Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID483]

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: Clinical Leaders of Thrombosis

Are you (tick all that apply):

X 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)?

Education Secretary, Clinical Leaders of Thrombosis

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

DVT and PE are currently usually treated with a 3-6 month course of anticoagulation, typically warfarin and low molecular weight heparin in combination at first and warfarin subsequently once the INR is stable. This method has the disadvantages of daily injections of LMWH and regular INR checks and dose adjustments for the warfarin.

Dabigatran has the advantage of not requiring regular testing and can be given at a standardised dose. This could be advantageous in speeding-up hospital discharges. However there may be questions over its use in patients who are very elderly or have cancer or impaired renal function who are more sensitive to its effects to the typical patient. Severely obese patients also are not recommended for treatment with Dabigatran. Patients with a history of GI bleeds will not be suitable for Dabigatran therapy. Patients who are non-compliant with their medication will not be protected, as there are no regular checks to assess this as there are with warfairn.

Dabigatran could be used in both primary and secondary care and in DVT clinics. Guidance and counselling regarding its use and any side-effect monitoring could be given by trained healthcare professionals (HCP). It is envisaged that this could be carried out by the same staff already dealing with VTE at present. It is already in use for post-operative DVT prophylaxis and for stroke prevention in AF in some areas.

The advantages and disadvantages of the technology

Dabigatran will represent an advantage in that the need for injections of LMWH and the regular monitoring of INR will not be required. However patients will still require blood tests for renal function and counselling regarding the use of the drug. Patients should carry an alert card to notify medical staff that they are taking an antiocoagulant.

Clinical trials of Dabigatran showed that 150mg bd was superior to warfarin ad 110mg bd was non-inferior to warfarin. However the clinical trials may not represent the situations that are found in UK clinical settings. For example, patients have issues with cognition and compliance, those who have co-morbidities, patients >80yrs and those who take drugs that may interact with Dabigatran will not benefit from the therapy in the same way as the trial subjects. They may be at risk of bleeding or thrombosis.

A further concern is that patients may be lost to follow up once they complete their course of medication. There may be patients who require input from a Haematologist for example if there is any indication that they have a recurrence of VTE or may have an underlying thrombophilia which has not been picked up on at initial diagnosis. Such patients would benefit from long-term anticoagulation therefore a final consultation with a HCP before discontinuing dabigatran would be advisable.

A major disadvantage is that there are still no routine laboratory tests in place in most hospitals to monitor Dabigatran levels in plasma should an overdose be suspected and no definitive antidote or protocol for rapid reversal of bleeding should this occur.

Any additional sources of evidence

No additions.

Implementation issues

Healthcare professionals will need to be aware that patients requiring surgery or emergency treatment may be on Dabigatran and will need to be treated appropriately. This represents an educational and training need for staff.

Protocols will need to be developed that cover the reversal of anticoagulation in case of major bleeds or emergency surgery. Hospitals may need to consider their requirement to stock reversal agents such as PCC, rFVIIa or FEIBA.

GP's will need to be aware of issues such as medication interactions that may affect their patients on Dabigatran.

Patients on Dabigatran would be best catered for under the care of the anticoagulant service for advice and monitoring if needed.

Equality

No issues