Venous thromboembolic diseases: diagnosis, management and thrombophilia testing

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Alliance Pharmaceuticals	General	General	No further comments at this stage, but please could you continue to involve us in future rounds concerning this guideline.	Thank you for your comment. Stakeholders will be kept informed of the development of the guideline.
Anticoagulation UK	General	general	Add page number to each page for ease of referencing for reader	Thank you for your comment. Page numbers will be added to the final version of the scope.
Anticoagulation UK	1	19	Does consideration need to be given to length of time to diagnosis. Current guideline is 24 hours. Recent FOI as reported in All Party Parliamentary Thrombosis Survey results 2018 found average time 29 hours www.apptg.org.uk	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on the length of time to diagnosis. Therefore this area of the guideline will not be updated. NICE provides implementation support for CG144 Venous thromboembolic diseases: diagnosis, management and thrombophilia on NICE's website.
Anticoagulation UK	2	16	*'does not improve diagnosis' does this indicate that there are other more reliable tests in place to ascertain if a patient has undiagnosed cancer i.e markers in blood?	Thank you for your comment. The evidence identified by the surveillance review comparing testing for cancer and not testing for cancer which is described in the scope. The update of the guideline will consider the review question "Do investigations for cancer in people with unprovoked VTE improve outcomes (morbidity and mortality)?" The wording in the scope about

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				why this update is needed has been amended.
Anticoagulation UK	3	24/25	Will this include people in nursing and care homes and those with limited mobility being cared for in home setting	Thank you for your comment. Yes these groups will include all older people and all people who have restricted movement. People in nursing or care homes has been added to the scope for clarity.
Anticoagulation UK	6	1.1	See comment above	Thank you for your comment, please see our response to your above comment.
Anticoagulation UK	6	1.3	Need for standardised patient information to be used across all NHS reviewed at regular intervals	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on patient information for people with VTE. Therefore this area will not be included in the update. NICE also has guidance on patient experience in adult NHS services (CG138).
Anticoagulation UK	7	1.7	Pleased to see this being reviewed and updated. Essential for physical and mental well being of patient in managing VTE episode, ongoing symptoms, Post thrombotic syndrome and health anxiety	Thank you for your comment.

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			issues	
Anticoagulation UK	10	21.4	Issue around lack of VTE risk awareness for patients diagnosed with cancer or, when in treatment. This needs to be addressed as if an unprovoked VTE occurs and cancer is not investigated, anticoagulant therapy may be compromised? Acknowledge this may be covered off in the Cancer/oncology pathway. New evidence here will be of interest for patient groups	Thank you for your comment. The update of the guideline will include updating the review question "Do investigations for cancer in people with unprovoked VTE improve outcomes (morbidity and mortality)?"
Association of Independent Healthcare Organisations	General	general	We need more clarity regarding effective VTE management / prevention in : 1. Neurosurgical patients (e.g. brain lesions, excision, craniotomy, etc) 2. Upper limb DVT associated with PICC line in oncology patients.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on VTE management in neurosurgical patients or upper limb DVT associated with PICC line in oncology patients. Therefore these areas will not be included in the update. Prevention of VTE is outside of the remit of this guideline but it is covered by the Venous thromboembolism: reducing the risk for patients in hospital, which has recently been updated and published in March 2018.
Association of	General	general	I would also suggest that we take a similar stance to the United	Thank you for your comment. The guideline

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Independent Healthcare Organisations			States where all the relevant professions met and agreed a plan forward. We can't have another scenario where a body like Association of Orthopaedic Practitioners question the guidance. We need a strategy that everyone can buy into so that the uptake goes well.	will be developed following NICE's processes described in Developing NICE guidelines: the manual. Stakeholders will be kept up to date during the process.
Association of Independent Healthcare Organisations	General	general	Aspirin in VTE Prophylaxis, please review this matter in depth.	Thank you for your comment. Prevention of VTE is outside of the remit of this guideline but it is covered by the Venous thromboembolism: reducing the risk for patients in hospital, which has recently been updated and published in March 2018.
Bayer PLC	general	general	We agree that technology appraisals 287 (Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism (2013)) and 261 (Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (2012)) should be incorporated unchanged in this guideline.	Thank you for your comment.
Bayer PLC	general	general	The results of the EINSTEIN CHOICE trial have recently been published which provide additional evidence regarding extended anticoagulation for patients who have completed 6 to 12 months of therapy and for whom there is equipoise regarding the need for	Thank you for your comment. Rivaroxaban has been included in the NICE technology appraisal guidance TA341, which will be reviewed and may be incorporated unchanged into the guideline.

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			continued anticoagulation. Weitz JI et al. Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism. N Engl J Med. 2017 Mar 30;376(13):1211-1222. doi: 10.1056/NEJMoa1700518. A cost effectiveness analysis has been undertaken considering the EINSTEIN CHOICE results and that we anticipate will be published in 2018.	
Boston Scientific	9	26-29	We would like the committee to consider the suggestion below in the diagnosis and management of DVT: D-Dimer tests are valuable in diagnosing the systemic presence of thrombus, but their accuracy has been questioned if the patient is anticoagulated. A second test, external duplex Ultrasound, is very useful in confirming the existence of DVT but is only accurate in locating thrombus below the inguinal ligament (femoropopliteal DVT), and often does not reveal the cause of the DVT. However, according to the current guidelines, the presence and age of thrombus in the proximal veins (Iliofemoral veins and/or IVC), along with the DVT cause, will drive the proper treatment choice (aggressive/thrombolytic/pharmacomechanical vs conservative/anticoagulation). The best way to confirm or rule out thrombus presence in the	Thank you for your comment. The guideline update will include considering the diagnostic accuracy of point-of-care D-Dimer tests and age-adjusted D-Dimer tests. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on other diagnostic techniques. Therefore these areas will not be included in the update.

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			proximal veins and to identify potential causes of the DVT is to use a Magnetic Resonance scan (MRV) of Veins or a Computed Tomography scan of Veins (CTV). Properly interpreted, these diagnostic methods will not only allow the confirmation of proximal DTV, but also indicate the age of the thrombus (acute, subacute or chronic) and the potential cause of the DVT. Based on the outcome of the above diagnostic tests, the proper treatment can be chosen and implemented, based on current guidelines. If these diagnostic tests confirm the presence of acute/subacute Iliofemoral thrombus and a common iliac vein compression/stenosis as the likely cause of the DVT, an aggressive endovascular/interventional approach should be the treatment of choice. This treatment normally features pharmacomechanical thrombectomy to remove the thrombus, followed by venous stenting to open the compression/stenosis and restore patency. An IVUS procedure should be performed pre, during and post procedure as follows: post wiring to confirm the age and consistency of the thrombus, post pharmacomechanical thrombectomy to confirm the complete removal of proximal vein thrombus and the exact dimensions of the stenosis, and post stenting to confirm the proper expansion of the stent and the successful treatment of the	

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			underlying cause. Therefore, we respectfully ask NICE to add CTV or MRV to the guidelines for proper diagnosis of the DVT extension into the proximal veins, and intravascular ultrasound, for confirmation of patency and treatment success.	
Bristol Myers Squibb and Pfizer	General	General	Secondary prevention of recurrent DVT and PE is an important therapeutic aim, especially in patients with unprovoked DVT or PE. Since the original guideline was published (2012), considerable new evidence has become available of the long-term use of anticoagulants to prevent recurrent DVT/PE. Apixaban, in particular, offers a bleeding profile comparable to placebo in extended anticoagulation[3], and this guideline should recognise the updated evidence base supporting the use of specific newer agents in patients requiring extended anticoagulation. **References** 1 Summary of Product Characteristics (SPC), Pradaxa 150mg hard capsules. Available at https://www.medicines.org.uk/emc/product/4703/. 2 Summary of Product Characteristics (SPC), Lixiana 60mg	Thank you for your comment. Apixaban has been included in the NICE technology appraisal guidance TA341, which will be reviewed and may be incorporated unchanged into the guideline.

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			Film-Coated Tablets. Available at https://www.medicines.org.uk/emc/product/6905/. 3 Apixaban for Extended Treatment of Venous Thromboembolism (the AMPLIFY-EXT trial), Agnelli et al (2013). NEJM 368(8);699-708.	
Bristol Myers Squibb and Pfizer	6	General	We welcome the incorporation of evidence on the non-VKA oral anticoagulants (NOACs) into the guideline by incorporating (or cross-referencing to) relevant (existing) technology appraisal guidance on pharmacological treatment for confirmed DVT and PE. There are practical advantages of using apixaban instead of alternative NOACs (especially dabigatan and edoxaban which both require bridging with at least five days' treatment with a parenteral anticoagulant[1,2]). These differences may have a meaningful effect on patient compliance and outcomes, so should be acknowledged in the guideline recommendations.	Thank you for your comment. The guideline will update the section on pharmacological anticoagulation strategies for people with suspected and confirmed PE or DVT. The technology appraisal guidelines TA354, TA 341, TA327, TA287 and TA261 will be reviewed and may be incorporated unchanged into the guideline.
British and Irish Hypertension Society	General	General	The proposed guidance is welcomed, and should be written so that acute management of massive and submassive PTE is a priority. Far too often patients are not risk stratified correctly. I have asked my own junior doctors about use of the guidance and management of acutely ill patients is the priority.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on risk stratification. Therefore this area will

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				not be included in the update.
British Association of Dermatologists	General	General	The British Association of Dermatologists requests to consider reviewing the influence of infection/cellulitis on D dimers and providing some guidance on this.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on the influence of infection / cellulitis on D-Dimer tests. Therefore this area will not be included in the update. However the update of the guideline will considered the accuracy of point-of-care D-Dimer tests and age-adjusted D-Dimer tests therefore if the evidence reviewed for these questions highlight an influence of infection / cellulitis on D-Dimer test in these circumstances this will be considered by the guideline committee.
British HIV Association	General	general	BHIVA recommends that the draft scope should include a recommendation to carry out HIV testing.	Thank you for your comment. This guideline focuses on diagnosis and management of people with venous thromboembolic disease. NICE has guidance on increasing uptake of HIV testing in people who may have undiagnosed HIV (NG60).

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British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	3/4	22	Specific consideration will be given to : although patients with stage 3 to 5 kidney disease has been included in to this categories, some guidance is required in both diagnosis and treatment in VTE in patients with liver impairment	Thank you for your comment. People with liver impairment are included in the guideline, therefore if any evidence in this population is identified during the update of the review questions it will be included. Specific sub-groups for separate analysis will be discussed with the committee when the review protocols are developed, and we will consider this information during the development of the review protocols.
British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	2	6	It is not clear when pharmacological treatment is given after first scan the results of a repeat scan may be impaired means clinically highly suspected DVT but the scan negative patients having repeat scan	Thank you for your comment. The update will include pharmacological treatments for treatment of VTE by the review question 1.2 "What is the clinical and cost effectiveness of different pharmacological treatments for people with suspected DVT prior to confirmed diagnosis?". This review question will consider the impact of giving pharmacological treatment prior to a confirmed diagnosis.
British Society for	3	21	Groups to be covered include adults age 18years and older but many adults units including intensive care units treat patients >16 years of	Thank you for your comment. The remit of this guideline is for adults aged 18 years and

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Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians			age	older therefore we are unable to include people aged under 18 years old.
British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	4	2	The patient weight rather than BMI would be better when considering limits of fixed doses.	Thank you for your comment. This part of the scope lists groups that the committee will be give specific consideration to when making recommendations. The recommendations will be made on based on the evidence review for the guideline and committee discussions. We will take into account the information you have provided, when the review protocols are considered.
British Society for Haematology and Royal college of Pathologists,	4	3	All levels of renal function need addressing (note edoxaban)	Thank you for your comment. All levels of renal function will be addressed in the update. NICE Guidance on edoxaban for treatment of VTE in those with renal impairment is covered in technology appraisal TA354 which will be reviewed and

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endorsed by Royal College of Physicians				may be incorporated unchanged into the guideline.
British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	4	21	Why age adjusted d-dimer only for PE?	Thank you for your comment. Following stakeholder comments the following question has been added to the scope: In people with suspected DVT, what is the diagnostic accuracy of age-adjusted D-dimer tests compared with D-dimer tests without age adjustment?
British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	5	9	More explicitly, the need for review at 3 months and any further reviews thereafter	Thank you for your comment. The follow-up question will consider the different factors that should be considered when deciding the optimum duration of pharmacological anticoagulation, this may include the timing of reviews.
British Society	6	Table	I think the evidence for thrombolysis and CDT for both DVT and	Thank you for your comment. NICE

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for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians		1.2	submassive PE should be reviewed. This included combined physical and lytic methods.	Interventional Procedure Guidance (IPG523 and IPG524) provide guidance on catheter directed thrombolysis for DVT and PE. We did not identify any new evidence that would impact the current recommendations on catheter directed thrombolysis. Therefore we will not be including this in the scope for the guideline update.
British Society for Haematology and Royal college of Pathologists, endorsed by Royal College of Physicians	6	Table 1.6	There is sufficient evidence to suggest that results of lupus anticoagulant testing is affected by presence of direct acting oral anticoagulant and the degree of the anticoagulant influence on DRVVT test depend on drug levels. Despite this many clinicians still test for lupus anticoagulant and may labelled patients as antiphospholipid syndrome which affect the duration of anticoagulation etc. This should be included as testing of lupus anticoagulant and interpretation should be done with special caution in patient treated with a direct acting oral anticoagulant	Thank you for your comment. No new evidence that would impact on the current recommendation 1.6.2 Consider testing for antiphospholipid antibodies in patients who have had unprovoked DVT or PE if it is planned to stop anticoagulation treatment. [2012], was identified in the surveillance review or scoping searches, therefore this area will not be updated.
British Society for Haematology and Royal college of	6	Table 1.7	Follow up should include in addition to new area of what factors to consider when reviewing pharmacological anticoagulation, what factors to consider in deciding duration and choice of anticoagulation. The threshold (future recurrence risk) for long term anticoagulation requires review in view of better safety profile of	Thank you for your comment. The update of the guideline will consider both the clinical and cost effectiveness of different pharmacological anticoagulation strategies for people with suspected or confirmed PE

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Pathologists, endorsed by Royal College of Physicians			DOACs	or DVT as well as what factors should be considered when deciding the optimum duration of pharmacological anticoagulation.
British Society of Interventional Radiology	General	General	Would be helpful to highlight the importance differentiating between an acute proximal (iliofemoral) DVT or is chronic/distal DVT. As the former maybe amenable to inpatient catheter-directed thrombolysis and the latter is outpatient pharmacological treatment. At the investigation stage if the patient is diagnosed with DVT on US, it is critical to clarify if the common femoral vein is involved. If it is, then to arrange a vascular surgical review to potentially work-up appropriate candidates with CT abdomen/pelvis with contrast to look for proximal extent and consider referring to IR for catheter-directed thrombolysis with the patient on a high-dependency bed. If it is not, then treat as this document details with outpatient pharmacological treatment.	Thank you for your comment. No new evidence regarding the proximal extent of the thrombus was identified to include it in the guideline update. The current guideline already includes the management of symptomatic ilio-femoral DVT 1.2.6 Consider catheter-directed thrombolytic therapy for patients with symptomatic iliofemoral DVT who have: • symptoms of less than 14 days' duration **and** • good functional status **and** • a life expectancy of 1 year or more **and** • a low risk of bleeding.
British Thoracic Society, endorsed by	General	general	The British Thoracic Society welcomes the scope of the proposed guideline – all areas are clinically relevant.	Thank you for your comment.

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Royal College of Physicians				
British Thoracic Society, endorsed by Royal College of Physicians	General	general	Please note that the BTS Guidelines for the initial outpatient management of pulmonary embolism will be published in April/May 2018.	Thank you for your comment and letting us know about the BTS Guideline. NICE recognises the value of consistent national guidance, where this fits with NICE standard methods.
British Thoracic Society, endorsed by Royal College of Physicians	4	5	It would be helpful if pregnant women were included.	Thank you for your comment. Pregnant women are excluded from this guideline because there is separate guidance on managing DVT and PE in this population group, published by the Royal College of Gynaecologists (RCOG), (RCOG, 2015). NICE has produced guidance on risk assessment of VTE in pregnant women (Venous thromboembolism: reducing the risk for patients in hospital, NICE Clinical Guideline 92).
British Thoracic Society, endorsed by Royal College of	5	8	Follow-up. We note that factors to be considered when deciding the optimum duration of pharmacological anticoagulation is planned to be assessed. We would suggest considering also considering patients who remain	Thank you for your comment. The follow-up question will consider the different factors that should be considered when deciding the optimum duration of pharmacological

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Physicians			symptomatic at follow-up: "At follow-up, which factors should be considered when deciding the optimum duration of pharmacological anticoagulation and what is the optimal way of identifying patients who may benefit from investigations for chronic thromboembolic disease +/- pulmonary hypertension"	anticoagulation, this may include the timing of reviews. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on pulmonary hypertension. Therefore these areas will not be included in the update.
Care Quality Commission	General	General	One of the most important issues for CQC is how the standards are subject to audit for compliance by the provider and recommendations for improvement are monitored.	Thank you for your comment. When making recommendations the committee will consider the implementation of the recommendations as described in Developing NICE guidelines: the manual.
Cook Medical	General	General	The draft scope seems to focus on pharmacological treatments only. We suggest that topic experts such as Stephen Black, Guy's and St. Thomas' NHS Foundation Trust, and Manj Gohel, Nuffield Health Cambridge hospital are consulted to shine on the use of other treatment options.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on non-pharmacological treatment options. Therefore these areas will not be included in the update.
Cook Medical	4	25-28	The draft scope seems to focus on pharmacological treatments only. We suggest that other treatment options such as thrombectomy, stenting and thrombolysis through referral to vascular surgeon are	Thank you for your comment. No new evidence that would impact on recommendations was identified in the

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			included for DVT	surveillance review or scoping searches on VTE management in thrombectomy and stenting for DVT. Therefore these areas will not be included in the update. NICE Interventional Procedure Guidance (IPG523 and IPG524) provide guidance on catheter directed thrombolysis for DVT and PE. We did not identify any new evidence that would impact the current recommendations on catheter directed thrombolysis. Therefore we will not be including them in the scope for the guideline update.
Cook Medical	4	20-21	The draft scope excludes other diagnostic options such as ultrasound, referral to vascular surgeon for venography, MRI or IVUS. We suggest that those are included in the scope.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on other diagnostic techniques. Therefore these areas will not be included in the update.
Cook Medical	5	8-9	We agree that there is a need to define the which pharmacological regiment patients should follow, and how often they should come	Thank you for your comment.

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			back for follow-up visit.	
Cook Medical	6	General	Stenting is not included as a treatment option for DVT. Please see presented clinical data from study on venous stenting in attached document	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on stenting for DVT. Therefore this area will not be included in the update. As part of NICE's processes we are unable to consider attachments to stakeholder comments as described in Developing NICE guidelines: the manual.
Cook Medical	11	5 and 8	Please see evidence on venous stenting for DVT in attached document	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on venous stenting for DVT. Therefore this area will not be included in the update. As part of NICE's processes we are unable to consider attachments to stakeholder comments as described in Developing NICE guidelines: the manual.
Faculty of	General	General	The existing guideline appropriately lists combined hormonal	Thank you for your comment. No new

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Sexual and Reproductive Health Clinical Effectiveness Unit			contraception as a risk factor for VTE and suggests consideration of stopping oestrogen-containing contraception prior to surgery. It does mention ensuring that alternative contraception is provided: I wonder if you would consider making this a little bit more robust by changing to "effective alternative contraception" and maybe giving some examples of alternatives (e.g. progestogen-only pill, subdermal progestogen-only implant, intrauterine system, intrauterine device), or if that is too much, just clarifying that the advice to stop does not apply to progestogen-only contraceptive methods. Or to note that "progestogen-only methods such as a POP, IUS or implant can be used in such patients too"	evidence that would impact on recommendations was identified in the surveillance review or scoping searches on alternative contraception. Therefore this area will not be included in the update. NICE has guidance on long-acting reversible contraception (CG30). During the development of the updated guideline recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.
LEO Pharma	general	general	There is no mention of updating 1.2.2 from the current guideline, we recommend that this section does require an update due to the numbers of licensed treatment options that have subsequently become available. It is thus our recommendation that SMPCs for relevant anticoagulants are compared in order to identify and state the anticoagulants which accommodate the needs of patients with active cancer as well as the treatment period (of 6 months). This is also in line with a number of other international guidelines including	Thank you for your comment. The guideline will update the recommendations, including 1.2.2, on pharmacological anticoagulation strategies for people with suspected or confirmed PE or DVT.

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			NCCN, ACCP & ASCO.	
LEO Pharma	2	10	Comment is made in relation 3.1 and 3.2 – Some anticoagulants route to market is via national & regional tender (discount/rebate) schemes and therefore these should be accounted for in the economic considerations of this guideline.	Thank you for your comment. The update of the guideline, including when considering the cost-effectiveness of treatments, will follow the processes and methods described in Developing NICE guidelines: the manual.
LEO Pharma	10	14	Comments below are made in relation 3.1 and 3.2 (What is the clinical and cost effectiveness of different pharmacological anticoagulation strategies in people with a confirmed diagnosis of PE or DVT, covering above mentioned "*patients with active cancer and VTE*". In conducting the Cost Effectiveness Analysis (CEA) the following clinical/safety parameters should be considered. • Initial DVT/PE; • Recurrent DVT/PE; • Fatal PE; • Major Bleeding; • (Fatal Bleeding)	Thank you for your comment and information. The guideline will update the recommendations on pharmacological anticoagulation strategies for people with suspected or confirmed PE or DVT. The guideline may incorporate the recommendations from the relevant Technology Appraisals unchanged into the guideline. The guideline will give specific consideration to people with cancer in all the review questions being updated. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. The outcomes listed in the scope are the

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			• Non Major Bleedings; • PHT (Pulmonary Hypertension) All parameters are expected to be associated with a cost, a resource utilization and a quality of Life component. However, apart from the basic structure, we highlight a number of considerations which could add valuable information to the model and thus the outcomes/conclusions of it. **Cancer types:** Variations in the risk of Venous Thromboembolism (VTE) (DVT or PE) and recurrent VTE (DVT or PE) per cancer type could be beneficial to incorporate. The cost effectiveness model could generalise across patients with active cancer, but in order to capture a potential variation in cost effectiveness ratios linked to cancer groups, it can be helpful to use subgroups segmented by cancer types (Cohen 2017; Lee, Kamphuisen, Meyer 2015) **Quality of Life:** In relation to a cost effectiveness model it is decrements in quality of life in relation to first VTEs and recurrent VTEs that are generally considered. In this context it is equally important to assign an	main outcomes that will be considered, the final set of outcomes to be considered for each review question will be defined in the review protocol. The review protocol will be developed with the guideline committee. With regards to the papers that you refer to, these are related to clinical questions that are being updated in this guideline.

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			accurate decrement in quality of life related to Adverse Events (AEs).	
LEO Pharma	10	14	**Cost of bleedings**: Cost of AEs will be part of the CEA, but it is not recommendable to have generalised the cost of AEs across therapies, especially in relation to bleedings. When reversal of bleeding is initiated, different reversal strategies needs to be followed according to which anticoagulation the patient has received. (Beyer-Westendorf 2014, Giustozzi M. 2017; Pereira 2004). The difference in these strategies, results in differences in resource utilization (for instance INR monitoring), as well as differences in the use of reversal agents for instance (example: price of reversal agent. Greater Manchester Medicines Management group; 2016). Thus this difference should be reflected in a CEA. In the same manner it is advisable to differentiate the long term bleeding risks and thus associated costs of bleedings (in long term). There can be a difference in the risk of bleeding according to the length of treatment. (Jara-Palomares L. 2017) **Mortality** Mortality related to VTEs will be presumably be part of the CEA. It is therefore also assumed that mortality related to major bleedings will be incorporated. Specifically to the latter, it can be argued that	Thank you for your comment and information. The guideline will update the recommendations on pharmacological anticoagulation strategies for people with suspected or confirmed PE or DVT. The guideline may incorporate the recommendations from the relevant Technology Appraisals unchanged into the guideline. The guideline will give specific consideration to people with cancer in all the review questions being updated. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. The outcomes listed in the scope are the main outcomes that will be considered, the final set of outcomes to be considered for each review question will be defined in the review protocol. The review protocol will be developed with the guideline committee. With regards to the papers that you refer

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			certain sites of bleedings are more common than others, but also have a higher mortality. For example the most common sites of bleeding in patients with malignancy are the gastrointestinal and genitourinary tracts (Lee A. 2017). The mortality of those patients, seems to be higher compared to bleedings in other sites (Wilcox 2009; Kumar 2011) . Hence; it would be of value to segment bleedings according to site of bleeding, as the outcomes are not necessarily the same. **Survival**: The general survival of cancer patients is increasing (Cancer statistics UK; 2018) and thus needs to be taken into careful consideration in relation to a CEA. As a PE can be the cause of a premature death for a cancer patient. Therefore it is important to incorporate the cost of life years lost (or life years saved in contrast) and relate the estimate to an "updated" life expectancy for cancer patients in general or per Cancer type. **References:** American College of Chest Physicians (ACCP); Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report.	to, these are related to clinical questions that are being updated in this guideline.

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			Chest 2016;149:315-352. The American Society of Clinical Oncology (ASCO); Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline; https://www.asco.org/practice-guidelines/quality-guidelines/guidelines/supportive-care-and-treatment-related-issues#/9911	
LEO Pharma	10	14	Beyer-Westendorf J. Rates, management, and outcome of rivaroxaban bleeding in daily care: results from the Dresden NOAC registry, BLOOD, 7 AUGUST 2014 x VOLUME 124, NUMBER 6 Cancer survival statistics, Cancer Research UK; http://www.cancerresearchuk.org/health-professional/cancer-statistics/survival#heading-One (accessed 1 Feb 2018) Cohen A. et al; Epidemiology of first and recurrent venous thromboembolism in patients with active cancer; A population-based cohort study; Thrombosis and Haemostasis 1/2017 Giustozzi M. Reversal of dabigatran-associated bleeding using idarucizumab: review of the current evidence. J Thromb	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the papers that you refer to, if these are related to clinical questions that are being updated in this guideline and meets the review protocol, this will be

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			Thrombolysis (2017) 44 Greater Manchester Medicines Management group ; Idarucizumab (Praxbind) for the reversal of dabigatran anticoagulation; new threapies subgroup;; march 2016 http://gmmmg.nhs.uk/docs/nts/Idarucizumab-Praxbind-for-the-reversal-of-dabigatran-anticoagulation.pdf Kumar R. Gastrointestinal Bleeding; Emerg Med Clin N Am: 2011; 239–252 Lee A.Y; Kamphuisen, P; Meyer G. et al; Tinzaparin vs Warfarin for Treatment of Acute Venous Thromboembolism in Patients With Active Cancer; A Randomized Clinical Trial; JAMA. 2015;314(7) Lee A.Y; When can we stop anticoagulation in patients with cancer-associated thrombosis. BLOOD, 7 Dec. 2017 vol. 130, no. 23 Lloyd A et al.; What Impact Does Venous Thromboembolism and Bleeding Have on Cancer Patients' Quality of Life; VIH Value in Health, 2017 National Comprehensive Cancer Network (NCCN) ; NCCN Guidelines	considered by the guideline committee during the update.

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			for supportive care; Cancer-Associated Venous Thromboembolic Disease https://www.nccn.org/professionals/physician_gls/default.aspx#vte Pereira J.: Management of Bleeding in Patients with Advanced Cancer; The Oncologist 2004;9 Jara-Palomares L et al; Tinzaparin in cancer associated thrombosis beyond 6 months: TiCAT study ; Thrombosis Research 157 (2017)	
LEO Pharma	10	14	**References (cont'd)** Wilcox M; Mortality associated with gastrointestinal bleeding events: Comparing short-term clinical outcomes of patients hospitalized for upper GI bleeding and acute myocardial infarction in a US managed care setting; Clinical and Experimental Gastroenterology 2009:2 21–30	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the paper that you refer to, if this relates to clinical questions that are being updated in this guideline and if it meets the review protocol, this will be considered by

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				the guideline committee during the update.
NHS England	General	General	The draft scope currently does not cover patients with superficial thrombophlebitis at risk of extension of clot to the deep veins. We feel this group could be included in the considerations because of lack of clear guidance about its management. It commonly presents in primary care.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on people with superficial thrombophlebitis at risk of extension of clot to the deep veins. Therefore this area will not be included in the update. NICE also has a Clinical Knowledge summary on Thrombophlebitis – superficial which provides advice about its management in primary care.
North West Boroughs Healthcare NHS Foundation Trust	3	1	Who the guidance is for section:- We would appreciate if this and any other guidance would specifically state it is relevant to Mental Health Trusts. As VTE guidance has been previously overlooked here and other Trusts. Although our Trust has no means to undertake tests other than the D-dimer. Aspects of the guidance that would be relevant are recognising VTE/assessment.	Thank you for your comment. The guideline will cover all settings where NHS-funded care is provided, including mental health trusts. No evidence was identified regarding the transition to and from acute trusts was identified, therefore this area will not be included in the update.

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			It would be good to recommend all Mental Health trusts have a pathway for VTE and the smooth transition to and back from the acute Trusts.	
Roche Diagnostics	2	3 - 4	The different pharmacological anticoagulation strategies and their effect on the reliability of D-dimer test results were identified as an area for investigation in the draft scope. Please see the references below which provide evidence on this topic. 1. Nagao T., Hunakubo H., Suzuki M., Kataoka T., Okumura S., Shinoda N., et al. Trends in physiological coagulation factors in Japanese patients receiving novel oral anticoagulants. Journal of Arrhythmia. 2017; 33(2):117–21. 2. Gurram M., Pulivarthi S. Effectiveness of D-dimer as a screening test for venous thromboembolism: An update. North American Journal of Medical Sciences. 2014; 6(10):491. 3. Couturaud F., Kearon C., Bates S. M., Ginsberg J. S. Decrease in sensitivity of D-dimer for acute venous thromboembolism after starting anticoagulant therapy. Blood Coagulation & Fibrinolysis. 2002;13(3):241–6. 4. Becker R. C., Alexander J. H., Newby L. K., Yang H., Barrett Y., Mohan P., et al. Effect of apixaban, an oral and direct factor	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the papers that you refer to, these are related to clinical questions that are being updated in this guideline. If this evidence meets the review protocol, this will be considered by the guideline committee during the update.

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			Xa inhibitor, on coagulation activity biomarkers following acute coronary syndrome. Thrombosis and Haemostasis. 2010; 104(5):976–83.	
Roche Diagnostics	4	23-24	The draft scope suggests that a key area to be investigated in the guideline includes age-adjusted D-dimer tests for PE. Please see the references below which provide evidence to support this. 1. Prochaska J. H., Frank B, Nagler M, Lamparter H, Weißer G, Schulz A, et al. Age-related diagnostic value of D-dimer testing and the role of inflammation in patients with suspected deep vein thrombosis. Scientific Reports. 2017; 7(1). 2. Pernod G, Maignan M, Marlu R. Questioning the use of an age-adjusted D-dimer threshold to exclude venous thromboembolism: analysis of individual patient data from two diagnostic studies: comment. Journal of Thrombosis and Haemostasis. 2016;14(12):2553–4. 3. Crawford F., Andras A., Welch K., Sheares K., Keeling D., Chappell F. M. D-dimer test for excluding the diagnosis of pulmonary embolism. Cochrane Database of Systematic Reviews. 2016; 5(8).	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the papers that you refer to, these are related to clinical questions that are being updated in this guideline. If this evidence meets the review protocol, this will be considered by the guideline committee during the update.

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			4. Nobes J., Messow C-M., Khan M., Hrobar P., Isles C. Age-adjusted D-dimer excludes pulmonary embolism and reduces unnecessary radiation exposure in older adults: retrospective study. Postgraduate Medical Journal. 2016; 93(1101):420–4. 5. Urban K., Kirley K., Stevermer J. PURLs: It's time to use an age-based approach to D-dimer. The Journal of Family Practice. 2014; 63(3): 155-56. 6. Righini M., Es J. V., Exter P. D. Age-Adjusted D-Dimer Cutoff Levels to Rule Out Pulmonary Embolism: The ADJUST-PE Study. Journal of Vascular Surgery. 2014; 59(5):1469.	
Roche Diagnostics	9	27 - 29	The diagnostic accuracy of point-of-care D-dimer tests compared with laboratory tests to identify DVT in people with suspected DVT has been identified as an area for investigation in the draft scope. Please see the reference below which provides evidence to support the diagnostic accuracy of point-of-care D-dimer tests. 1. Dempfle C-E., Korte W., Schwab M., Zerback R., Huisman M. V. Sensitivity and specificity of a quantitative point of care D-dimer assay using heparinized whole blood, in patients with clinically suspected deep vein thrombosis. Thrombosis and	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the paper that you refer to, this

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			Haemostasis. 2006; 96(1): 79-83.	are related to clinical questions that are being updated in this guideline. If this evidence meets the review protocol, this will be considered by the guideline committee during the update.
Roche Diagnostics	10	8 - 10	The diagnostic accuracy of point-of-care D-dimer tests compared with laboratory tests to identify PE in people with suspected PE has been identified as an area for investigation in the draft scope. Please see the references below which provide evidence to support the diagnostic accuracy of point-of-care D-dimer tests compared with laboratory tests. 1. Wells P.S., Anderson D. R., Rodger M., Ginsberg J. S., Kearon C., Gent M., Turpie A. G. G., Bormanis J., Weltz J., Chamberlain M., Bowie D., Barnes D., Hirsh J. Derivation of a Simple Clinical Model to Categorize Patients Probability of Pulmonary Embolism: Increasing the Models Utility with the SimpliRED D-dimer. Thrombosis and Haemostasis, 2000; 83: 416-20. 2. European Society of Cardiology. ESC Clinical Practice Guidelines: ESC Guidelines on the diagnosis and management of acute pulmonary embolism. 2014.	Thank you for your comment and suggestions. The update of the guideline will follow the processes and methods described in Developing NICE guidelines: the manual. Evidence reviews will be conducted for each of the review questions described in the scope which will include all published evidence which meet the review protocols developed for the guideline. With regards to the papers that you refer to, these are related to clinical questions that are being updated in this guideline. If this evidence meets the review protocol, this will be considered by the guideline committee during the update.

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Royal College of Anaesthetists	General	General	The scope should include people with a DVT/PE who require urgent/semi urgent surgery, in particular cancer surgery (perioperative pharmacological management in view of competing risks of bleeding and further thrombosis). This is not a specific exclusion, but it is not mentioned.	Thank you for your comment. The scope does not exclude this population, therefore if evidence is identified in this population it will be considered in the guideline.
Royal College of Anaesthetists	General	General	The scope should include people who have had a DVT/ PE and then require elective surgery, in particular cancer surgery (perioperative pharmacological management in view of competing risks of bleeding and further thrombosis). This is not a specific exclusion, but it is not mentioned.	Thank you for your comment. The scope does not exclude this population, therefore if evidence is identified in this population it will be considered by the guideline.
Royal College of Anaesthetists	General	General	The scope should consider when to refer for consideration of pulmonary embolectomy.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on when to refer for consideration of pulmonary embolectomy. Therefore will not be included in the update of the guideline.
Royal College of Anaesthetists	General	General	In patients with a low likelihood of PE (low 2-level Well's score), the scope should consider including the balance between benefit of	Thank you for your comment. The guideline will considered the clinical and cost

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			diagnosis and treatment of PE vs. harm associated with CTPA (cancer risk)?	effectiveness of pharmacological anticoagulation strategies for people with suspected or confirmed PE. The guideline committee will consider both the benefits and harms of treatment identified by the evidence review when making recommendations.
Royal College of General Practitioners	General	General	It would be helpful if the draft scope could look at the duration of anticoagulation required. It is straight forward in patients who have had one episode, but more difficult to work out in patients who have, for example, had two clots but both with provoking factors etc. Often these patients are started on anticoagulation by secondary care but then discharged to the GP for them to determine the duration of anticoagulation. Some clearer guidance would help with the issue. It will certainly be beneficial for the draft scope to consider age appropriate D-dimer levels, as this may reduce the number of unnecessary CTPAs etc. Point-of care D-dimer testing would have the advantage that it could be performed prior to patients being started on anticoagulation, but there is a cost implication for the organisations who will start to provide this service, partially in primary care who have no source of revenue to support the capital and ongoing consuamble costs.	Thank you for your comment. The draft review question "What factors determine the optimum duration of pharmacological treatment for DVT or PE?" will consider the optimum duration of pharmacological treatment for adults aged 18 years and older with suspected or confirmed DVT or PE. Specific sub-groups for separate analysis will be discussed with the committee when the review protocols are developed, and we will consider this information during the development of the review protocols. Thank you for your comment on D-dimer tests, the review questions on the accuracy of D-dimer tests and all other review

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				questions will be developed following the methods described in Developing NICE guidelines: the manual.
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) welcome the proposals by National Institute for Health and Care Excellence (NICE) to develop guidelines for diagnosis, management and thrombophilia testing of venous thromboembolic diseases. The RCN invited professionals who have knowledge of and/or care for patients with these disease to review the draft scope on its behalf. The comments below reflect the views of our reviewers.	Thank you for all the comments provided.
Royal College of Nursing	4/5	25	We hope that the restricted movement also covers those within critical and acute care. It is important to recognise that this group although restricted should be clearly identified. It is appreciated that this statement could be seen to cover these groups.	Thank you for your comment. This population includes all settings.
Royal College of Nursing	5	6	What about those in private nursing homes or private hospitals? These patients should also be covered even though NHS care is not delivered there.	Thank you for your comment. The guideline will cover all settings where NHS-funded care is provided.
Sanofi	4	5	We note that pregnant women are not included within the scope of	Thank you for your comment. Pregnant

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			the guideline. Considering that these are a group of patients at elevated risk of VTE it may be useful to provide some detail on the rationale to exclude this group.	women are excluded from this guideline because there is separate guidance on managing DVT and PE in this population group, published by the Royal College of Gynaecologists (RCOG), (RCOG, 2015). NICE has produced guidance on risk assessment of VTE in pregnant women (Venous thromboembolism: reducing the risk for patients in hospital, NICE Clinical Guideline 92).
Sanofi	11	1	When considering the outcomes to be assessed, including the long term sequelae such as symptomatic post thrombotic syndrome and/or chronic venous insufficiency (with leg ulceration) may be important. The vast majority of people who suffer from VTE survive the event, and a significant number develop these long-term consequences. This would be in line with outcomes captured in the final scope of NICE TA 170, 245, 261, 287, 327, 341, 354. These outcomes may also be important when assessing the clinical and cost effectiveness of the different pharmacological anticoagulation strategies in people with a confirmed diagnosis of DVT.	Thank you for your comment. The outcomes listed in the scope are the main outcomes that will be considered, the final set of outcomes to be considered for each review question will be defined in the review protocol. The review protocol will be developed with the guideline committee.
The London Clinic	General	general	We need more clarity regarding effective VTE management / prevention in :	Thank you for your comment. No new evidence that would impact on

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			1. Neurosurgical patients (e.g. brain lesions, excision, craniotomy, etc) 2. Upper limb DVT associated with PICC line in oncology patients.	recommendations was identified in the surveillance review or scoping searches on VTE management in neurosurgical patients or upper limb DVT associated with PICC line in oncology patients. Therefore these areas will not be included in the update. Prevention of VTE is outside of the remit of this guideline but it is covered by the Venous thromboembolism: reducing the risk for patients in hospital, which has recently been updated and published in March 2018.
The London Clinic	General	general	I would also suggest that we take a similar stance to the United States where all the relevant professions met and agreed a plan forward. We can't have another scenario where a body like Association of Orthopaedic Practitioners question the guidance. We need a strategy that everyone can buy into so that the uptake goes well.	Thank you for your comment. The guideline will be developed following NICE's processes described in Developing NICE guidelines: the manual. Stakeholders will be kept up to date during the process.
The London Clinic	General	General	Aspirin in VTE Prophylaxis, please review this matter in depth.	Thank you for your comment. Prevention of VTE is outside of the remit of this guideline but it is covered by the Venous thromboembolism: reducing the risk for

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				patients in hospital, which has recently been updated and published in March 2018.
Thrombosis UK	General	general	The draft scope does not pay any consideration for people who may already be anticoagulated who present with symptoms of fresh DVT or PE. We feel strongly that this needs to be included. We increasingly hear and have noted there is a rise in patient voice concerning this matter. Whilst initial diagnosis of fresh DVT or PE seems to be improving, for those already anticoagulated but who present with symptoms of fresh DVT or PE is becoming of increasing concern. Too often these individuals experience misdiagnosis and face being dismissed simply because the presenting individual is already anticoagulated.	Thank you for your comment. No new evidence that would impact on recommendations was identified in the surveillance review or scoping searches on people who may already be anticoagulated who present with symptoms of fresh DVT or PE. Therefore this area will not be included in the update.
Thrombosis UK	General	general	We are pleased the draft scope includes a focus on cancer as a cause of unprovoked DVT. However, we strongly urge the scope committee to also pay consideration as to how an unprovoked DVT/PE is categorized. We have heard from a sizable number of patients who have been told their PE or DVT is unprovoked despite them presenting with clear risk factors present. If a patient is told they may have cancer as the cause of their DVT or PE, it can be very traumatic for the patient and needs to be handled carefully.	Thank you for your comment. The current guideline includes a definition of unprovoked DVT or PE, we did not identify any evidence to suggest a change to this definition was required at this time. The update of the guideline will consider the review question "Do investigations for cancer in people with unprovoked VTE improve outcomes (morbidity and mortality)?". NICE also has guidance on

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				patient experience in adult NHS services (CG138).
University Hospitals of North Midlands NHS Trust	General	general	VTE includes any venous thrombosis and therefore the scope of this guideline should be expanded to include unusual site thrombosis. This includes upper limb, cerebral sinus and splanchnic vein thrombosis. These are important areas for clinical decision making and guidance from NICE will be helpful.	Thank you for your comment. No new evidence that would impact on the current guideline was identified in the surveillance review or scoping searches on unusual site thrombosis. Therefore this area will not be included in the update.