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: Diane Eaton

Name of your organisation:
Anticoagulation Europe

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) Patient representative for ACE**

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.

Prevention of strokes and systemic embolism in atrial fibrillation

Alternative therapeutic option to current anticoagulant Warfarin

(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.

Benefits:

Dispense with monitoring INR regularly
Unlike warfarin – will not need to be monitored by taking venous samples – avoid pains, discomfort and physical outcomes of regular blood tests(bruising)

Less time spent at Anticoagulation clinics in primary and secondary care

Will reduce strokes – minimise costs for caring with stroke suffers

Safety for patients – especially those at moderate to high risk

Less interaction with foods

Reduce bleeding incidences – reduces hospital admission

Taken orally

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).

Non –reversible at present – no antidote

No physical monitoring required – patients will need to be re/educated and assured

Compliance – will patients take the drug? Currently, warfarin requires INR testing which indicates anticoagulants are being taken. Possible challenge that some patients may not take this medication regularly?

Side effects – Dyspepsia

Half life of 12 – 17 hours – needs to be taken 2x daily

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

Existing warfarin users may need to be educated in how the drug works in order to understand why it doesn't need to be monitored as stringently as warfarin.

At risk patients (AF) may be more likely to take this drug knowing that it doesn't need monitoring and doesn't interact with other foods and medications

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 are warfarin intolerant.**
- **Those who are needle phobic**
- **Vulnerable patients who need carers to manage monitoring**
- **Those who's lives are greatly inconvenienced by regularly INR monitoring – a constant reminder of their state of health**
- **Those who do not take warfarin regularly and don't attend clinics**

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.

No treatment or prescribing warfarin

(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.)

- **Oral medication – easy to take**
- **No monitoring – dispenses with hospital and clinic visits. Advantage of non-invasive collection of venous blood sampling**
- **No known food interactions**
- **Reduction in bleeding**
- **Patient empowerment – psychologically assists with management of chronic condition**

(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).

- **Non reversible at present**

- **Possibly may not be able to monitor 'no-show' patients or assess whether they are taking medication regulary as would have been the case if they were attending an A/C clinic**

- **Side effects – may need supplemental medicines to help with Dyspepsia?**

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.

• Familiar with RE-LY trial and outcomes only
Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?
• As above
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?

- **This technology will revolutionise the way in which patients receive and manage their conditions.**
- **By removing regular INR monitoring, reducing the risk of food interactions, reducing bleeds or risking further thrombotic incidences by being outside of range, has to be beneficial to patients.**

- **The assessment, treatment and aftercare associated with an anticoagulated patient will in cost and time values be reduced.**

- **The patient will benefit from reducing necessary interactions with medics and thus be more empowered with looking after themselves therapeutically by taking medication daily with no need for venous sampling.**

- **It will allow vulnerable patients(elderly and young) to manage their own treatment with minimal support(dispensing of medications) and external intervention(where possible)**

- **Disclosed side affects (dyspepsia) from Dabigatran are lesser than risk of bleed and further thrombotic events due to rigour of staying in INR target**

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

Affect the patients in terms of:

- **Protection of the individual …**
- **Prevent lowering risk of stroke or embolisms in moderate to high risk patients**

- **Ethically improper not to allow patients to have an option/comparator to consider as treatment when extensive trial RE-LY has been undertaken and the results show that this is an alternative and new development for the future of all current and potential patients at risk and requiring anticoagulant therapy**

- **Minimise costs in terms of inconvenience, actual costs of attending clinics and well- being of patients who wish to manage their lives without the necessity of having intense and intrusive medical intervention and management.**
- **Unnecessary pain and distress caused by regular venous sampling.**

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

Only patients that may be affected by known side effects of Dypepsia

Other Issues

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

- Having reviewed the results of the RE-LY TRIAL(BoehringerIngleheim), it is noted that this drug can significantly reduce the risk of stroke and systemic embolism by 34% in patients with AF as compared to well – controlled warfarin. (dosage 150mg) The lower dose of 110mg demonstrated similar reductions in Stroke and systemic embolisms whilst reducing incidents of major bleeds by 20%
- The drug is administered orally, requires no monitoring and has minimal side effects as reported
- Patients previously unable to take Warfarin due to risk factors will now be provided with a drug which may prevent incidences and reduce mortality or incapacity.
- Associated costs when treating patients who suffer a bleed or thrombotic incident, assessment, in-patient and out –patient treatment and extended support by carers.
- Patients and Medical profession can make informed decisions on the correct and appropriate therapy from all drug options available

Connolly SJ, Ezekowitz MD, Yusuf S. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. N Eng J Med 2009; 361. Pubished online 30 August 2009