NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SHORT CLINICAL GUIDELINE

DRAFT SCOPE

1 Guideline title

Antimicrobial prophylaxis for infective endocarditis in adults and children undergoing interventional procedures

1.1 Short title

Prophylaxis for infective endocarditis

2 Background

a) The Department of Health has asked the National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') to prepare guidance on 'antimicrobial prophylaxis against endocarditis for adults and children undergoing an interventional procedure (including dentistry)'. The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisal guidance published by the Institute after an NSF has been issued will have the effect of updating the Framework.

c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and

their carers and families, where appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

a) Infective endocarditis (IE) is an inflammation of the inner lining of the heart, particularly affecting the heart valves, caused by bacterial or other infections. It is a rare condition, with an annual incidence of less than 10 per 100,000 population. It is, however, a life-threatening disease with significant mortality (approximately 20%) and morbidity. IE predominantly affects individuals with underlying structural cardiac defects who develop bacteraemia (presence of bacteria in the blood) with organisms likely to cause IE. Individuals with underlying structural cardiac defects constitute an important patient group ‘at risk’ of developing IE.

b) The prevention of IE has focused on the need to reduce bacteraemia in people at risk. This approach has three components: promotion of good oral hygiene, timely treatment of sepsis and giving antimicrobial prophylaxis to at-risk people undergoing an interventional procedure that is considered likely to cause bacteraemia. The frequency of bacteraemia after healthcare procedures varies depending on type and site of the procedure. There is, however, controversy about whether procedure-based bacteraemia causes IE. There is a view that cumulative bacteraemia is likely to cause IE, particularly in the case of dental procedures (including dentogingival manipulation).

c) It is considered biologically plausible that antimicrobial prophylaxis can reduce the risk of developing IE in people at risk. There is support for this position from animal models, although there is controversy about whether animal models can explain the pathophysiology of spontaneous IE in humans. The rarity of IE means that it is difficult to undertake controlled clinical trials, so evidence about the effectiveness of antimicrobial prophylaxis in

reducing the risk of developing IE is likely to come from well conducted observational studies. Potential risks of inappropriate use of antibiotics include serious adverse events (such as anaphylaxis) and development of antimicrobial resistance.

d) There is currently conflicting UK guidance relating to prophylaxis for IE. The chief area of controversy relates to the need for antibiotic prophylaxis for dental procedures, where there is concern that the likelihood of preventing IE by using antibiotics is less than the risk of the antibiotics causing serious adverse events.

4 The guideline

a) This document is the scope. It defines exactly what this 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.

b) 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) Adults and children with known underlying structural cardiac defects.

b) Adults and children who have previously had IE.

4.1.2 Groups that will not be covered

a) People at increased risk of IE who do not have structural cardiac defects (such as, injection drug misusers).

4.2 Healthcare setting

a) Primary dental care, primary medical care and community settings.

b) Secondary care.

4.3 Clinical management

a) Definition of people with structural heart lesions at risk of developing IE. This will include classifying structural heart lesions into those at risk and those not at risk of IE

b) Definition of interventional procedures considered to need antimicrobial prophylaxis for IE for specific at-risk groups. This will include:

- dental procedures
- other interventional procedures if there is considered to be an increased risk of IE in at-risk people. The following sites will be covered.
  - Upper and lower gastrointestinal (GI) tract.
  - Genitourinary tract. This includes urological, gynaecological and obstetric procedures (including childbirth).
  - Upper and lower respiratory tract. This includes ear nose and throat and bronchoscopy procedures.

c) Antimicrobial regimen to be used. This will include:

- specifying antibiotics that may be used
- the role of oral chlorhexidine.

d) The guideline, in accordance with other NICE guidance, will not offer detailed recommendations on the route of administration, timing and duration of antibiotic and antimicrobial regimen(s).

e) The information needs of individuals regarding the benefits and risks of antimicrobial prophylaxis for IE. This will specifically include advice regarding body piercing and tattooing that involves damage to mucosal tissue.

f) The guideline defines IE as bacterial endocarditis. Non-infective, fungal and atypical bacterial causes of IE will not be considered.

g) The Guideline Development Group will take reasonable steps to identify ineffective interventions and approaches to care. If robust and credible recommendations for re-positioning the intervention for optimal use, including the identification of appropriate patient subgroups, or changing the approach to care to make more efficient use of resources, can be made, they will be clearly stated. If the resources released are substantial, consideration will be given to listing such recommendations in the 'Key priorities for implementation' section of the guideline.

4.4 Key outcome measures

Key outcomes that will be considered when reviewing the evidence include:

- risk of dental and other interventional procedures causing IE
- risk of antibiotics prescribed for prophylaxis causing serious adverse events, for example anaphylaxis, in 'at risk' population
- mortality
- health-related quality of life
- resource use and costs.

4.5 Economic aspects

The developers will take into account both clinical and cost effectiveness.

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation period is 1 – 29 May 2007.

4.6.2 Guideline

The development of the guideline recommendations will begin in July 2007.

5 Further information

Information on the guideline development process is provided in:

- ‘The guideline development process: an overview for stakeholders, the public and the NHS’
- ‘The guidelines manual’.

These booklets are available as PDF files from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the website.

The Guideline Development Group will work in accordance with the methods set out in the documents above. The short clinical guidelines programme is in development and will be consulted on.