NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Venous thromboembolism in adults (update)

Date of quality standards advisory committee post-consultation meeting:
28 April 2021.

1. Introduction

The draft quality standard for Venous thromboembolism in adults was made available on the NICE website for a 4-week public consultation period between 20 November and 18 December 2020. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 22 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 to 4.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement-specific questions:

4. For draft quality statement 3: Are requests for proximal leg vein ultrasound scans usually made in a timely manner, or are delays experienced?

5. Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please provide details on the comments form.

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* Comments on the age groups that the statements apply to.
* Keep the QS separate for prevention and management of VTE.
* Make it clearer whether the statements include day cases.
* Guidance on how to engage underrepresented groups would be helpful.
* Add more detail on integrated working across teams to include a skills mix.

### Consultation comments on data collection

* Most centres have well established data collection processes.
* Problems may be caused by variation in data collection systems, such as manual data collection and data entry.
* It is feasible for diagnostics but might not be a priority.

### Consultation comments on resource impact

* Statement 5 is expected to result in cost savings.
1. Summary of consultation feedback by draft statement
	1. Draft statement 1

People aged 16 and over who are in hospital and assessed as needing pharmacological VTE prophylaxis start it as soon as possible and within 14 hours of hospital admission. **[2010, updated 2021]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

Statement

* Change “start it” to prescribe or administer.
* Clarify that patients have been “risk assessed” as needing prophylaxis.
* 14 hours is too long a delay for at-risk patients. A timeframe of 4 to 6 hours from admission was suggested.
* One stakeholder felt that a 14 hour timeframe will mean adjusting the timing of doses, which could lead to mistakes and possible bleeding.
* Suggested additions to make were:
	+ appropriate duration and dosing
	+ avoiding missed doses.

Measures

* Data can be collected locally by an audit and through electronic hospital prescribing having time stamping.
* Two stakeholders thought it would be challenging to measure the timeframe.
* Pharmacological prophylaxis is often given to all patients at the same time each day. Safety measures will be needed to prevent drug administration errors if patients receive it at different times.
* There might be a reduction in DVT incidence that would give a cost reduction.

Audience descriptors

* Change the healthcare professionals to say non-medical prescribers and doctors.
* Include assessment on admission and reassessment.

Definitions

* All patient groups should be included and not just medical, surgical and trauma patients.
* Clarify whether the statement includes day cases.
* Define “hospital admission” to identify applicable patient populations.
* Define “hospital associated thrombosis”.

Equality and diversity considerations

* Add text on heparins being of animal origin.
* Information should be given in a culturally appropriate way.

### Issues for consideration

* Does the rationale wording need to be amended to clarify that 14 hours is the upper time limit?
* Do we need to add detail on duration and dosing of pharmacological VTE prophylaxis?
* Add the definition of hospital admission from the guideline.
	1. Draft statement 2

People aged 16 and over who are in hospital and assessed as needing anti-embolism stockings are supported to wear them correctly and have their use monitored. **[2010, updated 2021]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

Statement

* As the Graduated compression stockings as adjuvant to pharmaco-thromboprophylaxis in elective surgical patients (GAPS study) trial has raised uncertainty over the use of stockings, stakeholders suggested the statement is less important and some suggested removing it.
* Include all types of mechanical thromboprophylaxis, including intermittent pneumatic compression devices and foot pumps.
* A statement on whether mechanical prophylaxis was clinically indicated with no contraindications present before offering it would have more impact.

Measures

* Data can be collected locally by an audit.
* Data on staff training for compression hosiery should also be collected.
* Collecting data on people being shown how to use stockings correctly could be challenging.
* Clarify how patient satisfaction should be measured.
* There might be a reduction in DVT incidence that would give a cost reduction.

Audience descriptors

* Service providers should also ensure that staff are trained in applying stockings.

Definitions

* Additional groups that should be included in the definition of “Assessed as needing anti-embolism stockings” were suggested, including pregnancy and postpartum patients.
* Skin condition should be inspected daily and stockings removed once a day and not worn continuously.
* The stockings should be measured to ensure they provide support.
* Include education, training and support and problem solving for when people are reluctant to wear the stockings in the definition of “support to wear them correctly”.

Equality and diversity considerations

* Include considerations for people who lack the mental capacity to make decisions.

### Issues for consideration

* Progress this statement to the final quality standard?
* Expand the statement to include all types of mechanical prophylaxis?
* Add more detail to the definitions of the population and support.
	1. Draft statement 3

People aged 18 and over with a deep vein thrombosis (DVT) Wells score of 2 points or more have a proximal leg vein ultrasound scan within 4 hours of it being requested. **[2013, updated 2021]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

Statement

* Limiting the ultrasound to the proximal leg vein will miss patients with ileo-femoral DVT, which has the poorest outcomes. Extend the statement to confluence of the inferior vena cava.
* Delays in pulmonary embolism (PE) management are more frequent and life threatening: change the statement to cover time to imaging for PE or interim anticoagulation within one hour of clinical suspicion for people with suspected PE.
* Delivering a scan within 4 hours is unachievable and providing a 24/7 ultrasound service would have a significant and unjustifiable cost.
* Extend the timeframe to 24 hours as this is a reasonable expectation and would limit heparin treatment to a single dose before diagnosis.
* Offering interim anticoagulation therapy if the wait will be more than 4 hours for a proximal leg vein ultrasound is more achievable and appropriate.
* Booking a scan and prescribing appropriate treatment should be the priority.
* Multiple factors affect the time between assessment and scan, including travel time, patient transport, time of day and specialist capacity.
* Most acute units use ambulatory care pathways to provide a booked appointment for a scan to patients to improve patient experience. This statement could push investigations back into secondary care, which will not improve experience.
* Include review of anticoagulation following imaging diagnosis.
* The statement does not specify the timescale for treatment following a positive scan result.
* Clarify whether d-dimer testing should be near-patient testing or blood tests.

Measures

* Data can be collected locally by an audit.
* Data will be difficult to collect on achieving the 4 hour timeframe due to relying on accurate coding of the Wells score and recording time of assessment.

Audience descriptors

* Service providers would need to ensure that pathways are in place for scans to be done within 4 hours, and if this is not possible, within 24 hours.
* Pathways need to include guidance on interim anticoagulation.
* Investment in education and training would be needed to achieve the statement as there is a national shortage of staff.
* Indicate prioritisation of imaging and radiology services, equipment and personnel to support the implementation of this statement.
* There is no detail on who performs the scan.
* Using “doctor” in the patient audience descriptor may be misleading as this will be an advanced practice role.

### Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

* Delays from requesting the scan are uncommon.
* Delays can result from a lack of clinical information, such as Wells score, and staff having to chase this up to prioritise scans.
* Delays are in performing the scan, such as over the weekend and out of office hours.

### Issues for consideration

* Change the timeframe to 24 hours?
* Change the statement to focus on what to do if the scan will take longer than 4 hours?
* Change the focus to people with suspected PE?
	1. Draft statement 4

People aged 18 and over taking anticoagulation treatment after a VTE have a review after 3 months and then at least once a year if they continue to take it long-term. **[2013, updated 2021]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

Statement

* The statement could offer potential cost saving through increased efficiency from streamlining the review.
* The review should be “at” 3 months rather than “after”.
* There should also be a review at 6 months.
* Include people with active cancer and extend the period for review to 3 to 6 months.
* The statement could be limited to those where a clear treatment decision has not been made at the point of VTE diagnosis to avoid unnecessary reviews for people with a clear anticoagulation strategy (long-term or short-term).
* It will be difficult to identify patients who require a review at 3 months when their care has transferred to primary care.
* Annual review will require considerable resources. Many centres do not have capacity and it would fall on primary care.

Measures

* Data can be collected locally by an audit.
* Clear coding of “review of VTE” will be needed to measure numbers of reviews, or else manual audit of notes will be needed.
* Systems for recall of patients for review varies between practices, so decisions about local data collection will need to consider this.
* Pathways would need to be put into place that indicate which clinical team is responsible for arranging the review.
* Consideration will be needed of how to measure this for people not engaged with healthcare systems, such as those not registered with a GP.
* Outcomes should include clinical outcomes and adverse events management, such as bleeding risks.

Audience descriptors

* Queries about who should do each review: a GP, a specialist or an anticoagulation service. VTE specialists were suggested for the 3 month review and GPs for the annual review.
* The review might be impractical in secondary care.
* Specialists should advise GPs and patients about whether short or long-term treatment is needed.
* Patients should be told about the review and who will do it when medication is initiated or on the discharge summary.
* Patients need to be aware of the need to monitor direct oral anticoagulants.

Definitions

* Identify the progress the person feels they have made and their wishes in the reviews.

Equality and diversity considerations

* Remove the text about heparins being of animal origin and move it to statement 1.
* Consider those who need support to access ongoing services, such as people receiving care, people with cognitive impairment or who do not speak English as a first language.
* Include the role of families and carers in the discussion about alternatives to heparin.

### Issues for consideration

* Include people with active cancer in the statement?
* Change the statement wording to clarify that the 3 month review is “at” 3 months?
* Add more detail and clarity on who does each review and where the reviews are carried out.
	1. Draft statement 5

People aged 18 and over having outpatient treatment for suspected or confirmed low-risk pulmonary embolism (PE) have an agreed plan for monitoring and follow-up. **[new 2021]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

Statement

* People with low-risk PE are less likely to need follow-up, so this does not reflect a key area for development.
* There should also be a monitoring and follow-up plan for patients who are intermediate and high risk of dying due to PE.
* The statement is unclear. Does it cover the period after diagnosis until a patient is seen in an anticoagulation clinic? Or long-term follow-up at 3 months, or the immediate care of the patient?
* The statement will be difficult to measure. Change it to measure provision of information on how and when to seek further medical attention.

Rationale

* Is the statement about measuring against hospital care or about supporting the best possible evidence-based care?

Measures

* Should the structure measure be measuring availability or provision of information?
* Pathways need to be evidence-based and relevant.
* Follow-up data will be hard to collect as it requires an audit.
* An audit to measure whether the agreed plan worked and achieved what was intended would be beneficial.
* Consideration is required of how to measure this for patient groups not fully engaged with healthcare systems.
* The outcome measure should specify that admissions are related to PE management.
* Patients might be admitted via ambulatory care pathways, so the outcome measure is confusing.

Audience descriptors

* Who is responsible for clinical review, the prescriber, the anticoagulant clinic or the acute medicine team?
* Delivering this locally will require greater investment in staff, clinic space and radiological imaging support.

Definitions

* There is no definition of the characteristics of the “suspected” group.

Equality and diversity considerations

* Consider groups who may need additional support.
* Written information might not always be the most helpful way to provide information to different groups, it should be tailored to the person.

### Issues for consideration

* Change the rationale to make the focus on providing patient information clearer.
* Change process measure to measure proportion of people given the information defined.
* Does the population need to be defined?
* Should the statement include people with higher risk of PE?
1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

* VTE risk assessment on admission and reassessment

Risk assessment on admission was discussed at the quality standards advisory committee meeting in September and not prioritised. The committee agreed that the national VTE risk assessments metric is being achieved. The committee felt that the area for quality improvement was thromboprophylaxis prescribing following risk assessment.

* Patient information

Stakeholders suggested that written and verbal information be given to patients on VTE assessment, prevention, management and recovery, and where to find further support and information. Signs of VTE and what to do if they are experienced was also raised. Giving patients information is covered under statements 1, 4 and 5 in the quality standard. Information and support was also discussed at the September meeting, and the committee agreed to prioritise a statement on having a monitoring plan and contact details for a healthcare professional (statement 5).

* Psychological support for patients following a VTE

Psychological support was raised at the September meeting in relation to psychological support about VTE risk post COVID-19, and also under equality considerations. The committee did not prioritise this as an area to include in the quality standard.

* Offering cancer investigations for unprovoked VTEs

Cancer investigations were covered under a discussion of further investigations and tests at the September meeting. The committee did not prioritise this area for inclusion in the quality standard.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

| **ID** | **Stakeholder** | **Section** | **Comments[[1]](#footnote-1)** |
| --- | --- | --- | --- |
| 1 | ALK Positive UK | General | Many thanks for the opportunity to comment on this QS. ALK Positive U.K. had nothing to add. |
| 2 | British Association of Day Surgery | General | In the 2010 guidance it states :This quality standard covers the reduction in risk of venous thromboembolism (VTE) in adults admitted as hospital inpatients or formally admitted to a hospital bed for day-case procedures. The draft document says **This quality standard covers** reducing the risk of venous thromboembolism (VTE) in people aged 16 and over who are in hospital. Does it no longer cover day cases? I think clarity is needed. I would like to point out that most day cases do not have a “hospital bed”. Most are done on an appropriate trolley via day surgery unit (DSU). The DSU is usually separate to the main hospital wards and therefore your current description is likely to exclude day cases. If that is your intention that is fine. However, as I mention below more  major surgery is being done as a day case and procedures that should have VTE prophylaxis eg Hip replacement.I do not think it is appropriate for BADS to comment on statements 3,4 or 5 |
| 3 | British Orthopaedic Association | General (on briefing paper) | * Orthopaedic surgery
* Stakeholders highlighted how risk assessment VTE prophylaxis is not considered or prescribed at the initial emergency department presentation and patients return home. There is then a delay in the risk assessment and appropriate prophylaxis until the orthopaedic teams review the patients in clinic. Stakeholders therefore supported the clinical and cost effectiveness of thromboprophylaxis for people with lower limb immobilisation.
* This statement is in direct contravention of the 2018 NICE Guideline recommendations. We would support risk assessment for VTE and bleeding in this setting, and then appropriate consideration of prescription of prophyalxis, but not the routine administration of medical anticoagulants in a vulnerable group of patients who are already bleeding from their fractures and associated soft tissue injuries. This would be likely to significantly increase the risk of complications and, potentially delay surgery, if required. We believe that the stakeholder comment may have been incorrectly reported or is an inaccurate statement of the existing guidance and the language modified to correctly reflect the guidance. We suggest:

“Stakeholders therefore supported the risk assessment of these patients in the ED, and where appropriate the consideration of prescription of thromboprophylaxis for people with lower limb immobilisation.” |
| 4 | British Thoracic Society | General | Thank you for inviting comments from the British Thoracic Society on this updated quality standard.  |
| 5 | Chelsea and Westminster Hospital NHS Foundation Trust | General | All standards should apply for patients aged 16 years and over |
| 6 | King’s College Hospital NHS Foundation Trust | General | Combining VTE prevention and management has restricted the scope and it would be preferable for these to remain independent, particularly as they evaluate completely different areas of practice.VTE risk assessment remains a significant issue, the last report published on NHS Digital for Q3 2018/19 demonstrated that >20% of NHS hospitals were falling short of the 95% risk assessment target. As NHS Digital has put this data collection on hold indefinitely, there is a need for a further incentive for hospitals to continue to aim to achieve this target, which retaining the previous QS1 would provide. Whilst the national report from the GIRFT Thrombosis survey evaluating VTE prevention practice has not yet been released, it is evident from site comparison that there are ongoing issues with provision of patient information. Furthermore, missed doses associated with patient refusal were prevalent highlighting a need for provision of information re VTE prevention. Therefore provision of patient information on admission and discharge should remain in the QS as it is not measured elsewhere. |
| 7 | NHS England and NHS Improvement | General | Commissioner role also includes the oversight of quality of service provision including where things do not happen as expected so suggest this needs reflecting in the guidance as not merely about making sure things are commissioned.  |
| 8 | NHS England and NHS Improvement | General  | Would be helpful to have further detail in this guidance about engaging traditionally under represented groups and communities to ensure they are not marginalised because of processes or systems which may only see them infrequently.  |
| 9 | NHS England and NHS Improvement | General  | Sheffield Children’s Hospital have a particularly good example of Thromboprophylaxis Guidelines for Perioperative and Intensive Care Period which is suggested for consideration as part of development of this guidance. |
| 10 | NHS England and NHS Improvement | General | Community nursing roles support people in their own homes as well as care setting with a range of long-term conditions which will be impacted by this guidance. Reference to how the systems and teams work in an integrated way to make the most of the skills available is suggested.  |
| 11 | Royal College of Nursing  | General | Thank you for the opportunity to contribute to this quality standard. We do not have any comments to add on this occasion. |
| 12 | Royal College of Paediatrics and Child Health | General | Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the Venous thromboembolic diseases quality standard. We have not received any responses for this consultation. |
| 13 | Royal College of Physicians  | General | We would like to endorse the response submitted by the British Thoracic Society (BTS). |
| 14 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | General | NICE quality standards for VTE prevention and treatment/management should continue to remain separate |
| 15 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | General | All standards should apply for patients aged 16 years and over (as per NICE NG89) |
| 16 | Society and College of Radiographers | Question 1 | Yes, seems to for the diagnostic side. |
| 17 | VTE National Network for Nursing and Midwifery | Question 1 | No, prevention and treatment QS should remain separate, they lose impact by merging them and appear disjointed. Several important safety and quality standards have been omitted.  |
| 18 | NHS England and NHS Improvement | Question 2 | Variation across systems to collect data as identified may cause problems and where reliance is upon manual data collection and data entry parallel process even more so - this may need considering in relation to numerators set.  |
| 19 | NHS England and NHS Improvement | Question 2 | Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.Links directly to question 2 above. Would suggest consideration as to the range of acute, community and mental health trusts and existing IT systems and local set up of such systems to maximise or develop systems to support data collection secondary to good care practice.  |
| 20 | Society and College of Radiographers | Question 2 | With regards to diagnostics this would be feasible but may not be deemed a priority. |
| 21 | VTE National Network for Nursing and Midwifery | Question 2 | Most centres have well established data collection processes for VTE prevention, as evidenced by the VTE GIRFT survey. |
| 22 | Society and College of Radiographers | Question 4 | Members of the SCoR advisory group involved in this work suggest that requests are usually in a timely manner within their service.An issue highlighted was the lack of clinical information (often do not state Wells or have D-dimers) which can cause delays, whilst chase this up in order to prioritise scans. |
| 23 | VTE National Network for Nursing and Midwifery | Question 4 | Delays uncommon in our experience. |
| 24 | All-Party Parliamentary Group on Vascular and Venous Disease | Statement 1 (measure) | -This draft quality standard does support a key area for quality improvement.-This data could be collected locally by an audit process involving VTE prevention team, pharmacy staff and the local audit team. -Local services would be able to deliver the aim of administering pharmacological prophylaxis within the recommended 14hours. However it is important to recognise that most NHS organisations administer pharmacological prophylaxis simultaneously to all patients on the ward at 18:00. Having a number of patients on a ward receiving pharmacological prophylaxis at differing times may introduce the possibility of drug administration errors. Service providers and healthcare professionals would have to implement safety nets to eliminate potential sources of error.-There are unlikely to be significant direct cost saving, however indirectly there may be a reduction in DVT incidence. This may yield a significant cost reduction.-Did the committee take into the consideration the recent update on thromboprophylaxis, by Professor Beverly Hunt “COVID-19 and Thrombotic or Thromboembolic Disease: Implications for Prevention, Antithrombotic Therapy, and Follow-Up: JACC State-of-the-Art Review” <https://pubmed.ncbi.nlm.nih.gov/32311448/>? |
| 25 | Anticoagulation UK | Statement 1 | There is a recommendation of up to a 14 hour window from admission to deliver pharmacological prophylaxis(PP) to a patient who has undergone a VTE risk assessment. We can find no information or reference point as to where this timeline has been evidenced. We understand that many patients will be offered PP in a timely manner however, if 14 hours becomes the standard benchmark in secondary care settings, this may negate the optimal priority and benefits of prophylaxis for an at -risk patient. When the VTE risk assessment is undertaken post admission, it’s key that a component of this process should be to advise the patient of their risk and offer prophylaxis at the earliest possible opportunity and advising when this will commence. We would suggest a timeframe of 4 – 6 hours from admission. This will provide continuity of care and reassurance to the patient. |
| 26 | British Association of Day Surgery | Statement 1 | Statement 1 People aged 16 and over who are in hospital and assessed as needing pharmacological VTE prophylaxis start it as soon as possible and within 14 hours of hospital admission. [2010, updated 2021]I would raise the same query re - Does it cover day cases? |
| 27 | British Geriatrics Society | Statement 1 | This would appear a sensible and clinically achievable standard, which should be increasingly easy to audit as electronic hospital prescribing becomes widespread (through prescription and dispensing having electronic timestamping). |
| 28 | British Orthopaedic Association | Statement 1 | Statement 1 – no additional comments |
| 29 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 1 (audience descriptor) | Should include assessment on admission and reassessment |
| 30 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 1 | Challenging to include and measure ‘within 14 hours of hospital admission’ |
| 31 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 1 | Review wording of ‘start it’ and clarify as prescribe or administer within 14 hours of admission |
| 32 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 1 | All patients groups aged 16 years and over should be included (and not just medical, surgical and trauma patients – NICE NG89 does not only include these patient groups); thus quality standards should reflect all patient groups in NICE NG89 |
| 33 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 1 | Include patient education on thromboprophylaxis – users unlikely to read page 7 section on ‘equality and diversity considerations’ that patients need to be given verbal and written information on possible side effects of VTE prophylaxis |
| 34 | Clinical Leaders of Thrombosis | Statement 1 | Good to have a timescale to start chemical prophylaxis as this is often given at the same time each day regardless of admitting time |
| 35 | King’s College Hospital NHS Foundation Trust | Statement 1 | There is no current evidence that delivery of initial thromboprophylaxis within 14h of admission will reduce the incidence of HAT. We suggest therefore that other areas also be included, such as provision of appropriate duration (including post discharge where applicable), and avoiding missed doses without a clinical indication as these are also contributory factors. |
| 36 | King’s College Hospital NHS Foundation Trust | Statement 1 | Local systems for monitoring: there should be existing local measures for auditing to demonstrate compliance with the previous QS. I note the GIRFT and AAPTG surveys are included as a means to monitor HAT. Both rely on local data collection and submission. Furthermore, the GIRFT Thrombosis survey was funded as a single survey and we await a decision from GIRFT as to whether a repeat survey can be funded. Most Trusts participating in the survey had a means for identifying HAT (albeit many either under-identified or did not submit full data), with many also investigating HAT. |
| 37 | LEO Pharma | Statement 1 | This quality statement needs to make it clear that the patients will be ‘risk assessed’ as needing pharmacological VTE prophylaxis.The NICE guideline (NG89) states under risk assessment that all patients (medical patients, surgical patients, pregnant patients, critical care unit patients, acute psychiatric patients) need to be assessed to identify the risk of VTE and bleeding. This will confirm whether VTE prophylaxis is appropriate for the patient.Reference:<https://www.nice.org.uk/guidance/ng89/chapter/Recommendations#risk-assessment> |
| 38 | NHS England and NHS Improvement | Statement 1 (outcome) | In the section what the quality statement means for different audiences under Health Care professionals, you document that Healthcare professionals (such as pharmacists, advanced nurse practitioners and doctors) prescribe pharmacological VTE prophylaxis. You may want to think about changing this to non-medical prescribers (V300) and doctors. I say this from my own perspective as a non medical prescriber but not an advanced practitioner working in the community and it may be in the future physiotherapists or nurses who are not advanced nurse practitioners would be in a position to prescribe pharmacological VTE.  |
| 39 | NHS England and NHS Improvement | Statement 1 | Important to ensure that individuals are provided with information in a way that they are able to understand – clarifying this point is key. Also as well as highlighting to patients what possible side effects can occur with VTE prophylaxis using verbal and written information, this medicine-consultation should extend to include all necessary consultation points e.g. indication, and should be conducted in a culturally competent way.  |
| 40 | Thrombosis UK | Statement 1 | We are unable to find any evidence that supports Statement 1 in recommending up to a 14-hour delay in initiating pharmacological thromboprophylaxis in anyone aged 16 and over who is admitted to hospital and assessed as requiring VTE prophylaxis. We appreciate NICE has given this time as from admission, however as part of the admission process all patients (16 years+) are required to be VTE risk assessed and managed, and if a time is going to be given, then this should be much shorter, and certainly no longer than six hours from time of admission. |
| 41 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 1 | Challenging to include and measure ‘within 14 hours of hospital admission’ |
| 42 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 1 | Review wording of ‘start it’ and clarify as prescribe or administer within 14 hours of admission |
| 43 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 1 | All patients groups aged 16 years and over should be included (and not just medical, surgical and trauma patients – NICE NG89 does not only include these patient groups); thus quality standards should reflect all patient groups in NICE NG89 |
| 44 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 1 | Include patient education on thromboprophylaxis – users unlikely to read page 7 section on ‘equality and diversity considerations’ that patients need to be given verbal and written information on possible side effects of VTE prophylaxis |
| 45 | University Hospitals Birmingham NHS Foundation Trust Haematology Service | Statement 1 | What is the evidence for 14 hours improving outcomes? For many patients, this will mean adjusting the timing of the first dose and then having a shorter gap before the second dose. This could lead to mistakes, confusion and possible bleeding. NICE would need to demonstrate that 14 hours is superior to 24 hours to justify this QS.NICE would also need to provide clear definition of ‘hospital admission’ to identify patient populations where this QS would be applicable.If we are to adapt this standard, NICE would also need to provide definition of ‘hospital associated thrombosis’. |
| 46 | VTE National Network for Nursing and Midwifery | Statement 1 | Statement 1 should include the need for thromboprophylaxis to be appropriate as incorrect dosing for weight or renal impairment remains the cause of potentially preventable HATs. This should include appropriate duration and avoidance of dose omissions as several centres have identified those factors as contributing to potentially preventable HATs.  |
| 47 | All-Party Parliamentary Group on Vascular and Venous Disease | Statement 2 | This draft quality standard does support a key area for quality improvement.-This data could be collected locally by an audit process involving VTE prevention team and the local audit team. Data on staff training for compression hosiery should also be collected at the same time.-It would be important to ensure that service providers are advised to ensure that staff involved in applying stockings have been adequately trained to do so. Teaching could be delivered via an online e-learning module.-There are unlikely to be significant direct cost saving, however indirectly the use of compression stockings would contribute to a reduction in DVT incidence. This may yield a significant cost reduction. |
| 48 | Anticoagulation UK | Statement 2 | In 2020, there has been a recent study published on Graduated compression stockings as adjuvant to pharmaco-thromboprophylaxis in elective surgical patients (GAPS study): randomised controlled trial <https://www.bmj.com/content/369/bmj.m1309> The outcomes state ‘For patients who have elective surgery and are at moderate or high risk of venous thromboembolism, administration of pharmaco-thromboprophylaxis alone is non-inferior to a combination of pharmaco-thromboprophylaxis and GCS. These findings indicate that GCS might be unnecessary in most patients undergoing elective surgery’ How will these findings now impact on the use of GCS as mechanical prophylaxis for patients in secondary care who are eligible for pharmacological thromboprophylaxis? We suggest that this QS be reviewed in light of the above.  |
| 49 | British Association of Day Surgery | Statement 2 | I support statement 2 |
| 50 | British Geriatrics Society | Statement 2 | This appears an appropriate standard to reduce the risk of inappropriate use of these stockings, which can result in skin damage particularly in older patients. |
| 51 | British Orthopaedic Association | Statement 2 | Statement 2 – no additional comments |
| 52 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 2 | Include intermittent pneumatic compression device |
| 53 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 2 | Challenging to measure and collect data on people shown how to use anti-embolism stockings correctly as part of administration processes. |
| 54 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 2 | Including a quality standard with VTE risk assessment and following assessment if mechanical thromboprophylaxis is clinically indicated with no contraindications present before offered would be have more clinical impact on VTE prevention measures |
| 55 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 2 (definitions) | Include pregnancy/postpartum patients as per RCOG guidanceAs quality standards are based on NICE NG89 – 1.3 recommends all patients for mechanical prophylaxisNICE NG89 recommendations include use of ‘mechanical VTE prophylaxis’ but not included on page 10 e.g. 1.8, 1.11.4, 1.11.5, 1.11.7, 1.11.8, 1.11.10, 1.13.1, 1.14.12, 1.14.14, 1.15.4, 1.15.6, 1.16.6, |
| 56 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 2 (definitions) | ‘People should be encouraged to wear their anti‑embolism stockings day and night until they no longer have significantly reduced mobility’ – patient skin condition should be inspected so anti-embolism stockings removed for at least 30 minutes in a 24 hour period; and not continuous wear. |
| 57 | Clinical Leaders of Thrombosis | Statement 2 | Use of AES following publication of GAPS trial showing in certain population low molecular weight heparin (LMWH) alone was non inferior to LMWH plus AES we would expect to see a reduction in the use of AES. Would question whether their use is common practice but acknowledge if used then need to be fitted and cared for properly |
| 58 | King’s College Hospital NHS Foundation Trust | Statement 2 | given the uncertain role of AES in preventing VTE as highlighted by the GAPP study; this is an area of lesser importance which could be removed. |
| 59 | LEO Pharma | Statement 2 | This quality statement should make reference to accurately measuring the anti-embolism stockings. There is a need for the stockings to be accurately measured to be able to provide the support. |
| 60 | NHS England and NHS Improvement | Statement 2 (measures)  | Ambiguity on what construct should be used to assess quality measure number 3 ‘patient satisfaction’ or if this is to be locally determined/defined?  |
| 61 | NHS England and NHS Improvement | Statement 2 | Consideration as to those who may temporarily or more permanently not have the mental capacity to make specific decisions needs to be considered here and reference given to supporting best practice in this area with these people to maximise their health and wellbeing.  |
| 62 | NHS England and NHS Improvement | Statement 2 | Need to ensure there is reference to those individuals who may be contraindicated for stockings.  |
| 63 | NHS England and NHS Improvement | Statement 2 | “Proportion of people aged 16 and over in hospital who use anti embolism stockings to prevent VTE and are satisfied with the support they receive to wear them.” Suggest needs further clarity to ensure this picks up the salient point and not just a ‘tick box exercise’ as there are several other numerators and ways to establish impact here.  |
| 64 | NHS England and NHS Improvement | Statement 2 | “Stockings should be fitted and people shown how to use them.” Suggest this is wider than this remit and about education, training to an extent and support. “People should be encouraged to wear their anti embolism stockings day and night until they no longer have significantly reduced mobility.” Suggest this should include problem solving where people are reluctant and need additional support.  |
| 65 | Thrombosis UK | Statement 2 | 2020 current published evidence from the GAPS trial (<https://www.bmj.com/content/369/bmj.m1309> ) suggests anti-embolic stockings are ineffective in moderate risk surgical patients and there is lack of evidence of their efficacy in medical or obstetric patients and indeed they do harm in stroke patients. Based upon this clinical evidence, we do not agree with this Quality Statement (two) and think we should not be asking hospital staff to concentrate on delivering a treatment that is poorly evidenced.We strongly urge NICE to reconsider and remove this statement. |
| 66 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 2 | Include intermittent pneumatic compression device or mechanical thromboprophylaxis to include any form |
| 67 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 2 (definitions) | Include pregnancy/postpartum patients as per RCOG guidanceAs quality standards are based on NICE NG89 – 1.3 recommends all patients for mechanical prophylaxisNICE NG89 recommendations include use of ‘mechanical VTE prophylaxis’ but not included on page 10 e.g. 1.8, 1.11.4, 1.11.5, 1.11.7, 1.11.8, 1.11.10, 1.13.1, 1.14.12, 1.14.14, 1.15.4, 1.15.6, 1.16.6, |
| 68 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 2 (definitions) | ‘People should be encouraged to wear their anti‑embolism stockings day and night until they no longer have significantly reduced mobility’ – patient skin condition should be inspected so anti-embolism stockings removed for at least 30 minutes in a 24 hour period; and not continuous wear. |
| 69 | University Hospitals Birmingham NHS Foundation Trust Haematology Service | Statement 2 | With the GAPS study suggesting no benefit for AES in addition to LMWH, their efficacy and value is coming under doubt now. However if they are used, it is important to do it properly of course. It could lead to even more paperwork for nurses, which isn’t welcome. |
| 70 | VTE National Network for Nursing and Midwifery | Statement 2 | Statement 2-many centres are now reviewing their use of AES as a result of the GAPs study, stocking use is less likely to have an impact on patient outcomes than appropriate thromboprophylaxis so could be removed. If this remains, it should include the use of all mechanical TP (IPC and foot pumps) and include daily skin checks and documentation standards. |
| 71 | All-Party Parliamentary Group on Vascular and Venous Disease | Statement 3 (rationale) | This draft quality standard does support a key area for quality improvement.-This data could be collected locally by an audit process involving both the vascular ultrasound department and the local audit team.-Service providers would have to ensure that pathways are in place for ultrasounds scans to be done within 4 hours and if this is not possible, in certain organisations over the weekend, then pathways should be in place for these scans to be performed within 24 hours. The pathways should also provide guidance on interim anticoagulation.-Requests for proximal leg vein ultrasound scans are usually made in a timely manner however delays in performing the scan may be delayed (for example over the weekend).-Limiting the ultrasound to the proximal leg vein will miss patients with ileo-femoral DVT, which have the poorest outcomes. We would kindly suggest that ultrasound is conducted as mentioned and extended onto the confluence of the IVC. |
| 72 | British Geriatrics Society | Statement 3 | The rationale for the timing of this standard appears less clear. Delivering Doppler ultrasound scanning within 4 hours of any suspicion of DVT is unlikely to be feasible. Most acute units have adopted ambulatory care pathways for these patients to remove them from an unselected admission queue (poor experience for patients) and provide the convenience of a booked appointment slot with a confirmed scan time. The rationale for this 4-hour standard appears to be the avoidance of unnecessary heparin treatment, but more evidence would need to be presented on the risks/harm of this approach. To genuinely provide a 24/7 ultrasound service would represent a significant cost that is unlikely to be justified for these risks, except in specific cases where a bleeding disorder exists. However, the document does note a more important problem of extreme delays to Doppler scanning resulting in multiple consecutive days of heparin treatment without diagnosis which does appear to be suboptimal care. It may be more sensible to target the quality standard timeframe to specifically identify these events, by extending the acceptable time window to 24 hours. This would be in keeping with reasonable expectations from high-quality ambulatory care services for management of these patients and would limit prophylactic heparin treatment to a single dose before diagnosis is made. |
| 73 | British Orthopaedic Association | Statement 3 | No additional comments |
| 74 | British Thoracic Society | Statement 3 | Statement 3 seems impractical and unachievable. The delay is not in the requesting of scans but in the time from request to scan being performed. DVT scanning slots are typically unavailable out of office hours and limited at weekends. Most patients in practice therefore get their scan the next day at the earliest and often longer if presenting over the weekend. The previous statement re: anticoagulation within one hour seemed more appropriate?It seems unrealistic that Doppler US scans requested outwith 8am-5pm will be done within 4 hours – the likely solution will be that these scans only get requested in normal hours |
| 75 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 3 | ‘Proximal leg vein ultrasound within 4 hours of request’ unlikely to be achieved as dependent on local radiology services – to include in the statement that interim anticoagulation therapy should be offered if more than 4 hours for a proximal leg vein ultrasound performed, with review of anticoagulation following imaging diagnosis |
| 76 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 3 | Statement would need to indicate prioritisation of imaging and radiology services/equipment/personnel to support this implementation of this statement |
| 77 | Clinical Leaders of Thrombosis | Statement 3 | Many hospitals are unable to offer Doppler ultrasound screening for DVT at weekends so achieve even within 24 hours of presentation let alone within 4 hours a scan will not be possible. The priority would be to ensure appropriate treatment is prescribed and a scan booked should be the priority |
| 78 | LEO Pharma | Statement 3 | This quality statement does not make clear whether the patient will be treated immediately/timescale following positive result of the proximal leg vein ultrasound scan. It should refer to this to allow for patients to be treated in a timely manner and appropriately depending on license and individual case history |
| 79 | King’s College Hospital NHS Foundation Trust | Statement 3 | DVT scan within 4h will not be possible in many cases and this will not be a cost effective quality improvement. All randomised controlled trials investigating risk stratification strategies for DVT imaging allowed 48-72h of interim anticoagulation. The NICE guidance itself advocates imaging within 24h and this would be a more appropriate standard (as per the previous QS29). Given the NCEPOD report highlighted omissions in early treatment and delays in PE imaging, and the greater potential for harm with delays in PE treatment, it may be prudent to retain the previous QS29 (statement 3) for interim anticoagulation (where PE imaging is not possible) within 1h of clinical suspicion.Delays uncommon in our experience and already monitored locally for targeted improvement. We see very few adverse incidents in relation to this. Delays in PE management/imaging more frequent and a greater cause for concern. |
| 80 | NHS England and NHS Improvement | Statement  | may well be resource implication to get ultrasound within 4 hrs of request 24/7  |
| 81 | NHS England and NHS Improvement | Statement 3 (measure) | Near patient testing of d-dimer: D-dimer is mentioned. Near patient testing is not specially mentioned. The views on the value of d-dimer near patient testing are mixed. Therefore clarity on the usefulness of this would be helpful. In reality, many clinicians will no longer perform d-dimer near patient testing. Instead, they will offer a blood test for a lab d-dimer before starting interim anticoagulation.  |
| 82 | NHS England and NHS Improvement | Statement 3 (measure) | 4 hour window from assessment to ultrasound has capacity implications and may not always be possible. This is especially dependent on the time of day (e.g. later afternoon/out of hours). A time window for when an ultrasound may be expected (e.g. “ideally same day but, when not available, within 24 hours” etc) might help with the realistic timeframes unless of course there is compelling evidence it should be performed within 4 hours at any time of the day.  |
| 83 | NHS England and NHS Improvement | Statement 3 (measure) | Meaningful data collection on the 4 hour window could be difficult. This relies on accurate coding of the Well’s score in patient notes and the time of assessment in general practices (or other settings). It also requires documentation of time of assessment in secondary care settings. Multiple factors will determine the time between initial assessment and ultrasound including travel time, patient transport availability, time of the day (e.g. out of hours) and specialist capacity so the resulting information would need to be interpreted with caution.  |
| 84 | NHS England and NHS Improvement | Statement 3 | “People aged 18 and over who have signs and symptoms of a deep vein thrombosis (blood clot) and whose doctor” suggest that this may also be an advanced practice role so the word ‘doctor’ may be misleading.  |
| 85 | Society and College of Radiographers | Statement 3 | There is mention of variability of access, but no detail of who performs the scans. There is limited capacity to train staff from outside the vascular or imaging departments. If this were to happen clear governance arrangements would need to be in place.  |
| 86 | Society and College of Radiographers | Statement 3 | This statement is unrealistic because there is currently a national shortage of radiographers, sonographers and radiologists [1, 2, 3] and significant pressure on imaging departments [1]. It is unlikely that all services would be able to offer a proximal leg vein ultrasound scan within 4 hours of being requested.Weekends and out of hours they are reliant on the on-call staff so provision is variable. Monday to Friday capacity, waiting lists and staffing can all impact on the provision of the service. In Scotland there is no funding for out of hours arrangements to perform these scans. Realistically solving this will be very difficult. Significant investment in education, training and on-going support/supervision would be required to provide such a service without impacting on the normal workflow. 1. <https://www.england.nhs.uk/wp-content/uploads/2020/10/BM2025Pu-item-5-diagnostics-recovery-and-renewal.pdf>
2. <https://www.sor.org/sites/default/files/document-versions/ultrasound_workforce_uk_census_2019.pdf>

https://www.rcr.ac.uk/publication/clinical-radiology-uk-workforce-census-2019-report |
| 87 | Society for Acute Medicine | Statement 3 | I note you have commented on time to USS for DVT but not imaging for PE – I would consider this more important as PE can be immediately life threatening in the way DVT may not be. PLEASE reconsider this |
| 88 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 3 | ‘Proximal leg vein ultrasound within 4 hours of request’ unlikely to be achieved as dependent on local radiology services and out of hours service – to include in the statement that interim anticoagulation therapy should be offered if more than 4 hours for a proximal leg vein ultrasound performed, with review of anticoagulation following imaging diagnosis |
| 89 | University Hospitals Birmingham NHS Foundation Trust Haematology Service | Statement 3 | There are some very effective and safe community pathways where access to a scan in 4 hours is impractical. This will require a lot of extra radiology resourcing and may push DVT investigations back into secondary care to comply with this standard which ultimately will not improve patient experience.Secondary care is already under pressure to accommodate current suspected DVT scans within 24h. QS3 seems unrealistic.Patients are risk assessed before initiation of anticoagulation. NICE will need to demonstrate that the risks of offering interim anticoagulation (following high clinical suspicion and positive D-dimers) outweigh the benefits. |
| 90 | VTE National Network for Nursing and Midwifery | Statement 3 | Statement 3 is unachievable for many centres at present.Statement 3 will not be possible in many cases and is unlikely to represent a cost effective quality improvement. The VTE NICE guideline states that scans should be performed within 24h, it would be better for the QS to be consistent with this.  |
| 91 | All-Party Parliamentary Group on Vascular and Venous Disease | Statement 4 (measure) | This draft quality standard does support a key area for quality improvement.-This data could be collected locally by an audit process.-Pathways would need to be put into place to ensure that a 3 month review would be carried out. The proposed pathway would have to indicate which clinical team would be responsible for ensuring the review was arranged.-The process of streamlining the review of anticoagulation would lead to increased efficiency and this may offer a potential cost saving.-An outcome measure of only “rates of adherence” would not accurately describe quality. This should be in combination with clinical outcomes and adverse events management, such as bleeding risks. |
| 92 | Anticoagulation UK | Statement 4 | … ‘have a review after 3 months and then at least once a year if they continue to take it long – term’We suggest that wording is changed from ‘after’ 3 months to ‘at’ 3 months with the QS ensuring that the follow up review appointment is notified to the patient at the time of initiation of medication or, stated on the discharge summary to ensure that the patient/carer is fully aware of the need for the review along with who will undertake i.e secondary care HCP, anticoagulation clinic or GP? From the patient perspective, prescriptions for anticoagulation medication are normally repeated at two monthly intervals and this provides an opportunity in primary care for a review date to be confirmed with the patient. Patients need to be made aware of the need to monitor Doacs – see attached a recent PIL produced by two Imperial College London medical students on their GP rotation. <https://anticoagulationuk.org/news/2020-12-01-anticoagulation-uk-and-imperial-college-london-students-produce-leaflet-for-patients-currently-taking-direct-oral-anticoagulants-doacs>  |
| 93 | British Geriatrics Society | Statement 4 | This statement assumes uncertainty in long-term anticoagulation strategy at the point of VTE diagnosis for every patient and this forms the rationale for a mandatory 3-month review. However, for many patients it may be clear at diagnosis that anticoagulation should be lifelong (e.g. recurrent VTE, proven coagulation disorder, co-existent cancer) or short-term (e.g. clearly provoked), which would make this review arguably unnecessary and burdensome for patient and healthcare services. Perhaps the standard could be limited to those where a clear treatment decision has not been made at the point of VTE diagnosis. |
| 94 | British Orthopaedic Association | Statement 4 | No additional comments |
| 95 | British Thoracic Society | Statement 4 | Who is required to conduct the review – can it be the GP? Or does NICE mean a specialist or anticoagulation service. The yearly follow up may be impractical in secondary care. What parameters will be needed at that yearly follow up? |
| 96 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 4 | Challenging to identify patients requiring a review at 3 months, when care transferred to primary care unless high risk |
| 97 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 4 | Unable to identify the outcome of rates of adherence to VTE anticoagulation treatment |
| 98 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 4 | Heparins of animal origin paragraph does not sit well under this section of review of anticoagulation therapy at 3 months and annually – consider removal and placing under statement 1 which related to pharmacological VTE prophylaxis |
| 99 | Clinical Leaders of Thrombosis | Statement 4 | Whilst most organisations would review patients between 3 to 6 months after starting anticoagulation it will require considerable resources to be able to review all patients annually. To ensure patients are reviewed by health care professionals, currently GP’s carry out the annual review of bloods on these patients may be a better standard. |
| 100 | King’s College Hospital NHS Foundation Trust | Statement 4 | Duration review should take place before 3 months as this represents the minimum duration of treatment. The annual review is desirable but would require audit in primary care (as most patients will be discharged to primary care following a documented decision to continue long term, especially post advent of COVID). |
| 101 | LEO Pharma | Statement 4 | This quality statement does not specifically refer to cancer associated thrombosis (CAT). We strongly propose including an additional quality statement for CAT. Patients with active cancer & VTE receive anticoagulation therapy for up to 6 months and are reviewed within the 6 months. There is clear evidence that patients with active cancer benefit from extended prophylaxis. The NICE guidelines (NG 158) recommend that patients with active cancer and confirmed proximal DVT or PE are treated with anticoagulation for 3 to 6 months and reviewed at 3 to 6 months according to clinical need. Furthermore, the NICE guidelines state when selecting anticoagulation treatment for patients with active cancer and confirmed proximal DVT or PE the below factors need to be considered:* Tumour site
* Drug-drug interactions
* Bleeding risk

In additional support, a prospective, open single arm study evaluated safety and efficacy in relation to bleeding risk and VTE recurrence in CAT patients treated with tinzaparin beyond 6 months of treatment. The study had a final sample size of 247 subjects, diagnosed with proximal DVT and PE, or both and active cancer. The patients received tinzaparin 175IU/kg subcutaneously once a day. Patients were initially followed up by visits at one month and then every 3 months until end of study or death to evaluate safety and efficacy. From month 7–12, 2 patients presented with VTE recurrence, with an incidence of 1.1% (95% CI 0.1 to 3.9%) compared to months 1–6 during which 11 patients presented recurrence with an incidence of 4.5% (95% CI 2.2 to 7.8%) (p=0.08). The study results showed that VTE recurrence at 6 and12 months was 4.7% and 6%, respectively.This quality statement does not accurately reflect the key areas of improvement in CAT patients and needs to reflect this, as cancer associated thrombosis is the leading cause of death in CAT patients after the cancer itself. This is supported by epidemiological data which demonstrates that people with cancer and VTE are at considerably more risk of recurrent VTE and death than those with VTE alone.References:<https://www.nice.org.uk/guidance/ng158> Jara-Palomares L et al. Tinzaparin in cancer associated thrombosis beyond 6months: TiCAT study. Thrombosis research 157 (2017)90-96.Levitan N, et al. Medicine 1999; 78: 285-291.Prandoni P, et al. Blood 2002; 100:3484-3488.SØrensen, Henrik Toft, et al. New England Journal of Medicine 343.25 (2000): 1846-1850. |
| 102 | NHS England and NHS Improvement | Statement 4 | When a patient is assessed by the specialist and given advice to start anticoagulation, advice from them to the GP and patient about short or longer term treatment will be helpful e.g. if it is likely to be appropriate to stop at 3 months or not. If a straightforward case, the GP may be well placed to have this review. If more complex, review by the specialist would be helpful.  |
| 103 | NHS England and NHS Improvement | Statement 4 | There is not a uniform system for recall of patients across practices. Therefore, any local data collection would need to take this heterogeneity into account when deciding how to collect data on recalling patients for review.  |
| 104 | NHS England and NHS Improvement | Statement 4 | To measure numbers who have had a review, there would need to be clear coding of “review of VTE.” Otherwise, it would need to be done manually as an audit of notes.  |
| 105 | NHS England and NHS Improvement | Statement 4 (measures) | It is feasible to have local systems in place to measure the quality measure, but considerations are required for patient cohorts that are not always engaged with healthcare systems e.g. not registered with GP, homeless and not contactable via telephone/postal invitation for review |
| 106 | NHS England and NHS Improvement | Statement 4 | “People aged 18 and over who have had a blood clot and are taking an anticoagulant (medicine to prevent another blood clot)” need to be clear who they will be seen by so as to manage expectations and allow the individual to negotiate their care.  |
| 107 | NHS England and NHS Improvement | Statement 4 | “The suitability, advantages and disadvantages of alternatives to heparin should be discussed with the person.” Needs to consider the role of families and carers where appropriate.  |
| 108 | NHS England and NHS Improvement | Statement 4 | Needs to consider those who may need support to access ongoing services such as those in receipt of care, those without a GP, those where English isn’t a first language, those possibly without a stable homelife or where reasonable adjustments are made for cognitive impairments etc. These groups are at risk of being marginalised here.  |
| 109 | NHS England and NHS Improvement | Statement 4 | Review after 3 months and once a year need to identify the progress the person feels they have made and their wishes as paramount also not just clinical indicators.  |
| 110 | NHS England and NHS Improvement | Statement 4 | “The suitability, advantages and disadvantages of alternatives to heparin should be discussed with the person.” Needs to reflect role of families and carers also where appropriate.  |
| 111 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 4 | Heparins of animal origin paragraph does not sit well under this section of review of anticoagulation therapy at 3 months and annually – consider removal and placing under statement 1 which related to pharmacological VTE prophylaxis |
| 112 | University Hospitals Birmingham NHS Foundation Trust Haematology Service | Statement 4 | It is rather vague on who should be doing this review and its purpose. Especially the annual review. The 3 month review should be with clinical staff who are specialists in VTE management but thereafter, it is more about the safety of the anticaogulation regime.NICE will need to define who will be clinically responsible for annual anticoagulation reviews and offer the guidance for it. This cannot be a secondary care duty |
| 113 | VTE National Network for Nursing and Midwifery | Statement 4 | Statement 4-the duration of anticoagulation should be reviewed prior to 3 months since this is the minimum duration of treatment. Annual reviews would be the ideal but many centres don’t have capacity for this and would fall to primary care. |
| 114 | All-Party Parliamentary Group on Vascular and Venous Disease | Statement 5 | This quality standard is less likely to reflect the key areas for development because the low-risk PE group may not require follow-up and there is no clear definition of what characteristics constitute the suspected group.-Local structures to deliver this quality standard will require greater investment in staff, clinic space and radiological imaging support.-Provided the service appropriately funded, local services should be able to provide the follow-up suggested.-There should also be a monitoring and follow-up plan for patients who are intermediate and high risk of dying due to PE. Can the committee take into consideration IPG524. |
| 115 | British Geriatrics Society | Statement 5 | This appears appropriate |
| 116 | British Orthopaedic Association | Statement 5 | No additional comments |
| 117 | British Thoracic Society | Statement 5 | This is unclear and will be difficult to prove / monitor. Does this mean being told to come back the next day for a scan is ok? Does it specifically require written document with patient agreement? Does it cover the period after diagnosis is made and until patient is seen in an anticoagulation clinic? Does it have to cover the plan for if the patient doesn’t have a PE? Indeed does this also refer to long term follow up at 3 months or is it specifically to the immediate care of the patient? This is becoming increasingly important as a strategy. |
| 118 | Chelsea and Westminster Hospital NHS Foundation Trust | Statement 5 | Outcome requires review of wording – patients may be admitted via ambulatory care pathways particularly when statement 5 relates to low-risk pulmonary embolism so ‘rates of emergency admissions ….. having outpatient treatment for PE’ is confusing |
| 119 | Clinical Leaders of Thrombosis | Statement 5 | The outcome measurement would read better if “Rates of emergency admissions relating to their PE management to hospital for people aged 18 and over having outpatient treatment for PE” Some admissions would not be related to the PE |
| 120 | King’s College Hospital NHS Foundation Trust | Statement 5 | This is somewhat vague and may be difficult to monitor. Whilst most Trusts should be able to demonstrate a pathway, providing evidence of individually patient agreed plans monitoring will be problematic. Suggest this is more specific to provision of information regarding when to seek further medical attention and how to do so. |
| 121 | LEO Pharma | Statement 5 | This quality statement may be hard to measure and conducting an audit of the agreed plan to measure whether the plan worked and achieved what it set out to do would be beneficial. |
| 122 | NHS England and NHS Improvement | Statement 5 | To measure “plan to have a review at 12 months” would need to be collected by local auditing of note.  |
| 123 | NHS England and NHS Improvement | Statement 5 (measures) | Pathways need to be evidenced based and relevant – this needs to be explicit.  |
| 124 | NHS England and NHS Improvement | Statement 5 (measures) | It is feasible to have local systems in place to measure the quality measure but again considerations are required for patient cohorts that are not fully engaged with healthcare systems  |
| 125 | NHS England and NHS Improvement | Statement 5 | “Clear arrangements for monitoring and follow-up for outpatients ensures that they receive the same quality of care as patients in hospital” is this about measuring against hospital care or about supporting the best possible care as per evidence bases? Terminology may need considering as local and regional variation may be evident. Right care, right place, right time.  |
| 126 | NHS England and NHS Improvement | Statement 5  | “Evidence that information is available” is this just about availability or provision? Please be explicit from the outset and ensure this reflects those who may need additional support. Also written information may not always be the most helpful way to provide information to certain groups so suggest this is reflected in the guidance – a range of ways are needed to be tailored to meet needs of the person.  |
| 127 | Society for Acute Medicine | Statement 5 | The follow up data might be hard to collect as you are relying on unit audit rather than data automatically generated |
| 128 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Statement 5 | Outcome requires review of wording – patients may be admitted via ambulatory care pathways particularly when statement 5 relates to low-risk pulmonary embolism so ‘rates of emergency admissions ….. having outpatient treatment for PE’ is confusing |
| 129 | University Hospitals Birmingham NHS Foundation Trust Haematology Service | Statement 5 | We agree with the spirit of the QS. NICE will need to clarify the ownership of clinical review; would responsibility lie with the prescriber? The anticoagulant clinic? Or the acute medicine team? |
| 130 | Anticoagulation UK | Additional statement | We reiterate our concerns around the lack of guidance or acknowledgement within NG 158 as to psychological support mechanisms to be offered/made available to patients following a VTE episode. This has been highlighted by a previously referenced study <https://bmjopen.bmj.com/content/9/2/e024805> . This is even more significant due to COVID 19 and the increased number of people hospitalised and discharged on anticoagulation potentially having to cope with the knowledge they may have heightened risk of VTE and other health challenges caused by the virus.We would also continue to emphasise the need for NHS to produce standardised patient information which will address, VTE risk assessment on admission to hospital, prophylaxis options and detailed information on the duration of treatment and follow up on discharge. We understand that the yellow book for anticoagulation therapy is currently being updated by NHSE Improvement and should be available next year. |
| 131 | Chelsea and Westminster Hospital NHS Foundation Trust | Additional statement | Disappointed and would encourage including VTE risk assessment completion on admission, and reassessment of risk assessment as a standard, particularly as VTE risk assessment is the initial step in VTE prevention measure and driver for quality improvement |
| 132 | Chelsea and Westminster Hospital NHS Foundation Trust | Additional statement | Disappointed to see the provision of verbal and/or written patient information is not included in the quality standard – appreciate included in the section on ‘what the quality statement means for different audiences’ but unlikely to be read and impacted on |
| 133 | Thrombosis UK | Additional statement | NICE VTE Guidelines (NG89) 1.2, recommends all hospital admitted patients are given information about their VTE Risk Assessment and how people can reduce their risk of VTE (such as keeping well hydrated and, if possible, exercising and becoming more mobile. The 2020 NHS GIRFT VTE Survey reports low levels of patient information being given:<https://www.youtube.com/watch?v=MWln33e_LEU&feature=youtu.be> (10mins 38 seconds, review data shared). Where only an average of 30% of patients overall received written information on admission or discharge.Evidence <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3987719/> indicates the psychological impact a VTE can have on patients and we are aware that receiving reliable and timely information can help alleviate the severity of this. Therefore, we would urge NICE to include a Quality Standard within the venous thromboembolism QS that recommends all patients receive information about venous thromboembolism, prevention, management and recovery, including sign posting to where further support and reliable information can be sourced. |
| 134 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Additional statement | Disappointed and would encourage including VTE risk assessment completion on admission, and reassessment of risk assessment as a standard, particularly as VTE risk assessment is the initial step in VTE prevention measure and driver for quality improvement |
| 135 | UK Clinical Pharmacy Association (UKCPA) Haemostasis & Thrombosis Committee | Additional statement | Disappointed to see the provision of verbal and/or written patient information is not included in the quality standard – appreciate included in the section on ‘what the quality statement means for different audiences’ but unlikely to be read and impacted on |
| 136 | VTE National Network for Nursing and Midwifery | Additional statement | VTE risk assessment and reassessment is the fundamental building block for quality VTE prevention care and yet we know that not all hospitals are meeting the target of >95% consistently. We know that potentially preventable HATs still occur due to failure to reassess patients’ VTE risk when condition changes. The VTE QS have provided a vital lever for VTE prevention leads to drive best practice in their Trusts where few other levers exist. Removing VTE risk assessment and reassessment would be a backwards step. The previous VTE prevention QS also provided ideal audit criteria for Trusts to monitor compliance against.VTE patient information should also remain a quality standard as a VTE NNMN audit showed that compliance was poor, this was supported by the recent GIRFT findings. We know that thromboprophylaxis is not always effective and with patients being discharged from hospital earlier, it is vital that they are aware of the signs and symptoms of VTE and what to do if they experience them.Processes for RCA of HATs and dissemination of learning should be included since this is in the NHS Standard Contract-NICE should be consistent with this.The quality standard for investigation into occult cancer for unprovoked VTEs should remain a quality standard since this has important patient outcome implications. |

## Registered stakeholders who submitted comments at consultation

* ALK Positive UK
* All-Party Parliamentary Group on Vascular and Venous Disease
* Anticoagulation UK
* British Association of Day Surgery
* British Geriatrics Society
* British Orthopaedic Association
* British Thoracic Society
* Chelsea and Westminster Hospital NHS Foundation Trust
* Clinical Leaders of Thrombosis
* King’s College Hospital NHS Foundation Trust
* LEO Pharma
* NHS England and NHS Improvement
* Royal College of Nursing
* Royal College of Paediatrics and Child Health
* Royal College of Physicians
* Society and College of Radiographers
* Society for Acute Medicine
* Thrombosis UK
* UK Clinical Pharmacy Association Haemostasis & Thrombosis Committee
* University Hospitals Birmingham NHS Foundation Trust Haematology Service
* VTE National Network for Nursing and Midwifery

# Appendix 2: Quality standard consultation comments table – respondents with links to the tobacco industry

| **ID** | **Stakeholder** | **Section** | **Comments[[2]](#footnote-2)** |
| --- | --- | --- | --- |
| 1 | Bayer | Disclosure | Current Situation• Bayer does not have direct or indirect links with, or funding from, manufacturers, distributors or sellers of smoking products but Bayer provides pesticides for crops, which would therefore include tobacco crops. • Bayer is a member of the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) (http://www.coresta.org/) within the scope of recommendations of pesticides used for protection of tobacco plants. • It is also a member of country and EU business federations such as the Confederation of British Industry (CBI) and ‘Business Europe’, which include tobacco companies. Past SituationIn 2006, Bayer and its subsidiary Icon Genetics piloted a new process for producing biotech drugs in tobacco plants. Icon Genetics was acquired by Nomad Bioscience GmbH from Bayer in 2012. |
| 2 | Bayer | Question 3 | Bayer welcomes the inclusion of the new quality statement 5:*People aged 18 and over having outpatient treatment for suspected or confirmed low-risk pulmonary embolism (PE) have an agreed plan for monitoring and follow-up.* ***[new 2021]***In the Home Treatment of Patients with Low-Risk Pulmonary Embolism with the Oral Factor Xa Inhibitor Rivaroxaban (HoT-PE) trial, the aim was to investigate the efficacy and safety of early transition from hospital to ambulatory treatment in low-risk acute PE, using the oral factor Xa inhibitor rivaroxaban. The study conclusion was that early discharge and home treatment with rivaroxaban is effective and safe in carefully selected patients with acute low-risk PE. The results of the trial support the selection of appropriate patients for ambulatory treatment of PE (1).   Regarding the consultation question 3: *“….Please describe any potential cost savings or opportunities for disinvestment.”,* it is to be expected that there will be cost-savings from introducing outpatient management of low risk PE (2). This study (2) conducted in Sweden, reported that the total cost per patient was 8293 EUR in the inpatient group, and 2176 EUR in the outpatient group (p < 0.001).Further, and taken directly from this publication (2): “*The use of LMH injections during institution of warfarin treatment is associated with prolonged hospital stay. As this is not necessary for treatment with rivaroxaban or apixaban, use of these DOAC might potentially have further beneficial effects on costs.* *Coleman et al showed that rivaroxaban use was associated with a 1.36-day shorter length of stay (LOS) and 2304 USD reduction in total costs compared to parenteral bridging during institution of warfarin. Furthermore, this cost reduction was achieved without increasing the short-term risk of readmission for VTE or major bleeding.* *Similarly, Bookhart and colleagues evaluated the impact of rivaroxaban on LOS among 321 hospitalized acute PE patients recruited into EINSTEIN PE in North America. In these patients, rivaroxaban use resulted in a 1.7-day mean reduction in LOS compared with enoxaparin and vitamin K antagonists, enabling a reduction of total hospital costs of 3000 USD per patient.”** + 1. Barco S, et al. Early discharge and home treatment of patients with low-risk pulmonary embolism with the oral factor Xa inhibitor rivaroxaban: an international multicentre single-arm clinical trial, European Heart Journal, Volume 41, Issue 4, 21 January 2020, Pages 509–518
		2. Ghazvinian et al. Outpatient Treatment in Low-Risk Pulmonary Embolism Patients Receiving Direct Acting Oral Anticoagulants Is Associated With Cost Savings. Clinical and Applied Thrombosis/Hemostasis. 2020. Volume 26: 1-8. DOI: 10.1177/1076029620937352
 |
| 3 | Bayer | Statements 1, 4 and 5 | Bayer supports the inclusion of guidance for healthcare professionals to ensure that patients are given written and verbal information about their treatment. This is also in line with the principles of shared decision making (1).* + 1. NICE. Shared decision making. <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making>
 |
| 4 | Bayer | Statements 1-5 | Bayer welcomes the inclusion of guidance for commissioners to:• ensure that services have written clinical protocols/ referral pathways/ systems in place • ensure that services have prescribing systems, equipment, healthcare professionals, capacity and resources available to deliver the services. |
| 5 | Bayer | Statement 4 | • People aged 18 and over taking anticoagulation treatment after a VTE have a review after 3 months and then at least once a year if they continue to take it long-term. [2013, updated 2021]Bayer welcome the quality statement advocating review of anticoagulant treatment after a VTE but consider there should be a review at 3 months, 6 months and then yearly if treatment is continued long-term. This is due to the need to potentially review the dose at 6 months. For example, the Xarelto summary of product characteristics (SPC) (1) states the following:Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE The recommended dose for the initial treatment of acute DVT or PE is 15 mg twice daily for the first three weeks followed by 20 mg once daily for the continued treatment and prevention of recurrent DVT and PE. Short duration of therapy (at least 3 months) should be considered in patients with DVT or PE provoked by major transient risk factors (i.e. recent major surgery or trauma). Longer duration of therapy should be considered in patients with provoked DVT or PE not related to major transient risk factors, unprovoked DVT or PE, or a history of recurrent DVT or PE. When extended prevention of recurrent DVT and PE is indicated (following completion of at least 6 months therapy for DVT or PE), the recommended dose is 10 mg once daily. In patients in whom the risk of recurrent DVT or PE is considered high, such as those with complicated comorbidities, or who have developed recurrent DVT or PE on extended prevention with Xarelto 10 mg once daily, a dose of Xarelto 20 mg once daily should be consideredThere are dose adjustments recommended in other DOAC SPCs following completion of at least 6 months therapy for DVT or PE. 1. https://www.medicines.org.uk/emc/product/2793/smpc |

1. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-1)
2. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-2)