NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Dabigatran etexilate for the prevention of stroke and systemic embolism 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: Mrs Jo Jerrome

Name of your organisation: Atrial Fibrillation Association

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)

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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.

1) At least equal if not greater reduction in risk of a stroke in AF patients: based on the results from the RE-LY trials. For patients who find warfarin difficult and time consuming to safely manage, or who are unsuitable to take current options, this is a life changing new option which offers an excellent risk reduction for the occurrence of stroke with a far greater improvement in daily quality of life.
2) Reduction risk of a bleed: current options (really only warfarin) are so difficult to manage it is easy to fall outside of therapeutic levels and be at risk of a severe bleed. Sadly, many patients have experienced this and feel helpless. The new technology significantly reduces this, reassuring and welcomed news for patients, their carers and their doctors.
3) Life style improvement: due to the minimal interaction with other foods / drink / medication, the new technology would significantly improve a patient's life style. --- Currently individuals face costly, time consuming and frequent (even weekly) visits to have INR tests. If the individual is in employment this is often an issue with their employer and can lead to unemployment. For older patients who may have retired, cost of travel to the anticoagulation clinics can be draining on their financial resources. They may also rely on support to attend appointments. Too often due to the frequency of appointments and the need to rely on others for help, leaves a person unable to maintain family, social or the life they once had.
Family life, work, social life, are all negatively affected by current medication – fear and worry are constant factors. The new technology would release patients from this burden and so would greatly improve their quality and life style.
- I don't think anyone can fully realise what freedom could be restored to individuals – able to freely choose what they eat and when; no longer a worry of taking other medications; able to travel without fear of missed tests / alternative foods / time changes etc.
4) Family and carer: many family/carers who have the responsibility taking a person to clinics for INR tests and who help manage the current medication which may change on a daily basis, find themselves unable to easily access or maintain work balancing this burden. The new technology could have a significant and positive effect on the quality of their lives as well as the financial burden.

(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
- pain
- level of disability

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- 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.

1) Safer therapy.
2) More effective medication.
3) Simple to use and manage.
4) Far fewer hospital / clinic appointments.
5) Possibly increased protection from stroke and from suffering a bleed.
6) Improved quality of work due to less worry / impact of medication and management.
7) Far fewer side effects than current medication.
8) Far, far less interaction with daily items as well as medication.
9) Allows a person to LIVE life rather than revolve it around management of current medication and medical appointments.

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 based on the 'usefulness' of this technology. I believe that most welcome this as a long awaited alternative option that is currently not available and one that is free of difficult and complex management issues.

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?

All patients suitable for this treatment may benefit, however those who would especially benefit are:
1) Those unable to tolerate current options but assessed as at high risk of stroke.

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2) Those unsuited to safely manage current medication options.
3) The young who require anticoagulation therapy but also trying to manage family / work life on which current options heavily impact upon.
4) The elderly who are already taking a cocktail of drugs and who struggle to maintain good therapeutic levels with current medication.

Those who may benefit less are individuals who have managed current medication very well.

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.

(i) Please list any current standard practice (alternatives if any) used in the UK.
Currently the only alternative is warfarin. For some this medication is difficult to tolerate causing other health problems. For some groups they are unable to take warfarin due to their medical history and currently have few other options, none of which offer the same amount of stroke risk reduction. The current treatment available is often feared and disliked by patients due to the immense impact it has on daily life and the difficulty to remain within therapeutic levels and so remain safe from a bleed or occurrence of stroke.

A few patients using warfarin may use home monitoring devices to overcome the requirement to attend regular INR clinics, however this is not suitable for many and often it is difficult for the patient to secure funding for the test strips or afford the cost of purchasing the monitor.

Devices fitted to 'plug' the left atrial appendage are sometimes an option, but as well as being very expensive and only able to be fitted by a few specialists, this option does not offer as much stroke risk reduction as warfarin or the technology being appraised – dabigatran.

(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.)

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(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.

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

Not that I am aware of, currently this drug is not available for stroke prevention in patients diagnosed with atrial fibrillation.

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.

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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 increase the number of AF patients whose risk of stroke would be reduced.These groups would include those who:
- cannot use current options and for whom dabigatran would be suitable;
-those who find it very difficult to remain within therapeutic levels when taking warfarin;
For individuals who face many issues balancing the requirements of family / work / mobility or finances accessing test required for current treatment, the new technology would offer a welcome alternative restoring quality of life and enabling them to maintain work, care or balance finances while remaining protected to the best levels against the risk of stroke.

1) For those unable to tolerate existing treatments, the new technology would greatly increase their protection against stroke due to AF.
2) For those who travel frequently, are immobile or have work / family commitments all of which make attending anticoagulation clinics very difficult / costly, the new technology would enable them to benefit from protection this offers while also avoiding costs / job issues / travel difficulties etc
3) For those who find remaining within therapeutic levels difficult, the new technology would enable them to have far greater consistent protection from stroke
4) The new technology would release family / carers from the burden of support and management currently often needed.

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

If the technology was not made available then:
1) Many people with AF would continue to remain at high risk of stroke or a bleed.
2) For some remaining within work or seeking work would be impossible due to the high number of medical appointments required by current treatment.
3) Vulnerable individuals, often the elderly or disabled, who struggle to attend INR clinics would remain at risk of stroke / bleed.
4) Responsibility of care would remain on families, often already under a great deal of pressure helping the individual diagnosed with AF.

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

Those unsuitable for blood thinning medication but requiring treatment to reduce their risk of stroke due to atrial fibrillation

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Other Issues

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

This is the first alternative treatment to reduce the risk of stroke in a person diagnosed with AF for more than thirty years which is at least as effective and safe as the current option, and in some levels of dose, more effective.

Currently, NHS figures suggest that 50% of people with AF who should be anti-coagulated, are not and that 50% of those who are, are not in therapeutic range at any one time. This is unacceptable – to the patient at risk, to the NHS facing annual costs of between £12,500 - £44,00 for stroke care. The cost and burden of this can only be estimated for families, carers and social care.

Dabigatran offers an effective and safe alternative which long term could reduce risks for many vulnerable groups of AF patients, reduce costs to carers, patients and NHS, reduce the risk of bleeds and stroke and ultimately, save lives.