Professional organisation statement template

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: Royal College of Nursing

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology?√
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?√
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?√
- other? (please specify) Guideline Development Group member of NICE 2007 guideline on" reducing the risk of venous thromboembolism in surgical inpatients.

What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

*Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.*

Patients undergoing major orthopaedic surgery of the lower limbs are at high risk of developing venous thromboembolism (VTE). Elective arthroplasty is commonplace major surgery for chronic osteoarthritis of the hip and knee. VTE is most preventable. However, there is strong evidence of regional and international variations between orthopaedic surgeons into the choice of venous thromboprophylaxis for such elective surgery. Among the technologies recommended are combined regimen of mechanical and pharmacological prophylaxes (NICE 2007) synthetic pentasaccharide such as Fondaparinux or Low Molecular Weight Heparin (ACCP 2004), LMWH and aspirin (SIGN 2002) LMWH and Graduated compression stockings (International Consensus Statement 2006). Clearly the divergence is the outcome of differences in opinion on venous thromboprophylaxis. By the same regards, there is some degree of consensus that both mechanical and pentasaccharide or LMWH are effective prophylaxis. Recently, Dabigatran etexilate, a direct inhibitor of the enzyme thrombin has proven to be clinically effective in the prevention of VTE in patients undergoing hip arthroplasty.

There is consensus that patients undergoing hip and knee arthroplasty require extended prophylaxis. Extended prophylaxis with LMWH is commonplace but clinical trials with rivaroxaban and enoxaparin have concluded that Rivaroxaban has superior efficacy to enoxaparin (Lassen et al 2008). Therefore this single technology under appraisal can be conveniently used in secondary care setting which will obviate the need for additional professional input. It will eliminate the need for the community nursing staff to undertake domiciliary clinical visit

to patients on extended prophylaxis who are unable or reluctant to give their own injection of LMWH. Rivaroxaban has shown to be more efficacious than enoxaparin for both hip and knee arthroplasty (Fisher et al 2007) and therefore can be readily used for extended prophylaxis.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

The technology was evaluated under conditions identical to observed clinical practice in UK. Primary efficacy outcome comprises composite of DVT as detected by venogram and non fatal PE and major bleeding. Main secondary efficacy outcome includes proximal DVT, nonfatal PE and death.

Advantages of the new proposed technology:
Rivaroxaban has good bioavailability (Perzban, Kubitza, Miselwitz, 2007).

- Very acceptable to patients
- Provides safe and efficacious extended prophylaxis
- Eliminates the need for additional resources from health professionals in the implementation of other forms of prophylaxis
- Little or no monitoring required. Rivaroxaban exposure can be assessed by estimation of prothrombin time and not International Normalized Ratio

(INR), suggesting that fixed dose of prophylaxis is possible (Mueck et al 2008).

- A good and efficacious alternative to LMWH (Kakkar et al, 2008)

Disadvantages of the technology:

- Rivaroxaban has marginally higher risk of bleeding than LMWH (Eriksson et al 2008).

- Like any other anticoagulants, it is contraindicated in patients with bleeding risk.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

No additional comments

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within
3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

- No additional resources are foreseen, other than education and training on this technology for Doctors, Nurses and Pharmacists.