NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Draft quality standard for management of venous thromboembolic diseases

1 Introduction

Venous thromboembolism (VTE) is a condition in which a blood clot (a thrombus) forms in a vein, most commonly in the deep veins of the legs or pelvis. This is known as deep vein thrombosis, or DVT. The thrombus can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism, or PE. The term VTE includes both DVT and PE.

VTE is an important cause of death and its prevention and management is a priority for the NHS. It has been estimated that 25,000 people in the UK die every year from preventable hospital-acquired VTE. It could cause more than 500,000 deaths in Europe (see Venous thromboembolism (VTE) in Europe: the number of VTE events and associated morbidity and mortality. Non-fatal VTE is also important because it can cause serious longer-term conditions such as post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension.

The diagnosis of VTE is not always straightforward because other conditions have similar symptoms. Failure to diagnose a case of VTE correctly may result in a patient not receiving the correct treatment and potentially suffering a fatal PE as a result.

This quality standard covers the diagnosis and treatment of venous thromboembolic diseases in adults, excluding pregnant women. For more information see the scope for this quality standard. This quality standard does not cover prevention as this is covered in NICE quality standard for the prevention of VTE.

This draft quality standard describes markers of high-quality, cost-effective care that, when delivered collectively, should contribute to improving the effectiveness, safety and experience of care for people with venous thromboembolic diseases in the following ways:

- Preventing people from dying prematurely.
- Enhancing quality of life for people with long-term conditions.
- Helping people to recover from episodes of ill health or following injury.
- Ensuring that people have a positive experience of care.
- Treating and caring for people in a safe environment and protecting them from avoidable harm.

These overarching outcomes are from The NHS Outcomes Framework 2012/13.

2 Draft quality standard for management of venous thromboembolic diseases

Overview

The draft quality standard for management of venous thromboembolic diseases (VTE) requires that services should be commissioned from and coordinated across all relevant agencies encompassing the whole management of VTE diseases care pathway. An integrated approach to provision of services is fundamental to the delivery of high quality care to adults with VTE.

No.	Draft quality statements
1	People with suspected venous thromboembolic diseases have diagnostic investigations completed within 24 hours of first clinical suspicion.
2	People with suspected deep vein thrombosis are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion.
3	People with suspected pulmonary embolism are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion.
4	People with proximal deep vein thrombosis are offered below-knee graduated compression stockings within 1 week of diagnosis.
5	People with venous thromboembolic diseases continuing anticoagulation therapy beyond an initial dose, have their dose adjusted for weight and renal function.
6	People with unprovoked venous thromboembolic diseases are offered investigations for cancer.
7	People with provoked venous thromboembolic diseases do not have testing for thrombophilia.
8	People with active cancer and venous thromboembolic diseases are offered 6 months treatment with low molecular weight heparin.
9	People with venous thromboembolic diseases without cancer receive a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months.

General questions for consultation:

Question 1	Can you suggest any appropriate healthcare outcomes for each individual quality statement?
Question 2	What important areas of care, if any, are not covered by the quality standard?
Question 3	What, in your opinion, are the most important quality statements and why?
Question 4	Are any of the proposed quality measures inappropriate and, if so, can you identify suitable alternatives?
Please refer to Quality standards in development for additional general points for consideration (available from www.nice.org.uk).	
Statement-specific questions for consultation:	
Question 5	For draft statement 5, is there evidence or information that care in this area is poor or variable and needs improvement? That is, is there any evidence from current practice showing that people with venous thromboembolism who are continuing anticoagulation therapy beyond a single dose **do not** have their dose adjusted for weight and renal function?
Question 6	For draft statement 6, is there evidence that people with unprovoked VTE are not receiving the stated investigations for cancer (would this statement provide a driver for quality improvement?)
Question 7	For draft statement 8, the outcome measure is mortality from PE. Is this linked closely enough with the draft statement?
Question 8	In addition to statement 9 would it be useful to include a statement on follow-up care for people with cancer?

Draft quality statement 1: Timing of investigations

Draft quality statement	People with suspected venous thromboembolic diseases have diagnostic investigations completed within 24 hours of first clinical suspicion.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with suspected venous thromboembolic diseases (VTE) have complete diagnostic investigations within 24 hours of first clinical suspicion. **Process:** The proportion of people who receive complete diagnostic investigations within 24 hours of first clinical suspicion. Numerator – The number of people in the denominator receiving complete diagnostic investigations within 24 hours of first clinical suspicion. Denominator – The number of people with suspected VTE. **Outcome:** The proportion of people with suspected DVT who progress to a pulmonary embolism in the absence of timely diagnostic investigations
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with VTE to have complete diagnostic investigations within 24 hours of first clinical suspicion. **Healthcare professionals** ensure people with VTE have complete diagnostic investigations within 24 hours of first clinical suspicion. **Commissioners** ensure they commission services for people with VTE to have complete diagnostic investigations within 24 hours of first clinical suspicion. **People with suspected VTE** have complete diagnostic investigations within 24 hours of first clinical suspicion.
Source clinical guideline references	NICE clinical guideline 144 recommendations 1.1.1(key priority for implementation), 1.1.2, 1.1.3 (key priority for implementation), 1.1.4 (key priority for implementation) 1.1.7, 1.1.8, 1.1.9 (key priority for implementation), 1.1.10 (key priority for implementation) and 1.1.14.
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome:** Local data collection.
Definitions	Complete diagnostic investigations: as outlined in the pulmonary embolism and deep vein thrombosis algorithms in NICE clinical guideline 144 Suspected VTE: diagnostic investigations have not yet confirmed VTE. First clinical suspicion would include clinical suspicion of VTE by any member of the clinical team including nurses.

Draft quality statement 2: Interim therapeutic dose anticoagulation therapy – DVT

Draft quality statement	People with suspected deep vein thrombosis are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with suspected deep vein thrombosis (DVT) are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion. **Process:** The proportion of people with suspected DVT whose diagnostic investigations take longer than 4 hours from the time of first clinical suspicion who receive interim therapeutic dose anticoagulation therapy. Numerator – The number of people in the denominator who receive interim therapeutic dose anticoagulation therapy. Denominator – The number of people with suspected DVT whose diagnostic investigations take longer than 4 hours from the time of first clinical suspicion. **Outcome:** Incidence of PE.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with suspected DVT to be offered interim dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion. **Healthcare professionals** ensure they offer people with suspected DVT interim dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion. **Commissioners** ensure they commission services that ensure people with suspected DVT are offered interim dose anticoagulation therapy if diagnostic investigations take longer than 4 hours from the time of first clinical suspicion. **People with suspected DVT whose diagnostic investigations take longer than 4 hours** from the time of first clinical suspicion are offered interim dose anticoagulation therapy.
Source clinical guideline references	NICE clinical guideline 144 recommendations 1.1.1 (key priority for implementation), 1.1.2, 1.1.3 (key priority for implementation) and 1.1.4 (key priority for implementation).
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome**: Local data collection.

Definitions	Suspected DVT: the diagnostic investigations have not yet confirmed DVT. First clinical suspicion would include clinical suspicion of VTE by any member of the clinical team including nurses.

Draft quality statement 3: Interim therapeutic dose anticoagulation therapy – PE

Draft quality statement	People with suspected pulmonary embolism are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with suspected pulmonary embolism (PE) are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion. **Process:** The proportion of people with suspected PE whose diagnostic investigations take longer than 1 hour from the time of first clinical suspicion who receive interim therapeutic dose anticoagulation therapy. Numerator – The number of people in the denominator who receive interim therapeutic dose anticoagulation therapy. Denominator – The number of people with a suspected PE whose diagnostic investigations take longer than 1 hour from the time of first clinical suspicion. **Outcome:** Mortality from PE.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with suspected PE to be offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion. **Healthcare professionals** ensure people with suspected PE are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion. **Commissioners** ensure they commission services that ensure people with suspected PE are offered interim therapeutic dose anticoagulation therapy if diagnostic investigations take longer than 1 hour from the time of first clinical suspicion. **People with suspected VTE whose diagnostic investigations take longer than 1 hour** from the time of first clinical suspicion are offered interim therapeutic dose anticoagulation therapy.
Source clinical guideline references	NICE clinical guideline 144 recommendations 1.1.9 (key priority for implementation) and 1.1.10 (key priority for implementation).
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome**: Local data collection

Definitions	Diagnostic investigations: as outlined in the PE algorithm in NICE clinical guideline 144 First clinical suspicion would include clinical suspicion of VTE by any member of the clinical team including nurses.

Draft quality statement 4: Mechanical interventions

Draft quality statement	People with proximal deep vein thrombosis are offered below-knee graduated compression stockings within 1 week of diagnosis.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with proximal deep vein thrombosis (DVT) are offered below-knee graduated compression stockings within 1 week of diagnosis. **Process:** The proportion of people with proximal DVT who receive below-knee graduated compression stockings within 1 week of diagnosis. Numerator – The number of people in the denominator who receive below-knee graduated compression stockings within 1 week of diagnosis. Denominator – The number of people with proximal DVT eligible for below-knee graduated compression stockings and without contraindications to stockings. **Outcome** – The incidence of post thrombotic syndrome.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with proximal DVT to be offered below-knee graduated compression stockings within 1 week of diagnosis. **Healthcare professionals** ensure they offer people with proximal DVT below-knee graduated compression stockings within 1 week of diagnosis. **Commissioners** ensure they commission services that offer people with proximal DVT below-knee graduated compression stockings within 1 week of diagnosis. **People with proximal DVT** are offered below-knee graduated compression stockings within 1 week of diagnosis.
Source clinical guideline references	NICE clinical guideline 144 (2012) recommendations 1.2.9 (key priority for implementation) and 1.3.4
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome:** Local data collection.
Definitions	NICE clinical guideline 144 states that below-knee graduated stockings should have an ankle pressure of 23 mmHg. Below-knee graduated stockings are recommended unless there are contraindications. Contraindications include: graduated compression stockings are contraindicated in patients with peripheral arterial disease, arteriosclerosis, severe peripheral neuropathy, massive leg oedema or pulmonary oedema, oedema secondary to congestive cardiac failure, local skin or soft tissue

	diseases such as recent skin graft or dermatitis, extreme deformity of the leg, gangrenous limb and ankle: brachial pressure index <0.8, or cellulitis. Proximal DVT: a DVT in the popliteal vein or above; proximal DVT in this context refers to 'above-knee DVT'.
Equality and diversity considerations	There may be equality issues for people with difficulty putting the stocking on. These people may need assistance and/or an application aid.

Draft quality statement 5: Assessing risk factors

Draft quality statement	People with venous thromboembolic diseases continuing anticoagulation therapy beyond an initial dose, have their dose adjusted for weight and renal function.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with venous thromboembolic diseases (VTE) continuing anticoagulation therapy beyond an initial dose, have their dose adjusted for weight and renal function. **Process:** The proportion of people with VTE continuing anticoagulation therapy beyond an initial dose, who have their dose adjusted for weight and renal function. Numerator – The number of people in the denominator who have their dose adjusted for weight and renal function. Denominator – The number of people with VTE continuing anticoagulation therapy beyond an initial dose. **Outcome:** Incidence of adverse events related to anticoagulation therapy.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with VTE continuing anticoagulation therapy beyond an initial dose to have their dose adjusted for weight, and renal function. **Healthcare professionals** ensure people with VTE continuing anticoagulation therapy beyond an initial dose have their dose adjusted for weight and renal function. **Commissioners** ensure they commission services that offer people with VTE continuing anticoagulation therapy beyond an initial dose, an assessment of weight and renal function for dose adjustment. **People with VTE on continuing anticoagulation therapy beyond an initial dose,** should be having their dose adjusted in line with weight and renal function.
Source clinical guideline references	NICE clinical guideline 144 recommendation 1.2.1 (key priority for implementation)
Data source	**Structure:** Local data collection. **Process:** Local data collection.

Draft quality statement 6: Investigations for cancer

Draft quality statement	People with unprovoked venous thromboembolic diseases are offered investigations for cancer.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with unprovoked venous thromboembolic diseases (VTE) are offered investigations for cancer. **Process:** The proportion of people with unprovoked VTE who receive investigations for cancer. Numerator – The number of people in the denominator receiving investigations for cancer. Denominator – The number of people with unprovoked VTE. **Outcome:** Incidence of cancer detected following unprovoked VTE.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with unprovoked VTE to be offered investigations for cancer. **Healthcare professionals** ensure people with unprovoked VTE are offered investigations for cancer. **Commissioners** ensure they commission services that offer people with unprovoked VTE investigations for cancer. **People with unprovoked VTE** are offered investigations for cancer.
Source clinical guideline references	NICE clinical guideline 144 (2012) recommendation 1.5.1. NICE clinical guideline 144, recommendation 1.5.2 (key priority for implementation), recommends further investigations for cancer with an abdominopelvic CT scan (and a mammogram for women) in all people older than 40 with a first unprovoked DVT or PE who do not have signs or symptoms of cancer based on initial investigation.
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome:** Local data collection.
Definitions	Unprovoked VTE is defined as a deep vein thrombosis (DVT) or pulmonary embolism (PE) in a patient with no antecedent major clinical risk factor for VTE who is not having hormonal therapy (oral contraceptive or hormone replacement therapy). Patients with active cancer, thrombophilia or a family history of VTE should also be considered as having an unprovoked episode because these underlying risks will remain unchanged in the patient. In this context, investigations for cancer refer to the investigation of patients who present symptomatically with a DVT and/or PE to determine whether the VTE could be related to a previously

	undetected cancer. The specific investigations are: • a physical examination (guided by the patient's full history) • chest X-ray • blood tests (full blood count, serum calcium and liver function tests) • urinanalysis.
Specific questions for consultation	For draft statement 6, is there evidence that people with unprovoked VTE are not receiving the stated investigations for cancer?

Draft quality statement 7: Thrombophilia testing

Draft quality statement	People with provoked venous thromboembolic diseases do not have testing for thrombophilia.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with provoked venous thromboembolic diseases (VTE) do not have testing for thrombophilia. **Process:** The proportion of people with provoked VTE who are tested for thrombophilia. Numerator – The number of people in the denominator who are tested for thrombophilia. Denominator – The number of people with provoked VTE.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place to ensure that people with provoked VTE are not tested for thrombophilia. **Healthcare professionals** ensure people with provoked VTE are not tested for thrombophilia. **Commissioners** ensure they commission services that do not test people with provoked VTE for thrombophilia. **People with provoked VTE** are not tested for thrombophilia.
Source clinical guideline references	NICE clinical guideline 144 (2012) recommendation 1.6.4.
Data source	**Structure:** Local data collection. **Process:** Local data collection.
Definitions	Provoked VTE is defined as VTE that occurred in the presence of an antecedent (within 3 months) and transient major clinical risk factor for VTE (for example surgery, trauma, significant immobility and pregnancy or puerperium). The NICE Guideline Development Group also considered VTE that occurred in association with hormonal therapy (oral contraceptive or hormone replacement therapy) to be provoked because it has been shown that these patients are at a lower risk of recurrence.

Draft quality statement 8: Treatment of active cancer patients

Draft quality statement	People with active cancer and venous thromboembolic diseases are offered 6 months treatment with low molecular weight heparin.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with active cancer and venous thromboembolic diseases are offered 6 months treatment with low molecular weight heparin (LMWH). **Process:** The proportion of people with active cancer and venous thromboembolic diseases who receive 6 months treatment with LMWH. Numerator – The number of people in the denominator prescribed 6 months treatment with LMWH. Denominator – The number of people with active cancer and venous thromboembolic diseases. **Outcome** – Mortality from PE.
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with active cancer and venous thromboembolic diseases to be offered 6 months treatment with LMWH. **Healthcare professionals** ensure people with active cancer and venous thromboembolic diseases are offered 6 months treatment with LMWH. **Commissioners** ensure they commission services that offer people with active cancer and venous thromboembolic diseases, 6 months treatment with LMWH. **People with active cancer and venous thromboembolic diseases** are offered 6 months treatment with LMWH.
Source clinical guideline references	NICE clinical guideline 144 (2012) recommendation 1.2.2 (key priority for implementation).
Data source	**Structure:** Local data collection. **Process:** Local data collection. **Outcome:** Local data collection.
Definitions	For the purpose of this recommendation, the Guideline Development Group considered the evidence available and defined ‘active cancer’ as cancer: receiving active antimitotic treatment; or diagnosed within the past 6 months; or recurrent or metastatic; or inoperable. This definition excludes squamous skin cancer and basal cell. carcinoma.

Specific questions for consultation	For draft statement 8, we have an outcome measure of mortality from PE. Is this linked closely enough with the draft statement?

Draft quality statement 9: Follow up

Draft quality statement	People with venous thromboembolic diseases without cancer receive a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months.
Draft quality measure	**Structure:** Evidence of local arrangements to ensure people with venous thromboembolic diseases (VTE) without cancer are reviewed within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. **Process:** The proportion of people with venous thromboembolic diseases without cancer receiving a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. Numerator – The number of people in the denominator receiving a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. Denominator – The number of people with diagnosis of VTE at least 3 months previously and who do not have cancer
Description of what the quality statement means for each audience	**Service providers** ensure systems are in place for people with VTE without cancer to be offered a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. **Healthcare professionals** ensure people with VTE without cancer are offered a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. **Commissioners** ensure they commission services that offer people with VTE without cancer a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months. **People with VTE without cancer** are offered a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months.
Source clinical guideline references	NICE clinical guideline 144 (2012) recommendation 1.2.3.
Data source	**Structure:** Local data collection. **Process:** Local data collection.
Specific questions for consultation	In addition to statement 9 would it be useful to include a statement on follow-up care for people with cancer?

In addition, other quality standards that should also be considered when commissioning and providing a high-quality management of VTE diseases service are listed in section 7.

3 Status of this quality standard

This is the draft quality standard released for consultation from 3 to 31 October 2012. This document is not NICE's final quality standard on management of venous thromboembolic diseases. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 31 October 2012. All eligible comments received during consultation will be reviewed by the Topic Expert Group and the quality statements and measures will be refined in line with the Topic Expert Group considerations. The final quality standard will then be available on the NICE website from March 2013.

4 Using the quality standard

It is important that the quality standard is considered alongside current policy and guidance documents listed in the evidence sources section.

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of healthcare. They are not a new set of targets or mandatory indicators for performance management.

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, we recognise that this may not always be appropriate in practice when taking account of patient safety, patient choice and clinical judgment so desired levels of achievement should be defined locally.

We have indicated where national indicators currently exist and measure the quality statement. National indicators include those developed by the Health and Social Care Information Centre through their Indicators for Quality Improvement Programme. For statements for which national quality indicators

do not exist, the quality measures should form the basis for audit criteria developed and used locally to improve the quality of healthcare.

For further information, including guidance on using quality measures, please see What makes up a NICE quality standard.

5 Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments will be published on the NICE website with the final version of the quality standard.

Good communication between health and social care professionals and people with venous thromboembolic diseases is essential. Treatment and care, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with venous thromboembolic diseases should have access to an interpreter or advocate if needed.

6 How this quality standard was developed

The evidence sources used to develop this quality standard are listed in appendix 1, along with relevant policy context. Further explanation of the methodology used can be found in the Quality Standards Programme interim process guide.

7 Related NICE quality standards

Patient experience in adult NHS services. NICE quality standard (2012).

VTE prevention. NICE quality standard (2010).

Appendix 1: Development sources

Evidence sources

The documents below contain clinical guideline recommendations or other recommendations that were used by the TEG to develop the quality standard statements and measures.

Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing. NICE clinical guideline 144 (2012).

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

Department of Health (2010) Venous thromboembolism (VTE) risk assessment.

Department of Health (2009) Venous thromboembolism prevention: a patient safety priority

Department of Health (2008) Using the commissioning for quality and innovation (CQUIN) payment framework (see guidance on national goals for 2011/12).

Department of Health (2007) Report of the independent expert working group on the prevention of venous thromboembolism (VTE) in hospitalised patients.