Professional organisation statement

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
British Orthopaedic Association

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? YES
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? YES
- 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.)? NOT QUITE
- other? (please specify) I am the British Orthopaedic Association lead for NICE. As such I have been asked to coordinate the orthopaedic community response to NICE VTE guidance

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 prevention of VTE following orthopaedic surgery is highly controversial and the potential costs and rewards for the manufacturer of successful therapies are huge. There is no difference of opinion between professionals that VTE should be minimised after surgery and the last thirty years of orthopaedic practice have been engaged in reducing the risk by changing anaesthetic and surgical technique, which has been documented to greatly reduce the incidence of VTE. Beyond these changes in surgical practice there are three sorts of technology which are efficacious.
1. Passive mechanical methods. This consists of the use of compression stockings. There is doubt over their efficacy but use is widespread.
2. Active mechanical methods. These consist of various intermittent compression devices. The evidence base suggests that these devices are effective, however, owing to lack of funding, the evidence is incomplete. Apart from inconvenience to the patient (which ahs been minimised by design modifications) the devices have no known complications. Start up cost however limits their availability. The majority of professionals would strongly advocate their use but may be frustrated by lack of funding.
3. Chemical prophylaxis. Dabigatran is the first of a new class of drug in this area. The problem with all forms of chemical prophylaxis is that they must cause surgical bleeding if they are to efficacious in reducing VTE. Therefore their use is a balance. It is in the assessment of this balance that surgeons differ. The balance reaches right into the surgical technique which is employed. A swift surgeon relies on speed of surgery and rapid mobilisation to reduce VTE but may accept a greater propensity of the wound to bleed. A slower surgeon may take more precaution against bleeding but will increase the risk of VTE by slower surgery. Thus the second surgeon will be more inclined to use chemical prophylaxis.

There is no disagreement between professionals that even minor bleeding after orthopaedic surgery may be disasterous.

There is considerable concern about two aspects of the chemical prophylaxis research base.

1. The studies use the surrogate endpoint of asymptomatic DVT. This may well not reflect the rate of clinically important events.
2. The use of chemical prophylaxis may actually increase the rate of death after orthopaedic procedures. This notion is supported by the National Joint Registry Database.

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?

Yes patients with thrombophilia, a history of VTE, cancer or who are immobile.

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)?
Secondary care extending into primary care. An advantage of this technology is that no extra inputs from healthcare professionals is needed…ie no injections and no monitoring.

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?
N/A

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. These were produced by the American College of Chest Physicians and are significantly discredited among orthopaedic surgeons.
NICE VTE guidance. These cause significant concerns among the orthopaedic community and are currently being updated.
AAOS guidelines. A highly authoritative document which takes account of the latest changes in practice and evidence base

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?
The advantage is the lack of need for injection (cf heparin) or monitoring (cf warfarin)

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.
N/A

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 research uses the surrogate outcome of asymptomatic DVT. The evidence that this is a valid surrogate for clinically significant events is very tenuous, relying on data from a meta-analysis in 1988. Furthermore, the real clinical endpoint is death from all causes.

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 adverse events associated with use of chemical prophylaxis are two.
1. Failure of wound healing due to oozing. This probably predisposes to deep infection, which is a disaster (quote from a patient recently seen in an outpatient clinic with a deep infection "I would be better off dead"). The rate of deep infection after total joint replacement is an order of magnitude greater than that of death from VTE.
2. Increase in death from causes other than VTE. For example GI bleeding (an obvious link) or myocardial infarction (due to stopping of cardioprotective drugs such as aspirin in order to allow use of of chemical prophylaxis). The notion that this may be important is supported by the finding that in the national joint registry, the reate of death from all causes is greater in patients treated with chemical prophylaxis.

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.

National joint registry

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)? Widespread implementation of chemical prophylaxis would probably lead to surgeons changing their clinical practice to give greater attention to ensure minimisation of minor surgical bleeding. This will slow operations and increase the risk of VTE. Patient mobilisation would be slower and this would in turn increase hospital stays and increase risk of VTE. Minor bleeding episodes and poor wound healing will prolong hospital stays and increase costs.