NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Fertility: assessment and management (update)

1.1 Short title

Fertility

2 The remit

This is an update of 'Fertility'', NICE clinical guideline 11 (2004), available from www.nice.org.uk/guidance/CG11. See section 4.3.1 for details of which sections will be updated.

3 Clinical need for the guideline

3.1 Epidemiology

a) Infertility can be primary, in people who have never conceived, or secondary, in people who have previously conceived. It is estimated that infertility affects one in six heterosexual couples in the UK. A typical primary care trust, health board or strategic health authority may therefore expect to see around 230 new consultant referrals (couples) per 250,000 population per year. It appears that whilst there has been a small increase in the prevalence fertility problems since the original guideline even more people now seek help for such problems than in the past. Since the publication of the 2004 guideline more NHS funding has been made available for fertility services.

b) The causes of primary infertility in the UK occur in the following approximate proportions:

- unexplained infertility (no identified male or female cause), 25%
- ovulatory disorders, 20%
- tubal damage, 15%
- factors in the male causing infertility, 30%
- uterine or peritoneal, 10%.

In about one third of cases disorders are found in both the man and the woman. Other factors may play a role, including uterine or endometrial factors, gamete or embryo defects, and any other pelvic condition such as endometriosis.

c) Making a diagnosis serves two purposes. By identifying the cause(s) of the problem it allows appropriate options for treatment to be discussed. It also provides infertile people with a prognosis. For infertility, the situation has changed with the introduction of assisted reproduction: in vitro fertilisation (IVF) treatment has become the ultimate treatment modality for all types of infertility. About 1.5% of babies born in the UK were conceived using assisted reproduction (see section 3.2 f).

3.2 Current practice

a) Infertility affects approximately 17% of heterosexual couples. Its psychological impact can be severe in some cases.

b) For heterosexual couples having unprotected regular intercourse, failure to conceive after 12 months is commonly taken as an indication for further assessment. Within that time about 85% of couples will conceive spontaneously. For non-heterosexuals where conception is being attempted using methods of donor insemination, and in the absence of any known cause of infertility, the majority of successful conceptions will have occurred within 6 cycles. Failure to conceive after that period is commonly taken as an indication for further assessment.

c) NHS funding for investigation of infertility is generally available but there is wide variation and often limited access to NHS-funded treatment, particularly assisted reproduction techniques. Generally the management can be shared, at least in the early stages of investigation, between the GP and hospital-based specialist services.

d) The provision of effective and appropriate investigations for men and women is critical to the operation of an infertility service. These investigations include semen analysis, assessing ovulation, assessing tubal damage, assessing uterine abnormalities and screening for infections such as Chlamydia trachomatis and susceptibility to rubella.

e) There are three main types of infertility treatment:

- medical treatment (for example, use of drugs for ovulation induction)
- surgical treatment (for example, laparoscopy for ablation of endometriosis)
- assisted reproduction techniques.

f) Assisted reproduction includes all treatments that deal with means of conception other than normal coitus. It frequently involves the handling of gametes or embryos. The existing NICE clinical guideline on fertility, published in 2004, provided a comprehensive coverage of the subject and allowed for a more evidence-based approach to investigation and management of infertility. However, its implementation has been variable.

g) The aim of this update is to revise recommendations on the topics listed in section 4.3.1 below in the light of new evidence and make recommendations in areas where there is important new evidence.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) People with explained or unexplained infertility.

b) Some specific patient subgroups that may need specific consideration in their treatment or care have been identified. These include:

- people in same-sex relationships who have unexplained infertility after donor insemination;

- people who are unable to, or would find it very difficult to, or who have been advised not to have heterosexual intercourse;

- people with conditions or disabilities that require specific consideration in relation to methods of conception.

c) People who are preparing for cancer treatment who may wish to preserve their fertility.

4.2 Healthcare setting

All settings in which care is funded by the NHS.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Tests for ovarian reserve.

b) Multifactorial prediction of success to determine clinical and cost effectiveness criteria for IVF treatment.

c) Effectiveness of different embryo/blastocyst transfer strategies as part of IVF treatment - number of embryos.

d) Effectiveness of different embryo/blastocyst transfer strategies as part of IVF treatment - timing of transfer.

e) Effectiveness of ovulation induction agents used in treatment programmes for infertility.

f) Effectiveness of intrauterine insemination, with or without ovulation induction agents.

g) Effectiveness of mild versus conventional IVF treatment.

h) Cryopreservation and vitrification.

i) Sperm washing.

j) Cross-references to related guidance (including the World Health Organization reference values for semen analysis and the Human Fertility and Embryology Authority code of practice) will also be updated.

4.3.2 Clinical issues that will not be covered

a) Multiple or recurrent miscarriage.

b) Surrogacy.

4.4 Main outcomes

a) Live full-term singleton birth.

b) Patient satisfaction.

c) Anxiety and/or depression.

d) Multiple births.

e) Fetal abnormalities.

f) Adverse pregnancy outcome (ectopic pregnancy, miscarriage, fetal growth restriction, spontaneous preterm delivery, perinatal death, pre-eclampsia, and gestational diabetes).

g) Ovarian hyperstimulation syndrome (OHSS).

h) Long-term effects on the woman of ovulation induction.

i) Long-term effects on children born as a result of assisted reproduction techniques.

j) Health-related quality of life – restricted to people seeking treatment for infertility.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness for NICE guidelines is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

In the case of fertility treatment, QALYs may be less suitable. A baby who might be conceived as a result of IVF will experience no loss in health-related quality of life if treatment is not offered. For couples, the psychological distress of ongoing infertility could be considered within a QALY framework but this would not be straightforward and data to inform this may be lacking.

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in October 2010.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be partially updated

This guideline will update and replace parts of the following NICE guidance:

- Fertility. NICE clinical guideline 11 (2004). Available from www.nice.org.uk/guidance/CG11.

5.1.2 Other related NICE guidance

- Weight management before, during and after pregnancy. NICE public health guidance 27 (2010). Available from www.nice.org.uk/guidance/PH27.
- Quitting smoking in pregnancy and following childbirth. NICE public health guidance 26 (2010). Available from www.nice.org.uk/guidance/PH26.
- Maternal and child nutrition. NICE public health guidance 11 (2008). Available from www.nice.org.uk/guidance/PH11.
- Antenatal care. NICE clinical guideline 62 (2003). Available from www.nice.org.uk/guidance/CG62.

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Multiple pregnancy. NICE clinical guideline. Publication expected September 2011.
- Pain and bleeding in early pregnancy. NICE clinical guideline. Publication expected November 2012.

6 Further information

Information on the guideline development process is provided in:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).