National Institute for Clinical Excellence

A submission to the Health Select Committee

NEW INQUIRY: THE PREVENTION OF VENOUS THROMBOEMBOLISM IN HOSPITALISED PATIENTS

1 Introduction

1.1 The National Institute for Clinical Excellence (NICE) has been asked to develop three pieces of guidance relevant to the prevention of venous thromboembolism in hospitalised patients.

1.2 The purpose of this memorandum is to describe the role of the Institute, to detail the three pieces of guidance relevant to this inquiry, and to set out key features of the process that the Institute will follow when developing this guidance.

2 The Institute and its guidance

2.1 NICE was established as a special health authority in 1999. Our role is to provide advice to the NHS in England and Wales on the clinical and cost effectiveness of drugs and other treatments. Our advice is for people who rely on the NHS for their care and for health professionals. Further information about the work of the Institute can be found at www.nice.org.uk.

2.2 A summary of the four main types of NICE guidance is set out below.

2.2.1 *Technology appraisals:* recommendations on the use of new and existing medicines and other treatments (devices, surgical and other procedures, diagnostic techniques and health promotion methods).

2.2.2 *Clinical guidelines:* recommendations on the appropriate treatment and care of patients with specific diseases and conditions, such as diabetes and schizophrenia.

2.2.3 *Cancer service guidance:* recommendations on the organisation and delivery of services for people with cancer.

2.2.4 *Interventional procedures:* guidance about whether interventional procedures used for diagnosis and treatment are safe enough and work well enough for routine use. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers) and ultrasound.

2.3 We publish around 25 technology appraisals, 12 clinical guidelines and 60 pieces of interventional procedures guidance each year.

2.4 NICE guidance is a key component of the national standards to which the NHS is now expected to work. Technology appraisals and interventional procedures guidance are 'core' standards, which require immediate implementation, and clinical guidelines are regarded as 'developmental' standards, the implementation of which will take place over a longer period.

2.5 The Institute is based in offices in central London. It has a budget of nearly £20 million, which is largely provided by the Department of Health but also includes a contribution from the Welsh Assembly Government, to which the Institute is jointly accountable. The Institute directly employs around 100 people.

3 Developing guidance on venous thromboembolism

3.1 The Department of Health and Welsh Assembly Government are responsible for selecting the topics for the NICE technology appraisal and clinical guideline programmes. Full details of the process they follow can be found on the Department of Health website at www.dh.gov.uk. Once a topic has been referred, the development of the subsequent advice is entirely the responsibility of NICE.

3.2 To date, the Department of Health and Welsh Assembly Government have referred the following topics relevant to this Inquiry to the Institute:

3.2.1 A clinical guideline on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures. The Institute is currently consulting on the scope for this guideline (attached for information as Appendix A), and the consultation period closes on 8 December 2004. The Institute expects to publish final guidance on this topic in May 2007.

3.2.2 Two technologies are in different stages of consideration by the Institute:

(i) Ximelagatran (an inhibitor of thrombin) is for use in the acute treatment and longer term management of venous thrombosis and pulmonary embolism. Applications for marketing authorisation have been submitted in the UK but currently this technology is not licensed for use. This Institute is currently consulting on the scope for this appraisal and anticipates publishing guidance in the fourth quarter of 2006.

(ii) The use of thrombophilia screening for the diagnosis of individuals at high risk of thrombosis. As a consequence of the responses received from stakeholders during consultation on the draft scope for this appraisal, the Institute has decided that further discussions are required with the Department of Health and Welsh Assembly Government to determine the nature of the final remit.

4 The guidance development process

4.1 Since its inception, the Institute has taken the approach that those whom its decisions affect are entitled to express their views on how we go about our work and on the development of individual pieces of guidance. We define these groups as including, but not necessarily limited to:

4.1.1 patients, carers and the public, and those who speak for them;

4.1.2 healthcare professionals;

4.1.3 NHS management;

4.1.4 healthcare industries;

4.1.5 the Government.

We recognise these constituencies as key stakeholders in our work alongside a much larger group including, for example, NHS agencies with related functions, research organisations and trade unions.

4.2 We make sure that our stakeholders (sometimes called consultees) have clear and reasonable opportunities to engage with us when we are developing guidance on a particular topic. The arrangements we have put in place have evolved as our experience of working with a diverse community of interested parties has grown. The main elements of these arrangements are summarised below.

4.2.1 Our processes and methods are developed in consultation with our stakeholders and with the independent experts who sit on our advisory committees. Drafts of our process and methods documents are exposed to public consultation and the comments received, together with the final versions of the documents, are approved by the Board in public session.

4.2.2 We consult with stakeholders on our interpretation (the 'scope') of the topics referred to NICE by the Department of Health and Welsh Assembly Government. These scopes form the basis of each guidance development project.

4.2.3 All draft guidance is subject to consultation with stakeholders and the wider public through the Institute's website.

4.2.4 All documentation associated with the development of guidance, other than where we have agreed to restrictions for reasons of commercial or academic confidence, is released into the public domain.

4.2.5 Comments submitted to the Institute by stakeholders are made publicly available along with the Institute's response.

4.3 We take the view that those who rely on our guidance should be able to understand how it has been developed. To this end each of our programmes displays a common set of characteristics, which are summarised below.

4.3.1 *Use of the best available evidence:* each programme secures a comprehensive evidence base, by contracting the work to an independent body or by undertaking the work in-house, and stakeholders are invited to check that all relevant evidence has been considered.

4.3.2 *Involvement of clinical and patient experts:* ensuring that our advisory bodies have access to clinical expertise and patient and carer perspectives as they interpret evidence is crucial both to the relevance of the recommendations and to their credibility.

4.3.3 *Independent advisory bodies:* the guidance that NICE publishes is prepared by independent standing committees (for technology appraisals and interventional procedures) and individual development groups (for clinical guidelines). All our advisory bodies include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The standing advisory committees also include people who are currently working in the healthcare industries.

4.3.4 *Genuine consultation:* all NICE guidance undergoes widespread consultation with stakeholders and the public. 'Genuine' means that our advisory bodies will respond to reasoned argument that can stand up to independent scrutiny and, if necessary, change their original thinking.

4.3.5 *Regular review:* technology appraisal guidance and clinical guidelines are reviewed at regular intervals to ensure that they remain current. Review dates are set on the basis of the advisory body's understanding of the anticipated pace of change in the evidence base.

5 Supplemental evidence

5.1 A copy of the draft scope for the clinical guideline on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures is attached at Appendix A for information.

5.2 Members of the Health Select Committee are also invited to review the detail of our arrangements for engaging with stakeholders in the process document for the clinical guidelines programme, which is enclosed as Appendix B for information.

6 Conclusion

6.1 NICE has been asked by the Department of Health and Welsh Assembly Government to develop three pieces of guidance relevant to the prevention of venous thromboembolism in hospitalised patients.

6.2 Our guidance will be developed using the expertise of the NHS and the wider healthcare community including NHS staff, healthcare professionals, patients and carers, industry and the academic world.

6.3 Once published, our guidance will support healthcare professionals and patients and their carers when making decisions about treatment and healthcare. It will improve the care of hospitalised patients by setting national standards for the prevention of venous thromboembolism and promoting equal access to clinically effective and cost effective treatments for this condition across the NHS in England and Wales.

National Institute for Clinical Excellence
November 2004

Encs Appendix A: Draft scope for clinical guideline on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures
Appendix B: The Guideline Development Process: An Overview for Stakeholders, the Public and the NHS

Appendix A

Draft scope for clinical guideline on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Venous thromboembolism: the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high risk surgical procedures.

1.1 Short title

Venous thromboembolism.

2 Background

(a) The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Acute Care to develop a clinical guideline on the prevention of venous thromboembolism for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see Appendix). 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 appraisals 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) Deep vein thrombosis occurs in about 30% of surgical patients and is commonly asymptomatic. However, the condition can lead to sudden death due to pulmonary embolism, or cause long-term morbidity due to venous ulceration and development of a post-thrombotic limb. Pulmonary embolism following lower limb deep vein thrombosis is the cause of death

in 10% of patients who die in hospital.

b) Most thrombi occur in the deep veins of the legs. Formation of thrombi is associated with inactivity and high-risk surgical procedures. The risk is particularly high in patients undergoing orthopaedic surgery and lengthy operations.

c) Current preventative measures for patients undergoing high-risk surgical procedures include mechanical prophylaxis (such as graduated elastic compression stockings) and pharmaceutical prophylaxis (such as low molecular weight heparin). Clinical practice varies and it is estimated that 4 out of 10 orthopaedic patients do not receive any form of prophylaxis[1].

d) This guideline will examine the risk of venous thromboembolism and assess the evidence for preventative measures. It will provide recommendations on the most clinically and cost effective measures to reduce adverse events and morbidity and mortality.

e) The Scottish Intercollegiate Guidelines Network issued guidance on the use of prophylaxis of venous thromboembolism in 2002[2].

4 The guideline

a) The guideline development process is described in detail in two publications which are available from the NICE website (see 'Further information'). *The Guideline Development Process – An overview for Stakeholders, the public and the NHS* describes how organisations can become involved in the development of a guideline. The *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers* provides advice on the technical aspects of guideline development.

b) 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 and Welsh Assembly Government (see Appendix).

c) 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) The guidelines will cover adults (age 18 and older) undergoing:

1 Department of Health (2003) Further action to tackle post-code lottery in care [press release]. http://www.dh.gov.uk

2 Scottish Intercollegiate Guidelines Network (2002) Prophylaxis of venous thromboembolism. *SIGN Publication* No. 62. Edinburgh: Scottish Intercollegiate Guidelines Network.

- orthopaedic surgery (including total hip or knee replacement, surgery for hip fracture, knee arthroscopy)
- major general surgery
- major gynaecological surgery
- urological surgery. (including major or open urological procedures)
- cardiothoracic surgery
- major peripheral vascular surgery.

4.1.2 Groups that will not be covered

Patients under the age of 18 will not be covered.

Adult patients who are at a high risk of developing venous thromboembolism but are not undergoing surgery will not be covered. For example, the following circumstances will be excluded from the guideline:

- acute myocardial infarction
- acute stroke
- cancer, including patients being treated with chemotherapy
- pregnancy and the puerperium
- use of oral contraceptives and hormone replacement therapy
- long-distance travel

4.2 Healthcare setting

The guideline will offer guidance for use in secondary and tertiary care.

4.3 Clinical management

a) The guideline will assess the risk factors associated with development of venous thromboembolism in the surgical procedures listed in 4.1.1.

b) The guideline will review the clinical and cost effectiveness, and possible morbidity, of interventions to prevent venous thromboembolism in patients under going the high-risk surgical procedures outlined in section 4.1.1.

c) Interventions that will be considered are:

- graduated elastic compression stockings
- intermittent pneumatic compression devices
- mechanical foot pumps
- low-dose unfractionated heparin
- low molecular weight heparin
- oral anticoagulants (warfarin)

d) Patients' views on all areas within the scope will be incorporated into the guideline where available. The guideline will include advice on the prevention of venous thromboembolism for patients undergoing high risk surgery.

e) Note that guideline recommendations on prescribing will normally fall within licensed indications; exceptionally, and only where clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use the Summary of Product Characteristics to inform their decisions for individual patients.

4.4 Status

4.4.1 Scope

This is the consultation draft of the scope. The consultation period is from 11 November to 8 December 2004.

There is a NICE technology appraisal in development entitled 'Venous thromboembolism (VTE) – ximelagatran' (publication expected in May 2006).

4.4.2 Guideline

The development of the guideline recommendations will begin in March 2005.

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*
- *Guideline Development Methods – Information for National Collaborating Centres and Guideline Developers*

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

Appendix– Referral from the Department of Health and Welsh Assembly Government

The Department of Health and Welsh Assembly Government asked the Institute to develop a guideline with the following title and remit:

Title: Venous thrombo-embolism: the prevention of venous thrombo-embolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures.

Remit: To develop safety guidance for the NHS in England and Wales on prophylaxis against venous thrombo-embolism (VTE) for patients undergoing orthopaedic surgery and other surgical procedures for which there is a high risk of VTE. The guidance should set out the principles of clinical and cost effective practice and in particular should address:

i the assessment of risk for particular procedures and for individual patients,

ii the circumstances in which prophylaxis can be recommended as clinically and cost effective, and

iii the appropriate selection of interventions including both pharmaceutical and mechanical methods of prophylaxis.