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:

██████████

Name of your organisation

Clinical Leaders of Thrombosis (CLOT)

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.)? **X**

Education Secretary & Committee Member Clinical Leaders of Thrombosis

- other? (please specify)

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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 current treatment is warfarin, which is widely used throughout the UK in a reasonably consistent manner. Warfarin has the disadvantages of having an unpredictable dose-response relationship, requiring repeated monitoring and interacting with numerous foods and drugs.

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?

Patients with renal impairment may not be suitable for treatment with dabigatran.

Patients who have medication compliance problems would not benefit as there would be no monitoring.

Dabigatran may not be suitable for patients undergoing cardioversion or ablation as its immediate efficacy cannot be monitored.

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)?

The technology could be used in all settings. No additional input is envisaged.

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?

Currently licensed for post-orthopaedic surgery VTE prophylaxis. Not used for other indications as far as we are aware.

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.

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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 major advantage of dabigatran over warfarin is the lack of need for regular monitoring making it much easier to use for the patient and for healthcare professionals. This also reduces the demands on clinical, nursing and laboratory services.

A reduction in drug and food interactions would also make dabigatran easier to use and safer than warfarin. Changes in patient lifestyle may not have such an impact on dabigatran as they do on warfarin.

Monitoring compliance with dabigatran will be more difficult as the patients do not have regular tests. Discontinuation and a subsequent increase in Stroke rates may occur.

A further problem is that there is no specific antidote to dabigatran as there is with warfarin in the case of overdosage.

The trials showed a higher discontinuation rate for dabigatran than warfarin which could have adverse effects if translated into widespread use.

The patients recruited for the trial were not >80yrs which very many warfarin patients are. These patients may respond differently.

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There may be problems within the elderly population with impaired renal function meaning that they will be unsuited to dabigatran.

The dyspepsia reported by many patients in the trial may lead to discontinuation of dabigatran in the general population or the need for additional medication to control these symptoms which will increase costs.

Any additional sources of evidence

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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.

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.

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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)?

Training in the appropriate prescribing of dabigatran would be required. Patients would require counselling before use as they do with warfarin.

There would be a reduction in the resources currently required as there would be no need for monitoring. Reduced staffing and reduced testing would be anticipated.

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