Venous thromboembolism - reducing the risk (full update)

Consultation on draft scope
Stakeholder comments table

11 December 2015 – 20 January 2016

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Anticoagulation Europe	1.1	1	We agree that all patients should be made aware of porcine origin for LMWH prophylaxis option, this needs to be incorporated in any information leaflet and recorded as discussion point on checklist risk assessment form	Thank you for your comment. We agree that patient communication is important and this was covered by a recommendation in the last version of the guideline. Including this in the patient information leaflet will be considered by NICE.
Anticoagulation Europe	1.2	1	We acknowledge that this specific group may be at less risk of developing VTE, however, good practice would be for family, carer or guardian at pre- assessment opportunity to be asked to disclose knowledge of any family history of clotting when a child or under 16 year old requires inpatient care.	Thank you for your comment. It is an important point but this update will only cover adults and young people (16 years and over).
Anticoagulation Europe	2	36	Clarity on what is construed as period of 'long term' care	Thank you for your comment. We have removed this bullet point from the scope to place greater emphasis on the on-going review/assessment of the patient rather than on the period of care. The scope covers all 'adults and young people (16 years and older) admitted to hospital as inpatients' regardless of length of stay.
Anticoagulation Europe	2	37	Clarification on what would be determined as a major traumatic event? Medical, surgical or both?	Thank you for your comment. We have removed this bullet point from the scope. The scope will include all 'adults and young people admitted to hospital as inpatients'. All traumatic events will be considered whether they are medical or/surgical.

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Anticoagulation Europe	2	41	Essential Lack of awareness by patients of risk of VTE when undertaking chemotherapy treatment per se. All Party Parliamentary Thrombosis Group (www.apptg.org.uk) published Venous Thromboembolism (VTE)in cancer patients. *Cancer, Chemo and Clots* report in Oct 15 on Cancer and VTE risk highlighting mandatory risk assessment and prophylaxis are not in place.	Thank you for your comment and information. We are pleased that you agree this population should be included in the scope.
Anticoagulation Europe	2	43	Currently an unmet need, needs to extend to carers, family or persons involved in the care of the vulnerable person. Will this extend/include to the prison population?	Thank you for your comment. During development consideration will be given to recommendations relating to vulnerable adults and recommendations that may require carers or family involvement in these. The NICE guideline under development on Physical health of people in prison (expected publication date November 2016) will consider the health care needs of prisoners.
Anticoagulation	3	82/83/84/85	Information must highlight the importance of continuance of	Thank you for your comment. This will

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Europe			treatment for the duration period to reduce risk of VTE (Doacs vary according to individual treatment recommendations eg hip and knee replacements (ortho)	be considered when writing recommendations and supporting text for each population.
Anticoagulation Europe	3	57	Community care – does this cover care residential and nursing homes?	Thank you for your comment. Yes this covers both residential and nursing homes
Anticoagulation Europe	6	154	Should specific reference be made to dental/maxio facial treatment/surgery in secondary setting be included or are these covered by BDA guidelines?	Thank you for your comment. The guideline covers all hospital patients. This group will be considered in this update.
Anticoagulation Europe	8	205	This must include ongoing responsibility for prescribing once patient has been discharged.	Thank you for your comment. This will be considered during the development of the guideline.
Anticoagulation Europe	89	89	Agree need, shortfalls in consistency of reassessment process once patient admitted.	Thank you for your comment.
Anticoagulation Europe	general	51/2	Agree need	Thank you for your comment.
Anticoagulation Europe	General	48	Agree need	Thank you for your comment.
Anticoagulation	General	49	Agree need	Thank you for your comment.

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Europe				
Bayer	3	79	The correct spelling is rivaroxaban.	Thank you for your comment. We have corrected this spelling mistake.
Bayer	3 & 7	77 & 190	We understand that the guideline should not revisit areas already evaluated under the technology appraisal process. Technology appraisals (TAs) have been published assessing the clinical and cost effectiveness of rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults (2009) NICE TA 170, dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults (2008) NICE TA 157, and apixaban for the prevention of venous thromboembolism after total hip or knee replacement in adults (2012) NICE TA 245. TAs 157, 170 and 245 were assessed as being up to date and were transferred to the static list in August 2011, May 2012 and March 2015 respectively. The recommendations from these technology appraisals should therefore be incorporated verbatim in this clinical guideline. This should be explicitly stated in section 2. Failure to make	Thank you for your comment. We are aware that there is likely to be an HTA report published during the development phase of the guideline that considers the use of NOACs in this context. Once this report is in the public domain we will assess the situation with colleagues in the TA team and if necessary consult further with stakeholders through the TA process.

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			this explicit in the scope may cause confusion amongst commissioners.	
Bayer	general	general	Information from the phase IV non-interventional study 'XAMOS' has been published since the last iteration of this guideline. "XAMOS (Xarelto(®) in the prophylaxis of post-surgical venous thromboembolism after elective major orthopedic surgery of hip or knee) was an international, noninterventional, parallel-group study to gain insight into the safety (major bleeding, side effects) and effectiveness (prevention of symptomatic thromboembolic events) of rivaroxaban in daily clinical practice."[1] This study also included 790 patients undergoing fracture related orthopedic surgery.[2] "A total of 17,701 patients were enrolled from 252 centres in 37 countries. Crude incidences of symptomatic thromboembolic events three months after surgery in the safety population were 0.89% in the rivaroxaban group (n=8,778) and 1.35% in the standard-of-care group	Thank you for your comment and informing us about this study. Searches are carried out at the start of the development process and then an update search is competed close to the draft guideline consultation. If published within our timelines we will assess this study to see if it matches any of our review questions and their inclusion/exclusion criteria set by the guideline committee.

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			(n=8,635; odds ratio [OR] 0.65; 95% confidence interval [CI] 0.49-0.87), and 0.91% and 1.31% (weighted) in the propensity score-adjusted analysis (OR 0.69; 95% CI 0.56-0.85), respectively. Treatment-emergent major bleeding events (as defined in the RECORD studies) occurred in 0.40% and 0.34% of patients in the rivaroxaban and standard-of-care groups in the safety population (OR 1.19; 95% CI 0.73-1.95), and in 0.44% versus 0.33% (weighted) in the propensity score-adjusted analysis (OR 1.35; 95% CI 0.94-1.93), respectively."[3] 1. Turpie AG *et al.* Rationale and design of XAMOS: noninterventional study of rivaroxaban for prophylaxis of venous thromboembolism after major hip and knee surgery. Vasc Health Risk Manag. 2012;8:363-70. doi: 10.2147/VHRM.S30064. Epub 2012 Jun 1. 2. Lassen MR et al. Rivaroxaban for Thromboprophylaxis After Fracture-Related Orthopedic Surgery in Routine Clinical Practice. Clin Appl Thromb Hemost. 2015 Sep 25. pii: 1076029615607303. [Epub ahead of print]	

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			3. Turpie AG *et al.* A non-interventional comparison of rivaroxaban with standard of care for thromboprophylaxis after major orthopaedic surgery in 17,701 patients with propensity score adjustment. Thromb Haemost. 2014 Jan;111(1):94-102. doi: 10.1160/TH13-08-0666. Epub 2013 Oct 24.	
Bayer	general	general	There is an ongoing trial to evaluate the efficacy and safety of rivaroxaban compared with placebo in the prevention of symptomatic venous thromboembolism (VTE) events and VTE-related death post-hospital discharge in high-risk, medically ill patients (MARINER). https://www.clinicaltrials.gov/ct2/show/study/NCT02111564. This trial is due to complete in January 2017.	Thank you for your comment and informing us about this study. Searches are carried out at the start of the development process and then an update search is competed close to the draft guideline consultation. If published within our timelines we will assess this study to see if it matches any of our review questions and their inclusion criteria set by the guideline committee.
British Geriatrics Society	5	128 - 132	risk of bleeding *when given chemical prophylaxis,* (assumed but not stated) as opposed to their natural baseline risk of bleeding	Thank you for your comment. Any risk of bleeding including that from 'chemical prophylaxis' will be covered

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				here.
British Geriatrics Society	6	172	This is ambiguous – "chronic medical admission" does not exist. This might mean those with longterm immobility – which is a specific group to be considered.	Thank you for your comment. We agree and have reworded this sentence to 'people attending hospital as medical admissions'.
British Geriatrics Society	7	177	This is similar to line 172 – almost no-one is now in hospital for longterm care. Page 8 Line 205 already raises the issue of deciding how long to give prophylaxis, which needs to be determined for all different clinical settings, including those where mobility is not recovered.	Thank you for your comment. We agree and have removed this bullet point from the scope.
British Geriatrics Society	8	217	Consider information or consent procedure which should be used for those patients lacking mental capacity to consent themselves. Is there a need for this explicitly perhaps when risks and benefits are closely balanced?	Thank you for your comment. A general recommendation relating to people who cannot make decision themselves is covered in NICE clinical guideline CG138 on patient experience. We will cross refer to this in the updated guideline documents. We will also discuss these concerns when making recommendations during the development of the guideline.
British	8	234	quality of life issues: I think we should consider the	Thank you for your comment. The list

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Geriatrics Society			evidence around patient discomfort from numerous bruises from injection sites, even where major bleeding does not occur. This is a QOL burden which needs to be evaluated. There are situations where injection site bruising is more likely.	of main outcomes is not an exhaustive list but the main outcomes that are expected to be used within the guideline. However the guideline committee will consider and prioritise outcomes for each review question which could include additional outcomes that are specific to each question.
British Orthopaedic Association	1	13-15	The guideline is for people using services, families and carers as well as healthcare professionals and commissioners, it requires being straightforward and not statistically correct but confusing. Unfortunately your guidelines are also used in law courts (despite previous NICE attempts to mitigate this) and coronial hearings where the level of understanding of risk and benefit has lead to some unfortunate cases where families have been mislead and legal cases started on a misunderstanding of your guidelines due to the presentation of risk. We would respectfully suggest that the guidelines clearly	Thank you for your comment. NICE guidelines now usually report absolute risks alongside relative risks. The intention is to do the same for this update.

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			set out at the beginning the absolute risks of the condition (VTE event) , the absolute (as opposed to relative) benefits of prophylaxis and the risks associated with prophylaxis. In your previous guidelines relative risk of benefit was often mentioned against absolute risk of harm. Individual patients require clear and explicit guidance for them as an individual. We deal with individuals both in the assessment of risk (clearly outlined in your previous document but due for updating) and the explanation of benefit and possible harm. We are supporting lines 83-4 later in your document.	
British Orthopaedic Association	10	280	These alarming figures should be broken down into those following or during a hospital admission (and subdivided by broad specialty grouping) to identify patient groups at risk. To highlight the effect of spontaneous VTE episode in the community to encourage compliance with therapy VTE events causing admission and death without preceding admission should be highlighted...	Thank you for your comment. We have restructured and edited this section to emphasise the numbers relating to hospital acquired VTE and not all VTE. The section is only intended to be brief so we have not presented figures by speciality.
British	10	289	We are keen to support proper risk assessment which	Thank you for your comment.

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Orthopaedic Association			reaches a rational conclusion for our patients.	
British Orthopaedic Association	2	31	We would suggest that a separate section is considered for those at high personal risk of VTE event because of previous VTE event or family history. This group of patients are of concern because the benefits of prophylaxis are at best unproven with one paper showing an incidence of DVT/PE of 8% despite prophylaxis. They are a significant number of patients. However these patients also carry personal concern because of previous experiences therefore for all the situations outlined later in this section where there may be little evidence of benefit in general for the community for this vulnerable group specific mention should be made.	Thank you for your comment. We agree that they are an important group. This will covered by risk assessment and will be considered when looking at evidence for individual populations.
British Orthopaedic Association	3	70	We trust that the true absolute risk of VTE is included; there are many population based orthopaedic registry studies looking at large numbers of index cases with absolute mortality rates and therefore the use of an estimated mortality is no longer acceptable. Furthermore recent	Thank you for your comment. We will consider the most accurate source of absolute risk of VTE when developing the guideline.

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			studies (including 1-3) below suggest that PE is not under-diagnosed as previously suggested.	
British Orthopaedic Association	3	82	We welcome the reassessment of prophylaxis length and hope that the complication risk is computed as well as the cost for the various pharmacological modalities for the whole period of active treatment.	Thank you for your comment. We are pleased that you welcome the inclusion of this area. Relevant costs will be presented to the committee when discussing this area.
British Orthopaedic Association	4	90	We trust that all the newly available drugs will be included not just those mentioned.	Thank you for your comment. Your comment refers to the section on 'areas not in the published guideline that will be included in the update'. Only apixaban is noted here as the other newly available drugs were included in the published guideline. Section 1.5 on key issues and questions, includes a list of prophylaxis methods to be considered if applicable, which includes apixaban, dabigatran and rivaroxaban (p7 line 190-197).

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British Orthopaedic Association	4	92	This is particularly relevant in our practice with large numbers of patients on anti-platelets and a variety of anticoagulants. We are encouraged by its inclusion. Clearly the risk of thrombotic event varies with the reason for anticoagulation however in the majority of patients this involves the prophylaxis of stroke during atrial fibrillation. Again the relative risks are often quoted but the absolute risks of discontinuing therapy are the important figure. Again there have been coronial enquiries where stopping a modern antithrombotic two days early has been blamed for a CVA, this is statistically untenable and unsettling for the relatives and patients. A unified protocol to discontinue prophylaxis requires a common programme and plan, as more therapeutic agents become available and the half life and biological response varies between drugs plans become more difficult to implement, an unnecessary complication when the absolute risk of short term discontinuation is so small.	Thank you for your comment. Bridging prophylaxis will be considered during development.

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			Coping with the complexity of reason for prophylaxis is, as you will find, dizzying enough. Recently it has been suggested that warfarin discontinuation (and other prophylactic drugs) creates a pro- thrombotic period and aspirin is suggested to cover this guidance on this would be welcome.	
British Orthopaedic Association	4	96	It is disappointing given the rapid and dramatic reduction in length of stay that this is not included in the review perhaps mention could be made though evidence is light.	Thank you for your comment. We agree that early mobilisation and leg exercises are an important area. Although it will not be updated, the section from the previous guideline will remain in the guideline and referred to as appropriate.
British Orthopaedic Association	4	109	Your economic plan should be based on the actual episodes not those which are asymptomatic and therefore cost nothing because they are not detected. If no cost is associated with the condition then no benefit can be obtained.	Thank you for your comment. Although asymptomatic episodes do not accrue treatment cost, the long-term consequences of these episodes (such as post-thrombotic syndrome) should

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			Absolute rates of VTE and complication should be used from the large registry based studies, the death rates quoted in the discussions of many papers are much higher than the actual death rates.	be included when developing economic models that assess long time horizon.
British Orthopaedic Association	5	120	We are disappointed that recent reports of the over-diagnosis (and therefore treatment of) subsegmental PE by CTPA is not being addressed. At over 60% over-diagnosis and the fact that the treatment of asymptomatic sub-segmental PE is of no proven benefit (ref 4)	Thank you for your comment. The aim of this guideline is to prevent VTE rather than diagnose and treat which is covered by CG144.
British Orthopaedic Association	7	185	Perhaps all devices should be examined, portable and static compression devices.	Thank you for your comment. We agree and these will be included under 'intermittent pneumatic compression devices'.
British Orthopaedic Association	7	190	We draw your attention to a previous meta-analysis carried out in the USA (refs 5 and 6) and also to the recent change in Guidance by the ACCP and the American Ass Orth Surgery which we mentioned in our previous communications. We have questioned the applicability of the evidence base	Thank you for your comment. We will look at this evidence when we start development.

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			from highly select randomised multicentre trials for individual drugs against one another which have better monitoring and a lower average age than that currently treated by arthroplasty in the UK.	
British Orthopaedic Association	8	228	It is disappointing to see a surrogate outcome (Asymptomatic DVT) included in your list of definite endpoints of considerable concern to us all. As with sub segmental PE this is a finding in studies used to achieve statistical significance, we are not aware of studies showing a significant change in the other outcomes we are trying to prevent, this should of course be clear in the patient guidance in the interests of informed consent.	Thank you for your comment. Asymptomatic DVT is an important outcome when considering prevention of VTE. People develop pulmonary emboli without any signs of DVT and therefore it is important to consider this as an outcome.
British Society of Interventional Radiology	General		IVC filters are mentioned as one of the potential prophylactic options. We believe it should be recognised in the final document that regardless of the indication, IVC filters should be inserted by somebody who is appropriately trained (often an Interventional Radiologist but in some cases other individuals eg. Intensivists for certain types of filter).	Thank you for your comment. If the committee decide to recommend the use of IVC filters then all these points will be considered.

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			It should also be recognised that availability around the country of such trained individuals is variable particularly out of hours and the final guidance should reflect this. A third point to consider that in the prophylaxis population, one would need to consider that many such filters may need to be retrieved. This has additional cost/resource implications. In addition, clarification with regards to the decision making process that would inform filter retrieval would be helpful.	
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Healthcare	**general**	general	The existing guideline appropriately lists combined hormonal 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 (eg 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	Thank you for your comment. We will consider this when considering recommendations in this area.

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			progestogen-only contraceptive methods.	
CLOT	1	Title, 33,39,41,43	The title states over 16 but in the document it refers to age 16 and over, which age group is being considered? If 16 and over this will be a big change in the volume of work	Thank you for your comment. We have corrected this to read 16 and over.
CLOT	2	42	Does cancer treatment mean chemotherapy? Will this be specific treatment regimens or across the whole spectrum – again this will be a significant increase in the current workload	Thank you for your comment. Cancer treatment includes chemotherapy. We will consider this when developing the guideline.
CLOT	3	77	Apixaban has not been included	Thank you for your comment. This section of the scope refers to 'areas form the published guideline that will be updated'. Apixaban was not included in the previous guideline which is why it is not listed here. However, it will be included in this update as stated in the section on 'areas not in the published guideline that will be included in the update' (page 4, line 91).

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CLOT	9	256	There have been concerns raised regarding the level of evidence available for the Geko device and whether this should be included alongside the existing mechanical methods of thromboprophylaxis	Thank you for your comment. The Geko device will be considered in the same way as other mechanical methods of thrombo prophylaxis. The evidence will be quality assessed using GRADE and the quality of evidence will be taken into consideration.
DoH	general	general	No comments	Thank you.
H&SC	general	general	No comments to make, agree with the draft scope of the guideline.	Thank you for your comment. We are pleased that you agree with the draft scope.
Medtronic	2	36	Consider addition of the term 'limited mobility' to this newly proposed population concerning long- term care. IPC is evidenced to clinically benefit people rendered immobile and at high risk of bleeding, due to their injury. The safety profile of IPC will be of benefit and potentially following publications: ○ Arabi 2013. Use of intermittent pneumatic compression and not graduated compression stockings is associated with	Thank you for your comment. We have removed specific reference to this population from the scope though they will still be considered when developing the guideline. Thank you for your suggested references. Intermittent pneumatic compression devices will be

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			lower incident VTE in critically ill patients: a multiple propensity scores adjusted analysis. ○ Vignon 2013. Intermittent pneumatic compression to prevent venous thromboembolism in patients with high risk of bleeding hospitalized in intensive care units: the CIREA1 randomized trial. ○ Zhang 2011. The efficacy of intermittent pneumatic compression in the prevention of venous thromboembolism in medical critically ill patients	considered for all populations in the guideline if their use is appropriate.
Medtronic	2	39	A recent Swedish study makes a good case for use of IPC in this population: 'Intermittent pneumatic compression reduces the risk of deep vein thrombosis during post-operative lower limb immobilisation: a prospective randomised trial of acute ruptures of the Achilles tendon; Domeji-Arverud 2015'	Thank you for your comment. Intermittent pneumatic compression devices are included in the guideline (p7, line 185). A search will be carried out for each review question and studies that meet the inclusion criteria for each question will be included.
Medtronic	2	41	Support the inclusion of adults and young people attending hospital for day cases including cancer treatment	Thank you for your comment

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Medtronic	2	43	Support the inclusion of this new area	Thank you for your comment
Medtronic	2	48	2. Supportive evidence for mechanical prophylaxis (IPC) in people whom pharmacological prophylaxis is contraindicated. Undoubtedly, people at high risk of bleeding will be contraindicated for heparin etc. The problem is that risk prediction tools for bleeding are inaccurate (Riva et al. Poor predictive value of contemporary bleeding risk scores during long-term treatment of venous thromboembolism. Thromb Haemost 2014; 112: 511–521). Consider a 'conservative approach', i.e. use IPC even at potential risk of bleeding if equivalent efficacy is accepted. On that note, these meta-analyses might be useful: ○ Ho 2013. Stratified meta-analysis of intermittent pneumatic compression of the lower limbs to prevent venous thromboembolism in hospitalized patients. ○ Pavon 2015. Effectiveness of Intermittent Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis in High-risk	Thank you for comment and suggested references. We will consider these during development.

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			Surgical and Medical Patients ○ Zagreba 2014. Meta-analysis of randomized trials comparing combined compression and anticoagulation with either modality alone for prevention of venous thromboembolism after surgery.	
Medtronic	2	51	Supportive evidence for mechanical prophylaxis (IPC) in people who require bridging prophylaxis	Thank you for your comment
Medtronic	5	120-149	Encouraged to learn risk assessment will be a key part of this update	Thank you for your comment. We are pleased that you agree risk assessment should be included in the scope.
Medtronic	7	184	Suggest specifying 'anti-embolic stockings' as evidence suggests graduated compression stockings will include stocking types that do not have an 'anti-embolic' effect. Whilst anti-embolic/anti-embolism stockings can be grouped under the term Graduated Compression Stockings (GCS) there are a number of products which are graduated in nature but may not be specifically designed, indicated and proven to prevent DVT/PE. For this reason, suggest	Thank you for your comment. We agree and have updated the scope accordingly.

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			the term Anti-embolism Stocking or Anti-embolic Stocking is potentially a more accurate term for the purpose of these guidelines.	
Medtronic	7	197	Rivaroxaban - wound infection rates as these have risen in the UK after switching to this product. Jameson SS et al. Wound complications following rivaroxaban administration: a multicenter comparison with low-molecular-weight heparins for thromboprophylaxis in lower limb arthroplasty. J Bone Joint Surg Am. 2012 Sep 5;94(17):1554-8.	Thank you for your comment and suggested reference. The guideline committee will select and prioritise the relevant outcomes considered for each review.
Medtronic	7	199	Evidence for mechanical prophylaxis with a UK experience, namely CLOTS 3 trial (NIHR HTA Vol 19, Issue 76 (Sept 2015)_ ISSN 1366-5278 (DOI 10.3310/hta19760)	Thank you for your comment. We have noted your references which we will review during guideline development.
RCGP	General	General	The RCGP welcomes this document and has no comments at this stage	Thank you for your comment
RCN	10	290	*'In 2010, the CQUIN target introduced a payment linked to at least 90% of adults being risk assessed on admission to hospital*'- this mentions 90% risk assessment for adults admitted in hospitals. This figure seems to conflict with the figure mentioned further on in the document (see below)	Thank you for your comment. We can confirm that the target started at 90% and was increased in year 2 to 95%, we have made this more clear in the scope.

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RCN	11	301	*'This included the mandatory VTE risk assessment 302 of 95% of all people admitted to hospital.'* - mentions 95% risk assessment. As above, these two percentage figures both relating to 2010 on risk assessment for adults in hospitals conflict and may need clarification?	Thank you for your comment. We can confirm that the target started at 90% and was increased in year 2 to 95%, we have made this more clear in the scope.
RCN	3	77	*'Pharmacological prophylaxis including aspirin'* – it is unclear what this is about - aspirin is not recommended for VTE prevention.	Thank you for your comment. Although the previous version of the guideline recommended 'Do not regard aspirin or other antiplatelet agents as adequate prophylaxis for VTE', this update will also include aspirin to review any additional evidence in this area and decide if to change the recommendation.
RCN	6	165	*'People discharged wearing lower-limb devices'* - does this include all below knee devices – i.e. POP and boots?	Thank you for your comment. Plaster of Paris and boots are included and the scope has been amended to clarify this.
RCN	General	General	The Royal College of Nursing (RCN) welcomes proposals	Thank you for your responses

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			to update this guideline. The RCN invited members who care for people with venous thromboembolism to review and comment on the draft scope. The comments reflect the views of our members.	
RCOG	General	120-134	Could all the questions be either singular or plural for consistency? 1.1 pertains to a patient admitted to hosp. 1.2 pertains to patients who are having day procedures. Same for 1.3 and 1.4	Thank you for your comment. We agree and have updated the scope.
RCOG	General	154-164	We suggest that it would be worth considering major vaginal surgery, in this section.	Thank you for your comment. This section is not meant to list all included populations. Those listed are to emphasise that the populations used in the current version of the guideline will also be considered for this update.
RCOG	General	25	The 'lay representative' on our Committee has suggested that you define what heparin is; suggest you change to " … inequalities relating to the anti-thrombotic agent heparin, which is derived from the tissues of pigs or cattle".	Thank you for your comment. We have updated the scope and equalities impact assessment as suggested.
RCOG	General	121 onwards	Best to include at the outset that VTE refers to both DVT and PE, rather than repeat this at each question.	Thank you for your comment. We have

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				amended the scope accordingly.
RCOG	general	General (and specifically line 46 and line 121)	We are sure that NICE are aware that the RCOG updated their guidelines ('Green-top Guidelines') on the prevention of VTE in women during pregnancy and in the puerperium (guideline 37a) and the immediate management of suspected VTE in pregnancy (37b) in April 2015. We would urge NICE to avoid producing conflicting guidance since this would inevitably lead to confusion, inconsistent practice and a failure to implement fully both NICE and RCOG guidance. Ideally we would respectfully ask you to remove pregnancy from the scope, and refer to our updated guideline instead, (which is NICE accredited). Of note, our guidelines do not address economic aspects (section 1.4) – we would be interested to learn whether you felt that economic considerations were relevant in obstetric practice.	Thank you for your comment. NICE guidelines always cover clinical and economic considerations. Therefore by including this area in the guideline we will be able to review both new clinical evidence and cost-effectiveness evidence of prophylaxis given to those pregnant women admitted to hospital
RCOG	General	211	We suggest rephrasing Q2.7 to 'What is the most effective prophylaxis strategy for patients in whom both mechanical	Thank you for your comment. We agree and have updated the scope

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			and pharmacological prophylaxis are contraindicated?'	accordingly.
RCOG	general	214	We suggest changing 'antiplatelets' to 'antiplatelet agents'	Thank you for your comment. We agree and have updated the scope accordingly.
Royal College of Anaesthetists	General	General	The scope proposal is comprehensive and ambitious. We suspect there will be very little hard evidence to support recommendations in a number of areas. We trust this will be recognised in the final document.	Thank you for your comment. All recommendations are supported by an evidence review and an assessment of the quality of evidence used to make them.
Royal College of Anaesthetists	General	General	The guideline is focussed on prevention of DVT/VTE. We note that there will be some consideration of major adverse consequences of anticoagulation. We are keen to see a more comprehensive review of morbidity associated with thrombo-prophylaxis. There is some evidence, particularly in major orthopaedics, that the unwanted events may outweigh advantages	Thank you for your comment. We will consider the outcomes when establishing the protocols. Although we list the main outcomes to consider for each population there may be more adverse outcomes that need to be considered.
Royal College of Anaesthetists	General	General	The scope does not appear to address patients with previous episodes of venous thrombosis, presenting for further surgery. Specifically do they require extended	Thank you for your comment. The guideline will include patients with previous episode of venous

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			prophylaxis post operatively	thrombosis. These patients will be identified during risk assessment and managed accordingly.
Royal College of Anaesthetists	General	General	The previous CG suggested that women of childbearing age should stop their OCP peri-operatively. In 1995, there was the OCP scare, which was then associated with a rise of terminations and maternal deaths. Does this advice need to be re-visited?	Thank you for your comment. We will consider this when considering recommendations in this area
Royal College of Anaesthetists	General	General	We can see no specific consideration of a differentiation between high risk elective and emergency surgery. Decision making after major trauma is inconsistent and more anecdote than evidence based.	Thank you for your comment. Although we list the populations as they were presented in the current version of the guideline we may reconsider these groupings when setting our protocols. We will consider your point when discussing these.
Royal College of Midwives			*special consideration should be given to pregnant women admitted to hospital and MLU and up to 6 weeks after birth*	-
Royal College of Midwives			*Prophylaxis* *Each of the following questions will investigate individual populations separately. Populations include -*	-

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			Pregnant women	
Royal College of Midwives	2	46	The RCM is very concerned that the needs of pregnant women are not adequately covered in this scope. The importance of antenatal prophylaxis for women with risk factors or a previous history needs to be addressed before women attend a unit for the birth. As highlighted in RCOG Green-top Guideline No. 37a "All women should undergo a documented assessment of risk factors for VTE in early pregnancy or pre-pregnancy" And any guidance on VTE prevention should be covering this issue. Particularly in the light of the recent MBRRACE *report Saving* *Lives, Improving Mothers' Care - Surveillance of maternal deaths in the UK 2011-13* with the finding the "VTE is once again the leading cause of direct maternal death"	Thank you for your comment. The guideline only covers pregnant women who attend hospital or midwife units. This will include risk assessment for VTE. Currently all patients who attend hospital should be risk assessed.

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			Many VTEs will be picked up when the woman attends the unit but not all. Also the precipitating factors in these cases are very different from the other hospital acquired VTE because of the underlying physiological changes during pregnancy and after birth.	
Royal College of Midwives	7	175	Following on from our comment above - does this imply that the question will address the whole population of pregnant women ?	Thank you for your comment. The guideline will cover any pregnant woman who attends hospital or midwife units.
Royal College of paediatrics and Child Health	general	general	No comments	Thank you.
Royal College of paediatrics and Child Health	**general**	general	No comments	Thank you.
Society of British Neurological	General	general	The current guideline has cranial and spinal surgery in a combined chapter on Neurosurgery. Spinal surgery is a high volume sub-specialty and is performed mainly by	Thank you for your comment and information. The guideline will investigate individual populations

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Surgeons			neurosurgeons as well as orthopaedic surgeons. The interventions vary from intermediate to complex procedures. The content on spinal surgery needs to be expanded to recognise the wide spectrum of interventions and VTE risks. The section on Spinal Injury has some common ground with Spinal surgery.	separately (including types of surgery) and this will be considered by the guideline committee. We have separated spinal and neurosurgery in the scope.
Society of British Neurological Surgeons	General	General	In cranial neurovascular conditions presenting with a brain haemorrhage the current guidance recommends pharmacological prophylaxis to commence after the bleeding source is treated. The update should provide additional guidance on these patients when an intracranial device (pressure monitor or CSF drain) is present.	Thank you for your comment. We will consider this when developing the guideline.
Society of British Neurological Surgeons	General	General	The ability to reverse the anticoagulation effect quickly is important if a complication occurs in patients with brain and spinal conditions. As such the recommendations should indicate which preparations are most suitable or to be avoided.	Thank you for your comment. This will be discussed during the development of the guideline.
Society of British Neurological Surgeons	General	General	The evidence on duration of treatment needs to be reviewed to advice on treatment even after discharge from hospital.	Thank you for your comment. We are pleased that you agree that duration of treatment should be included in the scope (see section 1.3).

Venous thromboembolism - reducing the risk (full update)

Consultation on draft scope
Stakeholder comments table

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Society of British Neurological Surgeons	General	general	The evidence on the use of groin vs knee length stockings needs to be reviewed in the light of evidence from the complications seen in Stroke patients	Thank you for your suggestion. The guideline committee will consider this when prioritising review questions.
UK Spine Societies Board	6	162	Would the committee please note that distinction needs to be made between cranial surgery and orthopaedic/neuro spinal surgery patients	Thank you for your suggestion. The guideline committee will consider this when finalising which populations should be assessed separately.
UK Spine Societies Board	6	168	Medical causes of potential paralysis that may require surgical intervention (MSCC , Spinal infection) Although previous NICE guidance about VTE is cross referenced in CG 75 MSCC this is not regarded as adequate and requires clarification	Thank you for your comment. We will consider this when formulating protocols.
UK Spine Societies Board	8	General regarding question 1.6	Additional outcome measures for spinal surgery should include: 1. Epidural haematoma with or without neurological compromise 2. Wound complications	Thank you for your comment. The outcomes listed in section 1.6 are the main outcomes for the guideline. This is not an exhaustive list rather a list of outcomes likely to apply to the majority of populations. The guideline committee will prioritise relevant outcomes for each review question.

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UK Spine Societies Board	General	General	In addition to 'bridging prophylaxis' it would also be useful to have guidance on when to stop anti-platelet agents i.e. aspirin/clopidogrel and anti-coagulant therapy in stroke or Ischaemic heart disease patients.	Thank you for your comment. We have expanded the scope to include a review question on VTE prophylaxis in patients using antiplatelets for cardiovascular disease (number 2.9, page 8).
UK Spine Societies Board	General	General	Guidance needed on prophylaxis in incidental durotomy patients – Should VTE prophylaxis be given?	Thank you for your suggestion. The guideline committee will consider which populations should be prioritised when considering the review questions.
UK Spine Societies Board	General	General	Guidance on pharmacokinetics of chemical agents to facilitate decision making on when to start prophylaxis	Thank you for your comment. We do not usually cover pharmacokinetics in guidelines. If specific issues are raised relating to this during development by the committee then they will be discussed.
UK Spine Societies Board	General	General	Acknowledgement that spinal surgery patients constitute a complex group with different needs to arthroplasty patients	Thank you for your comment. Spinal surgery patients will be considered separately to arthroplasty patients
UK Spine	General	General	Does the traditional thinking around risk factors need to be	Thank you for your comment. Risk

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Societies Board			re-visited i.e. more emphasis on significance of sum of risk factors as opposed to individual factors	assessment will be considered by the committee.
UK Spine Societies Board	General	General	In anticipation of the need to reduce morbidity and mortality from VTE in spinal surgery UKSSB and the constituent societies have commissioned a working party to develop guidelines for VTE prophylaxis in spinal surgery. We believe it has been necessary to develop a specialty specific document due to the complexity and variety of spinal conditions. I have also sent a draft copy seperately herewith for the committee's attention	Thank you for your comment and copy of the guideline.