Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Ivabradine for the treatment of chronic heart failure

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: British Association for Nursing in Cardiovascular Care

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? X
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?
- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

NICE Clinical Guidance 108 (Chronic Heart Failure) advocates that all patients be considered for first line treatment with ACE I and betablockers unless contraindicated or not tolerated.

Currently, Ivabradine is the only alternative heart rate lowering agent available for patients with left systolic dysfunction (LVSD), and in sinus rhythm, symptomatic and on optimal dose of ACE I or ARB whom betablockers are contraindicated or less tolerated.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

There is a potential risk that too early adoption of this technology might prevent improved use of betablockers.

In the light of concern that use of betablockers remain sub optimal, the NICE (2010) Partial update (Management of Chronic heart Failure) added a new recommendation that such drugs could be used in a variety of patients including older adults and those with peripheral vascular disease, erectile dysfunction, diabetes mellitus, chronic obstructive pulmonary disease without reversibility.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
Ideally, specialist clinics (such as Heart Failure Clinic/Cardiology clinic , regardless where these clinics are based) , where patient is receiving regular follow up for their heart failure from specialist team so as closer monitoring of these patients can take place especially when initiating and titrating of doses take place.

Strict criteria for selection of patients needs to be in placed.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?
Has already licensed in treatment of Angina.
Recently licensed in treatment of chronic heart failure.

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Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

NICE (2010) Partial update (Management of Chronic Heart Failure)

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

It should be noted that only one study (SHIFT trial) currently supports its use for this indication. Ace inhibitors and betablockers should still be the first line treatments, as both are supported by wealth of data demonstrating reduced mortality in addition to reduction in hospital admissions. Strict criteria need to be in placed to ensure that these drugs are fully optimised before considering initiation of Ivabradine.

It's a novel treatment and so there's no comparator.

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There is no evidence regarding the use of Ivabradine in patients with devices in situ.

Ideally, patients are under the care of specialist team for management of their heart failure. Strict criteria needs to be in place for selection of patients.

As mentioned above, there is a potential risk that too early adoption of this technology might prevent improved use of betablockers. Hence, the importance of this technology to be initiated and monitored by specialist team managing the patient's heart failure.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Equality
Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?