National Institute for Health and Clinical Excellence

NICE support for commissioners using the quality standard for venous thromboembolism in adults: diagnosis and management

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1 Introduction

Implementing the recommendations from NICE guidance and other NICE accredited guidance is the best way to support improvements in the quality of care or services, in line with the statements and measures that comprise the NICE quality standards. This report:

- considers the cost of implementing the changes needed to achieve the quality standard at a local level
- identifies where potential cost savings can be made
- highlights the areas of care in the quality standard that have potential implications for commissioners
- directs commissioners and service providers to a package of support tools that can help them implement NICE guidance and redesign services.

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. The statements draw on existing guidance, which provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement. For more information see NICE quality standards.

The Clinical Commissioning Group (CCG) Outcomes Indicator Set (formerly known as the Commissioning Outcomes Framework) is part of a systematic

approach to promoting quality improvement. The outcomes indicator set provides clinical commissioning groups and health and wellbeing boards with comparative information on the quality of health services commissioned by CCGs and the associated health outcomes. The set includes indicators derived from NICE quality standards. By commissioning services in line with the quality standards, commissioners can contribute to improvements in health outcomes.

Commissioners can use the quality standards to improve services by including quality statements and measures in the service specification of the standard contract and establishing key performance indicators as part of tendering. They can also encourage improvements in provider performance by using quality standard measures in association with incentive payments such as Commissioning for Quality and Innovation (CQUIN). NICE quality standards provide a baseline against which improvements can be measured and rewarded, enabling commissioners to address gaps in service provision, support best practice and encourage evidence-based treatments and care.

This report on venous thromboembolism in adults: diagnosis and management quality standard should be read alongside:

- Venous thromboembolism in adults: reducing the risk in hospital NICE quality standard 3 (2010)
- Venous thromboembolic diseases: diagnosis, management and thrombophilia testing NICE clinical guideline 144 (2012)
- Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism NICE technology appraisal guidance 261 (2012)
- Venous thromboembolism: reducing the risk for patients in hospital NICE clinical guideline 92 (2010)
- Anticoagulation therapy NICE guide for commissioners (2010)

2 Overview of diagnosis and management of venous thromboembolic diseases

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[1]. 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 having a fatal PE as a result.

People with VTE are treated with anticoagulation therapy. Currently people are usually given a brief course of heparin initially while they start a 3 month course of a vitamin K antagonist, such as warfarin. People who have had recurrent VTE or who are at high risk of recurrence may be given indefinite treatment with anticoagulants to prevent further VTE episodes[2]. The publication of Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (NICE technology appraisal guidance 261) in 2012 provided a further option for the management of VTE. For further information see the Guide for commissioners of anticoagulation therapy services.

[1] Department of Health and Chief Medical Officer (2007) Report of the independent expert working group on the prevention of venous thromboembolism in hospitalised patients.
[2] Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing (2012) NICE clinical guideline 144.
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2.1 Epidemiology of venous thromboembolic diseases

Primary care information was obtained for the period 2011–12 from IMS Disease Analyzer[3], a database that holds data from a sample of GP practice systems. There were 83,533 new cases of VTE (including DVT and PE) during this period in England. This represents around 0.2% of the adult population or 200 per 100,000 population.

For more information see the Guide for commissioners: anticoagulation therapy and the accompanying commissioning and budgeting tool.

3 Commissioning and resource implications

The cost of meeting the quality standard for VTE in adults: diagnosis and management depends on current local practice and the progress organisations have made in implementing Venous thromboembolic diseases (NICE clinical guideline 144) and Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (NICE technology appraisal guidance 261).

The costing report for NICE clinical guideline 144 and the costing template for NICE technology appraisal guidance 261 detail the potential savings and benefits of implementing the guidance.

Table 1 summarises the commissioning and resource implications for commissioners working towards achieving this quality standard. See section 4 for more detail on commissioning and resource implications.

Table 1 potential commissioning and resource implications of achieving the quality standard for venous thromboembolism in adults: diagnosis and management

[3] IMS collects data from a sample of GP practice systems. Around 100 are currently delivering data and the database has about 2.7 million patient records, almost 1 million of which were registered for the whole of the study year. These records are anonymised and are available for analysis via a tool called Disease Analyzer. The sample includes practices from England, Wales, Scotland and Northern Ireland and has a representative UK sample by age and sex. Disease Analyzer data have been collected from a stable panel over a period of more than 14 years. The database holds significant clinical events relating to any period in a patient's life where summarised into computer records by the practice. As in any observational database, data entered by panel doctors may be incomplete.

Area of care	Commissioning implications	Estimated resource impact
Diagnostic investigations	• Access to diagnostic services out of normal working hours, particularly at weekends • Access to low molecular weight heparin and/or rivaroxaban in relevant settings • Implementation of NICE recommendations on rivaroxaban for DVT at a local level	There may be costs to ensure access within 24 hours, especially out of normal working hours. See table 2 in section 4.1). No significant costs anticipated for interim therapeutic doses of anticoagulation therapy.
Investigations for cancer and treatment of patients with active cancer	• Ensure clear local care pathways are in place • Care pathways in place to support people receiving treatment with heparin, particularly those who cannot self-administer	There may be additional costs for further investigations and low molecular weight heparin. See table 5 in section 4.4.
Thrombophilia testing	• This may enable more people to be managed in primary care • Less need for testing and re-testing	There may be savings through reduced tests. See section 4.5.
Follow-up	• Ensure clear local care pathways are in place	Potential additional costs for patients without cancer, dependent on local service provision.

4 Commissioning implications and cost impact

This section considers the commissioning implications and potential resource impact of implementing the NICE quality standard for venous thromboembolism in adults: diagnosis and management.

4.1 Diagnostic investigations

Quality statement 1: Interim therapeutic dose of anticoagulation therapy for suspected deep vein thrombosis

People with suspected deep vein thrombosis are offered an interim therapeutic dose of anticoagulation therapy if diagnostic investigations are expected to take longer than 4 hours from the time of first clinical suspicion.

Quality statement 2: Diagnosis of deep vein thrombosis

People with suspected deep vein thrombosis have all diagnostic investigations completed within 24 hours of first clinical suspicion.

Quality statement 3: Interim therapeutic dose of anticoagulation therapy for suspected pulmonary embolism

People with suspected pulmonary embolism are offered an interim therapeutic dose of anticoagulation therapy if diagnostic investigations are expected to take longer than 1 hour from the time of first clinical suspicion.

VTE is a potentially life-threatening condition and therefore timely access to investigation and treatment is essential. Access to investigations in line with the quality statements also ensures that people do not receive an unnecessary second dose of anticoagulation therapy, with the associated risk of bleeding, if they do not have a DVT or PE.

Interim therapeutic dose anticoagulation therapy provides people with treatment until investigations are completed and a diagnosis is made. It prevents people with a DVT from developing a PE, and prevents further adverse effects in people with a PE.

People with symptoms of a DVT or PE may present with signs or symptoms of DVT (for example a swollen and/or painful leg) and/or PE (for example chest pain, shortness of breath or haemoptysis) at a number of different services, including GP practices, out of hours services and accident and emergency departments.

Commissioners should ensure that suspected VTE is assessed in line with NICE clinical guideline 144 on venous thromboembolic diseases.

Commissioners should be aware that many incidents of hospital-related thrombosis occur after a person has been discharged from hospital.

Diagnostic investigations for DVT and PE are covered in detail in NICE clinical guideline 144 and are therefore not repeated here but should be referred to when reviewing services for people with suspected VTE. NICE clinical guideline 144 also sets out the assessments that should be completed before interim anticoagulant therapy is offered and should be referred to when developing services. People who need an interim therapeutic dose of anticoagulation therapy for DVT can be given low molecular weight heparin (LMWH) or rivaroxaban. People with suspected PE should be offered low molecular weight heparin. Further NICE technology appraisal guidance on rivaroxaban for PE is available.

This statement reflects a change in current practice for many organisations, particularly as diagnostic services for VTE are not available at weekends in many areas. Commissioners should work with services locally to ensure that:

- diagnostic investigations for VTE are available out of normal working hours, including weekends
- services have the capacity to respond within 24 hours
- diagnostic investigations are reported and acted on within 24 hours of first clinical suspicion.

Commissioners should review current processes for the assessment and diagnosis of VTE across all settings. A number of service models exist for the diagnostic investigation of DVT and PE in community and secondary care settings, and commissioners may wish to review service models to ensure the most cost-effective option locally. See also Implementing 7 day working in imaging departments: good practice guide.

Offering an interim therapeutic dose of anticoagulation therapy may have an impact on costs, but only if patients are not subsequently diagnosed with DVT. There may be a saving of NHS resources by preventing VTE from further adverse effects when timely assessment is not available, for example

a DVT leading to a PE. Not only can PE cause sudden death, but those who survive may need intensive care, and recovery can take several weeks or months. The table below shows potential costs of non-elective inpatient spells that may be incurred in relation to VTE.

Table 2 Non-elective inpatient spell tariff

Investigation	HRG code	£[a]
Pulmonary embolus with major comorbidities complications (CC)	DZ09A	2861
Pulmonary embolus with CC	DZ09B	1549
Pulmonary embolus without CC	DZ09C	1549
Deep vein thrombosis	OZ20Z	554
[a] Tariff based on 2013/14 Road Test Tariff Information – Admitted Patient Care & Outpatient Procedures		

The costing report for NICE clinical guideline 144 demonstrates that the recommendations on diagnostic investigations made in the guideline may result in costs. The costs are likely to be associated with ensuring access to investigations within 24 hours, rather than the investigations themselves. Commissioners may wish to refer to the costing report for comparisons of costs between different investigations.

Table 3 Unit costs for diagnostic investigations

Investigation	HRG code	£[a]
Computed tomography scan – one area with post contrast	RA09Z	108
V/Q planar scan – Nuclear medicine (category 2)	RA36Z	178
V/Q SPECT scan – Nuclear medicine (category 3)	RA37Z	249
X-ray – diagnostic imaging [b]	812	33
Ultrasound scan less than 20 minutes	RA23Z	47
Blood tests – Haematology (excluding anticoagulant services)[c]	DAP823	3
Mammogram[d]		53
[a] Tariff based on 2013/14 Road Test Tariff Information – Unbundled Services (direct access services). The tariff includes the cost of reporting. [b] National Schedule of Reference Costs Year: 2011–12 – All NHS trusts and NHS foundation trusts – Outpatient Attendances Data. [c] National Schedule of Reference Costs – Year 2011–12 – NHS trusts and NHS foundation trusts. Direct Access: Pathology Services. [d] Obtained from direct communication with some primary care trusts.		

Organisations should review their practice and estimate any associated additional cost locally.

Commissioners and providers may wish to audit current practice using NICE clinical audit tools for CG144.

Two-level DVT and PE Wells scores are recommended in CG144 to help estimate the clinical probability of DVT and PE respectively. NICE has provided templates for local adaptation to allow the two-level Wells score for DVT or PE to be calculated and recorded in a format suitable for filing in the patient record.

The costing template for TA261 on rivaroxaban reviews the cost effectiveness of rivaroxaban for the treatment of DVT.

Detailed information on VTE can be found in section 4.2 of the NICE guide for commissioners: anticoagulation therapy.

4.2 Mechanical interventions

Quality statement 4: Mechanical interventions

This statement has been removed. For more details see update information.

4.3 Investigations for cancer and treatment of people with active cancer

Quality statement 5: Investigations for cancer

People with unprovoked deep vein thrombosis or pulmonary embolism who are not already known to have cancer are offered timely investigations for cancer.

The Guideline Development Group for NICE clinical guideline 144 indicated that historically cancer and VTE have been considered as two unconnected disease entities or diagnoses and that in current clinical practice the extent of investigations to determine the underlying cause of VTE is variable

Commissioners should ensure that care pathways for VTE and cancer are well integrated. Commissioners should specify that people with unprovoked venous thromboembolic diseases are offered investigations for cancer and services that are responsible for ensuring that this takes place.

Investigations for cancer to meet the quality standard may involve additional costs. The full guideline for CG144 indicates that about 20%[4] of patients with a VTE diagnosis will have unprovoked VTE which will require further investigation for cancer. Therefore, based on the incidence of patients diagnosed, the number of patients who need further investigations for cancer is approximately 16,700.

[4] Piccioli A, Lensing AW, Prins MH et al. (2004) Extensive screening for occult malignant disease in idiopathic venous thromboembolism: a prospective randomized clinical trial. Journal of Thrombosis and Haemostasis 2: 884–9.
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The initial investigations recommended by NICE clinical guideline 144 include physical examination, blood tests (full blood count, serum calcium and liver function tests) and urinalysis. For patients assessed in secondary care, these tests should form part of the routine assessment for all patients with VTE to determine severity of the VTE and safety of anticoagulation, so should not lead to additional costs. The X-rays and blood tests may be associated with additional costs where people with VTE are managed within primary care.

NICE clinical guideline 144 recommends that further investigations for cancer with an abdomino-pelvic CT scans and mammograms for women should be considered in all patients aged over 40 years with a first unprovoked DVT or PE who do not have signs or symptoms of cancer based on initial investigation. Additional costs may be incurred as a result of these investigations further. (See table 2 for diagnostic unit costs.)

Quality statement 7: Treatment of people with active cancer

People with active cancer and confirmed proximal deep vein thrombosis or pulmonary embolism are offered anticoagulation therapy.

NICE clinical guideline 144 recommended that patients with active cancer and confirmed proximal DVT or PE should be offered LMWH for 6 months or longer if necessary rather than a vitamin K antagonist for 3 months (as offered to patients without cancer). Expert clinical opinion suggests that this is not current practice in all areas. Therefore where recommendations from the guideline have not been fully implemented commissioners should ensure that local treatment protocols and care pathways specify that people with active cancer and venous thromboembolic diseases are offered 6 months' treatment with anti-coagulant therapy.

If recommendations from the guideline have not been implemented there may also be increased costs. LMWH and rivaroxaban are more expensive products than warfarin and a longer duration may have a resource impact (see table 5 for details of costs). However, the Guideline Development Group for NICE clinical guideline 144 suggested that the difference in cost to the

NHS between a vitamin K antagonist and LMWH is narrower once the costs associated with monitoring international normalised ratio (INR) are added to the cost of a vitamin K antagonist.

Table 5 Pharmacological treatment costs[a,]

Anticoagulant[b]	**6 Cycles of 28 days cost (£)**
Rivoroxaban	397
Dalteparin (Fragmin)	1225
Enoxaparin (Clexane)	1641
Tinzaparin (Innohep)	1999

[a]Drug acquisition costs were taken from the NHS Dictionary of Medicines and Devices (dm+d) database and dosages calculated assuming 76.5kg weight. [b]At the time of publication (March 2013) some types of anticoagulant do not have a UK marketing authorisation for 6 months of treatment of DVT or PE in patients with cancer. Prescribers should consult the summary of product characteristics for the individual anticoagulant and make appropriate adjustments for renal impairment. Informed consent for off-label use should be obtained and documented.

Commissioners should review respective administration and monitoring costs for each anti-coagulant therapy. Administration costs of treatment by injection (where patients are unable to administer themselves) and the monitoring of injection treatments should be compared with oral anti-coagulant therapies.

- Commissioners and providers may wish to audit current practice using NICE clinical audit tool on the treatment of venous thromboembolism and investigations for cancer.

4.4 Thrombophilia testing

Quality statement 6: Thrombophilia testing

People with provoked deep vein thrombosis or pulmonary embolism are not offered testing for thrombophilia.

Thrombophilia testing does not provide any benefit for people with provoked VTE. There may also be a psychological impact associated with thrombophilia testing that could lead to stress and anxiety in patients. Therefore it is important that these people do not undergo unnecessary testing for thrombophilia.

Commissioners should review local care pathways and should ensure that thrombophilia testing is carried out in line with NICE clinical guideline 144 and is not offered to people with provoked thromboembolic diseases.

The quality statement may reduce unnecessary testing for thrombophilia therefore saving the NHS resources. It is difficult to estimate the number of people who might be involved in the tests and the potential saving that may be achieved. A thrombophilia test costs approximately £71[5].

- Commissioners and providers may wish to audit current practice using the NICE clinical audit tool on thrombophilia testing.

4.5 Follow-up

Quality statement 8: Follow-up for people without cancer

People without cancer who receive anticoagulation therapy have a review within 3 months of diagnosis of confirmed proximal deep vein thrombosis or pulmonary embolism to discuss the risks and benefits of continuing anticoagulation therapy.

[5] Simpson EL, Stevenson MD, Rawdin A et al. (2009) Thrombophilia testing in people with venous thromboembolism: systematic review and cost-effectiveness analysis. Health Technology Assessment 13: 2.
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Quality statement 9: Follow-up for people with cancer

People with active cancer who receive anticoagulation therapy have a review within 6 months of confirmed proximal deep vein thrombosis or pulmonary embolism to discuss the risks and benefits of continuing anticoagulation therapy.

People receiving anticoagulation should be reassessed to ensure anticoagulation remains beneficial because of potential risks such as bleeding.

Expert opinion of the Topic Expert Group indicates that the routine review of people with venous thromboembolic diseases without cancer is not current practice.

Commissioners should ensure that care pathways are agreed with clinicians and providers to ensure that people with VTE are seen in the right clinical speciality according to their needs. Services carrying out review should have expert skills and competencies, particularly when making decisions about life-long therapy. Service models for review vary across the country, including primary and secondary care, and haematology clinics in primary care settings.

For people without cancer who have venous thromboembolic disease there may be an increase in follow-up appointments to discuss the risks and benefits of continuing anticoagulation beyond 3 months. Any potential additional costs will depend on local service models, therefore organisations are encouraged to review their practice and estimate any potential costs and savings at a local level. Once this is determined, commissioners will need to discuss with providers the potential extra activity and review whether current clinics will be able to manage the increased activity.

For people with cancer who have venous thromboembolic disease there should be no potential costs associated with the review of continuing anticoagulation because these people should already be receiving follow-up

appointments and continuing anticoagulation can be discussed at these appointments.

5 Implementation support

NICE has published a wide range of tools and resources to support commissioners and providers to implement NICE guidance on VTE, including:

- The NICE venous thromboembolism pathway, which provides an overview of all NICE guidance relating to the prevention and management of VTE.
- The NICE guide for commissioners: Anticoagulation therapy. Commissioners and providers can use the commissioning and budgeting tool to estimate the level of service needed locally and the cost of providing that service.
- Implementation support tools for NICE clinical guideline 144, including audit tools, educational resources, slide sets, clinical case scenarios and a baseline assessment tool, can be used by organisations to identify if they are in line with practice recommended in NICE guidance and to help them plan activity that will help them meet the recommendations.

6 Links to national drivers and other useful resources

Policy documents

- 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

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