National Institute for Health and Clinical Excellence

Venous thromboembolic diseases: scope consultation

Scope Consultation Table

29 March 2010 – 26 April 2010

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	AntiCoagulation Europe	1	4.1.1 a)	Within this adult population consideration should be given to giving special guidance for adults in Care homes and Residential homes. Diagnosis and treatment for this population is often sub-optimal	Thank you for your comment. We agree that this is an important group. We have added this group to the scope in section 4.1.1.d for special consideration.
SH	AntiCoagulation Europe	2	4.1.2 b)	As pregnancy is a risk factor for VTE pregnant women should be included	Thank you for your comment. We agree that pregnancy is a risk factor for VTE. However, pregnant women have not been prioritised in this guideline as there is guidance from The Royal College of Obstetricians and Gynaecologists that covers this group.
SH	Bayer Healthcare	1	4.3.1 b)	**Interventions to manage venous thromboembolic diseases.** Newer orally active anticoagulants are mentioned under section 3.2, bullet l, but not under 4.3.1 bullet b.	Thank you for your comment and pointing out this discrepancy to us. We are unable to include the newer drugs that are unlicensed within the guideline. Therefore, we have also removed them from section 3.2 of the scope.
SH	Bayer Healthcare	2	5.2	**Guidance under development.** Please be aware that rivaroxaban is also very likely to be referred. It has	Thank you for your comment. We will regularly check for any new technology

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				undergone topic selection obtaining a score of 17 which means it will be a high priority for a technology appraisal.	appraisals throughout the guideline development process.
SH	Boehringer Ingelheim	1	4.3.1 b)	Please consider adding to 'pharmacological' and add dabigatran etexilate as an oral anticoagulant in following section 'oral anticoagulants, such as warfarin' . Although dabigatran etexilate is unlicensed at this time for VTE treatment (this could be indicated by an asterix next to mention of dabigatran etexilate), the RECOVER trial was published in Dec 2009 and could potentially be considered as an alternative to warfarin.	Thank you for your comment. We are unable to include unlicensed drugs within the clinical guideline. However, if a NICE technology appraisal has been published during the development phase we will consider incorporating it into the guideline.
SH	British Nuclear Medicine Society	1	4.3.1 a)	BNMS welcomes the inclusion of diagnostic tests as a priority in the guideline, as discussed extensively at the scoping workshop. However the scope of "Diagnostics" is poorly reflected in the point 4.3.1 a) which states " Diagnostic tests in the assessment of deep vein thrombosis" Diagnostics are the most critical decision area in acute VTE/PE (pulmonary embolism) and not just in detection of DVT; the scope is therefore strongly advised to include • The Diagnostic pathway in Acute PE i.e. What test when? i.e. the proposed diagnostic algorithms) in the light of recent PIOPED II and other recent recommendations to include all relevant modalities such as VQ, CTPA, etc • New developments in imaging: that include an emerging body of evidence endorsing VQ SPECT/tomography (compared to conventional VQ planar imaging) as a more accurate modality for PE diagnosis with particular reference to the distal smaller vessel PE (when CTPA can be less	Thank you for your comment. We are pleased you agree diagnosis should be included. We have amended the scope section 4.3.1a to include diagnosis of venous thromboembolism rather than deep vein thrombosis. The guideline development group will prioritise the specific review questions that should be included in the guideline.

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				sensitive), becoming an accurate viable alternative to CTPA with contraindications to contrast etc and assessing overall burden of PE to guide management. • Radiation issues governing various diagnostic imaging tests	
SH	British Nuclear Medicine Society	2	General	Re : GDG Constituency. The "Radiologist OR Vascular Technologist" as proposed membership of the guideline committee presumes the two have a similar professional role. As discussed in the scoping group meeting, a vascular technician has a procedural role in the performance of venous US/doppler imaging whilst a Radiologist is a medically qualified doctor with Imaging specialisation. The guideline committee membership requires a Radiologist with an interest in Chest / PE imaging and a practising knowledge of all diagnostic modalities for VTE/PE to include CTPA, nuclear medicine(NM) tests i.e. VQ -SPECT scntigraphy in addition to US Doppler imaging. Any guideline group on the subject of PE / VTE without a Radiologist is ill equipped to deal with the complex issues concerning diagnostic pathways given imaging is at the core of this subject.	Thank you for your comment. We agree and have recruited a radiologist to the guideline development group.
SH	British Nuclear Medicine Society	3	4.1.2 b)	The exclusion of pregnant women from the guideline. The stakeholder considers that this is a very important patient sub-group where most management dilemmas arise with respect to diagnostics and management and should not be excluded from the overall scope, which is an opportunity to address the inconsistencies in current approach to this sub-group.	Thank you for your comment. We agree that pregnant women are an important group. However, they have not been prioritised in this guideline. The Royal College of Obstetricians and Gynaecologists has recently published guidance on VTE in pregnant women which covers diagnosis and management.

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SH	British Thoracic Society	1	General	The guideline appears to wish to consider venous thromboembolism, which implies deep venous thrombosis (DVT) and pulmonary embolism (PE). However, it is not clear in some areas of the document that both DVT and PE are to be looked at (3.2h, 4.3.1a)	Thank you for your comment. We agree that this is not clear. We have amended the scope (3.2h and 4.3.1a) to clarify that we will be considering venous thromboembolism (which includes deep vein thrombosis and pulmonary embolism).
SH	British Thoracic Society	2	3.1 d)	Add that non-fatal acute venous thromboembolism may result in chronic thromboembolic pulmonary hypertension in up to 5% of cases, which causes long-term morbidity and mortality.	Thank you for your comment. Section 3.1.d is intended to be an introduction to the scope and we are not able to cover all outcomes. We are including non-fatal pulmonary embolism in the guideline.
SH	British Thoracic Society	3	3.2 h)	This refers to DVT only. Is PE to be examined also	Thank you for pointing this out. We agree and have amended the text so that it also refers to pulmonary embolism.
SH	British Thoracic Society	4	3.2 h)	Many clinicians would not consider 3-6 months treatment as current standard practice, at least for PE, even after a first episode. The guidelines published by the American College of Chest Physicians recommend considering the risk/benefit ratio of long-term warfarin after a first episode in conjunction with patient preference. This is the standard practice for many expert clinics in the UK. It would be reasonable to say that standard UK guidance has been 3-6 months, but current practice differs – hence the need for a new guideline.	Thank you for your comment. We agree that there are differences in current practice and we are pleased that you agree that there is a need for guidance.
SH	British Thoracic Society	5	4.1.2	Pregnant women: investigation and management in pregnant patients - specific up to date consideration of the pregnant population by NICE and the Royal College of Obstetricians and Gynecologists (latter currently have a Green Top	Thank you for your comment. We agree that pregnant women are an important group. However, they have not been prioritised in this guideline as there is

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				guideline from Feb 2007) would be useful.	guidance from The Royal College of Obstetricians and Gynaecologists on VTE in pregnant women..
SH	British Thoracic Society	6	4.3.1	Would the guideline committee consider also reviewing the evidence for identification of low-risk PE patients for early discharge and home anticoagulation? This would then impact on length of hospital stay (4.4p)	Thank you for your comment. Management of pulmonary embolism is included in the scope. The guideline development group will prioritise the specific review questions.
SH	British Thoracic Society	7	4.3.1 a)	Is this just DVT or PE as well? This should include assessment of clinical probability.	Thank you for your comment. We have amended the scope section 4.3.1a to include diagnosis of venous thromboembolic diseases (DVT and PE). The specific review questions and diagnostic tests included will be prioritised by the guideline development group.
SH	British Thoracic Society	8	4.3.1 b)	Other important clinical areas to consider include: • Risk stratification on the basis of risk of early death (in-hospital or 30 day mortality) and prognostic assessment. This is recommended by the European Society of Cardiology and has an impact on both treatment and length of stay. • Which patients can be managed in an out-patient setting? • Inotropic support and pulmonary vasodilators • Incidental sub-segmental filling defects • What monitoring is required on anticoagulant therapies? • What follow-up should be offered if any, given the risk of chronic thromboembolic pulmonary	Thank you for your comment. The guideline development group will prioritise the specific review questions that will be included in the guideline.

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				hypertension?	
SH	British Thoracic Society	9	4.3.2	Is NICE also excluding cerebral vein thrombosis, splanchnic thrombosis and retinal vein thrombosis?	Thank you for your comment. We have excluded cerebral vein thrombosis, splanchnic thrombosis and retinal vein thrombosis as they are less common and have not been prioritised for this guideline.
SH	British Thoracic Society	10	4.4 m)	Chronic thromboembolic pulmonary hypertension	Thank you for your comment. We agree and have amended this as suggested.
SH	Department of Health	1	General	"We welcome the development of a clinical guideline by the National Institute for Health and Clinical Excellence (NICE) on the management of venous thromboembolic diseases (VTE) and the role of thrombophilia testing. In our view, this clinical guideline on the management of VTE will be an important contribution to the wider work on VTE that NICE and the Department of Health have been focussing on in partnership with key stakeholders, particularly the emphasis on VTE risk assessment for all patients admitted to hospital, and appropriate prophylaxis based on NICE clinical guidance".	Thank you for your comment.
SH	GlaxoSmithKline	1	General	GlaxoSmithKline supports the development of a guideline for the management of venous thromboembolism and the role of thrombophilia testing.	Thank you for your comment.
SH	GlaxoSmithKline	2	4.3.1 a)	GlaxoSmithKline suggest that as well as deep vein thrombosis, the assessment of pulmonary embolism is also considered as this is also an important factor in venous thromboembolic disease.	Thank you for your comment. We have amended the scope section 4.3.1a to include diagnosis of venous thromboembolic diseases (DVT and PE). The specific questions reviewed will

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					be prioritised by the guideline development group.
SH	Gloucestershire Hospitals NHS Foundation Trust	1	366	The guideline states that for lower limb plaster casts prophylaxis should be considered after evaluating the risks and benefits and discussion with patient, but does not go on to identify the risks that should lead to the use of pharmacological prophylaxis.	Thank you for your comment. We apologise that we are not sure what this comment is referring to. We think that this comment may be intended for the previous NICE VTE guideline on prophylaxis as this scope is not covering prophylaxis.
SH	LEO Pharma	1	3.1 g)	The Risk Factors outlined in point g) differ to those outlined in the DH Risk assessment for Venous Thromboembolism (VTE) tool http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113355.pdf and NICE clinical guideline 92 and should be expanded. Consideration should also be given to other at risk groups such as IV drug users and alcohol dependants.	Thank you for your comment. However, we have decided not to add the additional risk factors. Section 3.1.g is intended to be an introduction to the guideline scope, not an inclusive list of all the risk factors.
SH	LEO Pharma	2	3.1 j)	It should be noted that a number of patient groups other than oncology may need special advice on how to manage VTE, including but not limited to, renal dysfunction, obesity, pregnancy.	Thank you for your comment. We have considered these groups but decided that we do not agree they require special advice on managing VTE. We have not prioritised pregnant women for the guideline as there is guidance from The Royal College of Obstetricians and gynaecologists.
SH	LEO Pharma	3	4.1.1 b)	It should be noted again that a number of patient groups other than oncology may need special advice on how to manage VTE, including but not limited to, renal dysfunction, obesity, pregnancy.	Thank you for your comment. We have considered these groups but decided that we do not agree they require special advice. We have not prioritised pregnant women for the guideline as there is guidance from The Royal

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					College of Obstetricians and gynaecologists.
SH	LEO Pharma	4	4.1.2 b)	The 2007 Confidential Enquiry into Maternal and Child Health (http://www.cmace.org.uk/getattachment/927cf18a-735a-47a0-9200-cdea103781c7/Saving-Mothers--Lives-2003-2005_full.aspx) highlighted the increasing number of maternal deaths in the UK directly attributed to thrombosis and thromboembolism, excluding pregnant women from this NICE guideline, removes the potentially for NICE to correct this imbalance. Furthermore, if the decision to exclude this at risk patient group persists, the opportunity to direct readers to the National RCOG guidelines (http://www.rcog.org.uk/womens-health/clinical-guidance/thromboembolic-disease-pregnancy-and-puerperium-acute-management-gre) should be considered.	Thank you for your comment. We agree that pregnant women are an important group and that pregnancy is a risk factor for VTE. We have not prioritised pregnant women in this guideline as they are covered in guidance from The Royal College of Obstetricians and Gynaecologists.
SH	LEO Pharma	5	4.3.2	Removal of upper limb DVT from the clinical issues addressed may remove the opportunity for expert opinion in the management of this less prevalent complication to be transferred to a wider audience within the NHS	Thank you for your comment. However, we have decided we are not able to include this population in the scope. There are fewer incidences of upper limb DVT and therefore they have not been prioritised for this guideline.
SH	LEO Pharma	6	4.4	The measurement of asymptomatic DVT should be removed from the main outcomes assessed as this outcome is rarely used as either a primary or secondary endpoint in clinical trials.	Thank you for your comment. The guideline covers the management of suspected and confirmed venous thromboembolism. We have decided that this is an important outcome and should be included when reported.
SH	LEO Pharma	7	4.4	The measurement of HIT should not be removed from the main outcomes assessed as this is a common treatment outcome requested by clinicians. Furthermore consideration should be given to the wider inclusion of thrombocytopaenias	Thank you for your comment. We agree and have included HIT as an outcome measure. The adverse events will be reported for all the pharmacological

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				as the adverse event is not restricted to LMWHs	interventions listed in section 4.3.1b.
SH	LEO Pharma	8	4.4	The measurement of length of hospital stay as an outcome should be balanced by the inclusion of frequency of hospital admissions to provide a clearer picture of secondary care inpatient costs.	Thank you for your comment. The outcomes considered will be prioritised by the guideline development group once the review questions have been set.
SH	Luton and Dunstable Hospital NHS Foundation Trust	1	3.1 g)	Meaning unclear at end of list and previous DVT important so suggest change to *'Risk factors for venous thrombosis include a history of DVT or VTE, age over 60 years, surgery, obesity, prolonged travel, acute medical illness (including cancer), immobility, thrombophilia, pregnancy and oestrogen supplements.'*	Thank you for your comment. We agree and have amended the order to make this clearer. However, we have decided not to add the additional risk factors listed. This section is intended to be an introduction to the guideline scope, not an inclusive list of all the risk factors.
SH	Luton and Dunstable Hospital NHS Foundation Trust	2	3.2	If the guidelines are to include diagnosis and immediate emergency management of DVT and VTE, consider adding Current Practice sections for these eg iv filters, thrombolysis.and thrombectomy. We have very little experience of these therefore we are not in a position to comment on Current Practice..	Thank you for your comment. Vena caval filters and thrombolytic therapy are included as key issues in the scope (section 4.3.1). Section 3.1.g is intended to be an introduction to the guideline scope and we are not able to cover all current practices.
SH	Luton and Dunstable Hospital NHS Foundation Trust	3	3.2 i)	Add '*There is also a need to establish whether patients should have thrombophilia testing after DVT or VTE, and if so how this would affect subsequent treatment'* to this section instead of including it in 3.2.l	Thank you for your comment. We agree and have combined thrombophilia into one paragraph in section 3.2.
SH	Luton and Dunstable Hospital NHS Foundation Trust	4	3.2 j)	Suggest '*Patients with active cancer need special management of VTE due to the increased risk of complications'.*	Thank you for your comment. After careful consideration we have decided that we do not agree that 'active' should be added to this sentence. The current terminology would be inclusive of active cancer patients.
SH	Luton and Dunstable Hospital	5	3.2	Remove '*There is also a need to establish whether patients*	Thank you for your comment. We agree

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	NHS Foundation Trust		l)	*should have thrombophilia testing after DVT or VTE, and if so how this would affect subsequent treatment'* from this section and add it to 3.2.i as above.	and have removed thrombophilia from section 3.2l and expanded section 3.2i.
SH	Luton and Dunstable Hospital NHS Foundation Trust	6	4.1.1 a)	Suggest *'…..with a suspected or confirmed DVT or VTE'*	Thank you for your comment. We agree and have added 'confirmed' to the text.
SH	Luton and Dunstable Hospital NHS Foundation Trust	7	4.3.1 b)	Under pharmacological add *' - oral anticoagulants such as warfarin and the new anticoagulants'*	Thank you for your comment. We are unable to include the newer unlicensed drugs within the clinical guideline. However, if a NICE technology appraisal has been published on these drugs during the development phase we will consider incorporating it into the guideline.
SH	Luton and Dunstable Hospital NHS Foundation Trust	8	4.3.1 c)	Thrombolytic therapy and thrombectomy are a big controversial subject which deserve lengthy analysis – is it wise to include them in this document?	Thank you for your comment. We agree that it is an important subject and have decided to include it as it requires guidance.
SH	Luton and Dunstable Hospital NHS Foundation Trust	9	5.1	Suggest rearrange the order of these bulleted points to put dabigatran NICE 2008 second and rivaroxaban NICE 2009 third…. Chronological order shows less bias?	Thank you for your comment. We do not agree that the order should be changed. They were listed in reverse chronological order to list the most recent guidance first.
SH	NHS Direct	1	4.3.1	NHS Direct welcome the guideline and have one point: 4.3.1 Key clinical issues that will be covered a) Diagnostic tests used for initial assessment of suspected deep vein thrombosis. diagnostic testing needs to be reported/discussed in terms of its relevance to the particular setting especially with regard to	Thank you for your comment. The scope will cover diagnostic tests for initial assessment of suspected venous thromboembolism. The specific questions reviewed will be prioritised by the guideline development group.

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				primary care, for example, guidance is needed on the specific use and value of 'd-dimer testing' in general practice.	
SH	NHS Sheffield	1	3.1 g)	Suggest adding COCP and HRT as specific risk factors	Thank you for your comment. However, we have decided not to add these risk factors. Section 3.1.g is intended to be an introduction to the guideline scope, not an inclusive list of all the risk factors.
SH	NHS Sheffield	2	General	ought to perhaps cover acute management-- do all pts need to be seen immediately or could empirical treatment be given e.g LMWH injection and planned Ix during in hours times	Thank you for your comment. We agree and we have clarified this by amending the scope to cover management of 'venous thromboembolic diseases' (that includes pulmonary embolism). The specific review questions included will be prioritised by the guideline development group.
SH	Pfizer	1	4.1.1	We would agree that patients with cancer are a group requiring special consideration, as cancer associated thrombosis is a frequent and costly complication in patients with cancer (see Lee et al. Journal of Clinical Oncology 2009;27). Dalteparin (Fragmin) is the only low molecular weight heparin to be specifically indicated for the extended treatment of symptomatic venous thromboembolism and prevention of its recurrence in patients with solid tumours. The CLOT trial shows that the cumulative risk of symptomatic, recurrent VTE during 6 months of anticoagulation was 17% for patients treated with a VKA (warfarin or acenocoumarol) compared with 9% for patients treated with dalteparin, which results in a statistically significant relative risk reduction of 52% (p=0.002) and an absolute risk reduction of 8% (Lee AY et al. N Engl J Med	Thank you for your comment. We have noted your comments. The GDG will consider the evidence on the pharmacological treatments listed in section 4.3.1b of the scope for treatment of patients with VTE. This will include patients with cancer.

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				349:146-153, 2003.)	
SH	Rarer Cancers Forum	1	General	We welcome the development of this guidance as VTE is a significant complication in management of cancer causing an estimated 20% of cases of VTE. Cancer and its treatment is a significant risk factor for VTE which may affect 4-20% of cancer patients whose risk for VTE is elevated 7-fold and up to 28-fold in some malignancies. Cancer patients particularly at risk include bowel, brain, kidney, lung, pancreas, stomach, ovary and womb as well as blood cancers like lymphoma and leukaemias eg acute myeloid leukaemia(AML). Recent research has also shown prostate cancer patients have increased risk. Pancreatic cancer patients are particularly at risk as documented in many studies. A study from Warwick Hospital showed that whilst most cases will be in the common cancers the risk varies widely with cancer type with pancreatic cancer having the highest odds ratio and tumours of the head and neck having higher odds than previously reported. Studies show incidence is highest in patients presenting with metastatic disease, particularly those with high 1-year mortality such as pancreatic cancer with 17-57% incidence. From personal experience we know of many pancreatic cancer patients who have presented with VTE at time of diagnosis or soon after and the distress this can cause especially if misdiagnosed as muscle strain and if untreatable due to coexistant bleeding from ulcers or due to the tumour. VTE can also be a first symptom of cancer allowing diagnosis through further investigation and is the 2nd leading cause of death in cancer patients. Treatment or prophylaxis for VTE	Thank you for your comments. However, we are not able to include prophylaxis for cancer patients in this guideline. Prophylaxis of VTE has been covered in the previous NICE clinical guideline on VTE and has not been prioritised for this guideline. The scope does include bleeding as an important outcome (4.4.i and j) to be considered. Therefore, when there is evidence available it will be included in the review.

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				may also help fight cancer in ways other than just treating the VTE. Certain treatments also increase the risk including: • surgery • chemotherapy • central venous catheter • hormonal therapy • steroids • other treatments such as thalidomide **However most patients, and possibly many clinicians, are unaware of the increased risk of VTE unless patients are hospitalised eg for surgery and investigations. Therefore this guidance will not only ensure best practice in treatment of VTE but can also help to raise awareness of the increased risk in cancer patients.** The conclusion of a meeting in 2009 reported in April 2010 B.J.C supplement states that "Despite the problem posed by VTE in the setting of cancer, it is evident that a significant number of oncologists do not recognise the link between cancer, its treatment and thrombogenesis." . The awareness needs to be raised with medical professionals, patients and the public. **We also hope that the guidance can be extended to consider prophylaxis based on existing evidence and new trials just reporting.** **We feel that the guidelines should also deal with the complication in cancer where patients may have both DVT and bleeding due to nature of tumours or ulcers due**	

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				to unprotected use of painkillers	
SH	Rarer Cancers Forum	2	3.1 g)	We welcome recognition of cancer as a significant risk factor	Thank you for your comment. We are pleased that you agree with this statement in the scope.
SH	Rarer Cancers Forum	3	3.2 h)	Cancer patients are more usually treated with LMWH as in the recent ASCO guidelines. Lyman Gary .H., Alok A. Khorana, Anna Falanga, Daniel Clarke-Pearson, Christopher Flowers, Mohammad Jahanzeb, Ajay Kakkar, Nicole M. Kuderer, Mark N. Levine, Howard Liebman, David Mendelson, Gary Raskob, Mark R. Somerfield, Paul Thodiyil, David Trent, Charles W. Francis (2007) American Society of Clinical Oncology Guideline: Recommendations for Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer, Journal of Clinical Oncology, Vol 25, No 34 (December 1), 2007: pp. 5490-5505	Thank you for your comment. This section is intended to be an introduction to the scope and cannot include current practice for all patient groups.
SH	Rarer Cancers Forum	4	3.2 j)	We welcome recognition for special advice on management in cancer patients and would like this to include guidance on prophylaxis in ambulatory cancer patients undergoing treatment	Thank you for your comment. We have decided that we are unable to include prophylaxis in this guideline. There is a previous NICE guideline on prophylaxis and this guideline has prioritised

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					diagnosis and management.
SH	Rarer Cancers Forum	5	3.2 k)	You should also be aware of the recent ASCO guidelines and the NICE CG 92	Thank you for your comment and pointing out these two relevant guidelines. We have included the previous NICE guideline (CG92) in section 3.2k of this scope.
SH	Rarer Cancers Forum	6	4.1.1 b)	We welcome the fact that patients with cancer have been identified as a group requiring special consideration	Thank you for your comment. We are pleased that you agree with this statement in the scope.
SH	Rarer Cancers Forum	7	4.1.2 b)	What if they have cancer and are pregnant? Some cancers first appear or are diagnosed in pregnancy	Thank you for your comment. We are not able to include this specific group as pregnant women have not been prioritised in this scope. We have not included pregnant women as there is recent guidance from The Royal College of Obstetricians and Gynaecologists on VTE in pregnant women. Pregnant women with cancer are a small group that should be managed by clinical judgement.
SH	Rarer Cancers Forum	8	4.3.1 a)	We welcome this and especial consideration should be given to fact that existing DVT may not appear on eg first Doppler ultrasound and repeat testing may be required	Thank you for your comment. The guideline will include the diagnosis of venous thromboembolic diseases. The guideline development group will prioritise the review questions considered.
SH	Rarer Cancers Forum	9	4.3.1	We support this	Thank you for your comment. We are

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			b)		pleased that Rarer Cancers Forum agrees with this statement.
SH	Rarer Cancers Forum	10	4.3.1 d)	This will be especially important for cancer patients with ongoing risk	Thank you for your comment. We agree and have specified that patients with cancer are a group requiring special consideration.
SH	Rarer Cancers Forum	11	4.3.1 e)	This would be very welcome and is very important. Anything that can ensure earlier diagnosis of cancer is vital, particularly in pancreatic cancer	Thank you for your comment. We are pleased that The Rarers Cancers Forum agrees with this statement.
SH	Rarer Cancers Forum	12	4.3.1 h)	Clear information is always welcome and as stated above will help to raise awareness of the risk in cancer patients. In the case of injections carers may be required to administer the treatment and need support and training as well as patients. Also information can help patient's decision making. Healthcare professionals need a one-page simple information sheet such as the risk assessment document that the CMO's expert group produced and more info for patients pre any (cancer) treatment – surgery, chemo, radiotherapy Need also to get the message out to the public – not just patients	Thank you for your comment. We are pleased that Rarer Cancers Forum agrees that information and support should be included as a key issue.
SH	Rarer Cancers Forum	13	4.3.2 a)	We feel strongly that prophylaxis against VTE in cancer patients should be included. It is recommended in certain situations in the ASCO guidelines and current trials in pancreatic cancer eg FRAGEM in UK and CONKO-004 in Europe have produced new evidence that should be considered. The FRAGMATIC trial in lung cancer is ongoing	Thank you for your comment. However, we are not able to include prophylaxis for cancer patients in this guideline. Prophylaxis of VTE has been covered in the previous NICE clinical guidelines and has not been prioritised for this

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				but may provide some extra information. A. Maraveyas, J. Waters, R. Roy, D. Propper, D. Fyfe, F. Lofts, E. Gardiner, J. Sgouros, K. Wedgwood (2009) Gemcitabine with or without prophylactic weight-adjusted dalteparin in patients with advanced or metastatic pancreatic cancer (APC): a multicentre, randomised phase IIB trial (the UK FRAGEM study) European Journal of Cancer Supplements, Vol 7 No 2, September 2009, Page 362 H. Riess, U. Pelzer, G. Deutschinoff, B. Opitz, M. Stauch, P. Reitzig, S. Hahnfeld, A. Hilbig, J. Stieler, H. Oettle; (2009) A prospective, randomized trial of chemotherapy with or without the low molecular weight heparin (LMWH) enoxaparin in patients (pts) with advanced pancreatic cancer (APC): Results of the CONKO 004 trial. J Clin Oncol 27:18s, 2009 (suppl; abstr LBA4506) Also as cancer patients these days may take flights for holidays during treatment or treatment breaks consideration should be given towards prophylaxis for the additional risk of cancer plus flight.	guideline.
SH	Rarer Cancers Forum	14	4.3.2 b)	We do not understand why this is excluded although in personal experience cancer related VTE is usually in calf or lung	Thank you for your comment. However, we have decided we are not able to include this population in the scope. There are fewer incidences of upper limb DVT and therefore they have not been prioritised for this guideline.
SH	Rarer Cancers Forum	15	4.4	Quality of life is important – my husband who developed DVT in pancreatic cancer 20 months after diagnosis with	Thank you for your comment. We agree that quality of life is important and have

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			k)	inoperable cancer was advised against treatment. However he was still fit and his escape from cancer was long walks which were prevented due to the associated calf pain (he did then start FRAGMIN injections after starting thalidomide analogue treatment)	included it as a main outcome in the scope.
SH	Rarer Cancers Forum	16	General	Where no comments are made against items in the scope we support the proposals or do not have enough background knowledge to comment.	Thank you for your comment.
SH	Rarer Cancers Forum	17	General	Whilst the issue of VTE is important in all cancers this guidance is particularly important for pancreatic cancer due to such poor survival rates so that anything that may improve quality of life, diagnosis or survival is vital. Pancreatic cancer, although a rare cancer, comes out on top or near the top of risk factors (with all the other prevalent cancers included) in a variety of studies. High levels of tissue Factor (the initiator of the blood coagulation cascade) expression has been reported in pancreatic cancer patients as well as patients with other tumour types – brain, ovarian etc and this may be one reason for the prothrombotic state in patients with pancreatic cancer.	Thank you for submitting this information. We are pleased that the Rarer Cancers Forum agrees with the proposed scope that cancer patients should be given special consideration. Management of VTE in cancer patients will be considered but not by specific types of cancer.
SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline.	Thank you for your comment.
SH	Royal College of Nursing	2	3.1 a)	DVT mentioned as commonly in the leg but may also occur in the arm and pelvis	Thank you for your comment. We agree and have amended the section 3.1a to include pelvis. However, we have not prioritised DVT in the arm as there is a lower incidence of this.

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SH	Royal College of Nursing	3	3.1 c)	- Which may lead to a PE which can be fatal – there is no mention of non-fatal PE which can have devastating consequences – pulmonary hypertension	Thank you for your comment. Section 3.1.c is intended to be an introduction to the scope and we are not able to cover all outcomes. We are including non-fatal pulmonary embolism in the guideline.
SH	Royal College of Nursing	4	3.1 g)	Read as if history of pregnancy is a risk, which is NOT – the actual pregnancy is	Thank you for your comment. We agree and have amended the order of risk factors to make this clearer.
SH	Royal College of Nursing	5	3.2 l)	New oral anticoagulants only have a licence for thromboprophylaxis and as the trials with these drugs in treatment of VTE are not even finished yet, it does not seem appropriate to include these here (perhaps mention that there are new drugs on the horizon which may need to be considered in the future)	Thank you for pointing this out. We agree and have removed reference to these unlicensed drugs from this section.
SH	Royal College of Nursing	6	3.2 i and l	Thrombophilia mentioned in both sections – perhaps only in i?	Thank you for your comment. We agree and have combined these two sections.
SH	Royal College of Nursing	7	4.1.2 b)	It is not clear why pregnant women are excluded - midwives do assess VT at every encounter and have an assessment form for antenatal and then again for post natal. VT is assessed before transfer to post natal area, (or before leaving the women after a home birth).	Thank you for your comment. We agree that pregnant women are an important group. However, they have not been prioritised in this guideline. The Royal College of Obstetricians and Gynaecologists has recently published guidance on VTE in pregnant women which covers this group.
SH	Royal College of Nursing	8	General	A clear definition of bleeding should be given – Institute of Thrombosis and Haemostasis (ISTH) looked at this issue in Boston last year (2009)	Thank you for your comment. The guideline development group will define the outcomes included in the guideline.
SH	Royal College of Nursing	9	General	What about a reference at some point to the NPSA Alert 18 which looks at warfarin therapy and patient safety?	Thank you for your comment. We agree and will consider adverse outcomes of pharmacological treatment and may

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					refer to other guidance if appropriate.
SH	Royal College of Paediatrics and Child Health	1	4.1.2 a)	The College thinks it would be very helpful to include children and young people as a separate population in this guideline. We note there are some significant differences in approach, including dosages.	Thank you for your comment. We agree that VTE in children is an important topic but we are not able to cover it in this guideline. VTE is less common in children and we have prioritised the management of VTE in adults. You may want to consider suggesting a new topic to NICE for guideline development on management of VTE in children. There is a page on the NICE website to do this electronically.
SH	Royal College of Pathologists	1	1	We welcome a guideline on the topic of management of venous thromboembolic diseases	Thank you for your comment.
SH	Royal College of Pathologists	2	1	Guideline title – the presence of thrombophilia testing in the title suggests it will have a central role in the guideline scope yet it has little role in the management of most cases of venous thromboembolism	Thank you for your comment. We do not agree that thrombophilia testing should be removed from the scope. This topic was specifically included in the remit of the guideline from the Department of Health as it was considered an important issue that requires guidance.
SH	Royal College of Pathologists	3	3.1 a)	The description used for VTE implies that a thrombus that does not embolise would not be classified as an example of a venous thromboembolic disease, yet this is clearly not what is meant (3.1.c).	Thank you for your comment. This is technically correct. However, venous thromboembolic (VTE) disease is widely used and accepted. We have amended the introduction to clarify this.
SH	Royal College of Pathologists	4	3.1 c)	The term can also include thrombosis in other anatomical sites eg cerebral or splanchnic vein thrombosis. There would be a case for including these in the guideline.	Thank you for your comment. We do not agree. These sites of thrombosis are less common and have not been prioritised to be included in the guideline.

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SH	Royal College of Pathologists	5	4.1.1 a)	There would be a case for including children – less likely to develop VTE but important when they do.	Thank you for your comment. We agree that VTE in children is an important topic but we are not able to cover it in this guideline. VTE is less common in children and we have prioritised the management of VTE in adults. You may want to consider suggesting a new topic to NICE for guideline development on management of VTE in children. There is a page on the NICE website to do this electronically.
SH	Royal College of Pathologists	6	4.1.2	Why are pregnant women excluded from the scope? They were not excluded from the NICE guideline on VTE prevention (CG 92, 2010).	Thank you for your comment. Pregnant women have not been prioritised in this scope as there is recent guidance from The Royal College of Obstetricians and Gynaecologists on VTE in pregnant women.
SH	Royal College of Pathologists	7	4.3.1 c)	This should include both catheter-directed thrombolysis and pharmaco-mechanical thrombolysis.	Thank you for your comment. We agree and have amended section 4.3.1.c to cover 'thombolytic therapy including pharmaco-mechanical thrombolysis'.
SH	Royal College of Pathologists	8	4.3.2	Upper limb DVT comprises about 5% of cases – why should they be excluded?	Thank you for your comment. We have excluded this population from the scope as they comprise fewer incidences and have therefore not been prioritised.
SH	Royal College of Physicians	1	General	The Royal College of Physicians is grateful for the opportunity to respond to this draft scope consultation. We would like to make the following comments.	Thank you for your comment. We will respond to each comment separately.
SH	Royal College of Physicians	2	2 and	This scope addresses many key issues with regard to the important issues of diagnosis and management of VTE.	Thank you for your comment. We do not agree that thrombophilia testing should be removed from the scope. This topic

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			4.3.1 g)	Thrombophilia testing has a minor role in the management of VTE and there is the danger that including this in the guideline could divert resources from addressing more important questions. Consideration should therefore be given to removing this topic.	was specifically included in the remit of the guideline from the Department of Health as it was considered an important issue that requires guidance.
SH	Royal College of Physicians	3	4.3.1 a)	Diagnosis is an important and controversial area. We believe this section should include: i) whether to diagnose calf vein thrombosis ie the merits of two point compression ultrasound versus whole leg ultrasound ii) whether scans should be repeated after 3 to six months in order to aid the diagnosis of recurrences at a later date.	Thank you for your comment. We are pleased you agree diagnosis should be included. The guideline development group will prioritise the specific review questions that should be included in the guideline.
SH	Royal College of Physicians	4	4.4 d and f	Surely asymptomatic events cannot be an outcome in a guideline on the management of symptomatic VTE	Thank you for your comment. The guideline covers the management of suspected and confirmed venous thromboembolism. We have decided that this is an important outcome and should be included when reported.
SH	Royal College of Physicians	5	4.4 N	Spelling of thrombocytopenia	Thank you for your comment. We have amended the spelling accordingly.
SH	Salford Royal Foundation Trust	1	4.3.1 a)	The guideline should include how to diagnose pulmonary embolism, not just deep vein thrombosis.	Thank you for your comment. We have amended the scope section 4.3.1a to include diagnosis of venous thromboembolic diseases (DVT and PE). The specific questions reviewed will be prioritised by the guideline development group.
SH	SOCIETY OF BRITISH	1	Gener	Agreed. I attended the Scoping Workshop and the document	Thank you for your comment.

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	NEUROLOGICAL SURGEONS (SBNS)		al	reflects the consensus reached.	
SH	UKCPA	1	General	It would be useful to include some guidance as to the use of treatment in patients with renal failure. There is limited information available from companies of some of the LMWH for dose adjustments. It may be better to advise caution and consider alternative treatments such as unfractionated heparins or to use a product where data on dose adjustments is available. Should patients requiring haemofiltration be mentioned with this?	Thank you for your comment. The guideline development group will prioritise the specific review questions that will be included in the guideline, and will decide if patients with renal failure and those having haemofiltration require separate consideration.
SH	UKCPA	2	4.1.1 a)	Should there be a clarification as to why 'adult' is defined as >18years. Patients who are 15 years or older are usually admitted to non paediatric wards	Thank you for your comment. We have opted for this age cut-off for adults as this was the age selected by the previous NICE guidelines on VTE. Please note that we have defined adults as 18 years and older.
SH	UKCPA	3	4.4	Could include new incidences of cancer as an outcome measure following diagnosis of VTE	Thank you for your comment. The outcomes considered will be prioritised by the guideline development group once the review questions have been set.
SH	Vascular Society of GB and Ireland	1	4.1.2	we think pregnant women should be included	Thank you for your comment. We agree that pregnant women are an important group. However, they have not been prioritised in this guideline. The Royal College of Obstetricians and Gynaecologists has recently published guidance on VTE in pregnant women which covers this group.

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SH	Vascular Society of GB and Ireland	2	General	we think the radiologist position on the GDP should be a member of the British Society of Interventional Radiology	Thank you for your comment. The advert for GDG members is posted on the NICE website. All healthcare applicants will be considered in an open recruitment process. Successful applicants will meet the required person specifications stated in the advert.
SH	Vascular Society of GB and Ireland	3	General	we think there should be a nurse representative on the GDP	Thank you for your comment. We agree and have advertised for an anticoagulation or thrombosis nurse to join the guideline development group.
SH	York Hospitals NHS Foundation Trust	1	4.1.2 and 4.3.1 a)	Groups that will not be covered – pregnancy – is this because it is covered elsewhere by the Royal College of Obstetricians and Gynaecologists? Would prefer to see pregnancy included under diagnostic tests since pregnant women present in A&E and admission units and required diagnosis by a team which does not specialise in pregnant women.	Thank you for your comment. We have not prioritised pregnant women for this guideline as they are covered by guidance from The Royal College of Obstetricians and Gynaecologists. This guidance also covers diagnostic tests for pregnant women presenting with VTE.
SH	York Hospitals NHS Foundation Trust	2	4.3.1 b)	Need to consider the practical aspects of management especially administration of LMWH in the community (costs incurred in terms of safety of waste disposal, healthcare resources for patients unable to self administer injections etc Recommendations should consider safety of treatment – the VTE prophylaxis guidance recommends use of unfractionated heparin in patients with renal failure. The safety of administration and monitoring unfractionated heparin in organisations when LMWH is the norm now must be considered within the recommendations	Thank you for your comments. The scope includes pharmacological treatment (4.3.1.b) and self-monitoring by patients on pharmacological treatments (4.3.1.f) in the scope. The specific questions for these topics will be considered and prioritised by the guideline development group.
SH	York Hospitals NHS Foundation Trust	3	4.4 i and j	Would like to know what will be covered with respect to bleeding and whether clear guidance will be provided for reversal of treatment and management in patients bleeding	Thank you for your comment. Bleeding has been identified as an outcome included in the guideline (section 4.4)

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				on treatment doses of LMWH.	and this information will be reviewed when reported. We are not able to include guidance on management of patients bleeding on treatment as this is outside the scope of this guideline.