

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing

1.1 Short title

Venous thromboembolic diseases

2 The remit

The Department of Health has asked NICE: 'to produce a clinical guideline on the management of venous thromboembolic diseases, including use of thrombophilia testing'.

3 Clinical need for the guideline

3.1 Epidemiology

- a) Venous thromboembolism is a term used to describe a blood clot in a vein (a thrombus) that may dislodge from its site of origin to travel in the blood (called an embolism). The process of the thrombus forming is called 'thrombosis'. A thrombus most commonly occurs in the deep veins of the legs or pelvis; this is called a deep vein thrombosis (sometimes called a DVT). Venous thromboembolism includes both DVT and pulmonary embolism.
- b) Thrombophilia is an abnormal tendency for the blood to clot, which can cause venous thromboembolism in some people. Some types of thrombophilia are inherited, others develop later in life.
- c) Venous thromboembolic diseases cover a spectrum ranging from asymptomatic calf vein thrombosis to symptomatic DVT, which may

lead to a potentially fatal pulmonary embolism (when the clot blocks the blood supply to the lungs).

- d) Non-fatal venous thromboembolism may produce long-term illness, including chronic venous insufficiency. This is a condition that may cause venous ulceration and development of a post-thrombotic limb (chronic pain, swelling and skin changes in the affected limb following a DVT).
- e) The Hospital Episodes Statistics for 2008/09 reported 56,029 finished consultant episodes (that is, periods of care under a consultant within an NHS trust) of pulmonary embolism in England.
- f) An epidemiological model using extrapolation from European data for 2004 suggested that almost three quarters of all venous thromboembolism-related deaths were from hospital acquired venous thromboembolism.
- g) Risk factors for venous thromboembolism include a history of DVT, age over 60 years, surgery, obesity, prolonged travel, acute medical illness (including cancer), immobility, thrombophilia and pregnancy.

3.2 *Current practice*

- a) The current standard practice for treatment of venous thromboembolism is anticoagulation. There is a wide variation in practice, but patients are usually given a brief course of heparin treatment while they start on a 3–6 month course of warfarin. Patients who have had recurrent venous thromboembolism are often given life-long treatment with anticoagulants.
- b) There is a wide variation in practice as to when to test for thrombophilia in patients who have had a venous thromboembolism and controversy as to how thrombophilia should be managed. Guidance is needed to determine whether patients should have thrombophilia testing after a venous thromboembolism.

- c) People with cancer may need special advice on how to manage venous thromboembolism.
- d) NICE has published guidance on 'Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital' (2010). SIGN has published guidelines on prophylaxis of venous thromboembolism (2002) and antithrombotic therapy (1999).
- e) There is a need for guidance on the diagnostic tests used for the assessment of venous thromboembolism and the management of venous thromboembolic diseases.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) Adults (18 years and older) with a suspected or confirmed DVT or pulmonary embolism.
- b) Within this population, the following groups have been identified as requiring special consideration:
 - people with cancer
 - people who misuse intravenous drugs.

- residents of nursing homes and people with physical disabilities who have restricted movement following a venous thromboembolism
 - people with learning disabilities who require long-term medication taken at home.
- c) First-degree relatives of people with inherited thrombophilia and venous thromboembolic diseases.

4.1.2 Groups that will not be covered

- a) Children and young people (younger than 18 years).
- b) Pregnant women.

4.2 *Healthcare setting*

- a) Primary, secondary and tertiary settings.

4.3 *Clinical management*

4.3.1 Key clinical issues that will be covered

- a) Diagnostic tests for initial assessment of suspected venous thromboembolism.
- b) Interventions to manage venous thromboembolic diseases, including:
- mechanical:
 - vena caval filters
 - compression stockings
 - pharmacological:
 - unfractionated heparin
 - low molecular weight heparin
 - heparinoids
 - synthetic pentasaccharides, such as fondaparinux
 - oral anticoagulants, such as warfarin.

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

- c) Thrombolytic therapy including pharmaco-mechanical thrombolysis.
- d) The duration of treatment.
- e) Screening for undiagnosed malignancy in people with spontaneous venous thromboembolism.
- f) Self-monitoring by patients on pharmacological treatment.
- g) Thrombophilia testing for patients after a previous venous thromboembolism and for first-degree relatives of people with inherited thrombophilia and venous thromboembolic diseases.
- h) Information and support for patients and carers.

4.3.2 Clinical issues that will not be covered

- a) Prophylaxis against venous thromboembolism.
- b) Deep vein thrombosis in the arms.
- c) Cerebral vein thrombosis.
- d) Splanchnic thrombosis.
- e) Retinal vein thrombosis.

4.4 Main outcomes

- a) Mortality related to venous thromboembolism.
- b) All cause mortality.
- c) Symptomatic DVT.

- d) Asymptomatic DVT.
- e) Symptomatic pulmonary embolism.
- f) Asymptomatic pulmonary embolism.
- g) Composite venous thromboembolism (composite of recurrent, symptomatic, non-fatal DVT or pulmonary embolism and mortality).
- h) Recurrent venous thromboembolism rates.
- i) Major bleeding.
- j) Minor bleeding.
- k) Quality of life (validated quality of life scores only).
- l) Post thrombotic syndrome.
- m) Chronic thromboembolic pulmonary hypertension.
- n) Heparin induced thrombocytopenia.
- o) Diagnostic accuracy.
- p) Length of hospital stay.

4.5 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually only be from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in June 2011.

5 Related NICE guidance

5.1 Published guidance

- Venous thromboembolism: reducing the risk. NICE clinical guideline 92 (2010) (update of NICE clinical guideline 46). Available from www.nice.org.uk/guidance/CG92
- Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults. NICE technology appraisal guidance 170 (2009). Available from www.nice.org.uk/guidance/TA170
- Medicines adherence. NICE clinical guideline 76 (2009). Available from www.nice.org.uk/guidance/CG76
- Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults. NICE technology appraisal guidance 157 (2008). Available from www.nice.org.uk/guidance/TA157

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website)

- Apixaban for the prevention of venous thromboembolism in people undergoing elective knee and hip replacement surgery. NICE technology appraisal guidance. Publication date to be confirmed.

The following guidance will be incorporated if it is completed in time for publication of this guideline.

- Dabigatran etexilate for the treatment of acute venous thromboembolic events. NICE technology appraisal guidance. Publication date to be confirmed.

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website

(www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).