

ENCLOSURE: G  
AGENDA ITEM: 87/19

### Governing body meeting

DATE: 7 November 2019

<b>Title</b>	<b>Proposed amendment to IVF treatment policy</b>
This paper is for <b>decision</b>	
<b>Recommended action for the governing body</b>	<p>That the governing body <b>approve</b> the following changes recommended by the SE London Treatment Access Policy Group:</p> <ul style="list-style-type: none"> <li>• Rapidly amend the SE London Treatment Access Policy for IVF for single women, to enable them to have access to IVF on the same basis as same sex female couples.</li> <li>• As for same sex couples, eligible single women should have confirmed infertility, evidenced by unsuccessful cycles of artificial insemination (AI) within the 12 past months. This would be an indication for further assessment to take place, following which, IVF may be offered if the woman is eligible.</li> <li>• Review and update the whole of Section 2.26 Fertility treatments in the SEL Treatment Access Policy 2019/20 by the end of the financial year, in time for the next iteration of the Policy.</li> </ul>
<b>Potential areas for conflicts of interest</b>	n/a
<b>Executive summary</b>	<p>South East London CCGs have agreed to undertake a rapid review of their Treatment Access Policy for IVF for single women. The review was undertaken by public health colleagues on behalf of the six CCGs and is attached. All six CCG governing bodies will receive this report and are asked to consider the recommendations.</p> <p>The following outputs of the review are noted:</p> <ol style="list-style-type: none"> <li>1. NICE guideline CG156 makes recommendations for people in same sex relationships that are also applicable to single women.</li> <li>2. Centres that provide fertility treatments are required by law, and as a</li> </ol>

	<p>condition of their HFEA licence, to take account of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth. This is detailed in the HFEA Code of Practice Edition 9.0. There are no stipulations as to the relationship status of the person planning to have treatment.</p> <p>3. A review of current London policies for all 32 CCGs showed that</p> <ul style="list-style-type: none"> <li>• 22 explicitly include single women (also referred to as women not in a partnership)</li> <li>• These 22 also apply the same access criteria and treatment pathway for single women as for same sex couples where both partners are female.</li> </ul> <p>4. None of the policies reviewed mention either the ethics of restricting funding for NHS funded fertility treatments or issues pertaining to the welfare of the child. In the latter case, this is presumably because an assessment is done by the centres that give treatment, in line with HFEA licence requirements.</p> <p>Other relevant issues to consider include:</p> <ul style="list-style-type: none"> <li>▪ Whilst a change can be made to the SEL IVF policy regarding single women, we will need to review the policy for same sex couples, to ensure that these groups are treated in an equitable way and in line with good practice.</li> <li>▪ There is no specific provision in the SEL policy for same sex male couples and single men.</li> <li>▪ There is no specific provision in the SEL policy for the other indications for artificial insemination or IUI in NICE guideline CG156. This will need to be considered as part of a wider review.</li> </ul> <p>Once all six governing bodies have reached their decision, a communications plan will be implemented to ensure that key stakeholders are informed. We will communicate the change to relevant local hospitals and to general practices in south east London. CCG websites will have the revised treatment access policy with a note stating what the change is.</p> <p>We will engage with, and inform patient organisations such as Healthwatch. We will also contact those organisations and individuals who have written to us on this matter, and let them know the outcome of the rapid review. Health professionals and providers will also be contacted.</p>	
What are the organisational implications	Key risks	n/a
	Equality	The proposed amendment aims to ensure equitable access to IVF
	Financial	n/a

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# Options appraisal SEL CCG funding of fertility treatments for single women

Healthcare Public Health Section  
Southwark Public Health Directorate

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## CONTEXT

Clinical Commissioning Groups (CCGs) in England manage the majority of the NHS budget for healthcare services and commission fertility services for their area. Decisions about provision of different fertility investigations and treatments are made by single CCGs or collaborations of CCGs for their area.

The provision of fertility treatments in South East London (SEL) and eligibility criteria are detailed in the SEL Treatment Access Policy 2019/20 (Section 2.26).<sup>1</sup> The Treatment Access Policy was produced by a collaboration of six CCGs (Bexley, Bromley, Greenwich, Lambeth, Lewisham, and Southwark) with input from local authority Public Health departments.

Clinics or services in the UK that provide fertility treatments are regulated by the Human Fertilisation and Embryology Authority (HFEA) and must comply with the Human Fertilisation and Embryology (HFE) Act 1990 (as amended), the HFE Act 2008, and related legislation. The HFEA publishes a code of practice to guide clinics in how to meet these legal requirements.<sup>2</sup>

The most recent National Institute for Health and Care Excellence (NICE) guideline on assessment and treatment of fertility problems was published in 2013 and last updated in 2017.<sup>3</sup>

This options appraisal provides a review of the SEL Treatment Access Policy for CCG-funded fertility services for single women. Currently single women are not eligible for treatment under the SEL policy.

The document outlines information relevant to the background including guidelines and legislation. It presents a range of options for consideration and makes the recommendation that single women should be included in the Treatment Access Policy for CCG funded fertility services and that the entire IVF access policy be reviewed and amended in line with current NICE guidance.

## POLICY CONTEXT

### NICE guideline (CG156)

This is a clinical guideline on assessment and treatment of fertility problems. It does not differentiate between single women and women in a couple.

Three relevant sections of the guideline recommendations are shown below:

In: 1.2.13 Defining infertility<sup>3</sup>

1.2.13.6 A woman of reproductive age who is using artificial insemination to conceive (with either partner or donor sperm) should be offered further clinical assessment and investigation if she has not conceived after 6 cycles of treatment, in the absence of any known cause of infertility. Where this is using partner sperm, the referral for clinical assessment and investigation should include her partner. [new 2013]

1.2.13.7 Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:

- the woman is aged 36 years or over
- there is a known clinical cause of infertility or a history of predisposing factors for infertility. [new 2013]

Box 1.

In: 1.9.1 Intrauterine insemination<sup>3</sup>

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 semen analysis, offer a further 6 cycles of unstimulated intrauterine insemination before IVF is considered. [new 2013]

Box 2.

In: 1.11.1 Criteria for referral for IVF<sup>3</sup>

1.11.1.3 In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. [new 2013]

1.11.1.4 In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:

- they have never previously had IVF treatment
- there is no evidence of low ovarian reserve (see recommendation 1.3.3.2)
- there has been a discussion of the additional implications of IVF and pregnancy at this age. [new 2013]

1.11.1.5 Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, refer the woman directly to a specialist team for IVF treatment. [new 2013]

Box 3.

### **HFEA Code of Practice Edition 9.0 (Guidance note 8)**

It is a mandatory requirement of the HFEA licence conditions that “a woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.”<sup>2</sup> This is underpinned by the HFE Act 1990 (as amended). The centre is required to have documented procedures for this process and “to assess each patient and their partner (if they have one) before providing any treatment”.<sup>2</sup> The guidance note goes on to give a definition of supportive parenting, and outlines factors to consider in the assessment.

## Equality Act 2010

Chapter 1 of the Act states the protected characteristics.<sup>4</sup> An excerpt is shown below:

### 8 Marriage and civil partnership

(1) A person has the protected characteristic of marriage and civil partnership if the person is married or is a civil partner.

(2) In relation to the protected characteristic of marriage and civil partnership -

(a) a reference to a person who has a particular protected characteristic is a reference to a person who is married or is a civil partner;

(b) a reference to persons who share a protected characteristic is a reference to persons who are married or are civil partners.

Box 4.

Due to limitations in the data available, it is not feasible to determine whether indirect discrimination relating to other protected characteristics may result from the SEL Treatment Access Policy 2019/20. Protected characteristics data is not available by couple status and single status has no objective social or legal definition.

## RAPID POLICY REVIEW

### NHS England

There are currently no mandatory requirements or guidelines set by NHS England with regard to the provision or funding of fertility assessment and treatments.

### CCGs in the NHS London region

There are 32 CCGs in the London region, of which six have collaborated to produce the SEL Treatment Access Policy.

To support this options appraisal the policies of the other 26 CCGs have been reviewed to understand if there is variation in provision in London. This is a rapid review and so it has made use of the policies that are publicly available on the CCG websites. As a result we do not have any information on policies that may be in the process of being updated, how these policies are enacted in practice, or the outcomes of Individual Funding Requests (IFR) that may have been made.

Within the limitations described above, this review found that the policies of 22 CCGs explicitly included single women (also referred to as women not in a partnership) and apply the same access criteria and treatment pathway as for same-sex couples where both partners are female. Of these 22, eight CCGs have a single policy through the North West London collaboration of CCGs and 11 CCGs have individual policies that appear to be based on a common model.



Of the CCGs that do not explicitly include single women or potentially exclude them, one CCG funds IVF and ICSI only through the IFR process and information on other fertility treatments and assessments was not found. One CCG policy does not mention single women. One CCG policy states that applications from single women will be considered but does not lay out criteria or pathways in that document. One CCG policy has 'current long-term relationship' as an entry criterion to their pathway, which suggests that single women would not be eligible. The definition of 'long term relationship' is not provided and therefore is open to interpretation.

None of the policies reviewed mention either the ethics of restricting funding for NHS-funded fertility treatments or issues pertaining to the welfare of the child. In the latter case this is presumably because an assessment is done by the centres that give treatment, in line with HFEA licence requirements.

## **FINDINGS**

- NICE guideline CG156 makes recommendations for people in same-sex relationships that would also be applicable to single women.
- Centres that provide fertility treatments are required by law and as a condition of their HFEA licence to take account of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth. This is detailed in the HFEA Code of Practice Edition 9.0. There are no stipulations as to the relationship status of the person planning to have treatment.
- The state of being single or not in a partnership, civil partnership, or marriage, is not a protected characteristic under the Equality Act 2010. It is not feasible to establish the prevalence of protected characteristics in single women to make an assessment if they are being indirectly discriminated under the Equality Act 2010 .
- At least 22 CCGs in the NHS London region fund fertility assessment and/or treatment for single women (also referred to as women not in partnership). Therefore the SEL Treatment Access Policy is not in line with the rest of the London region.
- The SEL Treatment Access Policy is also not in line with NICE guideline CG156 with regard to treatment for women in same-sex relationships. The current SEL policy states that after three cycles of IUI women will be offered IVF. However NICE states that IVF should be offered after 12 cycles of artificial insemination six of which should be IUI. This is because 86% of women aged under 35 years and 75% aged over 35 years will become pregnant within 12 cycles of IUI. NICE recommends that after six IUI cycles women should be investigated for fertility issues and if no cause identified continue with another six. If a fertility issue identified after six attempts at IUI they should then be offered IVF.

## **OPTIONS**

This section will present a range of options which could be considered by the SEL Treatment Access Group. "SEL policy" refers to Section 2.26 Fertility treatments in the SEL Treatment Access Policy 2019/20.<sup>1</sup>

### **No change to SEL policy**

- This is not thought to amount to a breach of the Equality Act 2010 on the basis of recent advice to the department. However, the media discussion around the policy demonstrates that many people perceive it to be unfair.
- In the findings of the rapid review no clinical indication for excluding single women from NHS -funded treatment has been found.

### **Remove the SEL policy and determine access to funding for fertility treatments for all individuals through the IFR process**

- This would be in line with one other CCG in the NHS London region though, as already mentioned in the rapid policy review, their publicly available information is specifically related to IVF and ICSI. If this option is taken, further decisions would need to be made regarding funding for fertility investigations and for other treatments such as IUI.
- This option would allow all applications to be considered on an individual basis, however, it could lead to a lack of transparency in the process and a need for increased capacity in the local IFR process to deal with requests in an equitable and consistent manner.

### **Amend the SEL policy such that the provision for single women is the same as for same-sex couples, with no other changes**

- The current policy states that with regard to same-sex couples where both partners are female "if three cycles of privately funded IUI have been unsuccessful, the couple will be eligible for one NHS funded cycle of IVF or ICSI."<sup>1</sup> Under this option this would be extended to include single women.
- If this option is taken the policy would not be in line with NICE guideline CG156 with regard to treatment (see box 2.). The current SEL policy states that after three cycles of IUI women will be offered IVF. However NICE states that IVF should be offered after 12 cycles of artificial insemination six of which should be IUI, because 86% of women aged under 35 years and 75% aged over 35 years will become pregnant within 12 cycles of IUI. NICE recommends that after six cycles of artificial insemination women should be investigated for fertility issues and if no cause identified continue with another six. If a fertility issue identified after six attempts at IUI, IVF should then be considered.

## **Change to a different policy modelled on other policies in the NHS London region and NICE guideline CG156**

- **EXAMPLE City and Hackney CCG policy<sup>5</sup>** (one of nine similar policies covering 11 CCGs)
    - Same-sex female couples and single women are given the same provision under the policy.
    - Couples and single women who have not become pregnant after six cycles of IUI undertaken in a clinical setting are referred for further investigation. If a cause is found they are referred for treatment at this point. If no cause is found they have access to NHS-funded assisted conception if a further six cycles of IUI do not result in pregnancy (12 in total).
    - The CCG states that it does not routinely fund these IUI cycles (specific situations in which IUI will be funded are described in the policy) or the use of donor sperm
    - This pathway aligns with the NICE guideline CG156 (box 2.), with the exception that it only includes IUI and not artificial insemination more broadly. In this policy assessment for treatment can be considered after six cycles of IUI for women aged 36 or over, which is in line with the NICE guideline on referring this group earlier (box 1.).
  
  - **EXAMPLE North West London Collaboration of CCGs policy<sup>6</sup>** (covering eight CCGs)
    - Same-sex female couples and women not in a partnership are given the same provision under the policy.
    - The CCGs will fund IVF if the person has “an identified pathological problem or unexplained infertility”.<sup>6</sup> This is demonstrated by undergoing at least 12 cycles of artificial insemination with a licensed provider, of which six must be IUI, and appropriate clinical assessment and investigations. As stated in the policy, IUI with donor sperm is not funded by the CCG without an “established clinical need”. It is not stated if assessment and investigation of fertility problems are funded by the CCG.
    - This policy aligns with the NICE guideline CG156 as it accepts 12 cycles of artificial insemination of which at least six are by IUI as meeting the criteria for referral for IVF (box 3.) rather than mandating that 12 cycles of IUI be undertaken. It does not explicitly discuss at what point fertility assessment and investigations should be done.
  
  - **EXAMPLE Kingston CCG policy<sup>7</sup>**
    - Same-sex female couples and women not in a partnership are given the same provision under the policy for funding for IVF.
    - If six cycles of artificial insemination in a clinical setting do not result in pregnancy this is taken as an indicator of subfertility. Under the policy, the person should then have a period of expectant management involving up to six self-funded or NHS-funded cycles of IUI before referral for NHS-funded IVF.
    - The policy later states that the CCG will fund up to six cycles of donor insemination (including donor sperm) for several groups including couples in a
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same-sex relationship who have not conceived after six cycles of self-funded IUI in a clinical setting. Single women are not mentioned in this section.

- This policy aligns with the NICE guideline CG156 in terms of number of cycles of artificial insemination/IUI prior to referral for IVF (box 3.). It does not explicitly discuss at what point fertility assessment and investigations should be done.
- Changing the SEL policy could allow it to become more closely aligned with NICE clinical guideline CG156 and with policies in the rest of the NHS London region. It could also improve public acceptability. Making changes would almost invariably require reviewing the whole policy on fertility treatments. The potential changes discussed in this option have not been costed.

### **Other considerations**

- Any changes to the SEL policy regarding single women will require a review of the policy for same-sex couples, in order to ensure that these groups are treated equally.
- There is no specific provision in the SEL policy for same-sex male couples and single men, which there is in other policies (e.g. City and Hackney fertility policy).<sup>5</sup>
- There is no specific provision in the SEL policy for the other indications for artificial insemination or IUI in NICE guideline CG156 (see box 2.), which there is in other policies (e.g. City and Hackney fertility policy).<sup>5</sup>
- Surrogacy has not been included as it is outside the scope of this options appraisal. There are no CCGs in the NHS London region that provide funding for surrogacy and it is recommended that any amended policy explicitly excludes surrogacy.

### **RECOMMENDATION**

The recommendation is that single women should be included in the SEL Treatment Access Policy for fertility treatments and that the whole policy is reviewed and updated to ensure same sex couples and single people are treated equally and that all recommendations are in line with NICE guidance.

## REFERENCES

- 1 South East London Treatment Access Group. South East London Treatment Access Policy 2019/20. Available from <https://www.southwarkccg.nhs.uk/news-and-publications/publications/policies-strategies-registers/Documents/South%20East%20London%20Treatment%20Access%20Policy%202019.pdf> (accessed on 28 August 2019)
- 2 Human Fertilisation and Embryology Authority (2019). Code of practice, 9th edition – published 2019. Available from <https://www.hfea.gov.uk/media/2793/2019-01-03-code-of-practice-9th-edition-v2.pdf> (accessed on 28 August 2019)
- 3 National Institute for Health and Care Excellence. NICE Clinical guideline [CG156] Fertility problems: assessment and treatment (2013, updated 2017): recommendations. Available from <https://www.nice.org.uk/guidance/cg156/chapter/Recommendations> (accessed on 28 August 2019)
- 4 Equality Act 2010. Chapter 1: 8. Available from <https://www.legislation.gov.uk/ukpga/2010/15/contents> (accessed on 28 August 2019)
- 5 City and Hackney Clinical Commissioning Group. Fertility policy. Available from <https://gps.cityandhackneyccg.nhs.uk/service/infertility-service> (accessed on 28 August 2019)K
- 6 North West London Collaboration of Clinical Commissioning Groups. Commissioning Policy for In Vitro Fertilisation (IVF)/ Intracytoplasmic Sperm Injection (ICSI) within tertiary Infertility Services. Available from <https://www.hounslowccg.nhs.uk/media/128427/IVF-v5.pdf> (accessed on 28 August 2019)
- 7 Kingston Clinical Commissioning Group. Policy statement: Fertility treatments v2.0. Available from <https://www.kingstonccg.nhs.uk/Fertility%20treatments%20policy%20Kingston%20CCG%202017.pdf> (accessed on 28 August 2019)