

NHE East London and the City
Cover paper for OSCs

Title of Report:	Proposed NHS East London and the City Commissioning Policy: Assisted Conception Policy for Sub-fertility
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NHS East London and the City Commissioning Policy: Assisted Conception for Sub-Fertility

1. Introduction and context

NHS East London and the City inherited the current assisted conception policy from the North East London Specialist Commissioning Group. The NICE 2004 guideline is currently being updated to take account of evidence published in the intervening seven years and the revised version is anticipated during 2012; the local NHS East London and the City policy will need to be reviewed when the new guidance is published.

NICE Clinical Guidelines are not binding on commissioners unlike technology appraisals: they are recommendations made by NICE to the NHS and have no mandatory funding requirement.

The Department of Health reminded PCTs in January 2011 of the existing NICE Clinical Guideline. The legal context to the decision making is set out in section 6 of this paper, and NHS ELC Clinical Commissioning Groups (CCGs) and the Clinical Commissioning Committee were aware of this guidance when considering and approving this proposed new policy.

This paper sets out the:

- process that has been involved in revising the clinical criteria for assisted conception services;
- detailed changes to the existing policy and the reasons for them;
- responses from two public engagement seminar events to these changes
- legal context in relation to surrogacy and advice on public consultation

2. Process of review of the access criteria

In January 2011, East London and the City GP Commissioners proposed a reduction in the number of IVF cycles commissioned, and recommended that NHS East London and the City should move from funding three locally defined cycles of IVF to two.

Since then there has been extensive clinical engagement with both tertiary care specialists and lead GPs from across the cluster. The initially proposed policy revisions were modified by the Transitional GP Commissioning Board in May 2011 and version three of the policy was subject, on the advice of the ELC LINKs chairs, to a public engagement process to test public reaction and to have an opportunity to talk through the clinical complexity of the proposed changes.

3. Rationale for changes to the existing policy

The revised policy sets out three significant changes to the existing policy and a number of new criteria. These are set out in detail below:

3.1 Change to two fresh cycles

The current North East London wide policy defines a local cycle as transfer of either a fresh or frozen embryo. The NICE definition of a cycle is one fresh followed by up to two frozen embryo(s). This distinction was not widely understood. This means that

the three current North East London defined cycles may only be equivalent to one NICE defined cycle.

The proposal as set out in the policy is to fund two fresh cycles: couples would have the choice to self-fund freezing of any additional embryos produced as part of the fresh cycle for use at a later date.

The evidence shows that fresh embryo transfers generally result in a 10% higher chance of pregnancy than frozen embryo transfers.

3.2 Inclusion of surgical sperm retrieval

Clinicians identified the anomaly that some men with azoospermia due to vas dysfunction were required to self fund surgical sperm retrieval because it was not included in the tertiary infertility service contract. This was inequitable as NHS ELC routinely funds egg retrieval for women with tubal dysfunction. The new NHS ELC policy redresses this for an estimated fifty men per year.

3.3 Equity considerations

The policy makes clear that the aim of NHS funding is to treat infertility. If this can be demonstrated the policy would apply equally to single women, female same-sex couples and heterosexual couples.

3.4. New or modified criteria

Criterion	Current policy	This policy	Rationale
GP Registration	The couple have at least one year registration with a GP attached to a primary care trust based within NEL	Couples or single women, resident in City and Hackney, Newham or Tower Hamlets and registered with an NHS East London and the City (ELC) GP for the previous 12 months OR Both partners must be continuously resident in the UK for the past 1 year AND entitled to planned NHS treatment AND the female partner has been registered with a GP in NHS ELC for the previous 12 months	Provider trusts are now looking more closely at this and have discovered several couples where this criterion does not apply.
Duration of unexplained sub-fertility	The couple has 2 years of unexplained infertility or one year of diagnosed sub-fertility within the current relationship	'unexplained infertility' is defined as failure to conceive after frequent unprotected sexual intercourse for two years in couples of reproductive age where the female partner is less than 36 years of age, or 1 year where the female partner is 36 years or older.	This may help reduce the number of IFR requests for funding assisted conception for women over 40 years of age.
Woman's BMI	Between 19.0 and 29.9 kg/m ²	Between 19.0 and 29.9 kg/m ² for the 6 months prior to starting IVF treatment	To demonstrate stability of the BMI
Age of the male partner	Not in current policy	Treatment should start before the male partner's 55 th birthday	<ul style="list-style-type: none"> the age related risk of deteriorating sperm quality and increasing risk of DNA fragmentation equity between heterosexual couples and female same sex couples/

			single women whose HFEA regulated sperm donors have an upper age limit of 55 years for known donors: unknown donors have an upper age limit of 45 years
Previous treatment	Couples have had less than three previous NHS-funded IVF cycles leading to embryo transfer.	Couples/single women will not be funded if they have already had three or more previous fresh cycles of IVF/ICSI (irrespective of how these were funded) Previously untreated couples/single women or with a single self funded cycle will be eligible for two NHS ELC fresh funded IVF/ICSI cycles Those with two previous self funded cycles will be eligible for a single fresh cycle	This is intended not to deter or disadvantage couples from self funding in the first instance. Similar distinctions between the number of NHS funded and the total of NHS and self funded cycles apply in other areas including North West London. It in no way implies that NHS ELC considers 3 cycles 'an optimal care package'
Parental smoking	Not in current policy	Where couples smoke, only those who agree to, and take part in, a supportive programme of smoking cessation will be accepted on the IVF treatment waiting list, and should be non-smoking at the time of treatment	This is for the welfare of the child

3.5. Clarifications

The following exclusions to the policy apply:

- a) The policy relates only to treatment for sub-fertility.

The following areas that use IVF/IUI technology will require a specific addendum to the policy:

- for pre-implantation genetic diagnosis (PGD)
- as part of a viral transmission risk reduction programme, gamete/embryo storage
- storage of sperm, embryos or oocytes prior to potentially sterilising cancer treatments

Current clinical practice for patients or couples in these categories will continue unless or until we have agreed this new addendum to the policy

- b) IVF which is intended for a surrogate mother, as surrogacy is not commissioned by NHS ELC due to the complex medico-legal considerations

Clarification added as a result of public engagement:

- c) The cycle number criterion is per person rather than per couple: discussion identified that this was very unlikely to increase demand as the probability of couples changing a partner for this reason were low

3.6. Criteria which are unchanged

- Donor eggs or donor sperm will not be funded (on the grounds of affordability), though IVF using self funded eggs or sperm will be funded if all other criteria are met
- The couple should have no living children within the current relationship and not more than four between them from previous unions
- Neither partner will have previously undergone a sterilisation procedure

4. The Public Engagement Process

This is detailed in appendix 2.

4.1 In summary:

- Two public engagement events were held in October – one in Newham and one in the City – which all four LINKs were asked to publicise to their members. PALS teams at both BLT and the Homerton which provide assisted conception services in ELC were asked to publicise the events within their trusts
- The Newham session was well attended, with a diverse group of just under ten consultees present, the City session was attended by the LINK chair for the City
- Overall there was a good understanding in both groups of the difficult choices needed to balance NHS affordability with equity and effectiveness for individuals and couples. The debate was around where these lines should be drawn.

4.2 Areas of contention were:

- *Cycle number*: this was
 - Contentious in the City: the consultee wanted to move to three NICE defined cycles across the board.
 - Newham understood our need to make hard choices and on balance supported both recommendations
- *Surrogacy*
 - This generated debate in both groups: overall Newham considered the recommendation reasonable; the argument was made in City that this should be funded on the grounds that it constituted preferential treatment for disadvantaged groups provided there was no risk of legal liability to NHS ELC.
 - Infertility specialists additionally noted that shortage of surrogates in the UK meant that there could be significant applications for treatment within the EU as a result, and this may raise even more issues around 'expenses' and legal liability
- *Age of male partner*
 - In Newham of those who felt strongly the view was roughly split half and half. The City consultee was against the recommendation

4.3. All other changes were supported

5. The Clinical Commissioning Committee discussed and agreed to recommend to the Board the following:

5.1 *That NHS ELC fund two fresh IVF or ICSI cycles*

The move from three locally defined to two fresh cycles will result in a modest estimated annual cost reduction, based on 2010/11, prices of £290k which will offset the cost pressures of the proposed policy changes including surgical sperm retrieval; equitable access to infertility services for single women and same sex female couples and other small changes.

This will mean that, with the present exceptions to this policy (in 3.5.a) NHS ELC will not routinely fund freezing or storage of embryos, sperm or oocytes and this exclusion is made explicit in the policy.

5.2. *That NHS ELC do not fund surrogacy or IVF to assist surrogacy*

Legal advice is that this is primarily a legal issue rather than one of policy and therefore not a subject for public engagement. The current policy is silent on this issue and therefore it is not a substantial change to the existing policy.

5.3. *That NHS ELC include the criterion of an upper male age limit*

6. The legal context

- 6.1 The extent of the public engagement was discussed at the City and Hackney CCG Executive meeting. The advice is that the engagement described above should meet NHS East London and the City's obligations under s.242 of the NHS Act 2006 which sets out an obligation to consult on decisions that will impact on the provision or operation of services provided, as taken as a whole the changes being proposed do not constitute a substantial change to existing policy. Views are being sought from the four local authority OCSs.