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: x[redacted]

Name of your organisation
British Society for Haemostasis and Thrombosis

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)

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?

The approach to post surgical venous thromboembolism prophylaxis is variable both between and within treatment centres. There is a reasonable evidence base and clinical guidelines which are differently interpreted and applied. There are established alternative pharmacological approaches including heparin, low molecular weight heparin and fondaparinux and mechanical methods such as the use of mechanical compression devices to encourage blood flow. The major perceived advantage of the new technology (Dabigatran Etexilate) should it be confirmed to have a similar safety profile would be the route of administration which is oral. (presently confined to 2 non-inferiority studies in TKR JTH 2007:5(11):2178) and in THR Lancet 2007;370 (9591);949) This issue is particularly important in view of recent evidence that indicates a likely benefit in prolonged anti-thrombotic prophylaxis in high risk situations. Dabigatran would allow more simple discharge and would dispatch with the need to monitor platelet counts outside hospital which is required for patients receiving extended treatment with heparins.

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?

The risk of VTE post TKR/THR is extremely high. Certain groups of patients such as those with previous VTE, active malignancy, obesity, congestive cardiac failure and nephrotic syndrome do however represent a group with an even higher post operative thrombosis risk.
Certain individuals at high intrinsic risk of bleeding have an unacceptably heightened risk when given any anti-thrombotic medication

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)?

It should be initiated in secondary care as part of the peri-operative plan and continued where required outside of hospital. The additional support and input should be minimal.

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?

***Presently in clinical trials only*.**

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.

ACCP Guidelines 2004 (due for updating) Systematic Review and consensus on level of recommendation.

NICE Guideline 2007 Commissioned by NICE 2006. Methodology as per the Guidelines Manual. Systematic review with consensus on the recommendation. No levels of evidence or recommendation are given.

SIGN Guideline 2002 (Awaits review 2008) Systematic review using established SIGN methodology followed by nominated external review, an open meeting and extensive sounding.

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?

Dabigatran will be easier to administer both in and out of hospital (oral versus sub cutaneous), in addition it will dispatch with the need for platelet monitoring in hospital and after discharge which is required for patients using heparins. No other clinical tests will be required for its monitoring as long as there is no clear need for monitoring of liver function tests.

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.

None

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?

The circumstances described in the main clinical trial (JTH 2007: 5(11): 2178 is similar to what might be expected in UK practice. As in all clinical trials the groups of patients randomised tend to be "well" patients with a bias towards excluding patients who are likely to be problematic for whatever reason.

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?

In the clinical trials of Dabigatran the rates of complications, especially bleeding, were similar to that seen with the present "best" form of management (Enoxaparin). There has been concern about the hepatic toxicity of this drug which results in abnormalities of liver function tests in a small number of patients. The clinical studies have addressed this issue and present indications are that the rate of development of LFT abnormalities is similar in patients treated with Dabigatran and heparins.

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.

None

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)?
Broadly speaking the use of this drug would potentially enhance patient care because it would facilitate adherence to continuation of anticoagulant prophylaxis outside hospital. The nursing staff and medical staff and pharmacists in hospital would need minimal training to make them aware of the use of a new drug for this purpose. No new resources or equipment would be required.