assessment for 'welfare of the child' which is a requirement of the HFEA.

			• the woman is aged under 40 years **and** • they do not use contraception and have regular sexual intercourse. • Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%). **[2004, amended 2013]**		
3	1st time miscarriages: If, following 2 – 3 years of trying, a couple about to start IVF/ICSI, conceive naturally but then miscarry, should they restart the 2-year trying period?	No policy criteria – this applies only to recurrent miscarriage*	No other guidance on this matter. Current policy for recurrent miscarriages: *Recurrent miscarriage is not an indication for patients to access fertility services, although they may be referred for NHS gynaecological investigations and treatments if appropriate. If there is a requirement for assisted conception following NHS gynaecological investigations and treatments, then the referring clinician will need to outline the rational for the patient bypassing the 2-year trying period. The couple should meet all other areas of the policy access criteria.	Couples can continue with /commence IVF/ICSI after a period of 6 months trying, providing there is no further natural conception.	• 2 years of trying seems to be too long. • Hampshire CCG –allow for re-starting treatment after another 1 year of trying. • 6 months of trying and then to restart seems more appropriate. • 6 months provides the opportunity for natural conception • Consultants at each trust could agree timeframe on a case-by-case basis; providing decisions that are supportive.
4	Fertility preservation is currently funded for couples who have living children	Do not exclude patients from fertility preservation that have living offspring. This includes	12-17% of Dorset patients having sperm/egg and embryo	Amend fertility preservation policy to include access to sperm/egg and embryo storage	For couples who have living children but who are likely to become infertile due to medical

	already. This was changed at the last policy review but required review to make this a permanent change to policy.	genetic and legally adopted children and offspring who are adults but does not include foster children or stepchildren. All other criteria remain the same.	cryopreservation have children already.	for patients that have living offspring already. This includes genetic and legally adopted children and offspring who are adults. All other criteria remain the same.	treatment or specific disease reasons e.g. undertaking medical treatment due to cancer. This changed in last policy review in (2017) but required review for continuation of this policy criteria.
5	Defined disease groups that impact on fertility potentially requiring surrogacy are considered on a case-by-case basis as there is no CCG policy. CCG have approved creation of embryo and storage for x 3 Mayer-Rokitansky-Kuster-Hauser syndrome (MRKH) patients. 3 cases approved via IPT for creation and storage of embryos for females who are born without a uterus and/or vagina but have functioning ovaries.	The current assisted conception policy offers storage of sperm, egg and embryo for patients undertaking medical treatment that may impact fertility. Women should be offered oocyte or embryo cryostorage as appropriate if they are well enough to undergo ovarian stimulation and egg collection, if this will not worsen their condition and that sufficient time is available. After preservation treatment, if patients wish to access the NHS funded treatment, couples would be expected to meet all aspects of the fertility assisted conception access criteria. However, the surrogacy element is not funded	MRKH (Mayer–Rokitansky-Küster-Hauser) syndrome is a congenital (born with) abnormality, characterised by the absence of the vagina, cervix and the uterus (womb), which affects one in every 5,000 women. It is also associated with kidney, bone and hearing difficulties. The ovaries are usually present and function in the same way as other women by producing eggs and female hormones that maintain health. Chromosomes are the normal 46xx female karyotype. The second group is the treatment related patient group; those who develop cervical cancer or who have had the uterus removed prematurely. Other groups are less well defined, such as recurrent pregnancy loss,	Policy for fertility preservation to include: Defined disease groups that impact on fertility to be considered and assessed on case-by-case basis. **Wording to add to policy:** "Funding for fertility preservation will be offered to individuals who have a disease or a medical condition which requires urgent medically necessary treatment that has a significant likelihood of making them infertile and those whose medical treatment (such as radiotherapy or chemotherapy) may compromise fertility. In addition, the CCG will give consideration to those conditions which fall into a 'defined disease group' such as Mayer-Rokitansky-Küster-Hauser	Current policy for cryopreservation can be accessed if receiving medical treatment that would impact fertility, but this is not specific to disease groups that cause explained infertility. Considered unethical to refuse to fund the process of embryo creation itself in the circumstances of Mayer-Rokitansky-Küster-Hauser syndrome or similar. CCG have approved the creation of embryo and storage for x 3 Mayer-Rokitansky-Kuster-Hauser patients. The CCG do not fund the surrogacy element as the means of completing treatment.

		by NHS so funding would stop after the creation and storage of embryo.	recurrent miscarriage and recurrent IVF implant failure. Department of Health and Social Care: The Surrogacy pathway (February 2018, updated November 2019) found here: https://www.gov.uk/government/publications/having-a-child-through-surrogacy : Since the last review of the CCG's policy the DHSC has published guidelines on the practice of surrogacy (February 2018, updated November 2019) *The Surrogacy Pathway: Surrogacy and the legal process for intended parents and surrogates in England and Wales.* The guidelines state "Surrogacy is increasingly becoming an option for starting a family for people who are unable to conceive a child themselves. The Government supports surrogacy as part of the range of assisted conception options." Cost implication: Process of creating the embryo itself has a current tariff, this element is already funded by the NHS. The cost of embryo transfer and all relevant and additional embryo screening that is required for	syndrome. Each case is assessed on an individual basis."	Process of creating the embryo itself has a current tariff, this element would be funded by the CCG. The cost of embryo transfer and all other relevant and additional procedures, such as embryo screening that is required for completing treatment via surrogacy, would not be funded by the CCG.

			completing treatment via surrogacy costs approx. extra £2000.		
6	How do the CCG respond to transgender request for oocyte storage, embryo creation, and transplantation of embryo to partners when they are receiving treatment to transition?	The current assisted conception policy offers storage of sperm, egg and embryo for patients undertaking medical treatment that may impact fertility. Women should be offered oocyte or embryo cryostorage as appropriate if they are well enough to undergo ovarian stimulation and egg collection, and if this will not worsen their condition and that sufficient time is available.	Gender dysphoria has been recognised as a disease (ICD-11, and DSM-5) and access to hormonal therapies and gender affirming treatment are provided in the NHS, as gender dysphoria is recognised as a disease, where treatment for it will impair fertility. Cost Implication: Fertility preservation for transgender patients. (The greater level of complexity and workload leads many clinics not to treat transgender patients for fertility preservation).	Freeze and store sperm and eggs only.	As gender dysphoria is recognised as a disease, where treatment for it will impair fertility, NHS funding should be made available on the same grounds as other disease treatments e.g. malignancy, as per current policy. Issues exist with greatest level of complexity, often at quite a young age. Trying to determine the future at that point in time when considering embryo creation adds another level of complexity and ethical issues to consider. On this basis only eggs and sperm storage will be supported.
7	Criteria for eggs/ embryo and sperm cryostorage storage relating to age. (This is when medical treatment or diseased impact will impact fertility – as per number 5).	Female patient must not be older than 40. (This would enable some women to still meet the assisted conception policy and complete treatment by age 43).	No male age defined, but age 75 used to be the cut-off for men. **Somerset CCG policy (Feb 2020):** Overall IVF/ICSI policy: A male partner's age is <54 years of age. Male fertility has been shown to decrease with age, with evidence of greater incidence of disability, poor sperm function and DNA degradation.	**Male:** Sperm storage age cut-off to be at age 50. Anything outside of this will be considered via IPT. **Female** Align the egg/ embryo age category to the current IVF policy – treatment completed before turning age 43.	**Male:** Currently no age range defined for men, from clinical perspective sperm quality doesn't decline until after the age of 75. In practical terms men don't tend to have sperm storage over the age of 50, very small cohort of patients going through treatment at age of 75.

					Female: Current policy is age 40 cut-off for egg and embryo storage. There has been feedback from patients that this is an issue; that the CCG don't have a higher age cut off for women in line with the IVF policy (age 43). The cut off age of 40 is appropriate due to egg quality declining after that age. However, as it is accepted that this is difficult for patients to understand, it is agreed to align the egg / embryo age category on this basis.
8	No policy for cryostorage if patient / either partner has died and undergone treatment under fertility preservation policy.	No policy.		In the event a patient dies then sperm, eggs and embryos can continue to be stored as per policy (up to 10 years). The fertility centre will manage ongoing storage decisions based on patient consent and wishes (as per HFEA guidance), and with any living partner (and/or family).	Already funded for block period for 10 years. HFEA provides guidance for consent to use post death HFEA guidance: Consent to treatment | Human Fertilisation and Embryology Authority (hfea.gov.uk) All the appropriate consents for this need to be in place If individuals want their eggs, sperm or embryos to be used after death, they will need to

					have given all the appropriate consents for this. Individuals are encouraged to speak to their clinic as this can be quite a complicated area.

Recommendations to approve:

1. Include access for IVF/ICSI where the couple have living children (including adopted children and offspring who are adults) from the current relationship.
2. Remove the criterion of 3 years trying to conceive, and remove couple being in the same stable relationship, and instead maintain criterion of 'Having regular unprotected intercourse for the 2 years prior to referral'.
3. In instances when couples having been trying to conceive over 2-3 years and are already referred/about to start IVF/ICSI treatment, then conceive naturally but miscarry, then then couples can continue with IVF/ICSI after a period of 6 months trying, providing there is no further natural conception.
4. Funding for egg/embryo and sperm cryopreservation to include couples who have living offspring already.
5. Funding for fertility preservation will be offered to individuals who have a disease or a medical condition which requires urgent medically necessary treatment that has a significant likelihood of making them infertile and those whose medical treatment (such as radiotherapy or chemotherapy) may compromise fertility. In addition, the CCG will consider those conditions which fall into a 'defined disease group' such as Mayer-Rokitansky-Küster-Hauser syndrome. Each case is assessed on an individual basis
6. Fertility preservation for transgender/gender dysphoria patients will include the freezing and storage of sperm and eggs only.
7. Male Sperm storage age cut off to be set at age 50. Anything outside of this will be considered via IPT. Female egg/ embryo age cut off- to align with the current IVF policy which is up to the age of 43.
8. In the event a patient dies then sperm, eggs and embryos can continue to be stored as per policy (up to 10 years). In the event a patient dies then the fertility centre will manage ongoing storage decisions based on patient consent and wishes (as per HFEA guidance), and with any living partner (and/or family).

Table 2: Other Policy Issues considered

No.	**Issue:**	**Current CCG criteria**	**NICE guidance / HFEA guidance / local information to consider**	**Recommendation to CRG and GB**	**Rationale**
9	Access criteria: length of time trying and cost for same sex female couples. It is felt by female same sex couples that it is inequitable that they must demonstrate infertility and pay via 6 cycle of IUI, and a heterosexual couple with azoospermia being the cause of infertility can bypass the trying period and still access IVF funded by NHS. Same sex female couples' feedback is that they are azoospermic by nature that they do not produce sperm. (Male same sex?)	1. Couples must have been having regular unprotected intercourse for a 2-year period, documented by a GP prior to referral for assisted conception, unless exception criteria apply. 2. For patients who are diagnosed with a cause of absolute infertility, which precludes any possibility of natural conception and who meet all the other eligibility criteria, will have immediate access to NHS funded assisted conception services, including IVF/ICSI. 3. Same sex couples will need to evidence infertility. Proven infertility will be defined as: One partner has explained infertility i.e. blocked tubes or anovulation *(which is not corrected by oral ovulation induction agents)'* OR a woman of reproductive age who is using donor insemination to conceive should be offered	**1.NICE Quality Standard QS73:** https://www.nice.org.uk/guidance/qs73/chapter/Quality-statement-2-Referral-for-specialist-consultation: infertility is where there has been a failure to conceive after 12 months of unprotected heterosexual intercourse or after 6 cycles of IUI. **2.NICE Guidance CG156 (2103) recommendations https://www.nice.org.uk/guidance/cg156/chapter/Recommendations#intrauterine-insemination** : **1.2.1 Chance of conception** 1.2.1.1 People who are concerned about their fertility should be informed that over 80% of couples in the general population will conceive within 1 year if: • the woman is aged under 40 years **and** • they do not use contraception and have regular sexual intercourse. • Of those who do not conceive in the first year, about half will do so in the second year (cumulative	No change - policy for same sex access to remain the same but amend wording to *'Failure to conceive after 6 cycles of AI within up to 2 years '* *In cases where 6 cycles of self-funded DI need to be completed over 2 year period this will be considered/assessed on case by case basis.* To add: See highlighted yellow	Last policy review Dorset CCG reduced the number of self-funded Donor Insemination (DI) cycles from 12 to 6 for female same-sex couples, moving closer to NICE guidance and acknowledging that most couples would conceive after 6 DI cycles and this would reduce the financial burden. Therefore, if same sex couples can't conceive after 6 cycles of DI then they would be eligible for funding. Policy currently aligns with NICE guidance and ethical considerations have been taken into account. Same-sex couples are not paying to establish infertility. They are paying to conceive through available means, and if malfunction becomes apparent, they would be eligible for funding.

		further clinical assessment and investigation if she has not conceived after 6 cycles of donor insemination treatment, in the absence of any known cause of infertility. Donor insemination and intrauterine insemination in this situation would not be funded by the NHS.	pregnancy rate over 90%). **[2004, amended 2013]** Inform people who are using artificial insemination to conceive and who are concerned about their fertility that: • over 50% of women aged under 40 years will conceive within 6 cycles of intrauterine insemination (IUI) • **o**f those who do not conceive within 6 cycles of intrauterine insemination, about half will do so with a further 6 cycles (cumulative pregnancy rate over 75%). **[new 2013]** **Intrauterine insemination:** 1.9.1.1 Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse: • people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm. • people with conditions that require specific consideration in relation to methods of		

			conception (for example, after sperm washing where the man is HIV positive). • people in same-sex relationships. [new 2013] 1.9.1.2 For people in recommendation 1.9.1.1 who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semenalysis, offer a further 6 cycles of unstimulated intrauterine insemination before IVF is considered. [new 2013]. **3.Full NICE guidance for men and women in same-sex relationships not having vaginal intercourse** – see full NICE guidance, appendix one.		
10	Increasing numbers of female same-sex couples for IVF treatment wish to have eggs collected from one partner, fertilised with donor sperm and the resulting embryos put back in the other partner. The couples wish this so that they both have a greater connection to the child born.	In the case of women in which only one partner has proven infertility, clinicians should discuss the possibility of the other partner becoming pregnant before proceeding to interventions involving the partner with proven infertility. Same-sex couples should have access to professional experts in reproductive medicine to obtain advice on the options available	Impact: increases costs treating egg donation (HFEA) and both partners must be worked up for treatment. This is happening in private funding, but a request has not been made for Dorset CCG to fund this with NHS funded treatment.	No change in policy.	Considered a choice decision, additional service the NHS would not fund. Could be funded by the couple if they wished to do this separately.

	Impact: increases costs treating egg donation (HFEA) and both partners have to be worked up for treatment. (Gain cost / understand cost)	to enable them to proceed along this route if they so wish.			
11	Male same-sex access evidencing infertility and access to IVF using surrogate.	Male same sex couples will be referred for infertility investigation if no pregnancy results following six cycles of donor insemination for which the man's donated sperm has been used. The CCG will not fund donor insemination and intrauterine insemination in this situation. **Surrogacy:** Under the HF&E Act (1990) the woman who gives birth is the mother of the child regardless of the source of the embryo. Surrogacy, using IVF or otherwise, is not supported because of the potential legal and ethical issues involved. Treatments that are requested as part of a surrogacy pathway will not be supported because of the potential legal and ethical issues involved.	Surrogacy is not covered in NICE guidance other than that men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy using the sperm of one partner, the latter being the usual way that male couples will be able to have a baby in which one of them will be a genetic parent. The scope specified that surrogacy was not to be covered in this guideline. However, when a pregnancy does not occur through surrogacy after an appropriate period of time (equivalent to the 12 months with vaginal intercourse or six cycles of AI for other people), there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment.	CCG does not support surrogacy but amend section 13.5 and 13.6. See appendix 2 for amended wording that should be included in the next policy version.	Due to the legal and ethical issues involved continue with current policy of not supporting the funding of surrogacy.

12	Single female access	Policy covers couples only. Couples must be in a stable on-going relationship for more than 3 years (evidenced by GP) before referral.	Not covered in NICE guidance – guidance does not stipulate as to the relationship status of the person planning to have treatment. Commissioning for single women has not been included in the HFEA guidance. https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf However, change in the law earlier this year where single people are now eligible for assisted reproduction services under the Human Embryo Fertilisation Act (HEFA). https://www.hfea.gov.uk/i-am/single-women/ HFEA: 8A Interpretation of mandatory requirements. No treatment services regulated by the HFEA (including intrauterine insemination - IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth. Single status is not covered by the Equalities Act	No change in policy but considered through IPT process. Single female access will include following unsuccessful pregnancy after 6 cycles of self-funding of DI, like same sex couples, will be considered through IPT if any request is presented. **Will be assessed and considered through IPT process.*	• Recognise this could create further financial impact. • NICE guidance does not provide guidance for fertility treatments for single individuals; therefore, consideration should be given to male and females who are single. • Agreement that as there is no national guidance (NICE or HFEA) and there is a financial impact to consider. • NICE guidance and ethical considerations have been taken into account and based on the funding model which is applied to Dorset CCG policy (medical model), conception can only be achieved via donor insemination so necessary malfunction has to be demonstrated through available means. If malfunction is apparent through intercourse or donor insemination, then single women could be eligible for funding so long as welfare of the potential child is not in question.

			Other neighbouring CCG policies that fund single women to access funded NHS treatment if malfunction is apparent through intercourse or donor insemination so long as welfare of the potential child is not in question: Somerset CCG Berkshire West CCG Buckinghamshire CCG		• IPT request should consider wider determinants and welfare of the child.
13	Smoking and consider use of e- cigarettes within policy criteria	Both partners must be non-smokers for 6 months prior to a referral. Non-smoking status for both partners will be tested with a carbon monoxide breath test prior to commencement of any treatment. General Practitioners should refer any smokers who meet all other criteria~~,~~ to a smoking cessation programme to support their efforts in stopping smoking. Previous smokers must be non-smoking for 6 months prior to being put forward for assisted conception treatment and register below 5 on the Carbon Monoxide test.	PH advice in 2017-18: Recommend caution in using e-cigarettes as exclusion criteria for IVF, a) because of the lack of evidence; and b) because lots of people are using e-cigarettes as an aide to quitting smoking – and smoking is clearly known to be a massive issue.	No change.	Not enough evidence that vaping/e-cigarettes it is detrimental to fertility and this should not be an exclusion criteria.

Table 3: Cost modelling

	Issue:	Current CCG criteria	NICE guidance / HFEA guidance / local information to consider	Recommendation to CRG and GB	Rationale
14	Review number of cycles to increase offer moving to closer align with NICE guidance.	1 cycle (1 fresh and 1 frozen implantation)	A full IVF cycle, as defined by National Institute of Clinical Excellence (NICE) guidelines, consists of one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). **Other neighbouring CCG policies that fund the same 1 cycle as Dorset CCG:** • Hampshire & IOW (July 2019 reviewed) • Cornwall CCG • Devon CCG • Somerset CCG **Other neighbouring CCG policies that differ:** • Wiltshire CCG (2018) offer 1 cycle with 1 fresh implantation and up to 2 frozen implantations if embryo's available **HFEA commissioning guidance 2019:** Aligns to NICE guidance and women under 40 should be offered three full cycles of IVF treatment; except women aged 40-42 should be offered one full cycle of IVF treatment if they	Based on cost modelling, increase commissioning budget to allow for 3 cycles of IVF treatment (this includes 3 fresh cycles and 3 frozen embryo transfers) – see below appendix 3 for the cost modelling. Women over the age of 40 would only receive 1 cycle of treatment, as per HFEA guidance. Investment required: Current budget: £740k (includes cryopreservation etc) Investment required in addition to current budget for 3 cycles: £1,250,562 - £740k = **£510,562k** **Success rates:** Commissioning one cycle of treatment (and based on HFEA national success rates) would support 36% of couples achieving the birth of a child. Cost associated: £516,484k Commissioning two cycles of treatment (and based on HFEA national success rates) would	Clinically: To align with NICE guidance; but recognise the financial constraints. HFEA set out that economic commissioning fertility treatment can have positive economic effects. Offering same as Wiltshire. Need to consider: *Advantages:* Whilst offers some 7% of patients more than one frozen cycle some advantages (younger respond well), it is clinically recommended to use all frozen embryo before embarking on more risky and complex process of fresh cycle – will help that small number of patients. *Disadvantages:* This could appear more of a disadvantage to those with low egg reserve and no embryos to freeze, and who therefore need a fresh embryo/cycle – could feel bigger gap for those who can

<table>
<tr>
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<td>have normal ovarian reserve for their age. Guidance found here: <u>https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf</u>

The HFEA guidance sets out effective commissioning of IVF treatment is cost effective for CCGs:
‘Commissioning fertility treatment can have positive economic effects because it:
• Reduces rates of mental health issues relating to infertility in couples, and the costs associated with this.
• Reduces the incidence of multiple births, which can be very costly to neonatal services and long-term health and social care services.
• Reduces reproductive tourism, where people travel abroad for fertility treatment, which often leads to health complications or multiple births absorbed by the NHS.
• Generates long-term financial gain, as the resultant child makes a significant contribution to the economy.’</td>
<td>increase the success rates and more Dorset couples to achieve birth of a child from the referred/same cohort that started treatment – up to 54% (this is based on HFEA modelling).

Commissioning three cycles of treatment (and based on HFEA national success rates) would increase the cumulative success rates and more Dorset couples to achieve birth of a child from the referred/same cohort that started treatment – cumulatively up to 65% (this is based on HFEA modelling).

Cost of cycles:
<table>
<tr><td colspan="2">Total CCG Cost</td></tr>
<tr><td>1st Cycle</td><td>£ 561,484</td></tr>
<tr><td>2nd Cycle</td><td>£ 362,691</td></tr>
<tr><td>3rd Cycle</td><td>£ 256,386</td></tr>
<tr><td>Total</td><td>£ 1,180,562</td></tr>
</table>
Forecasted annual spend for ‘other spend’ cryopreservation, IUI/DI, PESA (based on 19-20 data) = £70k
<table>
<tr><td colspan="2">Total CCG Cost</td></tr>
<tr><td>1st Cycle</td><td>£ 561,484</td></tr>
<tr><td>2nd Cycle</td><td>£ 362,691</td></tr>
</table></td>
<td>only access one fresh embryo transfer.

Clinicians would prefer to offer more fresh cycles.

Cost modelling can be found in appendix 2.</td>
</tr>
</table>

				3rd Cycle	£ 256,386	
				Total	**£ 1,180,562**	
				Additional spend cryopreservation etc	**£ 70,000**	
				Total	**£ 1,250,562**	
				Financial Investment required: Investment required in addition to current budget for 2 cycles: £994,175k - £740k = £254,175k Current budget = £740k Investment required in addition to current budget for 3 cycles: £1,250,562 - £740k = £510,562k		

Model development, risk and recommendation

The modelling has been developed alongside using HFEA trend data and success rates, working with Salisbury Fertility Centre and our local Business Intelligence team

HFEA success data: Fertility treatment 2018: trends and figures | Human Fertilisation and Embryology Authority (hfea.gov.uk)

Modelling development:

- This has been based on using activity data from 19-20 data, which has been the highest activity year yet.
- Prevalence information has been requested from Public Health Dorset; however, the data accessed provided limited information to understand true prevalence. Therefore, basing the modelling on the highest activity year (2019-20) that the Dorset contract has seen seemed the workable option.

- HFEA data covers both NHS funded patients and self-funded patients, therefore may not reflect the true picture (i.e. NHS funded patients).
- The modelling for HFEA looks at births per embryo transfer as opposed to embryo transfer procedure, therefore the fertility centre feel that the success rates would be a slightly higher if birth success rates were based on birth rate per cycle. The HFEA data does not account for when there is lower embryo quality and when more than one embryo may be transferred.
- HFEA data does not differentiate between fresh and frozen cycles.
- Using the national success rates from HFEA provides a good basis and offers a closer to worst case scenario.

Assumptions:

- Assumes approx. 40% will have Frozen Embryo Transfer each time, although this may not be the case on the second cycle.

Risks:

- Less than half of all IVF cycles in the South West are NHS funded (41%). Although some of these may not be eligible on the NHS, but there may be an element of choice when people are able to afford this; compared to North East and North West which see 55-60% of cycles funded by the NHS.
- With potential for COVID impacting on income this may mean more people looking to the NHS over the next few years, so the CCG may need to build in contingency/review.
- The proposed changes may increase activity, but this is not deemed to be significant increases as some these changes have been implemented by other CCGs, e.g. single women access to IVF when demonstrated infertility, when one partner from the couple has a living child already. We are unable to gain data from other CCGs to understand impact of both these changes.

Options for commissioning:

Option 1: Commission 1 cycle of treatment for 35% birth success rate of the total cohort referred

Option 2: Commission 2 cycles of treatment for 54% cumulative birth success rate of the total cohort referred.

Option 3: Commission 3* cycles of treatment for 65% cumulative birth success rate of the total cohort referred.

*Note: Women should be offered three full cycles of IVF treatment; except women aged 40-42 should be offered one full cycle of IVF treatment if they have normal ovarian reserve for their age.

Recommendation:
Approve Option 3 – Commissioning of 3 cycles of treatment for 65% cumulative birth success rate of the total cohort referred, except women aged 40-42 should be offered one full cycle of IVF treatment if they have normal ovarian reserve for their age.

Rationale:

- Salisbury Fertility Centre believe their success rates for births are closer to approx. 30%, but using the national success rates from HFEA would provide a good basis and offers a worst case scenario for activity and funding.
- Based on improving chances of Dorset women having a baby, better value for money as well as the longer-term economic effects, increase the commissioning budget to allow for 2 cycles of IVF treatment (this includes 2 fresh cycles and 2 frozen embryo transfers).
- Economic effect of effective commissioning, from HFEA guidance:
    - Reduces rates of mental health issues relating to infertility in couples and the costs associated with this.
    - Reduces the incidence of multiple births, which can be very costly to neonatal services and long-term health and social care services.
    - Reduces reproductive tourism, where people travel abroad for fertility treatment, which often leads to health complications or multiple births absorbed by the NHS.
    - Generates long-term financial gain, as the resultant child makes a significant contribution to the economy.
- Monitor closely and review annually.

The Governing Body may want to consider building in a 3% contingency budget to consider public health advice for increased overall demand on the fertility budget

Appendix 1:

The below is extracted from NICE guidance CG156, page 78, also found here https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453 :

'The Scope of this guideline makes it clear that it is intended for people who have a possible pathological problem (physical or psychological) to explain their infertility.

For women in same-sex relationships, there should be some period of unsuccessful artificial insemination (AI) before they would be considered to be at risk of having an underlying problem and be eligible to be referred for assessment and possible treatment in the NHS. While the Scope did not allow the GDG members to make recommendations about this period of AI before referral for further assessment and possible treatment, they were of the majority view that ideally such AI should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations. However, they acknowledged that such pre-requisites and safeguards did not always apply.

Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy using the sperm of one partner, the latter being the usual way that male couples will be able to have a baby in which one of them will be a genetic parent. The Scope specified that surrogacy was not to be covered in this guideline. However, when a pregnancy does not occur through surrogacy after an appropriate period of time (equivalent to the 12 months with vaginal intercourse or 6 cycles of AI for other people) there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment.

In people using AI to conceive, as with people having vaginal intercourse, the success rates in women with normal fertility declines with age. Success rates also vary with the assisted reproduction method used. There are no data for the success of AI outside a clinical setting (sometimes called a 'do-it-yourself' approach where fresh donor semen is deposited in the upper vagina or even into the cervical os) and so the GDG was unable to comment on the efficacy of this approach. However, in a clinical setting, success rates are higher with fresh compared with frozen–thawed sperm and with intrauterine insemination (IUI) compared with intracervical insemination (ICI). These data show that in the absence of any known cause of infertility, the cumulative chances of a pregnancy occurring after ICI or IUI in women who are 35 years or less are:

- after 12 cycles of treatment (approximately 85% cumulative success over 12 months for women having vaginal intercourse, see Figure 5.1):
    - over 60% for ICI using thawed semen (Schwartz et al., 1982)
    - over 70% for ICI using fresh semen (van Noord-Zaadstra et al., 1991)
    - over 80% for IUI using mainly thawed semen (HFEA data http://www.hfea.gov.uk/ 1270.html#1299)
- after 6 cycles (approximately 70% cumulative success over 6 months for women having vaginal intercourse, see Figure 5.1)
    - over 40% for ICI using thawed semen (Schwartz et al., 1982)

- over 50% for ICI using fresh semen (van Noord-Zaadstra et al., 1991)
- over 60% for IUI using mainly thawed semen (HFEA data http://www.hfea.gov.uk/ 1270.html#1299).

Given these data, the GDG discussed the options for the number of failed cycles of AI that should be undertaken before further assessment and possible treatment be initiated. The aim was to decide the number of failed AI cycles that would be equivalent to failure to conceive after 12 months of unprotected vaginal intercourse. The GDG's discussions covered a number of ethical and practical issues relating to 'equivalence' including:

- the financial cost of AI and disadvantage of those attempting to conceive by that route
- the time to conception and disadvantage of those attempting to conceive by vaginal intercourse

Women having vaginal intercourse do not have to pay to get pregnant, whereas those in same-sex relationships are at a disadvantage as they have to pay for a number of cycles of AI before they can be considered for assessment and possible treatment in the NHS. Therefore, the cost to the woman and her partner would be lower if 6 cycles of AI were recommended compared with 12 cycles of AI.

The GDG recommends that people having regular vaginal intercourse should be assessed and possibly treated if they have not conceived after 12 months (see Recommendation 29). The GDG decided that in a same-sex couple 'numerical equivalence' would be 12 cycles of AI, with the AI being undertaken once a month over 12 months, though the GDG acknowledged that using the criterion of 12 cycles of AI did not quite give equivalence in terms of cumulative success rate compared with vaginal intercourse. The GDG discussed using a lower number of cycles of AI in order to offset the financial impact and inconvenience of AI. However, the GDG stated that using a lower criteria could give same-sex couples a perceived advantage in terms of the time they had until further investigations were required. Other factors that the GDG took into consideration in reaching a conclusion were:

- The acknowledged limited 'supply' of sperm donors in the UK.
- Recommending 6 cycles of AI would provide consistency with the recommended number of cycles of AI used in a therapeutic setting (see chapter 17).
- The cumulative success rates with AI are lower in cycles 7 to 12 compared with cycles 1 to 6.
- AI transfers are often not undertaken consecutively but spread over a longer period of time due to problems with scheduling of procedures. Therefore, undertaking 12 cycles of AI could take considerably longer than 12 months.

In the light of the AI data, the majority view of the GDG was that, for same-sex couples, failure to conceive after 6 cycles of AI within the 12 past months should be the indication for further assessment'

Appendix 2:

13.5 - Surrogacy is when a woman carries a baby for someone who is unable to conceive or carry a child themselves, with the intention of handing the baby over to the intended parents or parent ('IP'). The IP are couples or individuals who cannot have a child themselves and who are considering surrogacy as a way to become a parent. This includes heterosexual or same-sex couples in a marriage, civil partnership or living together/co-habiting, or individuals regardless of their relationship status. There are two different types of surrogacy arrangements:

- Straight surrogacy (known as 'traditional' surrogacy) – this is when the surrogate provides her own eggs to achieve the pregnancy and therefore has a genetic link to the child. The intended father, in either a heterosexual or male same-sex relationship, or an individual (including donor sperm via a fertility clinic), provides a sperm sample for conception through either self-insemination at home or artificial insemination with the help of a fertility clinic.

- Host surrogacy - (also known as 'gestational') surrogacy is when the surrogate does not provide her own egg to achieve the pregnancy. The embryos are created in vitro and transferred into the uterus of the surrogate using eggs of the intended mother fertilised with sperm of the intended father or donor; or eggs of a donor fertilised with sperm of the intended father, where the intended mother cannot use her own eggs, or the IPs are a same-sex male couple.

13.6 - Surrogacy is governed by the Surrogacy Arrangements Act 1985 and the Human Fertilisation and Embryology Act 2008. It is a complicated area, and raises a number ethical and legal issues, including:

Ethical issues:
- The risk of conflict between the surrogate mother's wishes and intended parents in relation to the best interests of the child;
- Rejection of the child in cases of multiple pregnancy, disability or birth trauma by both surrogate and intended parents;
- Surrogate mother changing her mind during pregnancy or after child has been handed over to intended parents;
- Long term psychological effects on all those involved in the surrogacy arrangement;
- Conflict arising in relation to decision making during the pregnancy and aspects of care;
- Risk of morbidity and mortality to either the child or the surrogate mother.

Legal issues:
- Commercial surrogacy arrangements remain illegal in the UK, but reasonable expenses can be paid for altruistic surrogacy;
- Some non-profit organisations can lawfully assist potential surrogates and intended parents to navigate their surrogacy;
- There are differing and complicated legal frameworks when surrogate mother or intended parents are foreign nationals;
- Surrogacy agreements are not legally enforceable;
- Surrogate mother has legal rights over the foetus and is regarded as the legal mother;
- A parental order ('PO') is required to transfer parentage and associated Parental Responsibility for decision making in treatment settings. The timing of a PO can result in difficult periods to navigate if the child requires treatment;
- NHS bodies are unlikely to be in a position to properly assess whether the parties have concluded a lawful surrogacy arrangement;

- Human Fertilisation and Embryology Act 2008 acknowledges that surrogacy involves complicated legal issues, and therefore all involved are advised to obtain legal advice prior to making any decisions.

As a result of the ethical and legal issues involved in this complex area which presents unique challenges for both surrogate mother, child and intended parents, Dorset CCG will not fund treatment which relates specifically to commissioning fertility treatments directly associated with surrogacy arrangements, or fund any payments to the surrogate mother (to cover expenses, legal costs, treatments abroad or transport costs). In addition, there is no clear guidance for CCGs nationally. This matter will remain under periodic review, in accordance with best practice regarding policy monitoring, to ensure any changes within UK law, or national guidance or central policy, regarding surrogacy arrangements, are noted for impact on the current funding position.

Appendix 3

Modelling:

		Activity	**Live birth success rate 26%	*40% of the 138 referred have a Frozen Embryo Transfer 40%	**Live birth success rate 24%	Activity	Live birth success rate 21%	*40% of the 89 have a Frozen Embryo Transfer 40%	**Live birth success rate 19%	Activity	**Live birth success rate 17%	*40% of the 63 have a Frozen Embryo Transfer 40%	**Live birth success rate 17%	
1 st Cycle	ICSI	65	17	26	6									
	IVF	73	19	29	7									
	Total	**138**	**36**	**55**	**13**									
2 st Cycle	ICSI					42	9	17	3					
	IVF					47	10	19	4					
	Total					**89**	**19**	**36**	**7**					
3 st Cycle	ICSI									30	5	12	2	
	IVF									33	6	13	2	
	Total									**63**	**11**	**25**	**4**	
Unsuccesful	ICSI													23
	IVF													25
	Total													**48**

Birth Success Rate of total after 1st cycle	Birth Success Rate of total after 2nd cycle	Birth Success Rate of total after 3rd cycle	Unsuccesful after 3 cycles
35%			
36%			
36%			
	54%		
	55%		
	54%		
		65%	
		66%	
		65%	
			35%
			34%
			35%

Activity Cost per cycle	
ICSI	£ 3,935
IVF	£ 3,427
FET	£ 1,010

Total CCG Cost	
1st Cycle	£ 561,484
2nd Cycle	£ 362,691
3rd Cycle	£ 256,386
Total	**£1,180,562**

*Note: Year on year we know approx 40% will have a FET. From the remaining 60% who started treatment some fall preganant and have a baby, and many will not have enough quality embryos to freeze.

**Note: Live birth rate goes down after each embryo transfer (either fresh or frozen)

		Activity	Success 26%	FET 40%	Success 24%	Activity	Success 21%	FET 40%	Success 19%	Activity	Success 17%	FET 40%	Success 17%	
1 st Cycle	ICSI	£ 255,775	£ 66,895	£ 26,255	£ 23,610									
	IVF	£ 250,171	£ 65,113	£ 29,284	£ 23,989									
	Total	**£ 505,946**	**£132,008**	**£ 55,538**	**£ 47,599**									
2 st Cycle	ICSI					£ 165,270	£ 35,415	£ 17,166	£ 11,805					
	IVF					£ 161,069	£ 34,270	£ 19,186	£ 13,708					
	Total					**£ 326,339**	**£ 69,685**	**£ 36,352**	**£ 25,513**					
3 st Cycle	ICSI									£ 118,050	£ 19,675	£ 12,117	£ 7,870	
	IVF									£ 113,091	£ 20,562	£ 13,127	£ 6,854	
	Total									**£ 231,141**	**£ 40,237**	**£ 25,245**	**£ 14,724**	
Unsuccesful	ICSI													£ 90,505
	IVF													£ 85,675
	Total													**£ 176,180**

PART 1: SYSTEM QUALITY ASSESSMENT IMPACT TOOL

Project title	Fertility – Assisted Conception Criteria Based Access Protocol
Project leads	Hannah Nettle – Principal Programme Lead
Project start date	08/10/2020
Date of QIA completion	07/01/2020
Person completing SQIA Name(s), job title(s) and organisation(s)	Hannah Nettle
Email address for Star Chamber feedback to be formally sent	Hannah.Nettle@dorsetccg.nhs.uk
Project summary (max 200 words)	The review of the Dorset fertility assisted conception policy which defines what assisted conception treatments are offered in Dorset and sets out the eligibility criteria for patients wishing the access these services. In the general population (which includes people with fertility problems), it is estimated that 80% of women would conceive within one year of regular unprotected sexual intercourse. This rises cumulatively to 90% after two years. There are three main types of fertility treatment: • Medical treatment (such as use of drugs for ovulation induction) which is not covered by this criterion based protocol; • Surgical treatment (for example, laparoscopy for ablation of endometriosis) which is not covered by this criteria based protocol; and • Assisted conception treatments, which are the subject of the policy.
Cost prediction (max 100 words)	

Key issues raised in QIA	There is a specific criteria based protocol that patients need to meet to be referred to the services.				
Summary of Quality Impact Assessment *(Total 21 domains)*	**Outcome**	**Positive**	**Neutral**	**Negative**	**Not applicable**
	Positive				
Summary of Clinical Risk Assessment *(Risk matrix as below)*	**Impact**		**Likelihood**		**Risk score**

		Likelihood				
Consequence		**1**	**2**	**3**	**4**	**5**
		Rare	Unlikely	Possible	Likely	Almost certain
1	Negligible	1	2	3	4	5
2	Minor	2	4	6	8	10
3	Serious	3	6	9	12	15
4	Major	4	8	12	16	20
5	Catastrophic	5	10	15	20	25

Low risk Green 1-3	Moderate risk Yellow 4-6	Significant risk Orange 8-12	High risk Red 15-25

For further information and detail relating to 'likelihood' and 'consequence' please refer to the Risk Matrix descriptors in Appendix A of the 'Procedure for undertaking System Quality Impact Assessments'

QUALITY IMPACT ASSESSMENT TOOL

QUICK REFERENCE GUIDE

PATIENT SAFETY	CLINICAL EFFECTIVENESS	PATIENT EXPERIENCE AND INVOLVEMENT	EQUALITY AND DIVERSITY
What are the current patient safety concerns, if any	What clinicial evidence demonstrates best practice?	What do patients and carers say about the current service?	How accessible is the current service to all people defined by the nine characteristics in the Equality Act 2010?
How to you know that the service developments will be safe?	How is this clinical evidence being used?	How will patients be involved in the decision-making process?	How will this accessibility be affected by the service developments?
What measurements/metrics will you use to demonstrate safety?	What more needs to happen to make sure best practice is achieved and patient outcomes improved?	How will the patient experience be monitored?	How will future access to services be analysed and monitored?
		Will patient choice be affected?	
		Anticipated level of public support?	

QUALITY IMPACT ASSESSMENT TOOL

In healthcare, 'quality' includes patient safety, patient experience and clinical effectiveness. These domains include Equality and Diversity, Dignity and Respect and the effects of planned changes on workforce.

What is a Quality Impact Assessment (QIA)?

This is a tool to help develop service change. It should be used at the *beginning* of a process to inform its development, ensuring that the core pillars of quality are covered and that the service is developed in a comprehensive way, based on rounded data and intelligence. The tool begins with some overarching questions in the quick reference guide. If there are any aspects of those questions which cannot be satisfactorily answered, there are prompts in the following workbook which will help provide assurance that the service is developing robustly. It is not a requirement that each section needs to be methodically worked through but intended as a tool to help where there are gaps in knowledge or experience.

Why undertake a QIA?

When a change to a service/care pathway is proposed, the Clinical Reference Group must ensure that the proposal has only **positive effects** on patient safety and patient experience, and are evidence based, and demonstrate best practice. Only then can we be assured of high-quality care. The QIA also need to demonstrate that issues of workforce planning, and skills transfer, together with education and training have been appropriately considered. This tool will enable the system to be assured that all essential factors are being considered and addressed through the development of service design.

Who undertakes a QIA?

The team responsible for service design should begin the QIA at an early stage, to ensure compliance with statutory requirements. The CCG Quality team are available to discuss any areas that need clarification or guidance.

Ratings

Use the form to make notes from which the self-assessment rating can be determined. The QIA threshold is designed to provide an assessment of the perceived impact that the service development will have on the quality of care delivered. Whatever the outcome of the threshold result, there may be individual indicators rated as having a negative impact on quality. In that case, due consideration should be given to all of these to establish how the scheme/plan could be changed to improve the quality impact or to ensure that on balance, the scheme is worth pursuing. In these cases, the reason for the decision to go ahead should be clearly documented.

The QIA threshold key

Outcome	Suggestion – the assessment suggests that this plan/scheme:
Negative	This development will have a negative impact
Neutral	There is no anticipated change in the impact of this development
Positive	This development will have a positive impact
Not applicable	This question is not relevant at this time

Please take care when completing this assessment. A carefully completed assessment should safeguard against challenge at a later date.

PATIENT SAFETY			
What is the potential impact of the service development on patient safety?	**Use these prompts to help you comprehensively evaluate the plans**	**Information to inform self-assessment**	**Self- assessment**
What are the known patient safety issues within the current service? (as identified by national/local audits, SIs, incident trend analysis, complaints, CQC and other external inspections, staff observation/feedback)	Has the current safety of the service been evaluated and known patient safety risks identified? Prompts to consider: • Specific safety issues within this pathway or service. • Analysis of available data/information to identify themes and trends. • The way in which the planned changes will address the identified patient safety issues. • Impact on preventable harm.	None identified – clinics have to be HFEA licensed and are inspected by HFEA	Neutral
How will the planned changes to service provision provide evidence of improved or continued safe	What are the current assurances in place for reviewing this service – if it is a new service what mechanisms will be	Relates to policy – contract monitoring of KPIs and outcomes	N/A

care?	used? Prompts to consider: • Existing patient safety measures Metrics to provide assurance that the changes made to the pathway/service are Improving patient safety or reducing the risk of harm. • Processes to review patient safety measures to provide assurance.		
Have staffing, skill mix and workload issues been considered within the plans?	What assurances have the service providers given with regard to assessing their workforce requirements to deliver this service/pathway safely? Prompts to consider: • skill mix, recruitment activity, vacancy levels and turnover, staff training and	N/A	N/A

	education, appraisal and personal development planning, and staff feedback (e.g. national and/or local surveys)		
Do the plans include changes to treatment involving medications, (including prescribing, administration or security)	What impact will the plans have on medicines security and have you received assurance as to how any risks will be mitigated? Prompts to consider: • Patient safety. • Competency in medicines administration. • Systems in place to ensure appropriate monitoring of patient outcomes/safety.	N/A	N/A
Will the plans impact positively or negatively on the organisation's duty to protect	Protocols to consider include: The NHS Constitution,	A licensed clinical setting required by law to ensure that donors, patients and any future children are protected by carrying out rigorous health tests and offering everyone involved counselling. HFEA Code of Ethics: No treatment	Neutral

children, young people and adults?	Partnership working, Safeguarding children or adults	services regulated by the HFEA (including intrauterine insemination - IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth	
Do the planned changes require ratification through a governance process?	In the event of a legal challenge, how thorough is the ratification process? Prompts to consider Current statutes / professional standards e.g. Mental Capacity Act, Mental Health Act, Dangerous Drugs Act, Children's' Act, No Secrets, GMC, NMC etc. Involvement of the appropriate specialist Responsible committees within each organisation and across the pathway *(Please note these may be outlined within the NICE Guidance)*	Yes. Governing Body to review and agree recommended changes to the ACS policy presented from the policy review group	N/A

CLINICAL EFFECTIVENESS			
What is the potential impact of the service development on clinical effectiveness?	**Use these prompts to help you comprehensively evaluate the plans**	**Information to inform self-assessment**	**Self- assessment**
Are there NICE Guidance and/or Quality Standards associated with this business case/service change/redesign?	• Which NICE Quality Standards are identified? • If there is no relevant Quality Standard, has other accredited evidence been sourced? If yes, please state which. • If there is no relevant accredited evidence, will good practice be defined by carrying out research? • Are there protocols or guidelines written which specifies good practice?	• NICE Quality Standards (2014) Fertility problems (see appendix 1) • NICE Guidance: Fertility problems: assessment and treatment: Clinical guideline CG156 (2013, last updated: September 2017): • https://www.nice.org.uk/guidance/cg156/chapter/Recommendations#access-criteria-for-ivf • Human Fertilisation and Embryology Authority (HFEA) – HFEA (2019) Commissioning guidance for fertility treatment https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf : • *'This guidance is intended for use by clinical commissioning groups (CCGs) to support them in commissioning fertility services for their local population and implementing the NICE guidelines on fertility treatment. It is produced by the Human Fertilisation and Embryology Authority (HFEA), the national regulator of fertility clinics, in conjunction with the main professional bodies, British Fertility Society, Association of Clinical Embryologists, Royal*	Positive – as per recommendation in CRG paper aligning with NICE and HFEA guidance

		College of Obstetricians and Gynaecologists, and Royal College of Nursing to assist CCGs in using available resources to make evidence-based clinical commissioning decisions. This recognises that CCGs face many competing priorities. This guidance aims to promote more consistent and better quality commissioning decisions across the UK, improve the cost-effectiveness of healthcare resources and deliver the significant public health benefits that are possible through accessing fertility treatment. The National Institute for Health and Care Excellence's (NICE) clinical guidance on diagnosing and treating fertility problems should be referred to. A benchmark price for IVF has been published in 2019 by NHS Improvement which will help to guide how much you are spending on IVF treatment in your area'	
Are the planned changes or service re-design in line with the most up-to-date guidance ensuring the business case is evidence- based? NICE baseline assessment tool can be accessed from www.nice.org.uk	Has a baseline assessment against the recommendations/indicators been undertaken? Does the plan reflect the Quality Standard Indicators? Are there gaps? If there are gaps, how will these be addressed?	Yes. The CCG currently commissions 1 cycle of IVF/ICSI and does not align with HFEA and NICE guidance which recommends 3 cycles of IVF/ICSI. Policy review will consider increasing number of cycles to 3	Positive
Has the NICE commissioning Costing Tools been used?	Use NICE costing tools alongside the guidance, where available. These can be accessed from:	N/A	N/A

	www.nice@org.uk		
What plans are in place for clinical audit or evaluation once changes have been imbedded into practice?	Audit against standards outlined in NICE guidance or professional standards. Use the NICE clinical audit tool where available www.nice@org.uk	Contract monitoring	Neutral
Health Outcomes for patients	What are the expected health outcomes for patients? How will the success against your expected health outcomes be measured? How do these compare with other available treatment or care pathway alternatives?	• By offering 1 cycle 36% of couples achieve pregnancy and birth of a child • By offering 2 cycles of treatment there is a cumulative success rate of 54% of couples to achieve birth of a child • By offering 3 cycles of treatment there is a cumulative success rate of 65% of couples to achieve birth of a child The service specification reflects Dorset CCGs commissioning for outcomes. The outcomes set out in the service specification reflect clinical safety, quality and success rates. The outcomes align with standards set out by the fertility regulatory Human Fertilisation and Embryology Authority (HFEA). The HFEA code of practice contains regulatory principles for licensed centres and guidance notes which provides guidance to help clinics deliver safe, effective and legally compliant treatment Commissioning fertility treatment can have positive economic effects because it https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf : *• Reduces rates of mental health issues relating to infertility in*	Positive

		couples, and the costs associated with this. *• Reduces the incidence of multiple births, which can be very costly to neonatal services and long-term health and social care services.* *• Reduces reproductive tourism, where people travel abroad for fertility treatment, which often leads to health complications or multiple births absorbed by the NHS.* *• Generates long-term financial gain, as the resultant child makes a significant contribution to the economy*	
PATIENT EXPERIENCE AND INVOLVEMENT			
What is the potential impact of the service development on patient experience and involvement?	**Use these prompts to help you comprehensively evaluate the plans**	**Information to inform self-assessment**	**Self- assessment**
What do patients and carers say about the current service?	Use positive and negative feedback from: • PALS and complaints, patient opinion, surveys • Real time feedback, focus groups, LINK/Healthwatch	Very few patient complaints across all three providers and/or current outstanding performance or quality issues. Issues regarding policy criteria are picked up via CCG complaints and via IPT	Neutral
How will patients, carers and key stakeholders be involved in the decision-making process around the development of this	At what point in the decision-making process will patients and public have a chance to influence the service development?	The policy review group consisted of Dorset secondary care clinical leads and the CCG contracted assisted conception service providers (consultants and business manager). Public engagement and consultation considered not required in proportion to the proposed changes	N/A

service?	What methods will be used to involve patients, public and stakeholders? Has advice been sought from the Strategic Public Involvement Group as to how best to manage this?		
How will the service development improve the patient experience?		There are several proposed changes that will improve the policy's clarity, as well as supporting better application of the criteria by the fertility centre and aid patient understanding. In some cases, it will reduce the need for requests to be raised through the IPT panel, for example, having clear criteria for fertility preservation will provide a more seamless pathway By adopting the recommended policy changes there is an opportunity to provide a more equitable and fair policy, move closer to align with HFEA and NICE guidance and to support more couples in Dorset to achieve a successful outcome and birth of a child	
How will the patient experience of the new service be monitored?	How will feedback be collected? Who will be analysing it and when?	Contract monitoring, CCG complaints, IPT requests and enquires	neutral
Will patient choice be affected?	Will choice be reduced, increased or stay the same?	N/A	N/A

	Do the plans support the compassionate and personalised care agenda?		
What level of public support for this service development is anticipated?	Do you expect people to • be supportive, • be a little concerned or • contact their MP or the press as a result of their objections?	Supportive	Positive
EQUALITY AND DIVERSITY			
What is the potential impact of the service development on equality and diversity	**Use these prompts to help you comprehensively evaluate the plans**	**Information to inform self-assessment**	**Self- assessment**
How accessible is the current service to people defined by the 9 characteristics in the Equality Act 2010? • Age • Disability • Gender re-assignment Marriage and civil partnership. • Pregnancy and	What kind of monitoring data is available to understand the current profile of patients who use the service? Has any research been done to look at whether different groups have different needs, experiences, issues and priorities in relation to the service	The policy review group assessed and deem policy to meet all protected characteristics Age: 2015 there was change in policy ensured aligning with the Equality Act (2010-2012) and increasing access to age range and in line with NICE guidance This policy review considered: Sexual orientation: Same Sex; Male and Female Access criteria have equitable access to assisted conception treatment and was considered via policy review group (see policy review issues for more detail)	Positive

maternity Race including nationality and ethnicity Religion or belief • Sex • Sexual orientation	development? Are there currently any problem areas for equality of access?	Gender re-assignment: Transgender access to fertility preservation was considered via policy review group (see policy review issues for more detail) Proposed changed to the policy further support accessible access to fertility treatment The policy will continue to be reviewed every three years, unless considerable issues arise earlier	
What is the expected impact of this service development for people defined by the above characteristics?	Have potential access issues been considered? If the service development will have an impact on any of these groups, how will equality of access or care be addressed? What mechanisms will be in place to evaluate continuing accessibility?		
How will accessibility be monitored?	How will monitoring information be used to understand access issues?	Contract monitoring, provider feedback, complaints, IPT requests Review of policy every three years, then annually	

	Who will be responsible for monitoring?		
Have you considered other groups and how your planned changes might impact on them: • People with Dementia Migrant workers, Homeless individuals and families, • Sex workers, • Gypsies and 16arginali, Rurally isolated, • Low socio-economic status, • People who may find it hard to access the service or are difficult to reach and talk to**.**	Has access from marginalized groups been considered in the development of this service? If there are any issues arising, how will these be addressed?	The proposed changes offer greater access to couples who are unable to self-fund assisted conception treatments This is a specialist service, and where couples have issues accessing the service provider location the CCG will consider on case by case basis – this has not been identified as an issue before The contract is delivered by three providers since 2019, it was historically one provider before which limited choice – choice of access to location is greater now	Positive

PART 2: EQUALITY IMPACT ANALYSIS

Assessor's Name	
Job Title of Assessor	
Date of Analysis	
Sponsoring Director/Lead	
What are the main aims and objectives of the service, policy or function being assessed?	

PART A: INITIAL SCREENING

What evidence is available to suggest that the proposed service/policy/function could have an impact on people from the protected characteristics or staff?

The below scoring matrix was used/will be used to assess the potential impact.

Perceived Positive Impact	Perceived Neutral Impact	Perceived Disproportionate Impact
+	N	-
Positive impact on a large proportion of protected characteristic groups. Significant positive impact on a small proportion of protected characteristic groups.	No change/ no assessed significant impact of protected characteristic groups.	Disproportionate impact on a large proportion of protected characteristic groups. Significant disproportionate impact on a small proportion of protected characteristic groups.

- If all elements of the service/policy/function are analysed as **Neutral Impact** or **Positive,** please proceed to sign off page at the end of the form.

- If any element of the service/policy/function is assessed as **Perceived Disproportionate Impact**, continue with the Full Equality Impact Assessment.

Protected Characteristic	Analysis + / N / -	Reason for Impact Analysis Provide recent evidence to demonstrate how people with the protected characteristic will be positively/adversely affected by service/policy/ function (*expand cell as necessary*)
Age	N	2015 there was change in policy ensured aligning with the Equality Act (2010-2012) and increasing access to age range and in line with NICE guidance
Disability	N	No issues identified as part of the review
Gender Reassignment	+	Continue to support access to fertility preservations treatments
Marriage and Civil Partnership	+	Couples have to try for 2-year period, without natural conception, before accessing IVF treatment
Pregnancy and Maternity	+	Improving success rates
Race/Ethnicity/Nationality	N	No issues identified as part of the review
Religion or Beliefs/Spirituality		No impact, equal access to all. Although if Religion or Beliefs/Spirituality meant couples have preference over treatment this will be considered on case-by-case basis, as it would be currently
Gender Men, Women	N	No issues identified as part of the review
Sexual Orientation	Y	Equitable access to assisted conception treatment, and period of evidencing infertility considered and align with NICE guidance
Staff	N	N/A
Any Other Group *Rural Isolation, Military, Homeless*	N/A	Military funded by NHS E

List of references – linked to evidence provided

PART B: FULL EQUALITY IMPACT ASSESSMENT

ENGAGEMENT			
Please list previous consultation which has taken place, or is planned, relating to the proposed service/policy/function with each element from the protected characteristics and staff.			
Protected characteristics	**Analysis + / N / -**	**Reason for impact analysis**	**Suggested mitigation**
Age			
Disability			
Gender reassignment			
Marriage and civil partnership			
Pregnancy/maternity			
Race/ethnicity/nationality			
Religion or beliefs/spirituality			
Gender (men, women)			
Sexual orientation			
Staff			
Any other group (rural isolation, military, homeless)			

Have you engaged stakeholders in the gathering or testing the evidence available? If not, what do you intend to do?		
If you have engaged groups, please list below and include who was involved, how they were involved and the key outputs.		
Groups engaged	**Date and type of engagement**	**Outputs from activity**

Summary of analysis of overall impact: *Considering the evidence and engagement activity you have listed, please summarise the impact of your proposals. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in service or expand their participation in public life.*

MONITORING
If applicable, include how the service specification and contract ensure that data is routinely collected so the identified impact can be reported and monitored.

ACTION PLANNING **For improvement, and to address health inequalities and discrimination**			
Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.			
Action	**Responsible person**	**By date**	**Progress/review**

REVIEW OF ANALYSIS	
I am satisfied that this service/policy/function has been successfully equality impact analysed.	
Signed by Sponsoring Director/Lead:	
Print name:	
Job title of Director/Lead:	
Date:	

PART 3: IMPACT TOOL FEEDBACK FORM

Project title	Fertility – Assisted Conception Criteria Based Access Protocol					
Date reviewed at 'Star Chamber'	11th February 2021					
Summary of Quality Impact Assessment *(Total 21 domains)*	**Outcome**	**Positive**	**Neutral**	**Negative**	**Not applicable**	
Summary of Clinical Risk Assessment *(Risk matrix as below)*	**Impact**		**Likelihood**		**Risk score**	
Key issues discussed at 'Star Chamber'	**Quality Impact Assessment Tool:**	Discussed and supported policy amendments. Area to be further discussed related to the number of cycles, this will go through financial prioritisation and GB approval processes				
	Equality Impact Assessment:	Neutral and positive impact noted.				
Star Chamber outcome	**Approve**		**Reject**			
	X					
Feedback and next steps (if necessary): The QIA was approved but acknowledged that would need further review pending final decision from prioritisation and Governing Body decision. The start chamber of clinical reference group recommended a move towards 3 cycles to align with NICE guidance whilst recognising that further discussions will take place in respect of financial consequence (prioritisation) and Governing Body approval.						
Date:	11th February 2021					
Completed by:	Vanessa Read, Director of Nursing and Quality, NHS Dorset CCG					

Appendix One:

NICE Quality Standards (2014) Fertility problems (Published date: 23 October 2014)

List of quality statements

Statement 1. People who are concerned that it is taking longer than expected to conceive are given advice on the impact that lifestyle can have on their chances of getting pregnant.

Statement 2. People are referred for specialist consultation if the woman has not conceived after 1 year of intercourse or after 6 cycles of artificial insemination, or earlier in certain circumstances.

Statement 3. People who are having problems conceiving are offered counselling before, during and after investigation and treatment for their fertility problems.

Statement 4. Services analysing semen samples use methods and reference values in accordance with the most recent World Health Organization laboratory manual.

Statement 5. Women aged under 40 years who meet the criteria for in vitro fertilisation (IVF) are offered 3 full cycles of IVF.

Statement 6. Women aged 40–42 years who meet the criteria for IVF are offered 1 full cycle of IVF.

Statement 7. Women having IVF are offered intracytoplasmic sperm injection (ICSI) only if there are severe deficits in semen quality, obstructive azoospermia, non-obstructive azoospermia or if previous IVF treatment resulted in failed or very poor fertilisation.

Statement 8. Women having IVF have 1 or 2 embryos transferred according to the woman's or donor's age, the cycle number and the quality of the embryos.

Statement 9. People preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation