

# HEALTH OVERVIEW AND SCRUTINY COMMITTEE

24<sup>TH</sup> NOVEMBER 2017

## ASSISTIVE REPRODUCTIVE TECHNOLOGIES – POLICY REVIEW

### Summary

This report advises the Committee of proposals under consideration by Kent and Medway Clinical Commissioning Groups (CCGs) in respect of proposed policy changes to Assistive Reproductive Therapies (ART) and funding of assistive conception treatments.

In line with many health economies across England, Kent and Medway CCGs are considering a range of difficult decisions to ensure that overall financial risks are minimized. CCGs have agreed to review the policies relating to Assistive Reproductive Therapies.

The review will focus on two aspects:

- Ensuring that the number of funded cycles is both affordable and reasonable. This may result in a reduction to the number of IVF cycles that are funded for eligible patients.
- Considering the funding of assisted conception treatments using donated genetic materials for all patient groups. A complainant highlighted that the current policy effectively excludes same sex couples access to NHS funded fertility treatment due to their requirement for donated materials.

This report outlines the national and local context with regard to ART policy development and proposes an approach to reviewing the current Kent and Medway CCGs' ART policies.

### 1. Budget and Policy Framework

- 1.1 Assistive Reproductive Technologies (ART) are funded by Clinical Commissioning Groups.
- 1.2 NHS Medway CCG is the lead commissioner for ART services for the eight CCGs across Kent and Medway.
- 1.3 Under Part 4 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 the Council may review and scrutinise any matter relating to the planning, provision and operation of the health service in Kent. In carrying out health scrutiny a local authority must invite interested parties to comment and take account of any relevant information available to it.

## **2. Background**

- 2.1 Regulation 23 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 requires relevant NHS bodies and health service providers (“responsible persons”) to consult a local authority about any proposal which they have under consideration for a substantial development of or variation in the provision of health services in the local authority’s area. This obligation requires notification and publication of the date on which it is proposed to make a decision as to whether to proceed with the proposal and the date by which Overview and Scrutiny may comment. Where more than one local authority has to be consulted under these provisions those local authorities must convene a Joint Overview and Scrutiny Committee for the purposes of the consultation and only that Committee may comment.
- 2.2 If this Committee and Medway Council’s Children and Young People’s Overview and Scrutiny Committee were to both determine that the proposals constitute a substantial health service development or variation the responsible persons will have to consult the Kent and Medway Joint Health Scrutiny Committee and only that Committee may make comments and require information on the matter.

## **3 National context**

- 3.1 Although the National Institute for Health and Care Excellence (NICE) Clinical Guideline 156 (CG156) Fertility (2013) recommends the NHS fund up to three full IVF cycles for eligible couples where the woman is aged under 40 years<sup>i</sup>, it is widely acknowledged that this level of provision is unaffordable to the NHS in most areas. A spokesperson for NHS England has been quoted as saying that NHS funding of IVF provision is legally a decision for CCGs “who are under an obligation to balance the various competing demands on the NHS locally while living within the budget parliament has allocated”.
- 3.2 Fertility Fairness<sup>ii</sup> audits the number of NHS funded IVF cycles provided by English CCGs. In May 2017 they reported:
- Five CCGs (2.4%) have decommissioned NHS funded IVF and provide 0 cycles<sup>iii</sup>;
  - 61% of CCGs offer 1 NHS funded IVF cycle<sup>iv</sup> for eligible patients;
  - 23% of CCGs offer up to 2 NHS funded IVF cycles for eligible patients; and
  - 13% of CCGs offer up to 3 NHS-funded IVF cycles for eligible patients.
- 3.3 In recent years there has been a marked reduction in access to NHS funded IVF in England. Fertility Network UK<sup>v</sup> reports the number of CCGs offering three cycles of IVF has reduced by 46%, from 50 in 2013 to 27 in 2017. Thirteen CCGs have made reductions to provision of fertility treatment since the beginning of 2017. Across England, there are potential further cuts ahead; eight CCGs are currently consulting on reducing or stopping their NHS funded fertility treatment.

- 3.4 The Human Fertilisation and Embryology Authority (HEFA) publish success the following information on their website<sup>vi</sup>, relating to success rates for IVF:

*“The below percentages show the average chance of a birth after one, two, three and four cycles of IVF depending on your age. After four cycles, there are very small increases in the average chance of a birth across all ages. 85% of people have one or two cycles of IVF. Only 5% of people have more than three cycles.*

**Chances of a live birth – women under 40**

*One cycle – 32%*

*Two cycles – 49%*

*Three cycles – 58%*

*Four cycles – 63%”*

**4 Local context: Development of current ART policies in Kent and Medway**

- 4.1 In response to the publication of NICE CG156 and other national policy and guidance in 2013, the Health Policy Support Unit (HPSU) was tasked by Kent and Medway CCGs to review the existing suite of ART policies. An expert group was convened to support this work. Work to support the review included: reviewing current guidance and legislation; identifying and assessing equality issues; establishing the local epidemiology, activity and availability of treatments; assembling and assessing the evidence base; conferring with local stakeholders including clinicians, patients and their representatives; and assessing the impact of potential new policies on the local health economy. The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered this work and agreed seven policy recommendations<sup>vii</sup> with associated eligibility criteria. These were ratified by all Kent and Medway CCGs and adopted in April 2014.

**4.2 Current Kent and Medway CCGs’ ART policies**

Currently Kent and Medway CCGs offer eligible couples a maximum of four embryo transfers including no more than two transfers from fresh IVF cycles (others would be frozen embryo transfers). This may be considered locally as two ‘full’ IVF cycles, though it does not comply with the NICE definition of ‘full’ cycles which does not put a limit on the number of frozen embryo transfers undertaken<sup>viii</sup>.

- 4.3 Kent and Medway CCGs also fund<sup>ix</sup>:

- Up to six cycles of intrauterine insemination (IUI) using partner sperm for patients who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem;

- Sperm washing (and subsequent IUI or IVF) for eligible couples where the man is HIV positive and his female partner is HIV negative; and
- Fertility preservation (egg, sperm or embryo cryopreservation and subsequent IVF) for people due to undergo treatments likely to make them infertile.

4.4 In order to access NHS funded fertility treatment, Kent and Medway patients must fulfil a number of eligibility criteria addressing: duration of subfertility; the woman's age; previous IVF cycles undertaken; the BMI of the woman; smoking status of the couple; ovarian reserve of the woman; previous children and previous sterilisation.

4.5 Assisted conception treatments (IUI or IVF) using donated genetic materials (eggs, sperm or embryos) and involving surrogates are currently not funded for any patient groups in Kent and Medway.

## **5. Proposed service development or variation**

5.1 The review will focus on two aspects:

- Ensuring that the number of funded cycles is both affordable and reasonable. This may result in a reduction to the number of IVF cycles that are funded for eligible patients.
- Considering the funding of assisted conception treatments using donated genetic materials for all patient groups. A complainant highlighted that the current policy effectively excludes same sex couples access to NHS funded fertility treatment due to their requirement for donated materials.

## **6. Advice and analysis**

6.1 The eight CCGs in Kent and Medway have now considered the potential impacts of a review of ART policies, and have agreed that a review should be undertaken. The proposed process for the review of policies relating to the number of cycles and use of donated genetic material is outlined below.

### **6.2 Review timeline**

1. November and December 2017: presentation of papers to Kent and Medway Health Overview and Scrutiny Boards summarising the CCGs plans to review the policy (this paper).
2. December / January: Proposed revised policy is produced. Pre-consultation engagement commences. Revised policy to Kent and Medway Health Overview and Scrutiny Boards for comment, consideration of significant variation and process.
3. February – April 2018: formal public consultation for three months. Further detail relating to the consultation is provided below.
4. May / June 2018 – outcome of the public consultation is analysed and presented to the Health Policy Reference Group (HPRG) alongside a

further report from the Health Policy Support Unit for decision. The report from the Health Policy Support Unit would provide further detail on financial impacts of potential changes and evidence reviews into areas that CCGs have requested further information on – such as the impact on success rates of a reduction to one NHS funded cycle of IVF. Feedback on public consultation to Kent and Medway Health Overview and Scrutiny Boards.

5. July / August 2018: the decision of the HPRG is presented to each of the individual CCGs for ratification via their individual governance procedures, alongside the revised schedule of policies (if applicable). If agreement is reached relating to policy changes, a new Kent and Medway schedule of policies for Assisted Reproductive Technologies will be published and implemented across Kent and Medway.

### **6.3 The public consultation process**

- 6.3.1 When considering significant changes to public services, CCGs have a legal duty to involve the public.
- 6.3.2 In order to ensure that a region-wide policy is maintained, CCG Chief Operating Officers (COOs) will oversee this policy review and discuss progress at regular region-wide meetings.
- 6.3.3 The North and East London Commissioning Support Unit (NEL CSU) will lead on the public consultation process, with support from individual CCGs.
- 6.3.4 The process of consulting with the public will be carried out through online questionnaires which would be hosted on each CCG's website and promoted via social media channels, and public meetings in each CCG area.
- 6.3.5 A full consultation plan will be developed by NEL CSU in the coming weeks. In addition, the report that is presented to the Health Policy Reference Group will include equality and diversity impact assessments for consideration by the group.

## 7. Risk management

7.1 Risks associated with reviewing the schedule of ART policies include:

<b>Risk</b>	<b>Description</b>	<b>Action to avoid or mitigate risk</b>	<b>Risk rating</b>
Poor response to consultation	Should there be a poor response to the consultation, CCGs may be required to amend the approach to the review, thus causing increased costs and a delay to the proposed timeline	Clear communication and consultation plan to be developed and implemented. Individual CCGs must support the consultation process	
Lack of input from one or more CCGs	CCGs are under pressure in a number of areas and it is possible that this work is not prioritised by all eight CCGs in Kent and Medway. This would cause a delay to the process and could potentially destabilise the review and consultation phase.	All CCGs are actively involved with this process at present, via Chief Operating Officers. All CCGs are represented on the HPRG and will take decisions via their own governance routes.	
CCGs are unable to agree the outcome of the policy review	At the conclusion of the review, there is the chance that consensus is not reached across the eight Kent and Medway CCGs. This could lead to the implementation of different policies in CCG areas and give rise to allegations of a "postcode lottery" for health services	Agreement exists relating to the need to undertake the review, however this risk must be tolerated to respect the sovereignty of individual CCGs.	
Challenge from patient groups/ reports in local media	ART services are highly emotive and proposed changes could lead to reputational damage for CCGs	Clear communication and consultation plan to be developed and implemented to help mitigate this risk.	

## 8 Implications for Looked After Children

8.1 At this juncture, there are no implications for Looked After Children associated with the proposed review of ART services.

## 9 Financial implications

- 9.1 The Health policy Support Unit estimate that should Kent and Medway CCGs reduce to one cycle of NHS funded IVF per eligible couple, this would have a cost saving of approximately £666k p.a. across Kent and Medway CCGs.
- 9.2 Depending on the outcome of the consultation and review relating to the use of donated genetic materials, there may be a cost pressure for Kent and Medway CCGs. This cost pressure is being calculated, and further work relating to the cost of the proposed review will be undertaken by the Health Policy Support Unit throughout the consultation phase.

## 10 Recommendations

- 10.1 The Committee is asked to note the review of Assistive Reproductive Technologies (ART) policies, set out in the report, in light of the financial challenges faced by Clinical Commissioning Groups (CCGs), and note the review process set out in section six of the report, in particular the public consultation element.

### Lead officer contact

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### Appendices

None

### Background papers

None

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<sup>i</sup> NICE define a full cycle of IVF as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos i.e. a fresh cycle and an undefined number of subsequent frozen cycles. NICE also recommend one cycle of IVF for some women aged between 40 and 42.

<sup>ii</sup> Fertility Fairness is a multidisciplinary umbrella organisation representing patient and professional bodies working in the field of fertility. It campaigns for fair and equitable access to NHS-funded fertility services in accordance with NICE recommendations.

<sup>iii</sup> Most of these CCGs now only fund fertility treatment for: (i) patients requiring fertility preservation as they are undergoing treatment that is likely to make them infertile e.g. chemotherapy and (ii) patients requiring sperm washing because the male is HIV positive and the woman is HIV negative.

<sup>iv</sup> IVF 'cycle' is not defined but it is likely to refer to the number of fresh cycles available to eligible patients

<sup>v</sup> Fertility Network UK is a patient-focused fertility charity that provides free and impartial support, advice, information and understanding for people affected by fertility issues

<sup>vi</sup> <https://www.hfea.gov.uk/treatments/explore-all-treatments/in-vitro-fertilisation-ivf/>

<sup>vii</sup> Policy recommendations addressed: IVF (with or without intracytoplasmic sperm injection [ICSI]), intra-uterine insemination (IUI) using partner sperm, surgical sperm retrieval, sperm washing, fertility preservation for patients receiving gonadotoxic treatments, assisted conception treatments (ACT; IVF or IUI) using donated genetic materials, ACT involving surrogates

<sup>viii</sup> NICE define a full cycle of IVF as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos i.e. a fresh cycle and an undefined number of subsequent frozen cycles.

<sup>ix</sup> Surgical sperm retrieval is now the commissioning responsibility of NHS England, however CCGs are responsible for commissioning subsequent storage and IVF with ICSI