**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: Michael Laffan**

**Name of your organisation Royal College of Pathologists**
**British Society for Haematology**

**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.)? **X**
- 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?

**UK NICE guidelines recommend mechanical prophylaxis and LMWH or Fondaparinux for routine elective surgery, extended for 4 weeks if additional risk factor for thrombosis**.
**ACCP guidelines recommend routine use of LMWH for TKR and THR.**
**SIGN recommends patients undergoing TKR or THR should receive thromboprophylaxis: mechanical** *(GECS±IPC, foot pumps)***, pharmacological** *(aspirin or heparin or warfarin)***, or both.**
**BOA guidelines (2006) suggest each unit should produce its own guidelines.**

**Despite these guidelines there is a general impression that the use of chemical thromboprophylaxis is controversial due to concern amongst surgeons that it increases the risk of bleeding and subsequent wound infection and that historical data do not reflect current thrombosis rates.**
**However, a survey of practice by orthopaedic surgeons (*Ann R Coll Surg Engl* 2006; 88: 108–115) had a 61% return rate; of those submitting returns, 61% used LMWH, 31% aspirin and 72% compression stockings for THR. In a similar survey in 1998, 63% used LMWH (Ann R Coll Surg Engl. 1998 September; 80(5): 350–355)**

**Thromboprophylaxis using mechanical methods and LMWH (via subcutaneous injection) is probably the best representation of current best practice.**
**Advantages of Rivaroxaban over standard LMWH therapy are:**
**1. avoids heparin induced thrombocytopenia**
**2. it is administered orally rather than by subcutaneous injection.**

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?

**Most available data exclude patients at high risk of bleeding or high risk of thrombosis. Rivaroxaban, LMWH and Fondaparinux all rely on renal excretion and data do not include patients with impaired renal function. Exclusion of paediatric and pregnant patients concerns a very small minority of patients.**

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)?

**Treatment with the technology will invariably be initiated in secondary care and although continued after discharge, will not necessarily involve primary care. Use of LMWH over the same extended period after discharge would likely necessitate use of district nurse and primary care resources.**

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 at present.**

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.

**See above for guidelines regarding current practice. However these do not include use of Rivaroxaban because they were all written before its introduction and license.**

## 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?

**In the submitted trials, Rivaroxaban proved more effective, than existing standard practice (LMWH). However this is unlikely to resolve the concerns amongst some surgeons. It is likely to be much easier to implement than current therapy, particularly with regard to extended prophylaxis and is likely to prove more acceptable to patients.**

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 study groups and methods are likely to reflect standard UK practice. The exclusion criteria are consistent with previous studies and reasonable given the endpoints of the trials.**
**The most important outcomes are all forms of VTE, and the safety endpoints of bleeding and wound complications. These are all addressed in the trials.**
**The use of venographically identified VT was accepted as valid in the NICE appraisal of Dabigatran and is used again here. The other endpoints are not surrogates.**

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?

**Haemorrhage may be regarded as the principal side effect but is also an unavoidable consequence of anticoagulant effect and affects all comparable therapies (except mechanical thromboprophylaxis). Rivaroxaban did not cause significantly more bleeding than Enoxaparin in the four trials available (RECORD 1-4).**
**It is too early to comment on routine clinical practice.**

**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)?

**No need for additional training, facilities or equipment. Oral administration of Rivaroxaban will likely use less resource than subcutaneous administration of LMWH, the principal comparator.**