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: **Heart Rhythm UK**

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)

  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).

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.

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

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

Firstly, it offers 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, dabigatran offers the opportunity for effective anti-coagulation without the need for clinic attendance. Potentially this would have a major impact on prevention of stroke due to AF in the elderly. Almost 50 % of patients at high risk of stroke who might benefit from anti-coagulation are currently not treated. One of the commonest reasons cited for not anti-coagulating this group of patients relate to the logistic difficulties of anti-coagulant clinic attendance.

The drug is also likely to offer a specific advantage in patients who experience specific side effects on warfarin (i.e. side effects not related to anti-coagulation).

(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.

Through extending effective anti-coagulant control to the above groups, the drug has the potential for a major population benefit in stroke prevention.

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 is a slightly increased risk of myocardial infarction in the RELY study together with an increase in gastrointestinal side effects in comparison with warfarin.

Lack of a readily available antidote to anti-coagulation as in the case of warfarin.

The potential lack of interaction of anti-coagulated patients with medical personnel currently provided by anti-coagulant clinics

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

None that we are aware of.

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?

As stated above, patients likely to derive greatest benefit are those who have poor anti-coagulant control on warfarin or who would find it difficult to attend an anti-coagulant clinic.

Patients with existing good anti-coagulant control with optimal time in therapeutic range are likely to benefit less, if at all, in terms of stroke prevention, althought they would benefit from the greater convenience.

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.

Warfarin. Less commonly phenindione.

Aspirin should not be considered as an alternative as it is much less effective than formal anti-coagulation in stroke prevention in AF

(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.)

As described above, advantages of improved anti-coagulant control in patients with poor control on warfarin and improved access to care in patients with difficulty in attending an anti-coagulant clinic.

(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).

As above, disadvantages of possibility of greater incidence of myocardial infarction and reduced opportunity for interaction with medical personnel.

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.

The drug is currently not as yet in use in the NHS in the treatment of AF.

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

Not yet in routine NHS use for AF.

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?

Reduction in incidence of stroke due to AF, through improved quality of anti-coagulation and improved uptake of anti-coagulant care.

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

A missed opportunity for stroke reduction

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

As for warfarin, there will be groups of patients in whom dabigatran is contra-indicated on account of bleeding risk.

Other Issues

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

The possible impact of introduction of the drug on anti-coagulant clinics, which will need to be maintained if only to care for patients with other indications for anti-coagulation.