NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation

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 Heart Rhythm UK

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)

  Heart Rhythm UK is an affiliated group of the British Cardiovascular Society and we have an interest in all aspects of cardiac arrhythmia care and electrical based device therapies. We have close working relationships with the Arrhythmia Alliance representing patients' groups, medical regulatory and advisory bodies (MHRA), and with colleagues in the medical equipment and device manufacturing industries (ABHI).

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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?

Currently vitamin K antagonists (predominantly warfarin) are used to treat this condition. Another drug (dabigatran) is under appraisal by NICE at present.

Use of the GRASP-AF tool (NHS Improvement) has shown that there is very significant variation in the uptake of anti-coagulation between GP practices and to a lesser extent between PCTs.

There is very little variation in clinical opinion as to the value of anti-coagulants. The only variation is perhaps in the threshold for anti-coagulation and in the degree of risk thought to merit anti-coagulation.

The main alternative is warfarin. The great advantage of rivaroxaban is dispensing with the need for anti-coagulant clinic monitoring.

It is likely that dabigatran will be licensed in the next few months. There is no "head to head" of rivaroxaban against dabigatran to enable direct comparison of the two 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?

Risk factors for stroke are well established amongst AF patients. CHADS represents a well established risk scoring system. More recently CHADSVASC has been suggested by the European Society of Cardiology as providing a better estimate of risk amongst low risk patients.

In common with warfarin, the greatest benefit from the drug will be amongst high risk patients. Patients with impaired renal function may be at greater risk from rivaroxaban and dose reduction may be appropriate.

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)?

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In common with other anti-coagulants used in the treatment of atrial fibrillation, the drug should be primarily used in primary care. There would be no requirement for additional professional 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?

The drug is not currently licensed.

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.

There are currently no relevant guidelines. The NICE appraisal of dabigatran will provide guidelines of relevance to this 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?

Rivaroxaban is likely to offer greater convenience to any patient taking warfarin for stroke prevention in atrial fibrillation.

In addition it potentially offers advantages over conventional management with warfarin in two main respects:

Firstly, it may offer the potential for more effective anti-coagulation and greater reduction in stroke for patients with sub-optimal anti-coagulation who demonstrate a sub-optimal time in therapeutic range on warfarin.

Secondly, in patients, such as the housebound elderly, in whom attendance at an anti-coagulant clinic may prove a major disincentive to anti-coagulation with warfarin, rivaroxaban offers the opportunity for effective anti-coagulation without the need for clinic attendance. Potentially this would have a significant impact on prevention of stroke due to AF in the elderly.

The potential relative merits of rivaroxaban and dabigatran are currently unclear.

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.

No comments

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?

I have no direct experience with the drug

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 common with other anti-coagulants, the major side effect is bleeding. The incidence of bleeding was similar to warfarin on direct comparison in the ROCKET AF trial.

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.

I have no such information.

Implementation issues

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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)?

I believe that uptake of this drug would offer some patients the possibility of improved anti-coagulant control and others improved access to anti-coagulant services,

I am not aware of any requirement for extra training or resources.

Equality

Are there any issues that require special attention in light of the NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

None that I am aware of