Venous Thromboembolic Diseases – Management
Consultation on draft guideline - Stakeholder comments table
7 August 2015 – 4 September 2015

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Anticoagulation (Europe)	Addendum	General		'This recommendation does not cover the use of elastic graduated compression stockings for the management of leg symptoms after DVT' AntiCoagulation Europe is aware of individuals who wear wear stockings to manage their PTS and we welcome the continuance of the use of stockings for this patient group and trust that the prescribers will support their use.	Thank you for your comment. The Committee considered evidence for stockings only in the context of PTS prevention following a proximal DVT. The recommendation should not be interpreted as guidance for prescribers managing existing PTS symptoms because that patient population was outside the remit of this update.
British Society for Haematology and Royal College of Pathologists	Addendum	8	N/A	Section 1.2.7.2 Line 4 – "offer" should be "cover" as per page 35, line 5.	Thank you, this error has now been amended.
British Society for Haematology and Royal	Adde	32	16	This paragraph presumably refers to the incidence of recurrent VTE (as per Figure 21) rather than PTS which is covered in the preceding paragraph.	Thank you, this error has now been amended.

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College of Pathologists	n d u m				
British Society for Haematology and Royal College of Pathologists	A d d e n d u m	26	3	It isn't clear why, despite favourable NICE Technology Appraisals, the newer oral anticoagulants have not been included as an option in this addendum (at least one had approval during the timeframe of the addendum).	Thank you for your comment. The recommendations regarding choice of anticoagulation (shaded in grey) are from the original guideline and were outside the remit of this update, which is focused on adjunctive thrombolysis for patients with pulmonary embolism who are haemodynamically stable but with signs of RVD. No RCT evidence was found for thrombolysis given in addition to any of the newer oral anticoagulants (NOACs). However, we acknowledge that NOACs are increasingly used in clinical practice in the Linking Evidence to Recommendations table (section 2.1.5) in the addendum. Information regarding those NOACs that have received approval via NICE Technology Appraisals for the management of VTE (to date, edoxaban, apixaban, dabigatran etexilate and rivaroxaban) is

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					already included in the current **NICE pathway** and will be incorporated into future updates of guideline CG144.
British Society for Haematology and Royal College of Pathologists	Addendum	26	3	Based on the review of the thrombolysis data in patients with haemodynamic stability and right ventricular dysfunction, do NICE have a view on the anticoagulant of choice in such patients?	Thank you for your comment. The review protocol specified that RCTs of adjunctive thrombolysis given with any standard anticoagulation would be included. Currently, the only published studies meeting the review protocol criteria all used heparin or fondaparinux. The Committee are unable to make recommendations for this patient population regarding choice of anticoagulation, as this was not the focus of this update. However, practitioners are encouraged to refer to the **NICE pathway** for options regarding anticoagulation.
British Society for Haematology and Royal College of Pathologists	Addendu	General	General	It isn't clear what evidence NICE has included and rejected for review in this addendum. One example would be Geersing GJ et al. *BMJ* 2014;348:g1340 doi: 10.1136/bmj.g1340 which suggests modifications to the Wells score for DVT diagnosis that forms part of existing guidance.	Thank you for your comment. Two specific review questions were the focus of this update: the first concerning thrombolysis for pulmonary embolism, the second looking at stockings for the prevention of PTS. The evidence reviewed for each review question is clearly detailed in the respective evidence tables (see Appendix G of the Addendum). All the studies that

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	m				were excluded are shown (with reasons for their exclusion) in Appendix F. The reference you cite is relevant to the section of CG144, concerned with DVT diagnosis, which was outside the remit of the current update. However, we will pass this information on to the NICE guideline surveillance team for consideration in future updates of CG144.
British Society of Interventional Radiology	Addendum	General		The guideline updates seem reasonable and I do not see any challenges for interventional radiology as treatment with intravenous thrombolysis and compression stockings is administered by clinical teams outwith interventional radiology. There are no other specific comments on behalf of BSIR.	Thank you.
British Thoracic Society	Full	26-27		These guidelines seem very thorough. We raise one question about the PE update 2015.	Thank you. We cannot comment specifically on a subgroup for whom there is no direct evidence (i.e. those patients you identify as having "a high symptom burden, deemed at low risk of haemorrhage"). Acute symptom control was not prioritised as an outcome

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				The definitive recommendation against thrombolysis for intermediate risk PE comes across as quite prescriptive - perhaps necessarily so for guideline purposes. The lack of mortality benefit and haemorrhage risk are clear and correctly highlighted, but perhaps a more important outlook for some patients is control of symptoms especially in the acute phase. PEITHO shows benefit in ameliorating risk of 'cardiorespiratory deterioration' (albeit specifically defined) with thrombolysis which to young patients (with low mortality and low risk of haemorrhagic complications) may be a more important outcome. The evidence for reducing the risk of CTEPH is weak from current studies and we do not think this is a means to justify thrombolysis in this group. Is there room for a comment along the lines of "in selected patients with intermediate probability PE with a high symptom burden deemed at low risk of haemorrhage, thrombolysis may be a justifiable treatment" - perhaps better worded - this is the approach we would take clinically with a breathless, tachycardic young person with high clot burden, RV	during development of the review protocol and data are not available from the studies included in this review to undertake a subgroup analysis on the basis of acute symptom control. The efficacy of thrombolysis in the PEITHO trial was driven mainly by the prevention of 'haemodynamic decompensation or collapse', including a persistent, isolated drop in systolic pulmonary artery pressure, which the authors acknowledged could be of questionable significance. What may be more relevant is that study patients were closely monitored and promptly treated when decompensation occurred. This may explain the lower rates of mortality in both arms compared with other cohort studies. When considering the available evidence to form a recommendation, the Committee noted the importance of closely monitoring patients with pulmonary embolism who are haemodynamically stable but with signs of RV dysfunction in order to permit the early detection of haemodynamic deterioration and subsequent reassessment of the risks and benefits of

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				dysfunction etc etc after an open discussion.	thrombolysis on an individual basis (see section 2.1.5 in the addendum). We agree that the current evidence for thrombolysis reducing the risk of CTEPH is weak and look forward to publication of long-term follow-up data from the PEITHO study.
Department of Health	Addendum	General		Thank you for the opportunity to comment on the draft for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you.
Intensive Care Society	Addend	General	General	The reviewers comment that "if patients' cardiopulmonary status should subsequently deteriorate, baseline mortality risk may increase. Clinicians should re-assess, on an individual patient basis, the risk: benefit ratio of giving thrombolysis to patients who become haemodynamically unstable following standard anticoagulation treatment". I was wondering what their recommendations would be	Thank you for your comment. The Committee is unable to make a recommendation specific to the subgroup of patients to which you refer as data are not available from the included studies to undertake a subgroup analysis for profoundly hypoxic patients.

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	um			for PTE patients who are profoundly hypoxic despite invasive ventilation but still haemodynamically stable.	
Intensive Care Society	Addendum	General	General	In 2.27, is it worth having a research question looking at the effectiveness of full length stocking compared to below the knee. My recollection from somewhere was that below knee were adequate for prevention but unsure.	Thank you for your comment. The review question did not exclude thigh-length stockings but only evidence for knee-length stockings was identified in the review (as was the case in the original guideline) – so the Committee was only able to consider 'knee-length' when forming their recommendation. Stocking lengths have been compared in the literature only in the context of a different patient population, namely post-operative surgical patients for preventing deep vein thrombosis (DVT - **http://www.ncbi.nlm.nih.gov/pubmed/22592717**). Those studies found no significant difference in the ability of the two modalities of leg compression to reduce the incidence of DVT in post-operative patients. The focus of this review was on long-term stocking wear to prevent PTS following a DVT. Stocking length was not considered an issue of importance by our

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					topic experts or standing committee members during development of this guidance. Without evidence that there is a question to answer, we do not feel a research recommendation comparing thigh- and knee-length stockings for the prevention of PTS is warranted at this time.
NHS England	Addendum	General		This addendum with regard specifically to thrombolysis for pulmonary embolism is most welcome. This is an area that causes the most difficulty in decision making in acute medicine. The authors are to be congratulated for producing clear statements around a) the definition of haemodynamic instability (BP <90mm Hg or drop of 40mmHg) as a recommendation for thrombolysis and b) the lack of prognostic importance of ancillary measurements of RV dysfunction. This will be most welcome.	Thank you for your comment.
Royal College of Obstetricians and Gynaecologists	Addendu	General	General	The RCOG support the addendum and have no suggested changes.	Thank you.

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Royal College of Radiologists	FULL	General	General	The RCR welcomes the opportunity to comment on the draft addendum. It has reviewed the consultation draft and supports the views of the British Society of Interventional Radiology (BSIR).	Thank you.
The British Lymphology Society	Addendum	35	lines 1-6 and 8-10	The British Lymphology Society appreciates the work undertaken to review compression post DVT. We have localised data suggesting the development of lymphoedema post DVT when compression has not been prescribed, however we also recognise the essential impact of concordance regarding long term compression wearing. As such the BLS is very supportive of the proposed research plan to look at the effectiveness of compression when concordance is adequate in this clinical field.	Thank you for your comment. When forming recommendations, the Committee takes account of published evidence that meets the inclusion criteria specified in the review protocol. We would encourage clinical organisations to work in partnership with academia to ensure that the kind of localised data to which you refer gets into the published literature so that it may be taken into consideration during future guideline updates.