

# Appendices

## Appendix A: Scope

FINAL VERSION

NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE

### Guideline scope

## Venous thromboembolism in people aged 16 and over: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism

#### *Topic*

This guideline will update the NICE guideline on [Venous thromboembolism in adults admitted to hospital](#) (CG92) as set out in the [update decision](#).

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the [context](#) section.

#### *Who the guideline is for*

- People using services, families and carers and the public
- Healthcare professionals in the primary and secondary sectors
- Clinical commissioning 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 heparin which is derived from the tissue of pigs or cattle. If recommended we will need to ensure that people

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with religious or personal beliefs about the use of animal-derived products are given the opportunity to express their concerns and to receive information about alternative options.

## **1 What the guideline is about**

### **1.1 Who is the focus?**

#### **Groups that will be covered**

- Adults and young people (16 years and older) admitted to hospital.
- Adults and young people (16 years and older) discharged from hospital (including from A&E) with lower-limb devices such as plaster casts and braces.
- Adults and young people (16 years and older) attending hospital for day procedures including cancer treatment and surgery.
- Adults and young people (16 years and older) with psychiatric illness admitted to community mental health hospitals or units.
- Special consideration will be given to:
  - pregnant women admitted to hospital and midwife units including up to 6 weeks after giving birth
  - people in whom pharmacological prophylaxis is contraindicated (**new area**)
  - people in whom mechanical prophylaxis is contraindicated (**new area**)
  - people already using anticoagulants in whom bridging prophylaxis is required for VTE prophylaxis. (**new area**)
  - people using antiplatelets for cardiovascular disease. (**new area**)
  - people who are obese
  - people who have kidney disease

#### **Groups that will not be covered**

- People with suspected or confirmed venous thromboembolism (VTE).

## **1.2 Settings**

### **Settings that will be covered**

- Primary and community care when continuing prophylaxis after hospital discharge.
- Secondary care.

### **Settings that will not be covered**

- Community settings and hospices, except when continuing prophylaxis that has been started in hospital.

## **1.3 Activities, services or aspects of care**

### **Key areas that will be covered**

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 medicine's summary of product characteristics to inform decisions made with individual patients.

### **Areas from the published guideline that will be updated**

1. Risk assessment
  - Patient risk factors for venous thromboembolism (VTE)
2. Methods of prophylaxis for reducing the incidence of VTE:
  - Mechanical prophylaxis including anti-embolism stockings (above or below the knee), intermittent pneumatic compression devices (full leg or below the knee), foot impulse devices, electrical stimulation, continuous passive motion and vena caval filters
  - Pharmacological prophylaxis including aspirin, dabigatran, fondaparinux, unfractionated heparin, low molecular weight heparin (LMWH), rivaroxaban and vitamin k antagonists [for example warfarin])
  - Timing of prophylaxis
  - Duration of prophylaxis

3. Information and support
  - Content of information on prophylaxis methods and VTE provided to patients and their family members or carers.

***Areas not in the published guideline that will be included in the update***

1. Risk assessment
  - Risk prediction tools (for bleeding or VTE)
  - Reassessment of risk
2. Methods of prophylaxis
  - New interventions (for example apixaban and geko devices)
  - Bridging prophylaxis
  - Prophylaxis for patients already prescribed antiplatelet agents for cardiovascular disease

**Areas that will not be covered**

***Areas from the published guideline that will not be updated***

1. Methods of prophylaxis
  - Early mobilisation and leg exercises
  - Physiotherapy
  - Hydration
  - Regional compared with general anaesthetic.

***Areas from the published guideline that will be removed***

1. Methods of prophylaxis
  - Leg elevation

***Areas not covered by the published guideline or the update***

1. Secondary prevention of VTE

Recommendations in areas that are not being updated may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

#### **1.4 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 an NHS and personal social services (PSS) perspective, as appropriate.

#### **1.5 Key issues and questions**

While writing this scope we have identified the following key issues, and key questions related to them. The term 'VTE' in this section refers to both deep vein thrombosis (DVT) and pulmonary embolism (PE):

1. Risk assessment:
  - 1.1 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of VTE in patients who are admitted to hospital?
  - 1.2 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of VTE in patients who are having day procedures (including surgery and chemotherapy) at hospital?
  - 1.3 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of VTE in pregnant women who are admitted to hospital or midwife units?
  - 1.4 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of major bleeding or the risk of bleeding in patients who are admitted to hospital?
  - 1.5 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of major bleeding or the risk of in patients who are having day procedures (including surgery and chemotherapy) at hospital?
  - 1.6 What is the accuracy of individual risk assessment or prediction tools in predicting the likelihood of major bleeding or the risk of bleeding in pregnant women who are admitted to hospital or midwife units?

1.7 How clinically and cost effective are risk assessment or prediction tools at reducing the rates of VTE in patients who are admitted to hospital?

1.8 How clinically and cost effective are risk assessment or prediction tools at reducing the rates of VTE in patients who are having day procedures (including surgery and chemotherapy) at hospital?

1.9 How clinically and cost effective are risk assessment or prediction tools at reducing the rates of VTE in pregnant women who are admitted to hospital or midwife units?

1.10 How effective is reassessment of patients who are admitted to or having day procedures at hospital?

If appropriate evidence is not identified from the questions above (1.1 to 1.10) the following 2 questions may also be considered:

1.11 What are the individual risk factors for VTE in patients who are admitted to hospital?

1.12 What are the individual risk factors for VTE in patients who are having day procedures (including surgery and chemotherapy) at hospital?

1.13 What are the individual risk factors for VTE in pregnant women who are admitted to hospital or midwife units?

## 2. Prophylaxis:

Each of the following questions will investigate individual populations separately. Populations include:

- people having the following types of surgery:
  - elective hip surgery
  - elective knee surgery
  - hip fracture
  - knee arthroscopy
  - other orthopaedic surgery
  - abdominal surgery (bariatric, liver, gastrointestinal, gynaecological, laparoscopic, thoracic and urological)

- cranial surgery
- spinal surgery
- cardiac surgery
- vascular surgery
- dental/maxillofacial surgery
- vaginal surgery
- people discharged with lower-limb immobilisation (including boots, braces, Plaster of Paris [POP] and other devices)
- people being treated for:
  - major trauma
  - spinal injury
  - stroke
  - acute coronary syndromes
  - cancer
- people attending hospital as medical admissions
- people with central venous catheters
- people having palliative care
- pregnant women and up to 6 weeks after giving birth
- people with psychiatric disorders
- people who are obese
- people with kidney disease.

Each of the questions will consider the following settings, if appropriate: people in hospital and those having day procedures (including surgery, chemotherapy)

Each of the questions will include the following prophylaxis methods, if applicable:

- mechanical prophylaxis, including:
  - anti-embolism stockings (above or below knee)
  - intermittent pneumatic compression devices (full leg or below knee)
  - foot impulse devices
  - electrical stimulation (including geko devices)

- continuous passive motion
- vena caval filters.
- pharmacological prophylaxis, including:
  - apixaban
  - aspirin
  - dabigatran
  - fondaparinux
  - unfractionated heparin
  - low molecular weight heparin (LMWH)
  - rivaroxaban
  - vitamin k antagonists (for example warfarin).

2.1 What is the effectiveness of different pharmacological and mechanical prophylaxis strategies (alone or in combination)?

2.2 What is the effectiveness of vena caval filters in people admitted to hospital who are at high risk of DVT or PE admitted to hospital?

2.3 What is the most effective timing for starting prophylaxis with LMWH for people having surgery?

2.4 What is the most effective prophylaxis duration (covering the time in hospital only or continuing after discharge)?

2.5 What is the most effective prophylaxis strategy for inpatients in whom pharmacological prophylaxis is contraindicated?

2.6 What is the most effective prophylaxis strategy for inpatients in whom mechanical prophylaxis is contraindicated?

2.7 What is the most effective prophylaxis strategy for patients in whom both mechanical and pharmacological prophylaxis are contraindicated?

2.8 What is the most effective VTE prophylaxis strategy for bridging patients who are already using anticoagulants agents for other reasons?

2.9 What is the most effective VTE prophylaxis strategy in managing patients who are already using antiplatelets for cardiovascular disease?

2.10 What is the most effective VTE prophylaxis strategy for pregnant women admitted to hospital or a midwifery-led unit during labour?



3. Information for patients, family members and carers:
  - 3.1 What specific information should be provided to people who need VTE prophylaxis?
  - 3.2 What information do patients, their family members and carers say they want about VTE prophylaxis?

### **1.6 Main outcomes**

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

1. All-cause mortality
2. Pulmonary embolism
3. Fatal pulmonary embolism
4. Deep vein thrombosis (symptomatic or asymptomatic)
5. Major bleeding
6. Fatal bleeding
7. Heparin-induced thrombocytopenia
8. Post-thrombotic syndrome
9. Pulmonary hypertension
10. Quality of life (validated scores)
11. Hospital length of stay
12. Readmission
13. Neurological events (for example haemorrhagic stroke)

## **2 Links with other NICE guidance, NICE quality standards and NICE Pathways**

### **2.1 NICE guidance**

- [Venous thromboembolism in adults admitted to hospital: reducing the risk](#) (2010) NICE guideline CG92
- [Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing](#) (2012) NICE clinical guideline 144
- [Caesarean section](#) (2011) NICE clinical guideline 132

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- [Stroke: Diagnosis and initial management of acute stroke and transient ischaemic attack \(TIA\) \(2008\) NICE clinical guideline 68.](#)
- [Apixaban for the prevention of venous thromboembolism after total hip or knee replacement in adults \(2012\) NICE technology appraisal 245](#)
- [Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults \(2008\) NICE technology appraisal 157.](#)
- [Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults \(2009\) NICE technology appraisal 170](#)
- [The geko device for reducing the risk of venous thromboembolism \(2014\) NICE medical technology guidance 19.](#)

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

- [Venous thromboembolism in adults admitted to hospital: reducing the risk \(2010\) NICE guideline CG92](#)

**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 VTE:

- [Patient experience in adult NHS services \(2012\) NICE guideline CG138](#)
- [Service user experience in adult mental health \(2011\) NICE guideline CG136](#)
- [Medicines adherence \(2009\) NICE guideline CG76](#)

## **2.2 NICE quality standards**

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

- [Venous thromboembolism prevention \(2010\) NICE quality standard 3.](#)

## **2.3 NICE Pathways**

When this guideline is published it will update the existing NICE pathway on [venous thromboembolism](#). NICE Pathways bring together all related NICE

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guidance and associated products on a topic in an interactive topic-based flow chart.

### **3 Context**

#### **3.1 Key facts and figures**

Hospital acquired venous thromboembolism, also known as hospital acquired thrombosis (HAT), covers all venous thromboembolism (VTE) that occurs in hospital and for 90 days after a hospital admission. Epidemiological studies have shown that HAT accounts for somewhere between 50-60% of all VTE seen. Hospital Episode Statistics showed that in 2013–14 there were 24,725 admissions for pulmonary embolism and 19,463 for DVT in England, resulting in 205,448 and 67,028 bed-days and 47,594 and 25,958 finished consultant episodes respectively. In 2013, in England and Wales there were 2,191 deaths recorded as due to pulmonary embolism (PE) and 2,816 due to deep vein thrombosis (DVT), but the actual number of people dying from these conditions is likely to be higher because of misdiagnosis and the failure to recognise VTE as the underlying cause. Thus hospital-acquired VTE accounts for thousands of deaths annually in the UK.

#### **3.2 Current practice**

In 2010, the CQUIN target introduced a payment linked to at least 90% of adults being risk assessed on admission to hospital. Figures reporting the uptake of some of the recommendations in CG92 are reported on [NICE's website](#). Recent evidence also estimates that the national mortality rate from VTE has fallen by 8–9% since the recommendations in CG92 were introduced.

In addition, since the publication of the last version of the guideline, [CG92](#), two new interventions for preventing venous thromboembolism (VTE) have become available: apixaban and geko devices.

### **3.3 Policy, legislation, regulation and commissioning**

#### **Policy**

The [National VTE prevention programme](#) was launched in England in 2010 by the Department of Health. This included the mandatory VTE risk assessment of 90% (later increased to 95%) of all people admitted to hospital. A risk assessment tool was created by the Department of Health and this was incorporated into the last version of this guideline. Risk assessment will be a key part of this update.

## **4 Further information**

Registered stakeholders were consulted with on the draft scope between 11 December 2015 and 20 January 2016.

The guideline is expected to be published in February 2018.

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

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