National Institute for Health and Clinical Excellence

Management of venous thromboembolic diseases
Quality Standard Consultation Comments Table
3rd October 2012- 31st October 2012

Notes for completion (NB this is for internal purposes – remove before posting on web)

ID – This is the comment Ids.
Stakeholder – Please include the organisation name only.
Statement number – Any comment relating to multiple statements should be duplicated and assigned to each relevant statement. Comments can also be recorded as 'general' if they do not relate to a specific statement. If a stakeholder does not specify what the comment relates to then please leave this blank for the technical analyst to complete.

ID	Stakeholder	Statement No	Comments	Response
1	Bayer plc	General	**Provision of information to patients** There is currently no statement covering the provision of information to patients. The NICE clinical guideline 141 discusses that "people with VTE should have the opportunity to make informed decisions about their care and treatment in partnership with their healthcare professionals". Also that "good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are 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". This is supported by recommendations 1.31 - 1.34.1. We would therefore suggest that a quality statement is included around the provision of information. **Proposed quality statement:** **People undergoing anticoagulant treatment for VTE should be given appropriate verbal and written information and advised to carry an 'anticoagulant alert card' at all times. We would also propose that in order to qualify as**	Thank you for your comments and suggested additional quality statement. The TEG acknowledged the role of information for people undergoing anticoagulant treatment and that there are important safety considerations. However the group were in agreement that the role of information and the need to understand the treatment options and risks is sufficiently addressed within the cross cutting quality standard on patient experience. However the TEG agreed to develop a statement to ensure adequate review for people receiving anticoagulation therapy.

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			"appropriate" information, at least that which is included in recommendations 1.31 and 1.33 should be covered. **(1) National Institute for Health and Clinical Excellence. Clinical Guideline 144 (CG144). Management of venous thromboembolic diseases. July 2012. Available from: http://guidance.nice.org.uk/CG144. (Last accessed: 10/2012).**	
2	Frimley Park Hospital NHS Foundation Trust	General	This latest draft on the management for VTE diseases from NICE has failed to include the beneficial role of early catheter directed thrombolysis for selective patients with proximal ilio-femoral DVT. There is good evidence to show that long term outcomes are better in terms of post-thrombotic syndrome for patients who have early thrombus removal. Thrombolytic therapy is not suitable for all patients with proximal DVT but the patients who do well are young patients, those with a history of symptoms of less than 2 weeks duration and patients with no background of malignancy, recent surgery or bleeding disorders. Enden T, Haig Y, Klow N, et al. Long-term outcomes after additional catheter-directed thrombolysis versus standard treatment for acute iliofemeral deep vein thrombosis (the CaVenT study): a randomised controlled trial. Lancet 2011; 379:31-38. Abstract.	Thank you for your comments. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. The TEG reviewed all the suggested additional statements and were content that these important issues were covered by the statements included in the quality standard.
4	Royal college of obstetricians and gynaecologists	General	Thank you for giving the RCOG the opportunity to comment on the NICE draft quality standard for management of venous thromboembolic (VTE) diseases. Since the quality standard excludes the management of VTE in pregnant women and does not deal with thromboprophylaxis, it is of limited direct relevance to obstetricians and gynaecologists	Thank you for your response
5	UK Clinical Pharmacy Association	General	Treatment course length and agent throughout standards. Standard 6: Recommended investigations if cancer suspected. Standard 4: how long to continue GECs.	Noted.

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6	Pfizer Ltd	General	Pfizer Ltd welcomes the opportunity to comment on this consultation. In terms of question 2 of the consultation ('What important areas of care, if any, are not covered by the quality standard?) we note that for non-cancer patients who continue anticoagulation beyond 3 months from diagnosis, there is no quality statement aimed at evaluating patients treated with warfarin to identify those with consistent INR measurements indicative of inadequate control. Since inadequate INR control can result in an increased risk of haemorrhage (Palareti et al 2009) and associated mortality in patients with VTE disease (Linkins et al 2003), the emphasis on evaluation of INR control would be an important way of identifying patients at increased risk of bleeding who would benefit from an alternative anticoagulation treatment for VTE disease, thereby improving patient outcomes in this indication. Secondly, we note that there is no quality statement that focuses on regular assessment of the quality of life (for example, by using a validated health-related quality of life instrument) of patients on anticoagulation therapy beyond 3 months from diagnosis. Regular assessment of quality of life may identify patients who are well controlled on warfarin, but who find the food and drug restrictions associated with warfarin use (Nutescu et al 2011) distressing, and who therefore pose a potential medication adherence risk. Such patients may benefit from alternative anti-coagulation treatments for patients with VTE disease. Third, we note that there is no quality statement to address the need to provide balanced information to patients about the risks and benefits of the current anti-coagulation therapy options available to them at diagnosis, or for those on maintenance therapy who experience difficulties with their current anticoagulation regimen.	Thank you for your comments. Concerning the evaluation of non cancer patients on anticoagulation beyond 3 months, it was the expectation of the TEG that some of this would be covered by the statement 8. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. Regarding the point raised around quality of life. Quality statements have now been added around the review of patients with and without cancer for people receiving anticoagulation therapy. The rationale presented alongside these quality statements does emphasise that the purpose of the review is to ensure anticoagulation therapy remains beneficial The TEG also considered your comments around patient information. Although this is recognised as an important area there is an expectation that this information would be captured within the quality standard on patient experience.

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			References: 1. Palareti G, Cosmi B. Bleeding with anticoagulation therapy - who is at risk, and how best to identify such patients. Thromb Haemost. 2009 Aug; 102(2):268-78. 2. Linkins LA, Choi PT, Douketis JD. Clinical impact of bleeding in patients taking oral anticoagulant therapy for venous thromboembolism: a meta-analysis. Ann Intern Med. 2003 Dec 2; 139(11):893-900. Nutescu E, Chuatrisorn I, Hellenbart E. Drug and dietary interactions of warfarin and novel oral anticoagulants: an update. J Thromb Thrombolysis. 2011 Apr; 31(3):326-43.	
7	LEO Pharma	Introduction	The quality standard excludes pregnant women. What is the reason for this? Injectable LMWH is not contraindicated in pregnancy and breastfeeding e.g. tinzaparin can be used in pregnancy if no safer alternative is available	Thank you for your comment. Pregnant women were considered to be outside the remit of the quality standard as it was agreed that the scope of the quality standard should mirror that of the clinical guideline
8	Society for Acute Medicine	Introduction	I have highlighted my comments in bold with further explanations between brackets. It has been estimated that 25,000 people in the UK die every year from potentially preventable hospital-acquired VTE We feel this point needs to be made, as there is a paucity of evidence that this number of deaths is actually likely to be prevented by hospital administration of VTE prophylaxis; many of the patients who currently die from PE following hospital admission may have also died from PE even if the prophylaxis had been administered during their hospital stay.	Thank you. The TEG considered your suggestions and have made your suggested changes where it was felt that clarity would be improved
9	UK Clinical Pharmacy Association	Question 1	Appropriate healthcare outcomes - decrease un-necessary bleeding by stopping anticoagulation if tests negative; decrease in occupied bed days	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included.
10	UK Clinical Pharmacy Association	Question 1	Appropriate healthcare outcomes – incidence of PE (if under-dosed)	Thank you for your suggestions. Where the TEG were confident that there was a clear

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				causal relationship between the action described in a statement and an outcome, the outcome has been included although we recognise that the statements may collectively contribute to wider outcomes.
11	UK Clinical Pharmacy Association	Question 1	Appropriate healthcare outcomes - decrease in un-necessary testing, cost-saving	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included. This has been further explored within the accompanying support for commissioner's document for the quality standard.
12	UK Clinical Pharmacy Association	Question 1	Appropriate healthcare outcome - decrease in recurrent events	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included although we recognise that the statements may collectively contribute to wider outcomes or those set out in the national outcomes framework.
13	UK Clinical Pharmacy Association	Question 1	QS3 Appropriate healthcare outcomes - decrease in pulmonary hypertension?	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included.
14	AntiCoagulation Europe	Question 2	We would like to make the following comment relating to an important and continuing issue surrounding patient care in this area and which is not referred to in the draft Quality Standard. NICE Clinical Guideline no 144, 1.4. Self – Management and self –monitoring for patients treated with a vitamin K antagonist 1.4.1 states that patients who have had a DVT or PE and are receiving VKA for treatment should not be routinely offered self –	Thank you for your comments around self-management. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. Self-management was not an area prioritised for this quality

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			management or self monitoring of INR(using hand held devices for this purpose)'Routinely' is open to interpretation – who decides to advise a patient that the technology is available and if a patient does decide to embark on self monitoring, will they be supported by the clinician responsible for their A/C care? At the present time, the 'testing strips' for the devices are available on prescription, the devices have to be purchased by the individual. Approx 1.4% of the population requires anticoagulant therapy at one time in the UK. Approximately, 18,000 people use a self –testing device out of choice, they have taken responsibility for self testing and enabling management of their treatment with the approval of their clinician. ACE acknowledges that some patients would not want or be able to self –test, however, by not routinely offering them the option, AC patients are being denied the opportunity to enable their own management of their treatment effectively	standard however it is acknowledged as an important area of care.
15	Society for Acute Medicine	Question 2	There is no mention of screening for pulmonary hypertension during follow up (at three months) for people who have had massive or submassive PE. It would be nice to have some sort of audit data for PE patients who required thrombolysis.	Thank you for your comments and suggested additional quality statements. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. The TEG reviewed all the suggested additional statements and were content that these important issues were covered by the statements included in the quality standard.
16	UK Clinical Pharmacy Association	Question 3	Statement 4: to prevent development of post-thrombotic syndrome.	Thank you for your response
17	UK Clinical Pharmacy Association	Question 3	Statement 5 to prevent progression to PE & bleeding	Thank you for your response

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18	UK Clinical Pharmacy Association	Question 3	Statement 7: to prevent unnecessary and costly investigations which are not likely to add value	Thank you for your response
19	Society for Acute Medicine	Question 3	The most important quality statements are (in my opinion): number 1, 2, 3, 4 and 8	Thank you for your response
20	UK Clinical Pharmacy Association	Question 3	Standard 1: to facilitate timely diagnosis & treatment initiation.	Thank you for your response
21	UK Clinical Pharmacy Association	Question 3	Statement 6: to facilitate earlier cancer diagnosis & initiation of an appropriate agent for an appropriate treatment duration.	Thank you for your response
22	UK Clinical Pharmacy Association	Question 3	Statement 8 to prevent VTE recurrence, to minimise risk of bleeding if warfarin prescribed instead of LMWH.	Thank you for your response
23	UK Clinical Pharmacy Association	Question 3	Statement 9 to review treatment appropriately and assess compliance.	Thank you for your response
24	UK Clinical Pharmacy Association	Question 4	Statement 5. Needs clarification around which drug treatment. Statement refers predominantly to LMWH. Not necessary if rivaroxaban initiated.	Thank you for your response. Following discussions with the TEG this statement was not progressed to the final quality standard.
25	UK Clinical Pharmacy Association	Question 4	Statement 6.Is this all patients or just patients above a certain age or with certain co-morbidities. Line saying patients with active cancer should be considered as unprovoked - need to clarify this in terms of treatment duration rather than investigations	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification about what the statement covers.
26	UK Clinical Pharmacy Association	Question 5	NPSA published treatment dose LMWH alert in 2010. No guidance on extremes of weight or dosing in renal impairment. Anecdotal evidence that still problem but unsure if any definitive evidence.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard.
27	Medicines and Healthcare products Regulatory Agency (MHRA)	Question 5	Dose adjustment of anticoagulant therapy by weight and renal function is important to prevent related adverse events of bleeding or under treatment; therefore the proposed statement is endorsed.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
28	Medicines and Healthcare products Regulatory Agency	Question 6	This statement is endorsed; patients with unprovoked VTE should be offered investigations for cancer, in order to optimize the number of early diagnosis.	Thank you for your response

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	(MHRA)			
29	UK Clinical Pharmacy Association	Question 6	Yes, would provide a driver	Noted
30	UK Clinical Pharmacy Association	Question 7	Statement needs to be more specific, is it course length or choice of agent that are main issues	Thank you for your response. It was the view of the TEG that sufficient detail has been provided
31	Medicines and Healthcare products Regulatory Agency (MHRA)	Question 7	Mortality from PE as outcome is linked to quality statement 8.	Thank you for your suggestions. Outcome measures are stated where the topic expert group felt these were appropriate, measureable and specifically attributable to the action stated in the statement. In addition to this, each statement is now followed by a rationale section which provides a brief explanation for why the statement is important with some reference to the outcomes that the action referred to in the statement has a potential causal link to
32	Society for Acute Medicine	Question 7	I had not linked PE mortality to this outcome measure (8) – it seems to refer to the treatment of VTE in patients with cancer.	Noted
33	Medicines and Healthcare products Regulatory Agency (MHRA)	Question 8	The proposal to add a follow up care statement of the venous thromboembolic disease for patients with cancer (quality statement similar to 9 for patients without cancer and follow up in 3 months), would not be necessary for patients with cancer because this group of patients will be followed up in any case for the oncology process, and normally managed by multidisciplinary teams that will assess the benefit/risk of the anticoagulant therapy together with the oncology treatment.	Noted
34	Society for Acute Medicine	Question 8	No	Thank you for your response.
35	UK Clinical Pharmacy Association	Question1	Appropriate healthcare outcome - decrease in PE; decrease in recurrent events through appropriate treatment	Thank you for your suggestions. Outcome measures are stated where the topic expert group felt these were appropriate,

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				measureable and specifically attributable to the action stated in the statement. In addition to this, each statement is now followed by a rationale section which provides a brief explanation for why the statement is important with some reference to the outcomes that the action referred to in the statement has a potential causal link to
36	Medicines and Healthcare products Regulatory Agency (MHRA)	Questions 1-4	The proposed quality statements cover the most important areas of care. Of special importance are quality statements 1 to 3 and 5: QS 1 (investigations completed within 24h), QS 2 (when suspected DVT, initiate treatment with anticoagulation if investigations take longer than 4 hours), QS 3 (when suspected pulmonary embolism, initiate anticoagulation if investigations take longer than 1h) and QS 5 (Dose adjustment of anticoagulation treatment beyond an initial dose, for weight and renal function); early diagnosis and prompt treatment are key elements to prevent Pulmonary Embolism, reduce mortality and prevent adverse events for unadaquete anticoagulation treatment. Quality statements 4 and 6 to 9 also cover important areas of care, but its importance it's subordinate to the four quality statements mentioned above	Thank you for your response
37		Questions 1-4	Of special importance are quality statements 1 to 3 and 5: QS 1 (investigations completed within 24h), QS 2 (when suspected DVT, initiate treatment with anticoagulation if investigations take longer than 4 hours), QS 3 (when suspected pulmonary embolism, initiate anticoagulation if investigations take longer than 1h) and QS 5 (Dose adjustment of anticoagulation treatment beyond an initial dose, for weight and renal function); early diagnosis and prompt treatment are key elements to prevent Pulmonary Embolism, reduce mortality and prevent adverse events for unadaquete anticoagulation treatment. Quality statements 4 and 6 to 9 also cover important areas of	Thank you for your response

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			care, but its importance it's subordinate to the four quality statements mentioned above	
38	British Nuclear Medicine Society	QS1	What is the evidence base for needing VTE diagnostic investigations being completed in 24 hours of presentation? This will have resource implications – particularly at weekends where staff are paid at premium time to undertake investigations. This disadvantages nuclear medicine techniques as nuclear medicine departments tend to be open Monday-Friday only. This quality statement will require weekend opening of nuclear medicine departments or patients presenting at weekends will only be able to have CTPA which is not always the most appropriate test, e.g. pregnancy, women of reproductive age (breast dose reduction), iodinated contrast allergy and renal failure. Since the NHS expenditure is fixed (and reducing) imaging VTE within 24hrs will likely result in other conditions being deprioritised unless quality statements are issued in all acute illness that require imaging, saying they too should be completed in 24 hours.	Thank you for your comments. Following review the quality statement now only includes people with suspected DVT. The TEG reviewed all the timescales included in the standard and have ensured that they are in line with evidence based recommendations or where these were not available, the expert opinion of TEG members who considered the issue you raised.
39	British Thoracic Society	QS1	'People with suspected venous thromboembolic diseases have diagnostic investigations completed within 24 hours of first clinical suspicion. This is going to be difficult to deliver as it will force every hospital to provide a 7 day service for leg Doppler examinations. NICE's aim is to reduce 'The proportion of people with suspected DVT who progress to a pulmonary embolism in the absence of timely diagnostic investigations'. Given that	Thank you for your comments. Standards aim to be aspirational but achievable. However, it is recognised that some standards may be more challenging than others and may require changes in services in order to achieve them. NICE has produced a support document to

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			these patients will already be on treatment with low molecular weight heparin it is difficult to see how bringing forward their investigations will alter this outcome.	help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both available from www.nice.org.uk.
40	LEO Pharma	QS1	There is no mention of a repeat ultrasound in 6-8 days in patients who have positive d-dimer and negative proximal leg vein ultrasound results. This is important to rule out proximal extension of distal DVT and should be included in the quality statement.	NICE quality standards are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care. The statements identify the most important 'markers' and do not replace the underpinning source guidance and recommendations, so the expectation is that this detail would be referred to in the clinical guideline.
44	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS1	Standard 1 Does this mean within 24 hours of first clinical suspicion in the community or within 24 hours after presentation to the investigating unit? Is it realistic to have all hospitals providing a diagnostic service 7 days a week?	Thank you for your response. The statement is aimed at both the community and hospital setting
45	Vascular society	QS1	Process: Complete diagnostic investigations within 24 hours will require 7 day working for imaging departments and this in itself maybe should be an outcome measure.	Standards aim to be aspirational but achievable. However, it is recognised that some standards may be more challenging than others and may require changes in services in order to achieve them. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and

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				carers what the quality standard means to them, both available from www.nice.org.uk.
48	King's College Hospital NHS Foundation Trust	QS1&2	Outcome. Progression to PE; this is a difficult outcome to measure. It is well recognised that 50% of patients with proximal DVT have coexistent 'asymptomatic' PE at presentation (Dorfman et al, 1987; Huisman et al, 2000; Moser et al, 1994; Nielsen et al, 1994). Furthermore, many will not undertake confirmatory imaging for PE in the presence of confirmed DVT as it is unlikely to change management.	Thank you for your comments and we do recognise that the majority of measures are likely to be process measures because of the issues of attribution or the constraints in reliably assessing these at local level. The outcomes are intended to offer a starting point which may inform further development.
49	LEO Pharma	QS2	There is no mention of a repeat ultrasound in 6-8 days in patients who have positive d-dimer and negative proximal leg vein ultrasound results. This is important to rule out proximal extension of distal DVT and should be included in the quality statement.	NICE quality standards are a concise set of statements designed to drive and measure priority quality improvements within a particular area of care. The statements identify the most important 'markers' and do not replace the underpinning source guidance and recommendations, so the expectation is that this detail would be referred to in the clinical guideline.
54	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS2	Does incidence of PE as outcome refer to symptomatic PE? It is probably not a closely associated measure of this standard.	Thank you for your suggestions. The outcome relates to the Incidence of PE in people who have undergone diagnostic tests for DVT.
55	Society for Acute Medicine	QS2	This differs from NICE CG 144 in that the 4 hour clock started when the radiology department got the request (as I understood it) – this now starts the clock when VTE is first considered in the differential diagnosis – a very different thing indeed.	Thank you for your response. The timeframe (4 hour) refers to the time from first clinical suspicion with the understanding that clinical investigations will be requested immediately. Following discussion with members of the TEG who also developed NICE CG 144 this

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				was also the intention of the guideline.
56	Society for Acute Medicine	QS2	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, 'unless they are considered to have a low clinical risk of VTE when using an appropriate clinical scoring system'. (though I realise this is contrary to guideline 144 – I am concerned because 75% of ?VTE patients don't have VTE and the % is even higher in the low clinical risk group – hence unnecessary anticoagulation of a lot of patients, which carries a risk of bleeding). NB: overall we now have 10-15% positivity rate and would subject many stable patients to unnecessary anticoagulation if this guideline acted upon	Thank you for your comments. The statement is in line with the underpinning evidence-based recommendations from NICE clinical guideline 144, from which the quality standard is derived.
57	Vascular society	QS2	See above for 7/7 working	Noted
58	UK Clinical Pharmacy Association	QS 2&3	Statements 2 and 3 - to prevent progression to PE and subsequent risk of death.	Thank you for your suggestions. Outcome measures are stated where the topic expert group felt these were appropriate, measureable and specifically attributable to the action stated in the statement. In addition to this, each statement is now followed by a rationale section which provides a brief explanation for why the statement is important with some reference to the outcomes that the action referred to in the statement has a potential causal link to

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63	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS3	Is first clinical suspicion the time they are seen in the investigating unit with suspected PE? An additional two standards might be considered for patients with high and intermediate risk pulmonary embolism. Patients with high risk PE should be considered for thrombolysis Patients with intermediate risk PE should be treated as inpatients and monitored on an appropriate unit so that they can be escalated to thrombolysis if required. In randomised trials of thrombolysis in patients with intermediate risk PE there was no mortality difference between those randomised to thrombolysis followed by anticoagulation and those randomised to anticoagulation alone. However, in the trials all patients were monitored and those who deteriorated within 72 hours and had not been given thrombolysis initially were then given it. Notably 25% of patients not randomised to thrombolysis required it. In England patients with intermediate risk PE are often admitted to low dependency units and are not monitored. Consequently, mortality from intermediate risk PE in England is not as low as it should be. Inpatient management on an appropriate dependency unit with pulse and BP monitoring would identify deterioration and allow thrombolysis to be given.	Thank you for your comments and suggested additional quality statements. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. The TEG reviewed all the suggested additional statements and were content that these important issues were covered by the statements included in the quality standard.
64	Society for Acute Medicine	QS3	There needs to be an understanding that GP referrals with ?PE often take > 1 hour to get to hospital – it is going to be difficult to start the 1 hour clock from the time of first clinical contact unless all ?PE patients come from their GP by blue light ambulance. Also, is a diagnostic investigation a CXR? (which then demonstrates a pneumothorax for example) or will the 1 hour target drive a massive increase in 'straight to CTPA' requests?	Standards aim to be aspirational but achievable. However, it is recognised that some standards may be more challenging that others and may require changes in services in order to achieve them. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both available from www.nice.org.uk. The intent of the statement is that GPs

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				would be able to access anticoagulation therapy where pulmonary embolism is suspected and if a confirmatory test is not immediately available.
65	Society for Acute Medicine	QS3	We disagree with the 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'. This should exclude patients who are at low clinical risk while awaiting D-Dimer, the vast majority of whom will not have PE. Furthermore: 'People in whom massive PE is suspected and thrombolysis is being considered should have investigations in under 1 hour and should not be anticoagulated until a decision not to thrombolyse has been made (i.e. don't give anticoagulation prior to thrombolysis, I fear it increases bleeding risk. Also, there will be a lot of patients with pneumonia or a pneumothorax (needing a drain) who will have been anticoagulated and this may delay their intervention)	Thank you for your response. After considering your comments it is acknowledged that the final decision to give anticoagulation would be based on clinical judgement. This may be based on factors such as bleeding risk
66	Vascular society	QS3	Agreed	Thank you for your response.
67	Frimley Park Hospital NHS Foundation Trust	QS4	Catheter directed thrombolysis has been omitted in the care of patients with proximal lower limb VTE.	Thank you for your comments
68	King's College Hospital NHS Foundation Trust	QS4	General The evidence for use of GCS in prevention does not support application within a particular time frame. The two studies with greatest reduction in incidence of post thrombotic syndrome applied either between 5-10days post DVT and 2-3 weeks post DVT (Brandjes et al, 1997; Prandoni et al, 2004). The optimal time for application of GCS is an area requiring further research (Musani et al, 2010). We suggest the quality statement be modified to 'People with proximal deep vein thrombosis are offered below-knee graduated compression stockings'. Outcome Whilst PTS is a clinically important outcome, use of GCS will not	Thank you for your comments. The TEG reviewed all the timescales included in the standard and have ensured that they are in line with evidence based recommendations or where these were not available, the expert opinion of TEG members who considered the issue you raised and concluded that stockings fitted by 3 weeks provides a pragmatic, measurable timeframe that is consistent with the intent of NICE clinical guideline 144.

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			eliminate PTS but reduce the incidence to ~20% assuming complete patient adherence. In the absence of complete adherence, the incidence is likely to be higher. Furthermore, PTS requires an active approach to diagnosis; NICE CG144 does not cover diagnosis of PTS. Unless a universal approach is adopted using a validated tool for diagnosis, the incidence will vary highly between centres with low incidence potentially related to under-diagnosis.	
72	Royal college of obstetricians and gynaecologists	QS4	We are pleased to see that in Statement 4, (Mechanical interventions) the equality issues of difficulty in putting on compression stockings has been recognised. Consideration should be given to incorporate the need to offer assistance in the Quality Statement itself.	Thank you for your response. The TEG considered your comments and this has been included in the equality analysis document that supports this quality standard.
73	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS4	In practice it can be difficult to apply compression stockings within 1 week of diagnosis due to swelling. It might be better to state that below-knee graduated stockings are applied within 1 week of diagnosis or as soon as reduced leg swelling permits	Thank you for your comments Additional detail has been added to the definitions and supporting information to account for contraindications and a pragmatic timeframe developed.
74	Society for Acute Medicine	QS4	People with proximal deep vein thrombosis are offered below-knee grade three graduated compression stockings on the affected leg within 1 week of diagnosis.	Thank you for your response
75	Urgo Medical	QS4	We note that on the draft Quality statement 4, page 10 Mechanical Interventions, it states that below- knee graduated compression stockings offered should have an ankle pressure of 23mmHg. This definition is referenced back to the NICE Clinical Guideline CG144. However, NICE Clinical Guideline CG144 states ‘offer below-knee graduated compression stockings with an ankle pressure greater than 23 mmHg to patients. Could this be clarified?	The definition has been updated to reflect this.

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76	Vascular society	QS4	We would support that stocking should be available immediately (24 hours), rather than within 1 week. Facilities for ABI measurement should also be available 24/7.	Thank you for your response
77	Bayer plc	QS5	This statement could lead to confusion as not all anticoagulant drugs licensed for the treatment of deep vein thrombosis (DVT) and/or pulmonary embolism (PE) require dose adjustment for weight and/or renal function. This statement is currently referenced to NICE clinical guideline 1441 recommendation 1.2.1, which specifically relates to the initial parenteral anticoagulant treatments e.g. low molecular weight heparin (LMWH), but not necessarily to vitamin K antagonists (VKAs) or rivaroxaban. This statement also does not accurately reflect recommendation 1.2.1, which states that people with confirmed proximal DVT or PE should be offered a choice of LMWH or fondaparinux (or UFH where appropriate), to be started as soon as possible and continued for 5 days or until the INR (adjusted by a vitamin K antagonist [VKA]) is 2 or above for at least 24 hours, whichever is longer,1 and does not specifically discuss dose adjustment for weight or renal function. A more accurate representation of recommendation 1.2.1 (which is a key priority for implementation) as well as of other closely related recommendations from GC144 (recommendation 1.2.3) and other NHS evidence accredited NICE guidance (NICE technology appraisal 2612) is proposed as follows: Proposed quality statement: People with confirmed VTE are offered at least 3 months of treatment with a choice of appropriate pharmacological interventions in accordance with relevant NICE guidance. (1) National Institute for Health and Clinical Excellence. Clinical Guideline 144 (CG144). Management of venous	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard.

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			thromboembolic diseases. July 2012. Available from: http://guidance.nice.org.uk/CG144. (Last accessed: 10/2012). (2) National Institute for Health and Clinical Excellence. Technology Appraisal 261 (TA261). Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. July 2012. Available from: http://guidance.nice.org.uk/TA261. (Last accessed: 10/2012).	
78	Bayer plc	QS5	The source evidence for quality statement 5 (as proposed above) should also include NICE technology appraisal 261,2 rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. Source guidance recommendations NICE technology appraisal 261: “Rivaroxaban is recommended as an option for treating deep vein thrombosis and preventing recurrent deep vein thrombosis and pulmonary embolism after a diagnosis of acute deep vein thrombosis in adults.”2 “The duration of treatment recommended in the summary of product characteristics depends on bleeding risk and other clinical criteria: short-term treatment (3 months) is recommended for those with transient risk factors such as recent surgery and trauma, and longer treatment for permanent risk factors or idiopathic (unprovoked) deep vein thrombosis.”2 (2) National Institute for Health and Clinical Excellence. Technology Appraisal 261 (TA261). Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. July 2012. Available from: http://guidance.nice.org.uk/TA261. (Last accessed: 10/2012).	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard

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79	Bayer plc	QS5	Rivaroxaban is also currently undergoing a single technology appraisal for PE treatment which is due for publication by July 2013 (3) National Institute for Health and Clinical Excellence. Technology appraisal in development. Pulmonary embolism (acute treatment, VTE prevention) - rivaroxaban [ID569]. 2012. Available from: http://guidance.nice.org.uk/TA/Wave22/20. (Last accessed: 10/2012).	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
80	British Thoracic Society	QS5	'People with venous thromboembolic diseases continuing anticoagulation therapy beyond an initial dose, have their dose adjusted for weight and renal function.' It is not clear why the initial dose administered to patients shouldn't be adjusted for weight and renal function as well.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
81	LEO Pharma	QS5	We suggest that a statement should be included to explain that LMWHs differ with regards to the dose adjustments needed for reduced renal function and that at certain levels of renal function some LMWHs will require a dose reduction whilst others will not.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
85	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS5	Is this redundant? Shouldn't adjustment for weight and renal function apply with the first dose?	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard,
86	Society for Acute Medicine	QS5	Warfarin dose is not adjusted according to weight or renal function – this specifically applies to UFH and LMWH.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
87	Society for Acute Medicine	QS5	People with venous thromboembolic diseases continuing (anticoagulation) LMWH therapy beyond an initial bridging dose, have their dose adjusted for weight and renal function.	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard

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88	Vascular society	QS5	Agreed	Thank you for your response.
89	Bayer plc	QS5	Rivaroxaban is also currently undergoing a single technology appraisal for PE treatment and the draft scope indicates that the subgroup of patients with active cancer present should be considered if the evidence allows.3 (3) National Institute for Health and Clinical Excellence. Technology appraisal in development. Pulmonary embolism (acute treatment, VTE prevention) - rivaroxaban [ID569]. 2012. Available from: http://guidance.nice.org.uk/TA/Wave22/20. (Last accessed: 10/2012).	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
90	Bayer plc	QS5	We suggest that it would also be useful to refer to the NICE pathway for venous thromboembolism here as it provides access to the full range of relevant guidance from NICE.4 (4) National Institute for Health and Clinical Excellence. NICE Pathways: Venous thromboembolism. Last updated Aug 2012. Available from: http://pathways.nice.org.uk/pathways/venous-thromboembolism. (Last accessed: 10/2012).	Thank you for your comments. Following discussions by the TEG this statement has not been progressed to the final quality standard
91	Airedale NHS Foundation Trust	QS6	There is an issue of resources in seeking primary tumours under these circumstances. A cross-reference to NICE CG104 would be appropriate; “Patients should be investigated according to guidance on Metastatic malignant disease of unknown primary origin” according to local arrangements.	Thank you. The TEG considered your comments and were in agreement that referencing NICE clinical guideline 144 was sufficient for this statement.
92	British Thoracic Society	QS6	‘People with unprovoked venous thromboembolic diseases are offered investigations for cancer.’ The wording of this seems a little vague. The supporting text doesn’t help, suggesting in one section that patients should have bloods, CXR and urinalysis whilst in another suggesting that those over 40 should also be offered CT abdo/pelvis +/- mammography. It would be helpful if they were more proscriptive in the quality statement over what investigations they expect to be performed.	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification.
97	Pancreatic Cancer UK	QS6	Pancreatic Cancer UK strongly supports the recommendation that all patients diagnosed with unprovoked venous thromboembolic disease are offered investigations for cancer.	Thank you for your response

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			In terms of the specific question of whether there is evidence that people with unprovoked VTE are not receiving the stated investigations for cancer – on our helpline we have come across two cases within the last two years in which younger patients presented with multiple VTE's (arms and legs) and were not investigated for cancer and they were later diagnosed with cancer. From this anecdotal evidence we cannot say how widespread an issue this is, however we do feel that it is important to have this quality standard to ensure that these type of investigations are carried out.	
98	Royal college of obstetricians and gynaecologists	QS6	Investigations for cancer in unprovoked thromboembolic diseases. The QS advises physical examination, CXR and blood tests (FBC, Calcium, LFT). There is a recognised association between ovarian tumours (malignant and benign) with thromboembolic disease. The investigations highlighted here might easily fail to diagnose such a tumour. Would you please consider the addition of pelvic imaging such as ultrasound?	Thank you for your comments. The statement developed to be in line with the underpinning evidence-based recommendations from NICE clinical guideline 144, from which the quality standard is derived.
99	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS6	As indicated under source clinical guidelines references NICE Guideline 144 states : Consider further investigations for cancer with an abdomino-pelvic CT scan (and a mammogram for women) 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. However under Definitions only a CXR, blood tests and urinalysis are included. According to CG144 an abdomino-pelvic CT scan (and a mammogram for women) should be included. As CG144 states 'consider' there is no option but to perform these investigations as there are no criteria to identify patients who do not require these investigations.	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification about what the statement covers. Reference to recommendation 1.5.2 which relates to a consideration of further investigations for patients aged over 40 years has been removed.

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100	Society for Acute Medicine	QS6	I was under the impression that the 'hunt the cancer' if a basic series of blood tests and a good physical examination was normal was a waste of resource with a very low yield and no evidence of any difference in outcome. I attach the DVT proforma which we use – page 6 has our cancer screening questionnaire. I agree with the list of investigations on page 14 but not on extra mammograms and body CT unless there is specific reason to be doing these tests. Guideline CG144 states that CT and / or mammography should be 'considered' in this group; this quality statement suggests that all patients should undergo these investigations; this will entail significant radiological exposure for a group with a low diagnostic yield (we abandoned our previous strategy where all patients with unprovoked VTE were investigated after finding only one cancer which was not 'clinically suspected' over 5 years). If you insert the line 'Following clinical assessment, CT and or mammography should be considered' this will reduce the likelihood of unnecessary radiation. I think it would also be helpful to state that ultrasound may be useful for patients with thin body habitus – if clear views are obtained of the abdominal and pelvic organs in a patient with low clinical likelihood of an underlying cancer this would save unnecessary CT being undertaken.	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification about what the statement covers. Reference to recommendation 1.5.2 which relates to a consideration of further investigations for patients aged over 40 years has been removed.
101	Vascular society	QS6	Agreed	Thank you for your response.

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102	King's College Hospital NHS Foundation Trust	QS7	Definition. Unprovoked VTE definition should NOT include those with active cancer, strong family history of VTE or known thrombophilia. Active cancer is a strong risk factor for VTE; further investigations are unlikely to identify a second occult malignancy. These patients were excluded from studies investigating occult malignancy. Patients with known thrombophilia and strong family history were also excluded from these studies and should therefore not be considered unprovoked (Di Nisio et al, 2005; Piccoli et al, 2004). The definition of unprovoked VTE from the evidence utilised by NICE was absence of history of known malignancy, trauma of leg, surgical procedures/immobilisation in previous 6 months, family history of unprovoked VTE, thrombocytosis, known thrombophilia, oestrogen use, pregnancy/postpartum (Piccoli et al, 2004). This definition should be used for the quality standard.	Thank you for your comments Additional detail has been added to the definitions to provide further clarification about what the statement covers,
103	King's College Hospital NHS Foundation Trust	QS7	Denominator Some patients will decline further investigations; consideration is needed for this to be reflected in the denominator (or for those offered screening to be the numerator even if investigations not undertaken).	Thank you for your comments
106	Royal college of obstetricians and gynaecologists	QS7	Statement 7 addresses thrombophilia testing in people with provoked VTE. In the section 'definitions', provoked VTE includes VTE occurring during pregnancy and the puerperium. We suggest that pregnancy and the puerperium should be removed since: (a) the guideline and quality standard specifically exclude the management of VTE in pregnant women; the interpretation of the results of thrombophilia testing during pregnancy and the puerperium is frought with difficulties the RCOG guideline on the management of VTE in pregnancy and the puerperium (RCOG GTG 37b) discusses the limitations of thrombophilia testing but acknowledges that the duration and intensity of anticoagulation will be altered in the presence of a thrombophilia.	Thank you for your comments. The statement is in line with the underpinning evidence-based recommendations from NICE clinical guideline 144, from which the quality standard is derived.

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107	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS7	At least as many patients with heritable thrombophilia suffer provoked as unprovoked VTE. Consequently, it is confusing to have a standard that states testing should be on the basis of whether venous thromboembolic disease was provoked or not. Heritable thrombophilia is a late onset familial genetic disease with low penetrance and there often has to be an additional provocation for VTE to occur. The decision to test or not is a complex one depending on family history and whether or not case-finding is being considered. Therefore, it should not be performed during the period of acute care but can be considered later by a clinician who is able to determine the relative benefit and disadvantage of testing and counsel the patient before testing. Would it not be easier simply to state that testing for heritable thrombophilia is generally not required. The situation with regard to acquired thrombophilia, principally Antiphospholipid Syndrome is different. This is not a familial disorder and testing in this situation is to identify patient who might be considered for continued anticoagulant therapy. In this context the recommendation that patients with provoked VTE should not be tested for APS is appropriate. Therefore, a suggestion for standard 7 is: People with provoked venous thromboembolic diseases do not have testing for Antiphospholipid Syndrome. Testing people with venous thromboembolic diseases for heritable thrombophilia is generally not required. In the section that explains the standard it could be stated that testing should not be performed during the acute phase of the disease, it might be performed later in exceptional cases but testing should only be requested by a clinician who is able to determine the relative benefit and disadvantage of testing and who is able to counsel the patient before testing.	Thank you for your comments. The statement is in line with the underpinning evidence-based recommendations from NICE clinical guideline 144, from which the quality standard is derived.

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108	Society for Acute Medicine	QS7	Is there evidence that people with unprovoked VTE having limited anticoagulation and with a family history of VTE are having thrombophilia screening? I think women of child bearing age with oestrogen-provoked VTE should be having acquired thrombophilia and antithrombin screening when coming off anticoagulation.	Thank you for your comments. The TEG considered your comments but were in agreement that based on evidence from the clinical guideline and current practise the statement is appropriate.
109	Vascular society	QS7	Agreed	Thank you for your response.
110	Bayer plc	QS8	We suggest that it would also be useful to refer to the NICE pathway for venous thromboembolism here as it provides access to the full range of relevant guidance from NICE.4 (4) National Institute for Health and Clinical Excellence. NICE Pathways: Venous thromboembolism. Last updated Aug 2012. Available from: http://pathways.nice.org.uk/pathways/venous-thromboembolism. (Last accessed: 10/2012).	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification about what the statement covers
111	Bayer plc	QS8	Draft statement 8 does not reflect the fact that rivaroxaban is also an option in people with active cancer and DVT. In the rixaroxaban technology appraisal TA 2612 “the Committee concluded that rivaroxaban should not be excluded as a treatment option for preventing venous thromboembolism in people with cancer.” Suggest that the statement is amended to read: People with active cancer and venous thromboembolic diseases are offered 6 months treatment with low molecular weight heparin. Rivaroxaban is also an option for patients with DVT. (2) National Institute for Health and Clinical Excellence. Technology Appraisal 261 (TA261). Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. July 2012. Available from: http://guidance.nice.org.uk/TA261. (Last accessed: 10/2012).	Thank you for your comment. This quality statement and the supporting information have now been updated to address the issues you have raised.

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112	Bayer plc	QS8	The source evidence for this quality statement should also include NICE technology appraisal 2612, rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. Source guidance recommendations: NICE technology appraisal 261: “Rivaroxaban is recommended as an option for treating deep vein thrombosis and preventing recurrent deep vein thrombosis and pulmonary embolism after a diagnosis of acute deep vein thrombosis in adults.”2 “Given the lack of clinical evidence for this group, the Committee was unable to make specific recommendations on the use of rivaroxaban in people with cancer but recognised the disadvantages of the currently available treatment, which involves regular injections, and which some people might choose to decline. The Committee concluded that rivaroxaban should not be excluded as a treatment option for preventing venous thromboembolism in people with cancer.”2 (2) National Institute for Health and Clinical Excellence. Technology Appraisal 261 (TA261). Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism. July 2012. Available from: http://guidance.nice.org.uk/TA261. (Last accessed: 10/2012).	Thank you for your comment. This quality statement and the supporting information have now been updated to address the issues you have raised.
113	Bayer plc	QS8	We suggest that in addition to mortality from PE, recurrent VTE events should be considered due to their significant burden to both the NHS and patients	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included.

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114	King's College Hospital NHS Foundation Trust	QS8	General Would be more valuable to include a quality standard that impacts on quality of care received by patient. For example, 'patients with unprovoked VTE who discontinue anticoagulation are tested for antiphospholipid antibodies'. This will identify those patients who are at high risk of recurrence and would benefit from re-initiation of anticoagulation. The current quality standard does not evaluate a clinically important outcome; omission of a test has no direct benefit to the patient. Published reports suggest these tests do not cause undue stress as suggested by GDG opinion (van Korlaar et al, 2005; Legnani et al, 2006).	Thank you for your comments and suggested additional quality statement. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes. The TEG reviewed all the suggested additional statements and were content that these important issues were covered by the statements included in the quality standard.
115	LEO Pharma	QS8	Specific questions for the consultation: Recurrence of VTE may be considered as well as or in addition to mortality from PE	Thank you for your comments. They have been considered by the TEG
116	LEO Pharma	QS8	It should be noted that not all LMWH are currently licensed for treatment up to 6 months	Thank you for your comment. We have included details on this within the Quality standard
118	Pancreatic Cancer UK	QS8	We support the statement than people with active cancer and venous thromboembolic diseases should be offered 6 months treatment with low molecular weight heparin.	Thank you for your response
119	Pancreatic Cancer UK	QS8	We believe it is important to include a quality statement on follow up care for people with cancer. We sometimes hear that patients have been put onto LMWH injections with insufficient explanation and no real follow up to see if they should remain on this medication after six months or are having any problems.	Thank you for your comments. An additional statement to cover follow up care for people with cancer has now been added

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120	Pfizer Ltd	QS8	Suggest that the statement is amended to the following to be in keeping with the wording used by NICE in CG144:At the time of publication (June 2012) some types of LMWH 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 LMWH and make appropriate adjustments for severe renal impairment or established renal failure. Informed consent for off-label use should be obtained and documented. (NICE CG144, 2012)	Thank you for your comments. Supporting information has now been added to the statement
121	Royal College of Pathologists, British Committee for Standards in Haematology for the British Society for Haematology, Cambridge University Hospitals NHS	QS8	Shouldn't the outcome measure be all recurrent VTE whilst on treatment not just mortality from PE.	Thank you for your suggestions. Where the TEG were confident that there was a clear causal relationship between the action described in a statement and an outcome, the outcome has been included.
122	Society for Acute Medicine	QS8	People with active cancer and venous thromboembolic diseases are offered a minimum of 6 months treatment with low molecular weight heparin. (I give them treatment for as long as their cancer is considered active – in most cases life- long). ACCO guidelines should be followed – ie indefinite duration unless otherwise specified by their Oncologist.	Thank you for your comments. The statement is in line with the underpinning evidence-based recommendations from NICE clinical guideline 144, from which the quality standard is derived.
123	UK Clinical Pharmacy Association	QS8	Yes - people with cancer, review at 6 months and if still risk factors LMWH or oral anticoagulant	Noted.
124	Vascular society	QS8	We are not sure why 6 months has been chosen. For patients with DVT/PE and cancer, often lifelong anticoagulation might be required.	The statement is derived from the underpinning evidence-based recommendations from NICE clinical guideline 144. The intent is to review within 6 months to ensure treatment remains beneficial. In the definitions section we have now stated that the summary of product characteristics should be referred to for the

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				chosen anticoagulant for more details on when, within the 6 month, period the review should take place.
125	Airedale NHS Foundation Trust	QS9	All people with VTE should be seen at 3/12 to discuss the risks / benefits of continuing anticoagulation." This should be evaluated and a decision made by the clinician responsible for the patients care at the start of treatment. It would be impossible for all VTE patients to be given review appointments in secondary care to have this discussion. Primary care personnel would not necessarily be in a position to offer this advice to patients.	Thank you for your comments. Standards aim to be aspirational but achievable. However, it is recognised that some standards may be more challenging that others and may require changes in services in order to achieve them. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both available from www.nice.org.uk.
126	AntiCoagulation Europe	QS9	The review period of 3 months from diagnosis refers to people who have a recent VTE. The guidelines (144) and draft QS do not appear to include guidance for long term VKA users in relation to annual monitoring of kidney and liver function which can be affected by VKA's therapy. What formal 'follow up' is recommended for long term anticoagulated patients and if not in place, consider inclusion in this QS.	Thank you for your comments and suggested additional quality statements. The quality standard is underpinned by recommendations from the published guideline for a concise set of improvement areas. The question will be most appropriately addressed as part of future guideline updates.
127	King's College Hospital NHS Foundation Trust	QS9	General. Needs to be provision for patients in whom LMWH is unsuitable, for example those with renal failure and for patients who refuse long term LMWH even when informed of advantage over VKA.	Thank you for your comments. The expectation is that all quality statements will be read alongside existing guidance and practice recommendations. The quality standards do not replace guidance but identify a concise set of key markers. In addition the requirements of choice and clinical judgement will prevail.

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128	LEO Pharma	QS9	Specific questions for consultation: We believe that it would be useful to include a statement on follow-up care for people with cancer since the increased risk of VTE in cancer continues beyond 6 months and therefore further review would be needed for patients who may require very long term anticoagulation	Thank you. A statement on follow up care for people with cancer has now been included. Although this review is expected to take place 6 months after diagnosis this does not mean that aspects of long term review are not important and would not be carried out
133	Pfizer Ltd	QS9	The statement should be amended to the following ' 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, including a discussion of the risks and benefits of the current anti-coagulation therapy options available to them'.	Thank you for your comments Additional detail has been added to the definitions and supporting information to provide further clarification about what the statement covers
134	Society for Acute Medicine	QS9	People with venous thromboembolic diseases without cancer and in whom a limited period of anticoagulation is being considered (i.e. not those who are for life long treatment) receive a review within 3 months of diagnosis to discuss the risks and benefits of continuing anticoagulation beyond 3 months.	Thank you for your response
135	Vascular society	QS9	Agreed	Noted