

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Rivaroxaban for the prevention of stroke in atrial fibrillation

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: Jo Jerrome

Name of your organisation: Atrial Fibrillation Association (AFA)

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- other? (please specify)

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition ?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

- In published trials, rivaroxaban was non-inferior to warfarin for the prevention of stroke or systemic embolism.
- Rivaroxaban has few interactions with other drugs / food and drink items making it far more predictable and ensuring that the patient has significant protection from stroke while taking the medication.
- Intracranial and fatal bleeding occurred less frequently in the rivaroxaban group.
- Reduces burden of INR appointments for current AF patients receiving warfarin.
- Currently as few as 20% of AF patients needing anticoagulation are within therapeutic level at any one time, resulting in preventable strokes. Rivaroxaban reduces the risk of suffering a stroke and ensures a patient stays within a protective level while taking rivaroxaban.
- An alternative to warfarin which protects those at high risk of stroke while enabling an improved quality of life free from frequent INR appointments.
- Currently AF patients taking an alternative (warfarin) face costly, time consuming and frequent visits to have INR tests. If the individual is employed AFA is aware of this becoming a significant burden and impact on their employment.
- For many patients, the need for regular testing restricts life style, commitments, travel and opportunity to enjoy 'normal' activities, including eating out and enjoying a varied diet.
- Travel for this potentially very unwell group of AF patients will very often require support from a family member or carer. This is both time consuming and costly.
- Until one is facing a high risk of stroke and taking the current anticoagulation option (warfarin), it is difficult to imagine the worry each action may have on your own stroke risk – from enjoying winter greens, a glass of wine, an occasional activity to suffering from seasonal infections or taking other medications. All may affect warfarin. AFA is aware that this is a daily worry for many tens of thousands of AF patients and their families.
- A simple, one dose per day medication has proven evidence to show greater improved compliance.
- GPs and those charged with managing patients on warfarin, would be reassured that an AF patient should remain within a therapeutic band reducing the risks of both stroke and a bleed.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

- Improved quality of life / access to employment / family.
- Improved independence.
- Reduced burden and reliance on support from family / social services or carer.
- Access to a far easier to manage therapy.
- Far fewer side-effects.
- Less worry on daily activities and food / life style choices.
- Far fewer hospital appointments.
- Day to day improved protection from stroke or a bleed.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. Disadvantages

Please list any problems with or concerns you have about the technology.

Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

-I am not aware of any.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

-I am not aware of differences in opinion between patients regarding the usefulness of this technology.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

More:

- Those who struggle to remain within acceptable therapeutic levels on current anticoagulation option.
- Those unable to tolerate current options.
- Individuals, already unwell and possibly taking a cocktail of medication for whom a once a day option would help simplify an already complex therapy regime.
- Those in employment or with commitments where once a day and no tests would enable them to maintain their work / family etc commitments.
- For an AF patient who may struggle to comply with the demands of a medication requiring more frequent dosage or regular tests.

Less:

- Those for whom management of the current option has shown to keep them easily within therapeutic levels.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

Currently the only alternatives widely considered are:

- aspirin, which is not a suitable alternative in AF patients at risk of stroke and does not offer the same level of protection.

Or

- warfarin: This can offer similar protection but is unpredictable making it very difficult to manage. It requires frequent INR tests to ensure the patient remains within quite a narrow therapeutic band. Many things interact with this medication, making management more challenging. Despite extensive evidence, warfarin is under-prescribed by doctors to AF patients at high risk of stroke. As a result, it is thought that almost half of the AF patients who should be prescribed an anticoagulant, are not, and half of those who are, are not within therapeutic range at any one time. Thus this alternative is not effective for the majority.

Dabigatran has recently received a positive FAD from NICE (November 2011). It has yet to be used widely and is a two dose per day therapy which may not be suitable for everyone.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Warfarin

Dabigatran has just received FAD (November 2011)

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

-One dose per day, evidence of far greater compliance.

-Far easier to use (one dose).

-Less worry with interaction between drug therapies / food and drink.

-Easier for physician to manage patient taking rivaroxaban.

-Inter-cranial and fatal bleeding occurred less frequently with rivaroxaban when compared with warfarin.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

None that I am aware of.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

-None that I am aware of.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

-None that I am aware of.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

-Analytical evidence gathered through patient surveys and interviews. Case studies available in AFA publications and on AFA website www.afa.org.uk .

-Burden of AF report published 2009

-AF Report due to be published December 2011.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

- If this technology was made available, it could significantly reduce the risk of stroke for a large number of AF patients. (AF diagnosed patients in England now known to be in excess of 1 million).
- Would offer a safer and easier to manage alternative for primary care clinicians managing stroke risk in AF patients.
- Protect AF patients who live at high risk of an embolic stroke due to AF but for whom there is not a suitable treatment.
- Reduce the number of embolic strokes due to AF.
- Reduce the worry caused from regular INR tests for AF patients facing mobility / employment / financial / family issues.
- Improve compliance to prescribed anticoagulation.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

- Stroke risk for many would remain high.
- The incident of printable strokes would continue.
- Compliance would remain problematic in some groups.
- The burden will remain on carers to support the taking, managing and testing of warfarin.
- Appropriate prescribing of an anticoagulant to reduce the risk of stroke in high risk AF patients would leave many tens of thousands at risk.
- Vulnerable individuals (elderly, disabled) would remain at risk of stroke / bleed.
- Those in centres such as care homes, and the carers managing therapies would still face the daily challenge, which too often results in not using an antiocagulant

Are there groups of patients that have difficulties using the technology?

- Those unable to take d thinning medication but do require treatment to reduce their risk of stroke due to AF.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

This is the first anticoagulant treatment which offers a one dose treatment option, little monitoring and at least equal safety and efficacy to the current alternative (warfarin).

The cost of a stroke – in human terms, financially to individual and their family as well as to the NHS, is immense. At least three quarters of the stroke events due to AF are preventable.

With this new technology, it is now possible to significantly protect an AF patient from a stroke and a bleed. In short, this technology has the potential to save lives, prevent suffering, improve patient outcomes and enable individuals and those close to them to regain a greatly improved quality of life. It could be expected, that long term, this technology would save money for the NHS, social and healthcare costs, and also for the individual and their family.