

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of NICE Technology Appraisal no. 170; Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults

This guidance was issued April 2009 with a review date of February 2012.

Background

At the GE meeting of 14 February 2012 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	<p>NICE has published a clinical guideline CG92 'Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery'. Although the clinical guideline does not reproduce the wording of TA170 verbatim, the recommendation has been effectively incorporated in that rivaroxaban is included in the list of options for pharmacological VTE prophylaxis after surgery in both elective hip and elective knee replacement. The related technology appraisal, TA157 on dabigatran etexilate for the same indication has been incorporated into the guideline in the same way and was moved to the static list in August 2011.</p> <p>There is no new evidence to suggest that the recommendations of TA170 should change nor any ongoing trials of rivaroxaban that might be expected lead to a change in the recommendations. There has been no relevant change to the price of rivaroxaban (it is now cheaper than it was at the time TA170 was developed).</p> <p>Based on this information, it is proposed that the guidance is placed on the static list until a decision is made</p>

	to update CG92. Moving TA170 to the static list means that the Technology Appraisal guidance will remain extant alongside the clinical guideline. This has the effect of preserving the funding direction. The review decision date for the clinical guideline is January 2013. If it is decided that the clinical guideline should be updated, then a new proposal for TA170 (and the related guidance TA157) can be developed during the pre-scoping stages of that guideline.
--	--

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be transferred to the 'static guidance list' ¹ .
--	---

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Anticoagulation Specialist Association	Agree	Anticoagulation Specialist is in agreement with NICE's proposal to move guidance to the static list because the latest information on the use of Rivaroxaban in AF and DVT does not change the use for prophylaxis in orthopaedic.	Comment noted. No action required.

¹ Guidance is placed on the static list when it is clear that there is no new research available that would have any material effect on the current guidance. Topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on the last guidance issued.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Healthcare Improvement Scotland	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to place this guidance on the static list.	Comment noted. No action required.
Royal College of Nursing	No comment	Nurses working in this area were invited to comment on the proposals to move this guidance to the static list. The feedback received suggests that they are not aware of any new evidence at this stage to warrant the review of this guidance. There are therefore, no further comments to make on behalf of the Royal College of Nursing regarding the proposal to move to this guidance to the static list.	Comment noted. No action required.

No response received from:

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> • Bayer Schering (rivaroxaban) <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> • Action Heart • Afiya Trust • Anticoagulation Europe • Black Health Agency • Blood Pressure Association • British Cardiac Patients Association • British Hip Society 	<p><u>General</u></p> <ul style="list-style-type: none"> • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service • Department of Health, Social Services and Public Safety for Northern Ireland • Medicines and Healthcare Products Regulatory Agency • National Association of Primary Care • National Pharmacy Association • NHS Alliance
--	--

- British Lung Foundation
- Counsel and Care
- Different Strokes
- Equalities National Council
- Heart Care Partnership UK
- HEART UK
- Lifeblood: The Thrombosis Charity
- Muslim Council of Britain
- Muslim Health Network
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Stroke Association

Professional groups

- Association of British Neurologists
- Association of Surgeons of Great Britain and Ireland
- British Association for Nursing in Cardiac Care
- British Association for Services to the Elderly
- British Association for Surgery of the Knee
- British Association of Stroke Physicians
- British Cardiovascular Society
- British Cardiovascular Intervention Society
- British Geriatrics Society
- British Heart Foundation
- British Hypertension Society
- British Lung Foundation
- British Orthopaedic Association
- British Society for Haematology
- British Society for Haemostasis and Thrombosis
- British Thoracic Society

- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Comparator manufacturer(s)

- Archimedes Pharma (bemiparin sodium)
- GlaxoSmithKline (fondaparinux sodium)
- Leo Laboratories (tinzaparin sodium)
- Pfizer Ltd (dalteparin sodium)
- Sanofi-Aventis Ltd (enoxaparin sodium)
- Valeant Pharmaceuticals Ltd (reviparin sodium)
- Boehringer Ingelheim Ltd (dabigatran etexilate)

Relevant research groups

- Antithrombotic Trialists' (ATT) Collaboration
- British Society for Cardiovascular Research
- British Stroke Research Group
- Cochrane Heart Group
- Cochrane Peripheral Vascular Disease Group
- Cochrane Stroke Group
- MRC Clinical Trials Unit
- National Heart Research Fund
- National Institute for Health Research
- Oxford Stroke Prevention Research Unit
- Research Institute for the Care of Older People
- Thrombosis Research Institute
- Safe Implementation of Treatments in Stroke(SITS)
- UK Stroke Research Network
- Wellcome Trust Cardiovascular Research Initiative

- British Vein Institute
- Clinical Leaders of Thrombosis (CLOT)
- College of Emergency Medicine
- Coronary Prevention Group
- National Association of Primary Care
- National Heart Forum (UK)
- Primary Care Cardiovascular Society
- Primary Care Neurology Society
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Physicians (Cardiology Committee & Intercollegiate Stroke Working Party)
- Royal College of Surgeons
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Royal Society of Medicine - Forum on Intellectual Disabilities
- Royal Society of Medicine's Cardiothoracic Section
- Society for Cardiological Science and Technology
- Society for Vascular Technology
- Society of British Neurological Surgeons
- Society of Cardiothoracic Surgeons of Great Britain and Ireland
- Society of Vascular Nurses
- United Kingdom Clinical Pharmacy Association
- Vascular Society

Others

- Department of Health

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline groups

- National Clinical Guidelines Centre

Associated Public Health groups

- None

- | | |
|---|--|
| <ul style="list-style-type: none">• NHS Camden• NHS Middlesbrough• Welsh Government | |
|---|--|

GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Richard Diaz

Project Manager: Andrew Kenyon

18 April 2012