

Patient/carer organisation statement template

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: [redacted]

Name of your organisation:

Arrhythmia Alliance (A-A)

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? - My mother has AF and has been assessed to need anticoagulation therapy.
- 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)
- I am the Founder and Trustee for A-A and CEO for Atrial Fibrillation Association
- other? (please specify)

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) The risk of stroke is hugely reduced. The RE-LY trials conducted gave patients needing anticoagulation new hope. Results have demonstrated that this is, at the very minimum, equally successful compared to current medication. Moreover, higher doses were shown to be even more effective.
- 2) Side effects chronic in previous medications are hugely reduced with the new technology. The same RE-LY trials showed the safety risks to be much lower.
- 3) The quality of life improvements experienced by patients using the new technology was dramatic. Due to the reduced need for interaction with other medications, food or drink, it is far easier for patients to live a more fulfilled lifestyle. Additionally, frequency of visits to INR clinics would be greatly reduced, yielding a number of benefits. Firstly, the patient will clearly have a significant time saving, causing less disruptions to employment, social and family life. This both enables the patient to achieve greater financial stability and less expenditure in travel to the clinic. INR clinics would also have more time for those patients unable to use the new technology. Less concern about management of the medication would also benefit the patient and be an enabler to life. Warfarin not only needs to be constantly monitored – causing stress to the patient and those around them – but also has the danger of being “out of therapeutic” levels, risking a bleed or stroke; both life threatening.
- 4) Financial issues should not be underestimated. Everyone would be better off – both the NHS and patients. As mentioned earlier, ending the need for such frequent trips to the INR clinic is financially beneficial to the patient. For the NHS, less crowded clinics would enable greater focus on other patients and free staff from the hugely time consuming activity of working out the interaction options of current medications.

(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
- 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) Management for patient and medical staff easier
- 2) therapeutic risks lessened
- 3) time and personnel saved due to less clinic/hospital appointments

- 4) quality of work and life improved as the patient is more confident regarding impact of medicine
- 5) reduced risk of stroke and bleeds from current medication
- 6) ability to travel by all means is improved
- 7) fewer general side effects

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).

There are no disadvantages that I am aware of.

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

I speak with many patients who are constantly worried about all aspects of their anticoagulation therapy – from their diet to being able to access regular blood tests; all look to this new technology as a safe, more efficient alternative which will vastly improve their own safety and quality of life. I am not aware of any difference in opinion in this.

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?

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Groups who would do especially well include:

- 1) sufferers from extreme side effects from current medication, including hair loss and diarrhoea. They may be at high risk of stroke, yet cannot tolerate the current medications
- 2) patients who have issues with the extreme management required
- 3) anyone attempting to maintain a family/work life balance, especially younger patients
- 4) maintaining acceptable therapeutic levels can be a key problem for the elderly. This would remove them from this by reducing the number of drugs administered

the minority of individuals who cope well with the current technology would benefit slightly less than others.

Comparing the technology with alternative available treatments or technologies

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

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

AF patients are assessed using the CHADS2 system. Any at particular risk of suffering a stroke (score 1 or 2 and above) would be advised to take warfarin, unless other symptoms contradict this. Warfarin can, in ideal conditions, offer between 64%-70% reduction in likelihood of stroke.

Warfarin is by no means an easy or suitable treatment for many patients. Firstly, it can present unpleasant side effects and even be dangerous to those who have previously experienced bleeds.

Secondly, the management needed to maintain correct levels is hugely inconvenient to both the patient and the NHS. Thirdly, if therapeutic levels become unsettled, dangers for the patient include continued risk of stroke or serious risk of bleed. Fourthly, maintaining the correct therapeutic levels is almost impossible due to the medication's interaction with almost everything. Fifthly frequent blood tests are required to sustain INR levels. Finally, patients are often unhappy taking what they see as a toxin, and also for all the reasons above.

Patients who suffer from only a very mild risk of stroke are eligible to take aspirin. Unfortunately, this is not suitable for those with a history of stomach bleeds or ulcers, (it can also cause these) and only reduces the risk of stroke by 20%, leaving the patient vulnerable.

(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)

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Single Technology Appraisal of dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation

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- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

trials suggest that the advantages from the new technology include:

- when given in the lower dosage it is at least as good as warfarin at reducing stroke. In a higher dosage, it exceeds it.
- Side effects are apparently non-existent and, unlike warfarin, it does not interact with any food, drink or medication
- monitoring can be hugely reduced
- unlike warfarin which can easily place a person at risk of a dangerous bleed, the new technology is extremely safe.
- Fewer tests ease the burden on patients juggling commitments with work and family
- Much easier for patients with mobility / transport problems.
- Cost to patients for travel is reduced.
- NHS clinics will have a reduced workload
- Because the interaction with food and drink is gone, patients can easily maintain a healthy diet rich in vegetables.
- Travelling abroad can be done more safely.

(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).

There are no disadvantages 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.

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As this is not currently available to AF patients, I am not aware of anyone using it.

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

I am not aware of any.

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.

No

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?

Making this new technology available on the NHS would help in the following ways:

- the new treatment is safer and easier to take than existing medications. It is also more effective at reducing the risk of stroke.
- Individuals could feel in control of their therapy. Additionally, the frequent worry of interaction with food and drink from warfarin would be removed.
- Ease of administering and managing be far better for patients.
- Warfarin is widely disliked for its side effects and complicated nature, so providing patients with this new technology would be hugely beneficial.
- Efficiency would be increased as the new medication can be administered by a GP

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

Due to warfarin's unpleasant side effects, it is estimated that 50% of AF patients do not take anticoagulation medication, despite a clear need for it. Many cannot tolerate the medicine; others are unwilling to sacrifice their daily lives to the demands of warfarin. These patients are at high risk of a stroke.

Two thirds of those who suffer a stroke due to AF die in the first year. Those lucky enough to survive frequently suffer from the debilitating consequences. Their families and others around them are obviously also significantly affected.

- Should this medication not be approved, many will continue to remain at an increased danger of stroke.
- Without even beginning to estimate costs to families, a stroke requires immediate treatment costing £44,000. The NHS and UK economy struggle to deal with this massive expense.
- Death rates for AF induced strokes will remain high without the new technology
- Quality of life for AF patients will continue to be severely impaired without this new technology.
- The risk of falling outside therapeutic levels will continue to place AF patients at risk of the serious consequences.

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

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I am unaware of groups who may have difficulties using this technology.

Other Issues

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

AF patient's needs are not currently met in the appropriate way as the services are overburdened. It is not unusual for an appointment at the INR clinic to be just a few minutes and yet during this time blood has to be taken and questions / guidance responded to.

Too often patients have or are aware of others who have suffered severe bleeds due to falling outside of therapeutic levels. This causes great anxiety and fear over existing options (warfarin) and discourages too many from using suitable anticoagulation therapy.

As this technology is so much easier to manage and far less of a burden on medical staff, this medication will be hugely beneficial to all involved in reducing stroke in AF patients.

As more people live longer and survive conditions, the number of AF sufferers grows rapidly, the new technology would ensure that the risk of stroke can now be appropriately and effectively addressed.

I urge you to consider this technology favorably.