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 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? X
- 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? **Thromboprophylaxis of high risk orthopaedic surgery such as total hip and knee replacement (THR and TKR) is variable between and within health boards/trusts. There is significant debate about what represents best practice with orthopaedic surgeons often disagreeing with haematologists and clinical pharmacologists. Current best practice is based on the use of injectable heparins during and after the hospital stay. The need to inject treatment combined with the need to monitor blood tests for potential side effects of treatment (heparin induced thrombocytopenia) are disadvantages that current treatment has when compared with rivaroxaban**

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 clinical trials only include patients who are at low-moderate risk of bleeding and have not been assessed in high risk groups for bleeding. Likewise most studies on LMWH and fondaparinux have the same limitations.**

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)? **Initiated in secondary care where the total course of treatment could be prescribed (typically 10 days for TKR and 30 for THR). The technology has the advantage of not requiring such extensive community/post-discharge nursing/pharmacist input**

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? Not** presently available but likely to be soon

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. **Present guidelines on VTE prophylaxis following major orthopaedic surgery are available from SIGN , NICE and ACCP. These do not include consideration of the new technology because of the timing of the writing/release of the drug.**

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 technology has shown superior efficacy to comparative LMWH regimens in preventing all VTE post TKR/THR (RECORD1-4). The benefit of the new technology is that it is taken orally, and does not require monitoring for the development of predictable side effects (which is required for LMWH). The oral route will help facilitate discharge especially in cases of THR where prolonged duration prophylaxis is of proven benefit**

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. **NA**

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 trials reflect UK practice reasonably (and as well as any previous studies of comparators). The exclusion criteria for these types of studies are fairly uniform – all excluding the groups of patients at highest bleeding risk and with most other co-morbidities. The outcomes measured are surrogate markers of symptomatic VTE – and as such are probably the best possible. Although some complain about the use of asymptomatic DVT as an endpoint – there is no better surrogate endpoint and indeed asymptomatic VTE may not be as benign as people think. Patients with asymptomatic DVT can develop post thrombotic syndrome which is troublesome and which increases their risk of future DVT and patients with asymptomatic PE may go on to develop pulmonary hypertension. In all of these studies it is difficult to achieve the type of numbers that would be required to identify a significant difference in , for example symptomatic or fatal PE.**

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? **Rivaroxaban does not appear to be associated with drug induced thrombocytopenia (as you would expect) it also is not associated with an increased risk of developing abnormalities of LFTs when compared to heparins for short periods of use (up to 30 days). Bleeding does not appear to be increased compared to heparins. Note studies on longer term use of rivaroxaban for AF and treatment of VTE need to be awaited before final statements on bleeding and LFTs can be made.**

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**

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)? **Minimal extra training required. Delivery of care to patients would be simplified and avoid injections**. **Discharge arrangements would be easier for extended prophylaxis post THR**