

Health and Social Services Committee

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Date: Wednesday 2 March 2005

Venue: Committee Rooms 3&4, National Assembly for Wales

Title: Fertility Services

1. Purpose

The Committee is invited to comment on the draft access criteria for tertiary fertility services

2. Summary

A consultation document on the proposed access criteria for infertility treatment in Wales was issued on 13 January 2005. The consultation period ends on 14 March 2005. The new IVF policy is scheduled to be implemented in Wales from 1 April 2005.

3. Background

Prior to April 2003 infertility treatment was commissioned by the former health authorities in Wales and its availability varied depending on which area a couple lived in. From April 2003 IVF has been commissioned by Health Commission Wales (HCW). In July 2001, the Secretary of State for Health in England and the Minister for Health and Social Services in Wales asked the National Institute for Clinical Excellence (NICE) to produce a clinical guideline for the NHS on the assessment and treatment for people with fertility problems. Consultation on the first draft of the guideline was complete on 27 June 2003, followed by a second consultation period completed on 24 September 2003. NICE issued its guidance on 25 February 2004.

4. NICE recommendations:

- a. Couples should be offered IVF on the NHS if they meet the following criteria:

Either;

- i. The woman is aged between 23 and 39 years old; and
- ii. There is an appropriately diagnosed cause of infertility of any duration, or unexplained infertility

of at least 3 years' duration;

Or;

- iii. The woman is younger than 23; and
- iv. There is an absolute indication of IVF (such as prior treatment for cancer).

b. IVF should consist of a maximum of three complete fresh treatment cycles;

No more than two embryos should be transferred during any one cycle.

5. Welsh Assembly Government actions

On the 25 February 2004, Jane Hutt, then Minister for Health and Social Services announced that:

- From 1 April 2005 all couples aged 23 –39 in Wales who meet the clinical criteria established by the National Institute of Clinical Excellence (NICE) and any social criteria to be established by the Welsh Assembly Government, should be offered one cycle of IVF treatment on the NHS. At the same time the Department of Health in England also announced that eligible couples would be offered one cycle.
- The NICE guidelines only cover clinical criteria. The All Wales Assisted Fertility Working Group was established by the Minister in Wales in July 2004 to develop and recommend evidence-based social criteria and any additional access criteria the Assembly may wish to apply. The Group comprises Consultant Obstetricians, Gynaecologists, a Consultant Embryologist, Nursing practitioners, Educationalists, patient representatives, UHW Hospital Chaplaincy, and officials from Health Commission Wales, NPHS, and WAG. The Group has met five times to date with further meetings scheduled.
- In order to produce criteria that were as specific and unambiguous as possible, the Working Group developed further refinements to the NICE Clinical Guidelines. The proposed criteria for Wales contain both social and clinical criteria and it was therefore recommended that the criteria be referred to as Access criteria.
- The Minister approved the recommendations of the Working Group for consultation. The consultation period ends on 14 March 2005.

6. Proposed Access Criteria

In these criteria IVF refers to IVF and other specialised assisted fertility techniques.

- i. The first cycle of treatment should start before the patient's 40th birthday;
- ii. The upper age limit of the woman, at time of referral to the tertiary service, should be 38 years 6 months;
- iii. Any previous completed cycles of NHS IVF treatment will exclude the patient from further IVF treatment;
- iv. Three or more privately funded IVF cycles will exclude the patient from NHS IVF treatment;
- v. Same sex female couples must demonstrate subfertility and must have been in the same relationship for at least two years before they can seek access to NHS IVF treatment; subfertility is defined as no live birth following insemination at or just prior to the known time of ovulation on at least ten non stimulated cycles or fertility problem demonstrated at investigation;
- vi. Neither of the couple have a living son or daughter of any age from their relationship or from any previous relationship. This includes a child adopted by the couple or a child adopted in a previous relationship.
- vii. Subfertility is not the result of a sterilisation procedure in either partner;
- viii. Women must have a body mass index of between at least 19 and up to and including 30, in order to be added to the IVF treatment waiting list, and must be within these limits at time of treatment;
- ix. Where either of the couple smokes – Only couples who agree to take part in a supported programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment;
- x. Couples not conforming to the Human Fertilisation and Embryology Authority (HFEA) Code of Practice will be excluded from having access to NHS funded assisted fertility or other treatment.

7. Access Criteria Rationale

- i. The first cycle of treatment should start before the female partner's 40th birthday

The chance of a live birth following IVF treatment varies with female age and the optimal female age range for IVF treatment is 23 – 39 years. Chances of a live birth per treatment cycle are:

Greater than 20% for women aged 23 – 35 years;

15% for women aged 36 – 38 years;

10% for women aged 39 years;

6% for women aged 40 years or older.

The effectiveness of IVF treatment in women younger than 23 years is uncertain because very few women in this age range have IVF treatment.

(NICE Guidelines)

- ii. The upper age limit of the woman, at time of referral to the tertiary service, should be 38 years 6 months

This is based on the evidence that a 12 – 18 month waiting list is beneficial to the infertile patient. There is a pregnancy rate of about 17% amongst those awaiting IVF/ICSI, 60% of these conceptions occurring within one year of referral. The implication of this is that the waiting list will always be 12-18 months.

- iii. Any previous completed cycles of NHS IVF treatment will exclude the patient from further IVF treatment

By definition.

- iv. Three or more privately funded IVF cycles will exclude the patient from further NHS IVF treatment;

The chance of a live birth following IVF treatment is consistent for the first three cycles of treatment. The effectiveness after three cycles is less certain but evidence suggests that the chance of live birth starts to decline.

- v. Same sex females couples must demonstrate subfertility and must have been in the same relationship for at least two years before they can seek access to NHS funded IVF treatment;

In order to be eligible for NHS treatment those in same sex partnerships must be demonstrably subfertile. The definition of subfertile is:

No live birth following insemination at or just prior to the known time of ovulation on at least ten non stimulated cycles or fertility problem demonstrated at investigation;

Where only one partner is subfertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the subfertile partner.

The Adoption & Children's Act 2002 does not specify that prospective adoptive parents have to be heterosexual. It refers to partners and therefore same sex couples can become adoptive parents.

- vi. Neither of the couple have a living son or daughter of any age from their relationship or from any previous relationship. This includes a child adopted by the couple or a child adopted in a previous relationship

The aim of the NHS funded treatment of subfertility is to enable those who wish to have a family life that includes a child to realise that aim if possible. It would be inappropriate for IVF

treatment to be available where the couple already have a child.

Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be eligible for treatment.

vii. Subfertility is not the result of a sterilisation procedure in either partner

Sterilisation is offered within the NHS, after adequate documented counselling, as an irreversible method of contraception. Individuals are made aware of this at the time of the procedure. The majority of requests arise for non-medical reasons (i.e. change of partner) and it would be inappropriate for NHS funds to be used to reverse this procedure.

viii. Women must have a body mass index of between at least 19 and up to and including 30, in order to be added to the IVF treatment waiting list and must be within these limits at time of treatment

A female body mass index outside this range is likely to reduce the success of IVF treatment. Women who have a body mass index of more than 29 are likely to take longer to conceive. Women who have a body mass index of less than 19 are likely to improve their chance of conception if they increase their body weight.

ix. Where either of the couple smokes – Only couples who agree to take part in a supported programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment

Maternal and paternal smoking can adversely affect the success rates of IVF treatment. The Working Group recommends that only non-smoking couples will be accepted on the IVF treatment waiting list.

Women who smoke are likely to have reduced fertility and passive smoking is likely to affect the chance of conceiving. In men there is an association between smoking and reduced semen quality.

The External Working Group accepted evidence from a paper published by the University of Nijmegen, Netherlands in June 2004, after publication of the NICE Guidelines, that the relationship between smoking and infertility was a lot stronger than the relationship between alcohol/caffeine drinking and infertility. Whereas, there are safe limits for women who drink alcohol/caffeine, there are no such safe limits for women who smoke.

x. Couples not conforming to the Human Fertilisation and Embryology Authority (HFEA) Code of Practice will be excluded from having access to NHS funded assisted fertility or other treatment

Within its Code of Practice, the HFEA requires those delivering reproductive services to consider the welfare of any child that might be born as a result of treatment as of paramount importance. Assisted

reproduction units are required to have in place clear written criteria for assessing the welfare of such children and are expected to include the importance of a stable and supportive environment for any child.

8. Financial Implications

The 2004 Budget Planning Round provided £2.4m for fertility services. The Director of Resources (SE 1805) has seen and noted the content of this paper.

9. Action for Subject Committee

The Health & Social Services Committee are invited to comment on the draft access criteria for tertiary infertility services.

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Minister for Health & Social Services

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