

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (update)

This guideline will partially update the NICE guideline on venous thromboembolic diseases: diagnosis, management and thrombophilia testing (CG144).

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

This guideline will also be used to update the NICE [quality standard](#) for venous thromboembolism in adults: diagnosis and management.

Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance report](#).

As part of the scoping process, NICE has also been asked to consider evidence in 2 areas that were not included in the surveillance report. These areas are point-of-care D-dimer testing and the use of pulmonary embolism rule-out criteria (PERC).

Point-of-care D-dimer tests to diagnose deep vein thrombosis (DVT) and pulmonary embolism (PE) are now available. If they are accurate and reliable, their use might increase early diagnosis in the community, and reduce both hospital transfers and length of stays in acute care hospital areas. Guidance on the use of these tests is needed.

Since the existing guideline was published, further research has become available on the use of PERC to identify people with a low likelihood of PE for whom invasive diagnostic testing might be safely avoided. Guidance on PERC is needed to help clinicians identify these people and reduce unnecessary testing.

Why the guideline is needed

Key facts and figures

In venous thromboembolism (VTE) a blood clot forms in a vein, usually one of the deep veins in the legs or pelvis. This is known as deep vein thrombosis (DVT). The clot can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism (PE). The term 'VTE' includes both DVT and PE. VTE can be fatal or cause long-term conditions such as post-thrombotic syndrome or chronic thromboembolic pulmonary hypertension.

Each year in the UK 1 to 2 people in every 1,000 has a VTE. The annual incidence of VTE rises with age, from around 1 in every 10,000 people aged under 40 to 1 in every 100 people aged over 80. Every year around 25,000 people in England develop a DVT in hospital that leads to a fatal PE.

Current practice

Diagnosis of DVT and PE is based on symptoms and signs, a two-level Well's score, a blood test to check for D-dimer and imaging. New evidence has indicated an increase in false positive D-dimer test results with increasing age. Age-adjusted D-dimer testing might reduce the need for imaging, particularly for people aged over 50.

Pharmacological treatment options for diagnosed PE and DVT include low molecular weight heparin, fondaparinux, unfractionated heparin and a vitamin K antagonist. Non-vitamin K oral anticoagulants (NOACs) are also used to prevent and treat PE and DVT. Uncertainties have been raised about the optimum timing and duration of pharmacological treatment.

In the past, most PE was treated in hospital but treatment in ambulatory care units has increased. There is evidence to suggest that people with PE and a low risk of adverse events can now be safely treated in an outpatient setting.

People aged over 40 with a first unprovoked VTE and no signs or symptoms of cancer are offered at CT of the abdomen and pelvis (and a mammogram for women). However new evidence indicates that this does not improve diagnosis of cancer or reduce death from cancer in these people.

Who the guideline is for

This guideline is for:

- healthcare professionals in primary and secondary care
- commissioners and providers of venous thromboembolic disease services
- people with suspected or diagnosed VTE, their families and carers, and the public.

It may also be relevant for voluntary organisations and patient support groups.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to disability and gender reassignment.

What the updated guideline will cover

Who is the focus?

Groups that will be covered

- Adults (18 and older) with suspected or confirmed DVT or PE.

Specific consideration will be given to:

- People with cancer.
- Older people.
- People who have restricted movement.
- People in nursing and care homes.
- People with learning disabilities.
- People with obesity III (a BMI of 40 kg/m² or more).
- People who have stage 3 to 5 chronic kidney disease.

Groups that will not be covered

- Pregnant women.

Settings

The guideline will cover all settings where NHS-funded care is provided. This includes outpatient settings, for example ambulatory care units, which are not covered in the existing guideline.

Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in these areas only.

Note that guideline recommendations for medicines 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 medicine's summary of product characteristics to inform decisions made with individual patients.

1. Diagnosing deep vein thrombosis.
 - Age-adjusted D-dimer tests for DVT.
 - Point-of-care D-dimer testing for DVT.
 - Pharmacological treatment for suspected DVT.
2. Diagnosing pulmonary embolism.
 - Pulmonary embolism rule-out criteria (PERC).
 - Age-adjusted D-dimer tests for PE.
 - Point-of-care D-dimer testing for PE.
 - Pharmacological treatment for suspected PE.
3. Treating confirmed deep vein thrombosis or pulmonary embolism.
 - Pharmacological treatment for confirmed DVT.
 - Pharmacological treatment for confirmed PE.
4. Investigations for cancer.
 - Investigations for cancer in people with unprovoked VTE.
5. Outpatient treatment for PE.
 - Outpatient treatment for people with low-risk suspected or confirmed PE.
6. Follow-up for deep vein thrombosis or pulmonary embolism.
 - Duration of pharmacological treatment for DVT or PE.

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plans to do for each area in this update.

Area in the guideline	What NICE plans to do
1.1 Diagnosis	
Diagnostic investigations for DVT	<p>Review evidence and update existing recommendations as needed in these areas:</p> <ul style="list-style-type: none"> • D-dimer testing, to include age-adjusted thresholds • pharmacological treatment for suspected DVT. <p>Review evidence in new area:</p> <ul style="list-style-type: none"> • point-of-care D-dimer testing. <p>Retain all other recommendations in this section.</p>
Diagnostic investigations for PE	<p>Review evidence and update existing recommendations as needed in these areas:</p> <ul style="list-style-type: none"> • D-dimer testing to include age-adjusted thresholds • pharmacological treatment for suspected PE. <p>Review evidence in new areas:</p> <ul style="list-style-type: none"> • point-of-care D-dimer testing • pulmonary embolism rule-out criteria (PERC). <p>Retain all other recommendations in this section.</p>
1.2 Treatment	
Pharmacological interventions for DVT and PE	<p>Review evidence and update existing recommendations as needed in this area:</p> <ul style="list-style-type: none"> • pharmacological treatment for confirmed DVT and PE. <p>Incorporate or cross-refer to relevant NICE technology appraisal guidance on pharmacological treatment for confirmed DVT and PE</p>
Thrombolytic therapy for DVT and PE	No evidence review: retain recommendations from existing guideline
Mechanical interventions for proximal DVT and PE	No evidence review: retain recommendations from existing guideline
Outpatient treatment for suspected or confirmed PE	Review evidence: new area in guideline
1.3 Patient information	

Patient information	No evidence review: retain recommendations from existing guideline
1.4 Self-management and self-monitoring for patients treated with a vitamin K antagonist	
Self-management and self-monitoring for patients treated with a vitamin K antagonist	No evidence review: retain recommendations from existing guideline
1.5 Investigations for cancer	
Investigations for cancer	Review evidence and update existing recommendations in this area: <ul style="list-style-type: none"> investigations for cancer in people with unprovoked VTE who are not already known to have cancer. Cross-refer to the NICE guideline on suspected cancer (NG12) as needed
1.6 Thrombophilia testing	
Thrombophilia testing	No evidence review: retain recommendations from existing guideline
Follow-up	
Follow-up: factors that determine the optimum duration of pharmacological treatment for DVT or PE	Review evidence: new area in guideline

Recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

Areas not covered by the guideline

These areas will not be covered by the guideline.

1. Prophylaxis against venous thromboembolism.
2. Deep vein thrombosis in the arms, cerebral vein thrombosis, splanchnic thrombosis, retinal vein thrombosis, superficial vein thrombosis and subsegmental pulmonary embolism.

Related NICE guidance

Published

- [Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism](#) (2018)
NICE guideline NG89

- [Suspected cancer: recognition and referral](#) (2015; updated 2017) NICE guideline NG12
- [Ultrasound-enhanced, catheter-directed thrombolysis for pulmonary embolism](#) (2015) NICE interventional procedure guidance 524
- [Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis](#) (2015) NICE interventional procedure guidance 523
- [The geko device for reducing the risk of venous thromboembolism](#) (2014) NICE medical technologies guidance 19
- [Apixaban for the prevention of venous thromboembolism after total hip or knee replacement in adults](#) (2012) NICE technology appraisal guidance 245
- [Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults](#) (2009) NICE technology appraisal guidance 170
- [Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults](#) (2008) NICE technology appraisal guidance 157

In development

- [Betrixaban for preventing venous thromboembolism in people hospitalised for acute medical conditions](#) NICE technology appraisal guidance. Publication date to be confirmed.

NICE guidance that will be reviewed and may be incorporated unchanged in this guideline

- [Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism](#) (2015) NICE technology appraisal guidance 354
- [Apixaban for the treatment and secondary prevention of deep vein thrombosis and/ or pulmonary embolism](#) (2015) NICE technology appraisal guidance 341
- [Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/ or pulmonary embolism](#) (2014) NICE technology appraisal guidance 327

- [Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism](#) (2013) NICE technology appraisal guidance 287
- [Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism](#) (2012) NICE technology appraisal guidance 261

NICE guidance that will be updated by this guideline

- [Venous thromboembolic diseases: diagnosis, management and thrombophilia testing](#) (2012, updated 2015) NICE guideline CG144

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to the diagnosis and management of venous thromboembolic diseases.

- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Medicines adherence](#) (2009) NICE guideline CG76

Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using a NHS and personal social services (PSS) perspective, as appropriate.

Key issues and draft questions

While writing the scope for this updated guideline, we have identified the following key issues and draft questions related to them:

1. Diagnosing deep vein thrombosis.

- 1.1 In people with suspected DVT, what is the diagnostic accuracy of age-adjusted D-dimer tests compared with D-dimer tests without age adjustment?
- 1.2 In people with suspected DVT, what is the diagnostic accuracy of point-of-care D-dimer tests compared with laboratory tests to identify DVT?
- 1.3 What is the clinical and cost effectiveness of different pharmacological treatments for people with suspected DVT prior to confirmed diagnosis?
2. Diagnosing pulmonary embolism.
 - 2.1 In people with suspected PE, what is the diagnostic accuracy of the pulmonary embolism rule-out criteria (PERC)?
 - 2.2 In people with suspected PE, what is the diagnostic accuracy of age-adjusted D-dimer tests compared with D-dimer tests without age adjustment?
 - 2.3 In people with suspected PE, what is the diagnostic accuracy of point-of-care D-dimer tests compared with laboratory tests to identify PE?
 - 2.4 What is the clinical and cost effectiveness of different pharmacological treatments for people with suspected PE prior to confirmed diagnosis?
3. Treating confirmed pulmonary embolism or deep vein thrombosis.
 - 3.1 What is the clinical and cost effectiveness of different pharmacological treatments for people with a confirmed diagnosis of DVT?
 - 3.2 What is the clinical and cost effectiveness of different pharmacological treatments for people with a confirmed diagnosis of PE?
4. Investigations for cancer.
 - 4.1 Do investigations for cancer in people with unprovoked VTE improve outcomes (morbidity and mortality)?
5. Outpatient treatment for PE.

5.1 What is the clinical and cost effectiveness of outpatient treatment for low-risk suspected or confirmed PE, and for whom is outpatient treatment safe?

6. Follow-up

6.1 What factors determine the optimum duration of pharmacological treatment for DVT or PE?

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- all-cause mortality
- VTE-related mortality
- recurrence of VTE
- length of hospital stay
- quality of life (both health- and social care-related quality)
- cancer-related morbidity
- adverse events.

NICE quality standards and NICE Pathways

NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- [Venous thromboembolism in adults: diagnosis and management](#) (2013)
NICE quality standard 29

NICE Pathways

When this guideline is published, we will update the existing NICE Pathway on [venous thromboembolism](#). NICE Pathways bring together everything NICE has said on a topic in an interactive flow chart.

Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in September 2019.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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