

1 anticoagulants (NOACs) for both prevention and treatment of PE and DVT.
2 These agents are now commonly given before a diagnosis of DVT has been
3 confirmed. However, evidence suggests that anticoagulant treatment might
4 impair the reliability of D-dimer test results. Guidance in this area is needed.

5 Uncertainties have also been raised about the timing of pharmacological
6 treatment for DVT. When given after a first scan the results of a repeat scan
7 may be impaired. If treatment is stopped too soon there is risk of a
8 suppressed calf vein clot extending.

9 When the existing guideline was published, most PE was treated in hospital.
10 Since then, treatment in ambulatory care units has increased. There is new
11 evidence to suggest that people with PE at low risk of adverse events could
12 be treated safely with anticoagulants in outpatient settings.

13 The existing guideline recommends that people aged over 40 with a first
14 unprovoked VTE and no signs or symptoms of cancer have CT of the
15 abdomen and pelvis (and a mammogram for women). However, new
16 evidence indicates that this CT does not improve diagnosis or reduce death
17 from cancer in these people.

18 ***Why the guideline is needed***

19 **Key facts and figures**

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

27 Each year in the UK around 1 to 2 people in every 1,000 has a VTE. The
28 annual incidence of VTE rises with age, from around 1 in every 10,000 people
29 aged under 40 to 1 in every 100 people aged over 80. Every year around
30 25,000 people in England develop a DVT in hospital that leads to a fatal PE.

1 **Who the guideline is for**

2 This guideline is for:

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

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

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

11 ***Equality considerations***

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

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

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

18 **What the updated guideline will cover**

19 ***Who is the focus?***

20 **Groups that will be covered**

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

22 Specific consideration will be given to:

- 23 • People with cancer.
- 24 • Older people.
- 25 • People who have restricted movement.

- 1 • People with learning disabilities.
- 2 • People with obesity III (a BMI of 40 kg/m² or more).
- 3 • People who have stage 3 to 5 chronic kidney disease.

4 **Groups that will not be covered**

- 5 • Pregnant women.

6 **Settings**

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

10 ***Activities, services or aspects of care***

11 **Key areas that will be covered in this update**

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

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

- 20 1. Diagnosing deep vein thrombosis.
 - 21 – Point-of-care D-dimer testing for DVT.
- 22 2. Diagnosing pulmonary embolism.
 - 23 – Age-adjusted D-dimer tests for PE.
 - 24 – Point-of-care D-dimer testing for PE.
- 25 3. Treating suspected pulmonary embolism or deep vein thrombosis.
 - 26 – Pharmacological interventions to manage suspected PE or DVT.
- 27 4. Treating confirmed pulmonary embolism or deep vein thrombosis
 - 28 – Pharmacological interventions to manage confirmed PE or DVT.
- 29 5. Outpatient treatment for PE.

- 1 – Outpatient treatment for people with low-risk suspected or confirmed
2 PE
- 3 6. Investigations for cancer.
- 4 – Investigations for cancer in people with unprovoked VTE who have a
5 previously undiagnosed cancer.
- 6 – cross reference to the NICE guideline on suspected cancer:
7 recognition and referral
- 8 7. Follow-up.
- 9 – Reviewing anticoagulant treatment.

10 **Proposed outline for the guideline**

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

13

Area in the guideline	What NICE plans to do
1.1 Diagnosis	
Diagnostic investigations for DVT	<p>Review evidence: update existing recommendations on pharmacological treatment of suspected DVT as needed. New area on point of care D-dimer testing</p> <p>No evidence review for existing recommendations: retain recommendations from existing guideline</p>
Diagnostic investigations for PE	<p>Review evidence: update existing recommendations relating to D-dimer testing to include age- adjusted thresholds; update existing recommendations on pharmacological treatment of suspected PE as needed. New area on point of care D-dimer testing</p> <p>Retain all other recommendations in this section</p>
1.2 Treatment	
Pharmacological interventions for DVT and PE	<p>Review evidence: update existing recommendations on pharmacological treatment of confirmed DVT and PE as needed</p> <p>Incorporate or cross-refer to relevant technology appraisal guidance on pharmacological treatment for confirmed DVT and PE as needed</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 of 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: update existing recommendations on investigations for cancer in people with unprovoked VTE who have previously undiagnosed cancer: update existing recommendations and cross reference to the NICE guideline on suspected cancer: recognition and referral as needed
1.6 Thrombophilia testing	
Thrombophilia testing	No evidence review: retain recommendations from existing guideline
1.7 Follow up	
Follow up	Review evidence on new area of what factors to consider when reviewing pharmacological anticoagulation

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

5 **Areas not covered by the guideline**

6 These areas will not be covered by the guideline.

- 7 1. Prophylaxis against venous thromboembolism.
8 2. Deep vein thrombosis in the arms, cerebral vein thrombosis, splanchnic
9 thrombosis and retinal vein thrombosis.

10 **Related NICE guidance**

11 **Published**

- 12 • [Suspected cancer: recognition and referral](#) (2015; updated 2017) NICE
13 guideline 12
14 • [Ultrasound-enhanced, catheter-directed thrombolysis for pulmonary
15 embolism](#) (2015) NICE interventional procedure guidance 524

- 1 • [Ultrasound-enhanced, catheter-directed thrombolysis for deep vein](#)
2 [thrombosis](#) (2015) NICE interventional procedure guidance 523
- 3 • [The geko device for reducing the risk of venous thromboembolism](#) (2014)
4 NICE medical technologies guidance 19
- 5 • [Apixaban for the prevention of venous thromboembolism after total hip or](#)
6 [knee replacement in adults](#) (2012) NICE technology appraisal guidance
7 245
- 8 • [Venous thromboembolism: reducing the risk for patients in hospital](#) (2010;
9 updated 2015) NICE guideline CG92
- 10 • [Rivaroxaban for the prevention of venous thromboembolism after total hip](#)
11 [or total knee replacement in adults](#) (2009) NICE technology appraisal
12 guidance 170
- 13 • [Dabigatran etexilate for the prevention of venous thromboembolism after](#)
14 [hip or knee replacement surgery in adults](#) (2008) NICE technology
15 appraisal guidance 157

16 ***In development***

- 17 • [Betrixaban for preventing venous thromboembolism in people hospitalised](#)
18 [for acute medical conditions](#) NICE technology appraisal guidance.
19 Publication expected September 2018

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

- 22 • [Edoxaban for treating and for preventing deep vein thrombosis and](#)
23 [pulmonary embolism](#) (2015) NICE technology appraisal guidance 354
- 24 • [Apixaban for the treatment and secondary prevention of deep vein](#)
25 [thrombosis and/ or pulmonary embolism](#) (2015) NICE technology appraisal
26 guidance 341
- 27 • [Dabigatran etexilate for the treatment and secondary prevention of deep](#)
28 [vein thrombosis and/ or pulmonary embolism](#) (2014) NICE technology
29 appraisal guidance 327
- 30 • [Rivaroxaban for treating pulmonary embolism and preventing recurrent](#)
31 [venous thromboembolism](#) (2013) NICE technology appraisal guidance 287

- 1 • [Rivaroxaban for the treatment of deep vein thrombosis and prevention of](#)
2 [recurrent deep vein thrombosis and pulmonary embolism](#) (2012) NICE
3 technology appraisal guidance 261

4 ***NICE guidance that will be updated by this guideline***

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

7 **NICE guidance about the experience of people using NHS services**

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

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

15 ***Economic aspects***

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

23 ***Key issues and draft questions***

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

- 26 1. Diagnosing deep vein thrombosis
27 1.1 What is the diagnostic accuracy of point-of-care D-dimer tests
28 compared with laboratory tests to identify DVT in people with suspected
29 DVT?

1 1.2 What is the clinical and cost effectiveness of different
2 pharmacological anticoagulation strategies in people with suspected
3 DVT prior to confirmed diagnosis?

4 2. Diagnosing pulmonary embolism

5 2.1 In people with suspected PE, what is the diagnostic accuracy of age-
6 adjusted D-dimer tests compared with D-dimer tests without age
7 adjustment?

8 2.2 What is the diagnostic accuracy of point-of-care D-dimer tests
9 compared with laboratory tests to identify PE in people with suspected
10 PE?

11 2.3 What is the clinical and cost effectiveness of different
12 pharmacological anticoagulation strategies in people with suspected PE
13 prior to confirmed diagnosis?

14 3. Treating confirmed pulmonary embolism and deep vein thrombosis

15 3.1 What is the clinical and cost effectiveness of different
16 pharmacological anticoagulation strategies in people with a confirmed
17 diagnosis of DVT?

18 3.2 What is the clinical and cost effectiveness of different
19 pharmacological anticoagulation strategies in people with a confirmed
20 diagnosis of PE?

21 4. Investigations for cancer

22 4.1 Do investigations for cancer in people with unprovoked VTE improve
23 outcomes (morbidity and mortality)?
24 (cross reference to the NICE guideline on suspected cancer: recognition
25 and referral)

26 5. Outpatient treatment for PE

27 5.1 What is the clinical and cost effectiveness of outpatient treatment,
28 and for which patients is outpatient treatment safe, for the management
29 of people with low risk suspected or confirmed PE?

30 6. Follow-up

31 6.1 What factors should be considered when deciding the optimum
32 duration of pharmacological anticoagulation?

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

1 **Main outcomes**

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

- 4 • all-cause mortality
- 5 • VTE-related mortality
- 6 • recurrence of VTE
- 7 • length of hospital stay
- 8 • quality of life (both health- and social care-related quality)
- 9 • cancer related morbidity
- 10 • adverse events.

11 **NICE quality standards and NICE Pathways**

12 ***NICE quality standards***

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

- 15 • [Venous thromboembolism in adults: diagnosis and management](#) (2013)
16 NICE quality standard 29
- 17 • [Venous thromboembolism in adults: reducing the risk in hospital](#) (2010)
18 NICE quality standard 3

19 ***NICE Pathways***

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

23 **Further information**

This is the draft scope for consultation with registered stakeholders. The
consultation dates are 30 January to 13 February 2018.

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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