

Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (Update)
Consultation on draft guideline - Stakeholder comments table
04/10/2017 to 15/11/2017

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Anticoagulati on UK (ACUK)	Full	232	22	Recommendations 4.1 As above issue around in context of research.... As above	Thank you for your comment.
Anticoagulati on UK (ACUK)	Full	233	General	Trade off between clinical benefits and harms. Reference made to the lack of evidence identified for the use of foot impulse devices (FID) or neuromuscular electrical stimulation(NMES) and stated the potential risk of skin damage associated with these devices... Again in MTG 19 states 'The Committee discussed other potential benefits of the geko device for patients. It noted the post-market surveillance data and heard expert advice that the geko device is simple to use and offers advantages in terms of mobility and comfort, which may help improve adherence to its use'. The Committee judged that the geko device may offer an acceptable alternative means of prophylaxis to those who are unable to use current methods'	Thank you for your comment. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.
Anticoagulati on UK (ACUK)	Full	234	4 th para	'IPC devices do not increase bleeding but may cause damage to skin and may necessitate stopping IPCD treatment' effectively leaving stroke patients without a prophylaxis option when an alternative is available. We note that the Clot 3 study (considered by NICE) indicates that there is a 4.5% risk of symptomatic	Thank you for your comment. The committee evaluated the relevant evidence that was identified for the use of IPCD in the stroke population and felt that there was evidence of clinical benefit for the use of intermittent pneumatic compression (IPC) thus decided to adopt the recommendation relating to IPC

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				<p>DVT with standard of care with IPC, increasing to 6.3% when no IPC is in place. There is an ongoing unmet need for those patients at risk without mechanical prophylaxis and ACUK are concerned that outcomes from heightened risk will impact on these vulnerable patients.</p>	<p>from CG92 and the clinical guideline addendum 92.1. The committee discussed the use of VTE prophylaxis and the appropriateness of different interventions (please refer to full guideline volume 1; pages 238-241). It was noted that it is standard practice for stroke patients to be administered anti-platelets as part of their treatment; the committee noted that it would not be necessary to recommend additional pharmacological prophylaxis.</p> <p>The committee would encourage clinicians to consider using mechanical VTE prophylaxis (IPC) in this population to reduce the risk of VTE.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices. Although, the committee do not recommend the use of these devices deleting this recommendation means there is no longer provides a barrier for clinicians considering</p>

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					other forms of prophylaxis.
Anticoagulati on UK (ACUK)	Short	10	22	MTG 19 Geko device 1.1 states case for adoption for people who have high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. It is also noted that there is a low risk of the device causing harm. For acute stroke patients who are contraindicated for IPC, this population will be at increased risk of VTE if the Geko can only be used within the remit of research. MTG19 states that there is a low risk of harm with the GEKO device and we are concerned that limiting it's use to only being used in the capacity of research will be detrimental to vulnerable patients who may not be aware that this mechanical prophylaxis option is available and approved by NICE	Thank you for your comment. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.
ARJO UK	Full Vol 1	15 15 133 139	6-7 18-19 No.2 No.7	The assumption is that 'Thromboprophylaxis' means Anticoagulants. We are concerned that this is interpreted that other means of prophylaxis that don't have a bleeding risk e.g. Mechanical prophylaxis are not considered for these patient groups where clinically appropriate. Should the wording include 'which type' as opposed to 'whether'?	Thank you for your comment. Thromboprophylaxis encompasses mechanical and pharmacological prophylaxis. The guideline committee has noted your comment and amended the wording to make this clearer that these recommendations refer to pharmacological prophylaxis.

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	Short	4	7-8		
		5	1-3		
ARJO UK	Full Vol 1	16	34-43	We are concerned that patients may not understand the importance of ensuring correct sizing of anti-embolism stockings if not included on the list of considerations for patients who are being discharged?	Thank you for your comment. Recommendation 1.3.2 highlights the use of correctly sized stockings. The guideline committee felt that the sizing does not need to be explicitly explained to patients.
		17	1		
		167	20		
	Short	7	11-21		
ARJO UK	Full Vol 1	18	35-40	We are concerned that the statement in the recommendation 'and there may be an associated increased risk of surviving with severe disability' could be misinterpreted to suggest that IPC may increase these risks. Other interventions in the document do not suggest this risk.	Thank you for your comment. The committee believe it is important that clinicians make patients aware of both the potential harms and benefits of IPC devices in stroke patients. The evidence included in the guideline showed that while there is a reduction in VTE there is also a chance of surviving stroke with severe disability.
		232	No. 44		
	Short	11	1-6		
ARJO UK	Full Vol 1	18	32-34	We are concerned that the 3 day period for initiation of IPC is not supported by clear evidence.	Thank you for your comment. The committee discussed your comment and felt that starting IPC within 3 days of acute stroke is appropriate as this is the time period used in the evidence included in the guideline.
		232	No. 43		
				We are concerned that the importance of starting IPC as soon as possible on admission where it is considered appropriate clinically is not part of the	

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	Short	10	27-29	recommendation. Additionally, it is inconsistent with recommendation to wear IPC for as much time as possible e.g. short guideline version, page 9, line 18 (1.3.11)	
ARJO UK	Full Vol 1	18	41-43	We are concerned that this recommendation may be misinterpreted to mean that there only needs to be a 30 day duration of IPC with Stroke patients and then this form of prophylaxis is removed as it is considered safe to do so. Some stroke patients may still be at risk post the 30 day period.	Thank you for your comment. The duration of 30 days for IPC in the stroke population is based on the evidence identified. The committee acknowledges that there will sometimes be exceptions to this duration; IPC can be used for longer periods of time if clinically appropriate.
	Short	11	7-9		
ARJO UK	Full Vol 1	20	22-26	We are concerned that this may cause confusion. Can an explanation be given for the conditions where using Intermittent Pneumatic compression may be contraindicated and it is recommended to consider Anti Embolism stockings instead?	Thank you for your comment. The committee do not think there are many circumstances where stockings would be used over IPC for this patient group; IPC are the preferred choice. However, the committee believe there may be some high risk women undergoing surgery who are pregnant for which stockings would be more beneficial. This aligns the recommendation with the major abdominal surgery recommendation (1.5.37 to 1.5.39) where found combined prophylaxis with stockings was found to be cost effective.
		324	No. 69		
	Short	15	16-18		
		16	1-5		
ARJO UK	Full Vol 1	32	13	We are concerned that that the recommendation and evidence on why not to use foot devices is unclear	Thank you for your comment. The recommendation against using foot impulse or

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					neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.
ARJO UK	Full Vol 2	150 224	No. 83 No. 85	We are concerned that the recommendation to use IPCD with Elective Knee Surgery and AES with Elective Hip surgery may be confusing for staff as both of these patient groups will be nursed in the same clinical areas.	Thank you for your comment. The option recommended for each population has been chosen based on the clinical and cost effectiveness analysis. The guideline committee noted that the differing recommendations for elective hip replacement surgery and elective knee replacement surgery could raise some concerns but felt that it is crucial that these populations are considered separately as they are associated with different VTE risks. The recommendations are a reflection of the difference in the evidence identified between the two populations. It is important when implementing these recommendations that measures are put in place to ensure that each patient receives the optimal option.
ARJO UK	Full Vol 2	222	No. 40	As the evidence discussed was comparing IPCD to no prophylaxis, should this line read that 'there was possible clinical benefit of IPCD..' as opposed to 'There was possible clinical benefit of AES..'	Thank you for your comment. You are right, this has been amended.

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Association of Independent Healthcare Organisations	General	General	General	<p>Re Aspirin for TKR and THR. My objections are that I don't believe that the evidence base supports this change in practice. The trials and meta analyses are not specified or powered to answer the question, about both risks and benefits for this strategy vs established practice. This paper sums up my objections.</p> <p>https://www.ncbi.nlm.nih.gov/pubmed/23324504 <i>Ann Pharmacother.</i> 2013 Jan;47(1):63-74. doi: 10.1345/aph.1R331. Epub 2013 Jan 16.</p> <p>Aspirin for the prophylaxis of venous thromboembolic events in orthopedic surgery patients: a comparison of the AAOS and ACCP guidelines with review of the evidence.</p>	<p>Thank you for your comment. We agree that single trials may not be sufficiently powered to show differences between the interventions considered and this is one of the reasons for using network meta-analysis as a technique for evidence synthesis as it combines evidence from a large number of trials and patients. While there is still uncertainty with the results it still provides the best evidence available.</p> <p>The results were discussed with the orthopaedic subgroup and main committee and both agreed there was enough evidence to support the use of aspirin alone for elective knee replacement but not for elective hip. We did not identify evidence to demonstrate the aspirin combined with mechanical was an effective regimen so have not recommended this.</p> <p>All RCTs included in the paper cited were also considered for this guideline.</p> <p>The committee also noted that for some orthopaedic surgeons aspirin is the choice of prophylaxis used and has been for some time</p>

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					with large observational studies examining its effects.
Association of Independent Healthcare Organisations	General	General	General	The guidance refers to 'high risk' and 'low risk' patients. Current guidance refers to 'at risk' patients and provides a risk assessment. How do we objectively assess a low or high risk patient? Will NICE be providing a risk assessment with parameters for low and high risk to be able to do this?	<p>Thank you for your comment. The committee did look to provide clearer guidance for this but found no evidence to show how the risk of VTE is balanced against the risk of bleeding. Even the risk tools which provide some quantification of risk for VTE and bleeding do not give a method of weighing up the results to state whether VTE risk is outweighed by bleeding.</p> <p>The terms are used for oral and maxillofacial and ENT surgery to emphasise that prophylaxis is not usually required in these groups. The term low risk of bleeding is used for lower limb fragility fractures to emphasise that there is concern with bleeding with fondaparinux. Low risk of VTE is used for non-arthroscopic knee surgery and varicose veins surgery to emphasise there is a group for which VTE prophylaxis is not required.</p> <p>The committee are of the opinion that clinicians need to decide on a case by case basis whether an individual is more at risk of</p>

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					VTE or bleeding.
BMS-Pfizer Alliance	Both versions	General	General	<p>Apixaban significantly reduces the VTE burden in elective THR and TKR patients without increased bleeding, compared with enoxaparin</p> <p>Randomised controlled trials ADVANCE-2 (Lassen MR et al, Lancet 2010;375:807) and ADVANCE-3 (Lassen MR et al, NEJM 2010;363:2487) demonstrated that apixaban (2.5mg bd) was statistically superior to enoxaparin (40mg od) in the primary composite efficacy endpoint, with no significant increase in either major or clinically-relevant non-major bleeding.</p> <p>The oral administration of apixaban is a clear advantage, alongside no requirement for dose reduction even in extremes of age or in patients with mild to moderate renal impairment. Compared to subcutaneous enoxaparin, patients may be expected to prefer oral apixaban, and the NHS may require fewer healthcare resources to manage patients with apixaban.</p>	<p>Thank you for your comment. The ADVANCE 2 trial mentioned has been already included in the network meta-analysis. The lower cost associated with oral administration of apixaban has been included in the economic analysis.</p> <p>Patient preference for oral administration has been taken into account by recommending rivaroxaban (for THR and TKR) and aspirin (for TKR) which are both orally administered.</p>
BMS-Pfizer Alliance	Full	215 216	3-5 23-24	<p>Elective knee replacement</p> <p>Within the full draft guideline document (volume 2, page 215), the authors note that 'The results of this analysis reflect the very large uncertainty seen in the eTKR NMAs and in particular the uncertainty in the PE NMA which appeared to be driving the results of</p>	<p>Thank you for your comment. We agree that the results of our analysis show large uncertainty echoing that reported in Sterne et al. However, the best estimate is still the mean value.</p>

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				<p>Please insert each new comment in a new row</p> <p>the economic model. This has been reflected in the very small difference in QALYs gained, the very wide 95% CIs'. Indeed in the final conclusions (volume 2, page 216), the authors conclude 'these results, however, are subject to high uncertainty given the imprecise effectiveness results from the NMAs that underpinned this analysis'.</p> <p>Additionally, the NIHR study (Sterne <i>et al</i>, 2017) makes the same assessment of the evidence of thromboprophylaxis in eTKR - 'substantial uncertainty around the relative costs and benefits of these interventions'.</p>	<p>Please respond to each comment</p> <p>The committee took this uncertainty into account and opted to recommend more than one option of VTE prophylaxis to take into account the presence of contra-indications as well as patient preferences.</p>
BMS-Pfizer Alliance	Full Vol 2	139	4-7	<p>Elective hip replacement</p> <p>Within the full draft guideline (volume 2, page 139), the authors make a similar observation (with respect to elective hip replacement) to the authors of TA245 - '...the choice of a prophylaxis strategy is not clear cut. This is likely to be the result of the uncertainty around the relative effectiveness estimates for the different interventions; which was clearly shown in the results of the NMAs that informed the economic model.'</p> <p>This level of uncertainty, in both the clinical and economic data, was also expressed in the NIHR study (Sterne <i>et al</i> [2017]; also referenced in the full guideline):</p> <ul style="list-style-type: none"> • <u>Page 260</u>, 'We also found that rivaroxaban was likely to be cost-effective for primary 	<p>Thank you for your comment. We agree that the results of our analysis show large uncertainty echoing that reported in Sterne <i>et al</i>. However, the best estimate is still the mean value.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its main recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. Apixaban and dabigatran are</p>

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				<p>Please insert each new comment in a new row</p> <p><i>prevention after TKR and THR. However, despite including a larger number of trials in a NMA than previous cost-effectiveness models, our interpretation is tentative because of imprecise estimates about effect and safety'</i></p> <ul style="list-style-type: none"> <i>Page 263, 'Rivaroxaban has the highest expected net benefit over the range of willingness-to-pay thresholds we explored, but with substantial uncertainty: its probability of being the most cost-effective was 0.35 for willingness-to-pay threshold of £30,000 per QALY.'</i> 	<p>Please respond to each comment</p> <p>now also included in a further recommendation that specifies the circumstances under which these DOACs might be considered</p>
BMS-Pfizer Alliance	Short	General	General	<p>Concern over recommendation for individual recommends made via a Clinical Guideline</p> <p>At a more fundamental level, we question the decision to recommend an individual medicine over similar others based on cost-effectiveness in the absence of a full technology assessment. Unlike a Technology Appraisal, the Clinical Guideline process does not allow a submission from stakeholders supporting an interpretation of the evidence. The Guideline Development Group may call for specific evidence as required, but the guideline process does not facilitate the submission of a full economic analysis by a manufacturer. Should stakeholders dispute the Guideline Development Group's interpretation of the evidence, the guideline process</p>	<p>Thank you for your comment.</p> <p>Dabigatran and apixaban are now included the recommendation. However, as both were not cost effective compared to rivaroxaban, the committee decided that these options could only be considered if all the three recommended options are not suitable for the person (for example due to contraindications or issues related to patient preference). It was the guideline committee and the orthopaedic committee's view, based on the evidence presented, that the three DOACs considered are not therapeutically equivalent and should not be treated as such. This was</p>

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				<p>does not allow an appeal to the final decision. For these reasons, we disagree with the process leading to the recommendation of rivaroxaban in preference to other DOACs in this Clinical Guideline.</p> <p>In addition, the NICE document '<i>Medicines optimisation: key therapeutic topics</i>' (Jan 2017; page 46) gives clear direction that no restrictions should be placed upon access to any of the three licensed NOAC</p>	<p>based on both clinical experience and information about the mechanism of action of the three agents</p>
BMS-Pfizer Alliance	Short	19 and 20	7 - 12 4 - 9	<p>Unjustified preferential recommendation for rivaroxaban over other DOACs</p> <p>We strongly disagree with the Guideline Development Group's decision to give a preferential recommendation to rivaroxaban over the other Direct Oral Anticoagulants (DOACs; apixaban and dabigatran) licensed for the use in thromboprophylaxis in elective hip and knee replacement.</p> <ul style="list-style-type: none"> • We believe that there is too great a level of uncertainty in both the clinical and economic data to differentiate in this indication. • We request that all DOACs licensed for this indication (apixaban, dabigatran and rivaroxaban) are treated equally within the 	<p>Thank you for your comment. It is the view of the guideline committee members that these DOACs are not clinically equivalent and should not be considered to have a class effect.</p> <p>The evidence considered in this guideline includes more recent trials that were published after the publication of TA245. It also includes all relevant comparators, and not only enoxaparin.</p> <p>We acknowledge that there is uncertainty in the analysis, however, the mean incremental net monetary benefit (INMB) is still considered to be the best estimate on which to base the decision to recommend an intervention over</p>

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				<p>The differentiation between the DOACs in elective hip and knee replacement is at odds with previous documented conclusions from NICE's appraisal of apixaban (TA245). In this appraisal, the NICE Appraisal Committee concluded that there was insufficient clinical evidence to determine whether or not apixaban was more or less clinically effective than rivaroxaban. The Final Appraisal Determination also concluded that apixaban had a 53% probability of being the most cost-effective agent (compared to 47% for rivaroxaban).</p>	<p>another, in addition to clinical expert opinion which clearly favoured recommending one DOAC to standardise practice, minimise error and reduce costs.</p> <p>The complete rationale for recommending rivaroxaban in the THR population has been explained in the linking evidence to recommendation section on page 153, full guideline, volume 2. This states: "The committee and the orthopaedic subgroup noted that out of the three DOACs included in the model (rivaroxaban, apixaban and dabigatran), rivaroxaban dominated dabigatran and was cost-effective compared to apixaban (ICER: £12,242 per QALY-gained). Apixaban had higher probability of being the most cost-effective compared to rivaroxaban (2.2% versus 0.2%%; respectively); however there was more uncertainty around the rank of apixaban compared to that of rivaroxaban (95% CI around the mean rank 2 to 14 for apixaban and 2 to 13 for rivaroxaban). Additionally, apixaban had double the probability of being the least cost-effective option compared to rivaroxaban (0.16% vs 0.08%, respectively).</p>

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					<p>The committee took this decision uncertainty into account and noted that the conclusion that rivaroxaban is on average more cost-effective than apixaban for people undergoing total hip replacement largely agreed with the findings of most of the previously published economic evaluations which have been selectively excluded from this review. It was in line with the results of TA170 where rivaroxaban was found to dominate dabigatran.²²⁹ A recent analysis funded by the NIHR found that rivaroxaban dominated dabigatran and was cost-effective compared to apixaban with an ICER of £114 per QALY gained.²⁸¹ TA245 also found that dabigatran was dominated, apixaban was extendedly dominated and rivaroxaban had an ICER of £22,123 per QALY gained compared to fondaparinux.²³⁰ Hence, the committee determined that it would be beneficial to standardise practice in order to minimise costs and reduce errors and, hence, recommend the most cost-effective DOAC, rivaroxaban. This would also minimise costs and reduce e. Apixaban and dabigatran already have current technology appraisal guidance associated with them and are, therefore, also recommended.</p>

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					<p>However, as both were not cost effective compared to rivaroxaban, the committee decided that these options could only be considered if all the three recommended options are not suitable for the person (for example due to contraindications or issues related to patient preference).”</p> <p>The committee’s rationale for recommending rivaroxaban in the TKR population has been explained in the linking evidence to recommendation section on page 229, full guideline volume 2. This states “The committee and the orthopaedic subgroup noted that out of the three DOACs included in the model (rivaroxaban, apixaban and dabigatran), rivaroxaban was dominant (more effective and less costly) compared to both apixaban and dabigatran. The committee noted that this was in line with previously published economic evaluations, the economic models assessed as part of TA170 and TA245 and a more recent analysis funded by the NIHR.^{229,230,281} Dabigatran was also, on average, worse than no prophylaxis. The orthopaedic subgroup also noted recent</p>

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					<p>reports of increased risk of wound complications and subsequent increased length of hospital stay when using dabigatran.³⁵ The committee noted that despite being dominated and having low INMB, apixaban had high probability of being the most cost-effective (43%). However, there was higher uncertainty around its cost-effectiveness; with around 5% probability of being the worst (compared to 0% for rivaroxaban) and 95% CI around its mean rank of 1 to 13 (compared to 1 to 11 for rivaroxaban). Hence, the committee recommended rivaroxaban as the most cost-effective DOAC with the aim of standardising practice to minimise costs and reduce errors.”</p> <p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered.</p>
British Association of Day	General	General	General	We are concerned that there is no mention of Day Surgery in this document. It refers to patients who are admitted to hospital, where as 80% elective	Thank you for your comment. Day surgery is covered by the guideline. It is not specifically mentioned in individual recommendations

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Surgery				surgery is now undertaken on a day case basis. Patients are ambulatory at discharge however may have a variety of risk factors for VTE. There are a variety of published audits but no clear recommendations regarding chemical prophylaxis in these patients whether a single dose of heparin, a 5 or 7 day course is recommended. It seems a pity that such a large proportion of the surgical population is not covered in this document. We would welcome your advice/comments	because the recommendations apply to anyone undergoing surgery regardless of whether it is day procedure or requires a hospital stay. Recommendations within the guideline usually state the duration of prophylaxis in relation to a specified number of days or to when the person's risk is no longer increased. We have also added a definition to the guideline to make it clear that day surgery is considered an admission. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
British Hip Society	Full Vol 1	191 & 195	General	Patients taking oral anticoagulants and anti-platelet drugs are not unusual. Very often these patients will have medical risk factors that far outweigh their VTE risk, and the priority should be to get them re-established on this medication expediently. There is a simple pragmatic approach used by many surgeons that is at least worth a mention and discussion. Oral anticoagulants need to be omitted	Thank you for your comment. We agree that oral anticoagulants need to be omitted preoperatively to allow for a safer operation. We did not find evidence to support or refute using antiplatelet agents as thromboprophylaxis as well as for their treatment. Consequently, we have made a softer recommendation so that clinicians consider whether additional prophylaxis is

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				preoperatively to allow for a safe operation, and then restarted and allowed to “double” for the patients’ thromboprophylactic agent. Anti-platelet agents play a vital role in patients with cardiac and cerebrovascular disease. Aspirin should be considered to be allowed to double for both the medical condition and thromboprophylactic agent.	required. The committee also note that this would be part of the risk assessment where the need for VTE prophylaxis is assessed against the individual’s personal circumstances.
British Hip Society	Full Vol 2	General	General	Minimal attention is paid to patients at higher risk of VTE. A risk stratification approach would be welcomed. Patients with a past personal history of VTE require a different approach, with many surgeons opting for an extended period of full anticoagulation post operatively as well as mechanical methods. Whilst there is little or no evidence on what to do in each of the situations (such as past VTE, recent cancer, history of thrombophilia), there is an opportunity to emphasise the extra consideration that these groups require.	Thank you for your comment. The guideline committee agree that the risk of VTE varies across different population groups; it is particularly high in the population that you have mentioned (such as past VTE, recent cancer, history of thrombophilia). The risk assessment recommendations highlight the need for clinicians to assess patients’ risk of VTE in medical and surgical populations. Whilst emphasis has not be placed on those in the groups you have mentioned, this should be encompassed within the risk assessment using risk tools which normally take these specific factors into consideration.
British Hip Society	Full Vol 2	General	General	No mention is made of major and minor operations around the hip other than hip replacement, such as hip arthroscopy, hip debridement for impingement, and osteotomy. These would generally be considered to have a similar risk profile, and merit similar consideration, to knee replacement.	Thank you for your comment. These populations were not highlighted during scoping of the guideline and were not prioritised for inclusion by stakeholders. As a result, they were not included in this update of the CG92 guideline.

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					The committee appreciate that this is an important area. These patients should be risk assessed as all surgical patients do, clinicians will need to decide whether prophylaxis is required.
British Hip Society	Full Vol 2	57	General	The recommendation for research into aspirin versus other agents is welcomed, but on the available evidence it should be considered as an option in conjunction with other modalities. It cannot be over-emphasised that the risk posed to the elderly with fragility fractures, from wound leakage (leading to infection and death) caused by potent anticoagulants used for VTE prophylaxis, far outweighs the risk of VTE.	Thank you for your comment. The guideline committee considered the available evidence for aspirin. The only study identified, the PEP trial, used aspirin in conjunction with with UFH, LMWH and/or anti-embolism stockings. Because of this the committee were unable to determine if the observed effects of aspirin were down to aspirin alone, in combination with stockings or in combination with other pharmacological agents. Therefore the guideline committee decided that a research recommendation was important to determine whether aspirin can be used for VTE prophylaxis.
British Hip Society	Full Vol 2	65	General	The evidence base relates mainly to old studies that are largely irrelevant to contemporary practice in hip replacement surgery. Three quarters of the studies were published in the last century, several are over 40 years old. These are inappropriate for consideration. The older studies generally focus on comparing two	Thank you for your comment. We agree that most of the evidence considered for the THR population came from RCTs conducted more than 5 years ago. This was extensively discussed with the orthopaedic subgroup and the main guideline committee and it was felt that as we are using these RCTs to assess the relative efficacy of the interventions; the

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				<p>or more chemical regimes with no mechanical methods involved, with a high proportion of general anaesthesia, and often with asymptomatic DVT's as the outcome measure. It was then the norm to mobilise patients after several days of bed rest, and for patients to be in hospital for 12 – 14 days. By contrast, in modern practice most patients have regional anaesthesia, mechanical prophylaxis and are fully mobile within 24-48 hours. These are all factors that have major impacts on VTE rates, their absence make the older studies of historical interest only.</p> <p>With such a paucity of RCT evidence based on contemporary practice it is wrong to ignore observational data. Much of this data concludes that aspirin is at least as good, and possibly safer than the use of potent anticoagulants, when used in conjunction with a multimodal approach. This is favoured by most UK hip surgeons – and indeed internationally.</p> <p>2 examples of <u>recent large and high quality observational studies</u> are these:-</p> <p>Bayley E, Brown S, Bhamber NS, Howard P. Fatal pulmonary embolism following elective total hip</p>	<p>fact that they do not reflect contemporary practice in terms of other adjunctive and concomitant treatments should not be a reason to exclude older trials; as randomisation should largely address this issue. If, however, the baseline risk of VTE is different in these old trials then randomisation may not completely address the issue as the effectiveness of an intervention may be affected by the baseline risk. It is not possible to know whether this is the case in this instance or not. Limiting inclusion to the most recent 5 years would mean that only two trials will be included.</p> <p>The committee discussed the use of observational studies to estimate the relative treatment effects; however, the consensus agreement was that these studies suffer from residual confounding and will result in biased estimates. Problems with inaccurate data linkage with other databases used in these studies such as HES and ONS data were also a source of concern. Additionally, the committee members were aware of a number of limitations of the NJR including incomplete</p>

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				<p>arthroplasty: a 12-year study. Bone Joint J 2016;98-B:585–588. http://bjj.boneandjoint.org.uk/content/98-B/5/585?ijkey=8c706ecec3689431226eabd56fd549aba6f86c62&keytype2=tf_ipsecsha</p> <p>Aspirin for thromboprophylaxis after primary lower limb arthroplasty. Early thrombotic events and 90 day mortality in 11,459 patients. Ogonda L, Hill J, Doran E, Dennison J, Stevenson M, Beverland D. BJJ 2016; 98-B 341-8. http://bjj.boneandjoint.org.uk/content/98-B/3/341</p> <p>Two <u>recent reviews of the place of aspirin in hip replacement</u> can be found here, and are commended to the committee: Aspirin and the prevention of venous thromboembolism following total joint arthroplasty. Azboy, R. Barrack, A. M. Thomas, F. S. Haddad, J. Parvizi. -2017-0337.R2 Published 1 November 2017 http://bjj.boneandjoint.org.uk/content/99-B/11/1420</p> <p>Venous Thromboembolism Following Hip and Knee Arthroplasty: The Role of Aspirin.</p>	<p>recording, difficulty in identifying the doses of the VTE prophylaxis options used, and the possible discrepancy between the prescribed prophylaxis as reported in the NJR and what the patient actually received.</p> <p>The committee also noted an observational study based on NJR data that attempted to adjust for confounding with propensity score matching. This showed a reduced mortality rate with LMWH compared to aspirin. While this result could be due to residual confounding it still does not suggest equivalence and makes it difficult to recommend aspirin alone given that this could lead to more deaths for what is an elective procedure. It was also the only study we are aware of that attempted to adjust for confounding in elective hip replacement. The GC therefore believes that RCT evidence was needed to test the effectiveness of aspirin alone and have made a research recommendation (Jameson SS, Charman SC, Gregg PJ, Reed MR, Van Der Meulen JH. The effect of aspirin and low-molecular-weight heparin on venous thromboembolism after hip</p>

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				<p>Parvizi J, Ceylan HH, Kucukdurmaz F, Merli G, Tuncay I, Beverland D. J Bone Joint Surg Am. 2017 Jun 7;99(11):961-972</p>	<p>replacement: A non-randomised comparison from information in the National Joint Registry. Journal of Bone and Joint Surgery - Series B. 2011; 93 B(11):1465-1470.</p> <p>Observational data has been used for this review for two areas of data: (1) when calculating the absolute risk of events for the baseline treatment we used the National Joint Registry data for 2015 to reflect current practice. We have described in detail how we used NJR data as a source of baseline risk in the economic analysis in appendix P, Section P 1.3.2 page 635.</p> <p>(2) For the major bleeding outcome for aspirin, as the only RCT that assessed its relative efficacy did not report this outcome. The observational study that we used was based on NJR data.</p> <p>The committee acknowledged the orthopaedic surgeons' clinical experience which supports aspirin as a safe and effective prophylaxis strategy; however, in absence of good quality RCT evidence to demonstrate this, it was not possible to recommend it as one of the</p>

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					<p>prophylaxis strategies for this population. Consequently, as stated above a research recommendation has been made to address this issue and encourage the clinical community to undertake this much needed RCT.</p> <p>All the studies that are included in the reviews mentioned have been checked and any that met the inclusion criteria for the guideline were included in the evidence review.</p>
British Hip Society	Full Vol 2	65	General	<p>It is stated that meta-analyses/systematic reviews and guidelines from other bodies are considered, but if they have indeed been for hip surgery then they have not been documented or heeded. There are several important systemic reviews/meta-analyses that should be considered – listed below, as well as the guidance that covers hip surgery in America, Canada and Australia (via ACCP, AOOS, AOA). All in essence support the use of regional anaesthesia, mechanical methods, early mobilisation and a choice of chemical agents that all include aspirin. Their interpretation of the data is that no single chemical agent shows a clear advantage.</p> <p><u>Recent Metanalyses/Systematic reviews</u></p>	<p>Thank you for your comment. Systematic reviews and guidelines are checked to identify relevant primary studies that can be potentially included in the guideline review. These studies are then assessed against the guideline inclusion criteria and may or may not be included. The systematic reviews listed in your comment did not meet the inclusion criteria but all have been checked and all relevant trials that met the inclusion criteria of the guideline review were included.</p> <p>The committee made its recommendations based on original reviews and health economic analysis rather than using other</p>

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				<p>Brown GA. Venous thromboembolism prophylaxis after major orthopaedic surgery: a pooled analysis of randomized controlled trials. J Arthroplasty 2009;24(6 Suppl):77–83.</p> <p>Sharrock NE, Gonzalez Della Valle A, Go G, Lyman S, Salvati EA. Potent anticoagulants are associated with a higher all-cause mortality rate after hip and knee arthroplasty. Clin Orthop Relat Res 2008;466:714–721.</p> <p>Wilson DG, Poole WE, Chauhan SK, Rogers BA. Systematic review of aspirin for thromboprophylaxis in modern elective total hip and knee arthroplasty. Bone Joint J 2016;98-B:1056–1061</p> <p>An VV, Phan K, Levy YD, Bruce WJ. Aspirin as thromboprophylaxis in hip and knee arthroplasty: a systematic review and meta-analysis. J Arthroplasty 2016;31:2608–2616.</p>	<p>guideline recommendations. Aspirin was not found to be cost effective based on the economic analysis undertaken for this topic and hence was not recommended as an option.</p> <p>Other systematic reviews are checked for RCTs to ensure we have included all that meet our protocols.</p> <p>The committee also noted an observational study based on NJR patients showing a reduced mortality rate with LMWH compared to aspirin when data were propensity score matched. While this result could be due to residual confounding it still does not suggest equivalence and makes it difficult to recommend aspirin alone given that this could lead to more deaths for what is an elective procedure. The GC therefore believes that RCT evidence was needed to test the effectiveness of aspirin alone and have made a research recommendation (Jameson SS, Charman SC, Gregg PJ, Reed MR, Van Der Meulen JH. The effect of aspirin and low-molecular-weight heparin on venous thromboembolism after hip replacement: A</p>

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					<p>non-randomised comparison from information in the National Joint Registry. Journal of Bone and Joint Surgery - Series B. 2011; 93 B(11):1465-1470).</p> <p>With regards to the other interventions you mention this guideline also recommends early mobilisation and regional anaesthesia.</p> <p>Mechanical methods are considered on individual basis and the most cost effective for this population (AES) have been recommended when pharmacological prophylaxis is contra-indicated.</p>
British Hip Society	Full Vol 2	65	2 onwards	<p>The PEP study (Lancet 200) has not been reconsidered (reference 248). It contains data on both hip fractures and hip replacement. The study was considered valid enough for inclusion by the American College of Chest Physicians (ACCP), the Australian Orthopaedic Association (AOA) and American Academy of Orthopaedic Surgery (AAOS). The trial is generally only criticised by those who are fundamentally opposed to the inclusion of aspirin as an agent in combination with other regimes, and should be included.</p>	<p>Thank you for your comment.</p> <p>The committee and orthopaedic subgroup considered the issue of aspirin with an open mind and were quite willing to recommend which ever intervention or interventions were considered the most cost-effective. All NICE guideline reviews are approached using systematic methods using predefined protocols, rigorous quality assessment.</p> <p>The PEP study was included in the the review for lower limb fragility fractures and was</p>

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					<p>presented to the committee and orthopaedic subgroup. However, the evidence from this did not contribute to the recommendations for the total hip and total knee replacement populations for the following reasons:</p> <p>Data for elective hip and knee replacement were analysed together in this study whereas the reviews in the guideline required them to be analysed separately. Consequently this analysis was excluded. It is also noted that this study shows no benefit of aspirin over placebo.</p> <p>For hip fracture the committee noted that the PEP trial allowed centres to include other prophylaxis. The data reported include just over 50% of patients with either LMWH or UFH, and around 30% using AES. It is not reported how many of these patients received both heparin and AES, or who had aspirin alone or no prophylaxis at all. The study also reported a post- hoc analysis for the combined outcome of pulmonary embolism and symptomatic DVT. This showed that a reduction in symptomatic VTE events using</p>

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					aspirin (plus or minus AES) without the use of heparin and a reduction of symptomatic VTE events with AES (plus or minus the use of heparin). The outcomes of major bleeding or clinically relevant non-major bleeding were not adequately reported in the study and were therefore excluded from the current review. Overall, it was decided that the trial could be included on the basis of providing effectiveness information for the VTE outcomes for aspirin when combined with other prophylaxis, but not for aspirin alone, and that its effect on bleeding was still unknown.
British Hip Society	Full Vol 2	124 150	General	Many hip surgeons carry out both hip and knee replacement, and consider that the VTE risk for both procedures (in the context of contemporary surgery and multi-modal prophylaxis) is both similar and low. A unified policy for both procedures would run less risk of confusion, and that which is proposed for knee replacements is the clear preferred option.	Thank you for your comment. Based on observational studies that analysed the National Joint Registry data, THR and TKR populations have different baseline VTE risk. This also reflected the views in the guideline committee. Hence, the two populations were considered separately in this guideline. The recommended options have been decided based on the clinical and cost effectiveness analysis specific for each of these populations.
British Hip Society	Full Vol 2	131 140	6, & 7	It is totally misleading and worryingly unscientific to say that aspirin is the least favourable (cost effective) option. There is a huge overlap of the	Thank you for your comment. The sentence clearly reflects this uncertainty and states that this lack of cost effectiveness relates to the

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				<p>confidence intervals - as there is so little data on which to base the analysis. It would be far preferable to say the analysis revealed no statistical difference.</p>	<p>point estimate. It then goes on to qualify this, highlighting the uncertainty around these point estimates.</p> <p>In addition to this uncertainty aspirin came out worse than no prophylaxis. Therefore the committee did not believe there is evidence to recommend aspirin alone and have made a research recommendation.</p> <p>The committee also noted an observational study based on NJR patients showing a reduced mortality rate with LMWH compared to aspirin when data were propensity score matched. While this result could be due to residual confounding it still does not suggest equivalence and makes it difficult to recommend aspirin alone given that is could lead to more deaths for what is an elective procedure. The GC therefore believes that RCT evidence was needed to test the effectiveness of aspirin alone and have made a research recommendation (Jameson SS, Charman SC, Gregg PJ, Reed MR, Van Der Meulen JH. The effect of aspirin and low-molecular-weight heparin on venous thromboembolism after hip replacement: A</p>

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					non-randomised comparison from information in the National Joint Registry. Journal of Bone and Joint Surgery - Series B. 2011; 93 B(11):1465-1470).
British Hip Society	Full Vol 2	150	General	There is a major cost implication in choosing 10 or 28 days of LMWH over aspirin alone. For 10 days of LMWH the extra cost of the drug alone would amount to around £30,000 for a large hip unit, and around £3 million <u>per annum</u> for the whole of England and Wales.	Thank you for your comment. We agree that including LMWH, either for 10 or 28 days, is much more costly than aspirin alone.. However, they are also more effective and overall more cost effective compared to aspirin alone. The committee also noted that this strategy is cheaper than current recommended practice of combined mechanical and pharmacological prophylaxis for 28 days.
British Orthopaedic Association	Full Vol 1	21	32	The guideline suggests offering VTE prophylaxis to people undergoing elective hip replacement surgery and to choose any one of: <ol style="list-style-type: none"> 1. Low Molecular Weight Heparin (LMWH) for 28 days with Anti Embolism Stockings (AES) until discharge; 2. LMWH for 10 days followed by Aspirin for 28 days; 3. Rivaroxaban (duration not specified); or AES until discharge if pharmacological interventions contraindicated. <p>However, This is in contrast to the new</p>	Thank you for your comment. THR and TKR populations have different baseline VTE risk and hence were considered separately in this guideline. The recommended options have been decided based on the clinical and cost effectiveness analysis specific for each of these populations. Aspirin as prophylaxis option is not recommended as it was not found to be clinically or cost effective for THR patients compared to the other options. However, it has been recommended for TKR patients.

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				<p>recommendations for Total Knee Replacement (TKR): "1. Aspirin alone for 14 days; 2. LMWH for 14 days with AES until discharge; 3. Rivaroxaban; or intermittent pneumatic compression if pharmacological prophylaxis contraindicated."</p> <p>Given the paucity of evidence considered, unifying recommendations for TKR and THR would be helpful.</p> <p>The use of Aspirin instead of LMWH or Novel Anticoagulants (NOACs) has been supported in major studies in view of equivalent efficacy in minimising VTE risk, while also minimising the risk of bleeding complications. As well as this, the use of Aspirin alone for VTE thromboprophylaxis has been incorporated into the guidelines of a number of international societies including the Association of Chest Physicians of America, American Academy of Orthopaedic Surgeons and American Orthopaedic Association.</p>	<p>We acknowledge that the recommendations made in this guideline are different from those issued by other guideline producing bodies. This is partly because the guideline development methodology and the level of evidence used are different from those used by other organisations.</p> <p>The evidence considered in this NICE guideline is the most up-to-date trial evidence available. We did not include observational studies when assessing the relative efficacy of the interventions. These were included in the American guidelines.</p> <p>Additionally, the committee noted that aspirin doses considered in the evidence used to inform the development of the American guidelines include those > 300mg daily which are not included in our guideline as they are not considered standard doses to use in this population in the UK.</p>
British Orthopaedic Association	Full Vol 1	22	3	Direct oral anticoagulants (DOACs) should be recommended rather than specifically recommending Rivaroxaban as a particular prophylaxis as many hospitals have a specific contract for DOAC's and recommend using one	Thank you for your comment. It is the guideline committee's opinion that the DOACs should not be treated as a class as there are individual differences between the three drugs included in our analysis (rivaroxaban,

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				drug as it reduces cost and error.	apixaban and dabigatran). Recommending rivaroxaban is based on the clinical and cost effectiveness analysis results to optimise patient outcomes. We agree that recommending only one drug will minimise costs and errors. The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its first recommendation. Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered .
British Orthopaedic Association	Full Vol 1	23	3	We believe that the proposal to provide chemical prophylaxis in patients undergoing a knee Arthroscopic procedure under anaesthetic over 60 minutes duration will lead to an unnecessary prescription of chemical prophylaxis in patients undergoing an Anterior Cruciate Ligament Reconstruction (ACLR). We support the use of mechanical means of prophylaxis, such as TED stockings, foot pumps etc.	Thank you for your comment. The recommendation has been changed to specify the duration to be more than 90 minutes, as suggested.

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				<p>We are recommending chemical prophylaxis only in patients who belong to “groups at higher risk for VTE” or following an anaesthetic over 90 minutes.</p> <p>Patients undergoing ACLR are typically of young age, the tourniquet time during surgery is between 40-45 minutes and the anaesthetic 75-80 minutes. They get mobilised soon after surgery and discharged home at the same day.</p> <p>There is no strong scientific evidence that anaesthesia beyond 60 minutes or indeed 90 minutes increases the VTE risk in this group of young patients, however we fear that the 60 minutes rule will unnecessary expose them to a pharmaceutical intake with all the associated medical and budgetary risks.</p>	
British Orthopaedic Association	Full Vol 1	133	17	<p>We strongly agree with the following recommendation: “Balance the person’s risk of VTE against their risk of bleeding when deciding whether to offer thromboprophylaxis to medical patients.”</p>	Thank you for your comment.
British Orthopaedic Association	Full Vol 1&2	General 65	General	<p>The BOA broadly welcomes the approach of renewing the draft NICE Guideline - Venous thromboembolism in over 16s. However, Only a small proportion of the data cited in relation to hips</p>	Thank you for your comment. We agree that most of evidence considered for the THR population came from RCTs conducted more than 5 years ago. The use of RCTs conducted

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				<p>and total hip replacement (THR) is from the last 5 years. Although there are much older studies cited, we are concerned they will not have direct relevance to contemporary THR practice. The lack of recent RCTs and absence of any (RCTs) that use current methods and patients means that using observational data/studies and registry data including the National Joint Registry, which is almost the only source of evidence based on contemporary practice, is important. This does not appear to have been considered.</p>	<p>more than 5 years ago was extensively discussed with the orthopaedic subgroup and the main guideline committee. It was agreed that as we are using these RCTs to assess the relative efficacy of the interventions; the fact that they do not reflect contemporary practice in terms of other adjunctive and concomitant treatments would not be a reason to exclude older trials as randomisation should largely address this issue. If, however, the baseline risk of VTE is different in these old trials then randomisation may not completely address the issue as the effectiveness of an intervention may be affected by the baseline risk. It is not possible to know whether this is the case in this instance or not. Limiting inclusion to the most recent 5 years would mean that only two trials will be included.</p> <p>The committee discussed the use of observational studies to estimate the relative treatment effects; however, the consensus agreement was that these studies suffer from residual confounding and will result in biased estimates. Problems with inaccurate data linkage with other databases used in these</p>

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					<p>studies such as HES and ONS data were also a source of concern. Additionally, the committee members were aware of a number of limitations of the NJR including incomplete recording, difficulty in identifying the doses of the VTE prophylaxis options used, and the possible discrepancy between the prescribed prophylaxis as reported in the NJR and what the patient actually received.</p> <p>However, when calculating the absolute risk of events for the baseline treatment we used the National Joint Registry data for 2015 to reflect current practice. We have described in detail how we used NJR data as a source of baseline risk in the economic analysis in appendix P, Section P 1.3.3 pages 635-637. This is in line with NICE reference case for economic analyses which stipulates that a large cohort study that accurately reflects the characteristics of the target population should be used as the source of data when it comes to calculating baseline risk of events.</p>
British Orthopaedic	Full Vol 2	General	General	Despite reference to a number of risk stratification mechanisms, there is no validated risk stratification	Thank you for your comment. The guideline committee has noted that there is limited

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Association				score. Development of a validated score would be welcomed so that patients can be properly advised.	evidence for a clinically effective risk assessment tool and agrees with the view that further research is required. This has been emphasised with the inclusion of a research recommendation for risk assessment of VTE.
British Orthopaedic Association	Full Vol 2	General	General	There is no specific consideration of hip arthroscopy procedures within the guideline.	Thank you for your comment. These populations were not highlighted during scoping of the guideline and were not prioritised for inclusion by stakeholders. As a result, they were not included in this update of the CG92 guideline. The committee appreciate that this is an important area. These patients should be risk assessed as all surgical patients do, clinicians will need to decide whether prophylaxis is required.
British Orthopaedic Association	Full Vol 2	General	General	There is an opportunity to provide guidance on how to manage patients that are already on warfarin, direct oral anticoagulants or aspirin, and to also provide guidance on how to manage patients at high risk, those patients who have previously had a DVT/PE or have a strong family history, where normal prophylactic methods are known to be inadequate.	Thank you for your comment. Please refer to the recommendations for people using anti-platelets and anticoagulation therapy. In regards to patients who have individual/family history of DVT/PE, clinicians should take these risk factors into consideration, balancing the risk of VTE and the risk of bleeding.
British	Full Vol 2	General	General	There should be a particular section focussed on	Thank you for your comment.

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Orthopaedic Association				those patients who have previously had a DVT/PE or have a strong family history as they are likely to have justifiable concerns which should be taken into account when deciding prophylaxis despite the poor sensitivity of scoring systems. There should be specific guidelines regarding patients on anti-platelet medication prior to elective THR/TKR.	<p>As highlighted in the scope of the guideline, there is a focus on primary VTE prophylaxis. However, the guideline committee acknowledges that these factors are important and believe that they should be taken into consideration throughout the guideline.</p> <p>Although there is not specific guidance for patients on ant-platelet medication prior to elective total hip replacement surgery and elective total knee replacement surgery, there is a recommendation for all people using anti-platelets underpinned by an evidence review.</p>
British Thoracic Society	Short	General	General	<p>We note that on 48 separate occasions , the reader is told to assess or balance risks of VTE against risk of bleeding. However clear guidance is needed on how – for example a reference to an assessment tool, and indication that this is not immediately obvious and may need advice from senior individuals: There are 48 entries stating “assess” or “balance” risk of bleeding and VTS risk, but only one entry on page 35 that refers to what this means ““The potential impact of giving unnecessary prophylaxis is that people may be at increased risk of bleeding and discomfort through repeated</p>	<p>Thank you for your comment.</p> <p>The committee did look to provide clearer guidance for this but found no evidence to show how the risk of VTE is balanced against the risk of bleeding. They discussed their concerns with balancing the need for prophylaxis with the consequences of giving unnecessary prophylaxis. More detail is provided in the section on ‘Recommendations and link to evidence’ of the full version volume 1 section 5.8. Even the risk tools which provide some quantification of risk for VTE</p>

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				<p>injections”</p> <p>a) It is not until page 35 of the 42 page document that there is a section on “What is the accuracy of individual risk assessment tools in predicting the risk of VTE and risk of bleeding in people admitted to hospital? Even then, this is just followed by a vague statement “The potential impact of giving unnecessary prophylaxis is that people may be at increased risk of bleeding and discomfort through repeated injections.” This is suitable for Yr 8 science teaching and needs much more detail.</p> <p>b) We have evidence that in one bleeding condition, where patients are at high risk of VTE (Livesey et al Thorax 2012, PMID 22169361), thromboprophylaxis is often withheld (Devlin et al New Engl J Med, PMID: 23445111).</p>	<p>and bleeding do not give a method of weighing up the results to state whether VTE risk is outweighed by bleeding. The committee are of the opinion that have left this for the clinicians to decide whether an individual is more at risk of VTE or bleeding.</p> <p>The committee also noted that the recommendations are similar in what is stated to what was in the previous version of the guideline.</p> <p>Following consultation we have amended our risk assessment recommendation to note that the Department of Health’s national VTE risk assessment tool is the most commonly used and have provided a copy of this in both the full and short version of the guideline. .</p>
British Thoracic Society	Short	23, 28	General	Related, and potentially contradictory statements (for actual clinical practice) are 5 pages apart:	<p>Thank you for your comment.</p> <p>We have deleted recommendation 1.3.78.</p>

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				<p>P 23: 1.3.78 Be aware that cerebrospinal fluid drains and intracranial pressure 7 monitors may increase the risk of intracranial bleeding. [2018] 1.3.79 Do not offer pharmacological VTE prophylaxis to people with ruptured 9 cranial vascular malformations (for example, brain aneurysms) or people 10 with intracranial haemorrhage (spontaneous or traumatic) until the lesion 11 has been secured or the condition has stabilised. [2018]</p> <p>P28: 1.3.99 Consider pharmacological VTE prophylaxis with LMWH49 for a minimum 3 of 7 days for people who are undergoing open vascular surgery or major 4 endovascular procedures, including endovascular aneurysm repair whose 5 risk of VTE outweighs their risk of bleeding. [2018]</p>	
Chelsea and Westminster NHS Foundation Trust	Full	General	General	<p>'Venous thromboembolism in over 16s' Age definition for this guideline is a concern. There is limited evidence for VTE risk in those aged between 16-17 years old. VTE risk assessment in this age group seems an additional and unnecessary step when there is minimal VTE risk, and would encourage overuse of thromboprophylaxis increasing cost and resource burden.</p>	<p>Thank you for your comment. The committee are of the opinion that some people aged 16-18 are at risk of VTE, for example girls in this age group may be taking a contraceptive pill. The current age range was in the scope and the committee reiterated that all patients should be offered the same prophylaxis if considered at risk of VTE. Risk assessment would determine if an individual requires</p>

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					prophylaxis. If shown to be at increased risk then prophylaxis should be offered according to their condition.
Chelsea and Westminster NHS Foundation Trust	Full	General	General	It would be useful if the guideline clarified guidance for and defined 'patients' as 'inpatients, outpatients and day cases' as appropriate.	Thank you for your comment. We have added a definition for admission that addresses this. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
Chelsea and Westminster NHS Foundation Trust	Short	General	General	Many of the recommendations advise a minimum of 7 days of pharmacological thromboprophylaxis. There is limited evidence to support this duration of thromboprophylaxis, particularly post-discharge which will have financial and resource implications. Consider 'Offer pharmacological thromboprophylaxis during admission'	Thank you for your comment. The guideline committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80).

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Chelsea and Westminster NHS Foundation Trust	Short	General	General	Mechanical thromboprophylaxis - when stated in the guidance would be useful to add 'Offer mechanical VTE prophylaxis, unless contraindicated, ...'. Important to add 'unless contraindicated' as may be offered without clinical assessment and review of any contraindications to prevent harm from use.	Thank you for your comment. The committee agrees that clinical assessment is needed to identify any contraindications, but felt that this does not need to be explicitly mentioned within the recommendations. It is generally assumed that all recommendations apply to patients unless contraindicated. We have general recommendations where we refer to when mechanical prophylaxis is contraindicated.
Chelsea and Westminster NHS Foundation Trust	Short	General	General	Mechanical thromboprophylaxis – would be helpful to specify types of mechanical forms in the guidance e.g. anti-embolism stockings or intermittent pneumatic compression with place in therapy e.g. 1 st line, 2 nd line	Thank you for your comment. General information about the types of mechanical VTE prophylaxis has been provided (please see the full guideline volume 1; pages 172-173). The committee felt that in the absence of evidence to indicate that one mechanical intervention is better than another, the type of mechanical prophylaxis that should be used, should not be specified.
Chelsea and Westminster NHS Foundation Trust	Short	General	General	Consider changing 'VTE prophylaxis' to 'thromboprophylaxis'	Thank you for your comment, The committee discussed your comment and did not think it was necessary to change the wording.
Chelsea and Westminster NHS	Short	15-16	16 - 18	<i>Recommendation 1.3.47</i> Differences between the recommendation for	Thank you for your comment. The guideline committee felt that continuing mechanical prophylaxis until the woman no longer has

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Foundation Trust				mechanical prophylaxis between NICE and RCOG in relation to mobility status. Clarification required.	<p>significantly reduced mobility relative to her normal or anticipated mobility or until discharge from hospital was appropriate. The committee noted that RCOG provide limited details about mobility status. It states the use of properly applied anti-embolism stockings (AES) of appropriate size and providing graduated compression with a calf pressure of 14–15 mmHg in pregnancy and the puerperium for women who are hospitalised and have a contraindication to LMWH. These include women who are hospitalised post-caesarean section (combined with LMWH) and considered to be at particularly high risk of VTE (e.g. previous VTE, more than four risk factors antenatally or more than two risk factors postnatally) and women travelling long distance for more than 4 hours, uses the same words for postpartum.</p> <p>Whilst RCOG recommended the use of anti-embolism stockings, the committee felt that after evaluating evidence in other populations for mechanical prophylaxis, an extrapolation would be appropriate. Intermittent pneumatic compression (IPC) in combination with LMWH is more clinically effective than ant-embolism</p>

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					stockings in combination with LMWH.
Chelsea and Westminster NHS Foundation Trust	Short	4	9, 10	<p><i>Recommendations 1.1.3/1.1.8</i></p> <p>A national VTE risk assessment tool (developed by the Department of Health) exists, with the following advantages:</p> <ul style="list-style-type: none"> • consistent risk stratification amongst healthcare organisations in England • standardisation of risk categories and risk factors, which is helpful for medical staff particularly when rotating through various healthcare organisations to improve accuracy of completion, offering thromboprophylaxis to appropriate patients at risk, with accurate identification of patients for root cause analysis of hospital associated VTE events • patients may be risk assessed differently if organisations develop local tools/checklist, leading to varying thromboprophylaxis being given and classification of risks • Avoid locally developed tools that may omit certain risk factors leading to inaccurate completion of risk assessments <p>Consider changing 'published tool or checklist' to 'National VTE risk assessment tool'.</p>	<p>Thank you for your comment. We have amended our recommendations to state:</p> <p>“Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)”</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better.</p>

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					Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.
Chelsea and Westminster NHS Foundation Trust	Short	4	13	<p><i>Recommendations 1.1.5/1.1.10</i></p> <p>Concern with specifying a timeframe (within 14 hours) on when thromboprophylaxis should be prescribed – this is not practical and will depend on other factors e.g. presenting complaint, blood test results etc.</p> <p>Consider changing to ‘If using pharmacological VTE prophylaxis to treat medical patients, start it after the risk assessment...’</p>	Thank you for your comment. We have amended our recommendation to state “.....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations”.
Chelsea and Westminster NHS Foundation Trust	Short	5	13	<p><i>Recommendation 1.1.13</i></p> <p>Consider specifying VTE risk assessment recommended by the Royal College of Obstetricians and Gynaecologists (RCOG) for pregnancy-related thrombosis and bleeding risk factors and remove ‘published tool or checklist’ for standardisation, consistency and accuracy.</p>	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.

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Chelsea and Westminster NHS Foundation Trust	Short	5	26	<p>Reassessment of VTE risk assessment 'within 6 hours' is not recommended by the RCOG It would be useful if the national bodies (NICE and RCOG) covered the same recommendations for consistency and transparency.</p> <p>Reassessment 'within 6 hours' may not be practical or feasible following birth, miscarriage or termination of pregnancy due to management of acute events.</p>	Thank you for your comment. The guideline committee noted that there is a lack of evidence for reassessment within 6 hours but felt that following expert opinion, recommending reassessment within 6 hours of giving birth, having a miscarriage or having a termination of pregnancy or when clinical condition changes is practical.
Chelsea and Westminster NHS Foundation Trust	Short	10	22 - 29	<p><i>Recommendations 1.3.19/1.3.20/1.3.21</i></p> <p>Consider changing 'VTE prophylaxis' to 'mechanical thromboprophylaxis' for clarification and differentiation to pharmacological thromboprophylaxis.</p>	Thank you for your comment, The wording is as such to maintain consistency throughout the guideline. The committee did not think it was necessary to change the wording.
Chelsea and Westminster NHS Foundation Trust	Short	10	27 - 28	<p><i>Recommendation 1.3.21</i></p> <p>Intermittent pneumatic compression (IPC) – may not be indicated or tolerated in people who are immobile and admitted with acute stroke. Consider changing to 'Consider intermittent pneumatic compression as mechanical VTE prophylaxis for people who are immobile and admitted with acute stroke if indicated and tolerated as appropriate'.</p>	Thank you for your comment. Recommendation 1.4.4 (previously numbered 1.3.21) is a 'consider' recommendation, clinicians are able to decide that it is not appropriate for IPC devices to be used in specific clinical scenarios. This would be acceptable; the committee felt that it was not necessary to explicitly state this within the recommendation.
Chelsea and Westminster NHS Foundation Trust	Short	10	29	<p><i>Recommendation 1.3.21</i></p>	Thank you for your comment. The committee

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Westminster NHS Foundation Trust				'If using, start it within 3 days of admission' consider changing to 'If using, start it as soon as possible after admission'. The initial days into admission may be a high risk period and mechanical thromboprophylaxis can be delayed.	discussed your comment and felt that starting IPC within 3 days of admission is appropriate as it may be difficult to judge which survival cohort the patient is in during the very early hours of a stroke, so this is a balanced recommendation. Different clinical scenarios would require different initiation times and the committee are of the opinion that this is best judged by the clinician assessing the individual.
Chelsea and Westminster NHS Foundation Trust	Short	11	End note - 2	LMWH does not have a UK marketing authorisation for use in young people under 18 for this indication – this will complicate processes if VTE risk assessment is performance for 'over 16s' with thromboprophylaxis management	Thank you for your comment. The committee acknowledges that there is not a UK marketing authorisation for use in young people under 18 for this indication, clinicians should consider appropriate alternatives for VTE prophylaxis for over 16s. The committee were clear that some young people will be at risk and therefore should be considered for prophylaxis.
Chelsea and Westminster NHS Foundation Trust	Short	11	11	<i>Recommendation 1.3.24</i> Concern with offering VTE prophylaxis 'for a minimum of 7 days to acutely ill medical patients' who may not be in hospital for 7 days. Limited evidence to suggest extended thromboprophylaxis	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the evidence available and clinical experience of the guideline committee. Cost

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				will be of benefit in ambulant patients following short hospital admission, which will have implications to the discharge process, additional financial and resource impact. This will increase the risk of bleeding particularly in certain patient populations e.g. elderly.	effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
Chelsea and Westminster NHS Foundation Trust	Short	12	12	<i>Recommendation 1.3.28</i> Dosing guidance for aspirin would be useful. Not included in the full guidance.	Thank you for your comment. The dose in the included trials was 100 mg once daily. However, along with other recommendations throughout the guideline we have not specified a dose in our recommendations.
Chelsea and Westminster NHS Foundation Trust	Short	12	15	<i>Recommendation 1.3.29</i> Consider other high risk cancer groups e.g. lung or pancreatic cancer for pharmacological VTE prophylaxis receiving chemotherapy based on evidence	Thank you for your comment. Evidence was only identified for pancreatic cancer. The guideline committee did not feel it would be appropriate to extrapolate to other cancer populations in the absence of evidence to assess the clinical and cost effectiveness of prophylaxis in these populations.
Chelsea and Westminster NHS Foundation Trust	Short	13	2	<i>Recommendation 1.3.31</i> There is limited evidence to suggest pharmacological thromboprophylaxis for people with central venous catheters who are having chemotherapy for cancer. This will have financial implications, increase resource burden and increase bleeding risks.	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed.
Chelsea and Westminster NHS Foundation Trust	Short	14	12	<i>Recommendation 1.3.39</i>	Thank you for your comment. The committee

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Westminster NHS Foundation Trust				Reassessing VTE and bleeding risk daily in critical care units will be challenging to implement in clinical practice, and dependent on the current situation. Consider changing to 'Reassess VTE and bleeding risk regularly/whenever clinical situation changes for people in critical care units'	discussed your suggestion and felt that this is a population that requires careful monitoring for other changes as well as for reassessment of prophylaxis need. Hence, it is unlikely that the recommendation will lead to a significant change in practice.
Chelsea and Westminster NHS Foundation Trust	Short	15	4	<i>Recommendation 1.3.44</i> Concern with specifying a timeframe (within 14 hours) on when thromboprophylaxis should be prescribed for pregnant women following risk assessment – this is not practical and will depend on other factors e.g. presenting complaint, blood test results etc. A specific timeframe is not specified by RCOG guidance on when thromboprophylaxis should be initiated. Consider changing to 'If using LMWH in pregnant women, start following completed risk assessment and continue until the woman is no longer at increased risk of VTE or until discharge...'	Thank you for your comment. The guideline committee felt that a timeframe is useful, as it provides an auditable goal which is safe, sensible and achievable. As highlighted in the 'recommendations and link to evidence' section, in the full volume 1, chapter 21, pages 331-336, "The committee recommend a time point that is in line with current NHS policy on time to consultant review of acute inpatients. This standard states that all emergency admissions must be seen and have a thorough clinical assessment by a suitable consultant as soon as possible but at the latest within 14 hours from the time of admission to hospital. The committee agreed that recommending a similar timeframe within which pharmacological prophylaxis should be given (if indicated by risk assessment) makes logical clinical sense and will ensure clinical care is not delayed". We have amended the

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					recommendation to read "If using LMWH in pregnant women, start it as soon as possible and within 14 hours of the risk 4 assessment being completed"
Chelsea and Westminster NHS Foundation Trust	Short	15	9	<i>Recommendation 1.3.45</i> Remove '6-8 hours' and consider changing to 'next medication round' so LMWH is offered at a practical time.	Thank you for your comment. This recommendation (now number 1.6.5) has been amended . The lower value in the range has been lowered to 4 hours instead of 6 hours. The guideline committee appreciate that there is limited evidence for initiation of LMWH and recommended the timeframe based on consensus expert opinion.
Chelsea and Westminster NHS Foundation Trust	Short	15	10	<i>Recommendation 1.3.45</i> Not all women will require LMWH for a minimum of 7 days and will be dependent on VTE score, assessed using RCOG VTE risk assessment criteria. RCOG (April 2015) guidance now advice a minimum of 10 day LMWH dependent on VTE score. Please review to ensure transparency and consistency between national bodies.	Thank you for your comment. The guideline committee agree that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to

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					reduce risk of VTE.
Chelsea and Westminster NHS Foundation Trust	Short	16	3	<i>Recommendation 1.3.47</i> Differences between the type of mechanical prophylaxis between NICE and RCOG. Clarification required. RCOG advise anti-embolism stockings as first-line and NICE recommend intermittent pneumatic compression as first-line.	Thank you for your comment. There was limited relevant evidence available for pregnancy, evidence from abdominal surgery was extrapolated to this population (please refer to full volume 1 of the guideline, pages 325-330). This evidence presented intermittent pneumatic compression (IPC) in combination with LMWH as more clinically effective than anti-embolism stockings in combination with LMWH. As a result, the guideline committee concluded that it is appropriate to recommend IPC over anti-embolism stockings.
Chelsea and Westminster NHS Foundation Trust	Short	16	11	<i>Recommendation 1.3.48</i> Limited (or no) evidence is available on the incidence of VTE in people with psychiatric illness, thus query to why a VTE risk assessment is being recommended – further research is required in this patient. This will have a resource burden, increase costs and will increase bleeding risk in this group.	Thank you for your comment. A research recommendation has been made to address this paucity of evidence and assess the burden of VTE associated disease in psychiatric inpatients. However, the guideline committee was of the opinion that as some patients are at risk of developing VTE, these patients should still be assessed and offered prophylaxis. It is the committee's view that the incremental cost of prophylaxis in this population is likely to be offset by the cost saving achieved from the

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					averted VTE events.
Chelsea and Westminster NHS Foundation Trust	Short	17	22	<p><i>Recommendation 1.3.56</i></p> <p>Consider adding a VTE risk assessment to patients in lower limb immobilisation to guide on thromboprophylaxis management Definition for lower limb immobilisation will be helpful to clinicians e.g. plaster casts, braces, splints, walking boots Consider changing to 'Consider pharmacological VTE prophylaxis in patients at increased risk of VTE with LMWH or fondaparinux for people with lower limb immobilisation'</p>	<p>Thank you for your comment. There is general VTE risk assessment recommendations for all patients (please refer to recommendations 1.1.1-1.1.8). The lower limb immobilisation recommendation highlights the need to balance the risk of VTE and risk of bleeding, thus a VTE risk assessment and the consideration of VTE prophylaxis. It has been acknowledged that the risk of VTE in this heterogeneous population is generally low. The recommendation indicates that if patients have been identified as low risk of VTE after risk assessment, prophylaxis may not be necessary, vice versa with high risk patients.</p> <p>A definition for lower limb immobilisation can be found in volume 2 of the glossary of the full version of the guideline.</p>
Chelsea and Westminster NHS Foundation Trust	Short	18	12	<p><i>Recommendation 1.3.59</i></p> <p>Consider inclusion of both types of mechanical thromboprophylaxis; anti-embolism stockings or intermittent pneumatic compression (IPC) for people with fragility fractures of the pelvis, hip or proximal femur IPC will be a cost and resource burden, and would</p>	<p>Thank you for your comment. After evaluating the evidence for mechanical prophylaxis in this population, the guideline committee concluded that IPCD should be recommended due to its clinical effectiveness. Little evidence was identified for anti-embolism stockings. Expert opinion has also presented concerns about the harms associated with the use of</p>

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				need to be widely available via the NHS procurement supply.	anti-embolism stockings in terms of skin breaks as patient's skin may be fragile.
Chelsea and Westminster NHS Foundation Trust	Short	19	4 - 7	<i>Recommendation 1.3.60</i> Mechanical thromboprophylaxis to be added to each pharmacological thromboprophylaxis regimen (LMWH and aspirin, and DOAC options) for clarity Mechanical thromboprophylaxis is included in line 5 but not lines 4 or 7 It will add confusion on mechanical thromboprophylaxis is indicated if not offered to all patients, when evidence supports use in reduced VTE risk	Thank you for your comment. The interventions recommended were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, it is not possible to recommend any of these combinations. Minimising errors should be addressed through implementing adequate measures to ensure patient safety
Chelsea and Westminster NHS Foundation Trust	Short	19	4 - 5	<i>Recommendation 1.3.60</i> Consistent duration of thromboprophylaxis courses for various regimens would be helpful to ensure patients receive appropriate duration of therapy following surgery	Thank you for your comment. The recommended duration of prophylaxis is based on the trial evidence and the interventions' licensed durations (where applicable).
Chelsea and Westminster NHS Foundation Trust	Short	19	1	Consider removing 'elective' and keep as 'Hip replacement' This will provide clear thromboprophylaxis guidance for patients undergoing hip replacement surgery e.g. hip fracture surgery repaired via hip replacement surgery and to consider both elective and non-elective cases	Thank you for your comment. The population covered by these reviews does not include non-elective hip or knee replacement. The hip fracture population was considered in a separate review (see the section covering Fragility fractures of the pelvis, hip and proximal femur)
Chelsea and Westminster NHS Foundation Trust	Short	19	4	<i>Recommendation 1.3.60</i>	Thank you for your comment. We

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Westminster NHS Foundation Trust				<p>Recommendations to VTE prophylaxis are different to the recommendations from the American College of Chest Physicians and the American Academy of Orthopaedic Surgeons advising on aspirin use post-surgery (without the need for LMWH for 10 days). It suggests conflicting advice based on the same available evidence.</p>	<p>acknowledge the differences in the recommendations, however, the guideline development methodology that NICE adopts is different to that used by other organisations.</p> <p>The evidence considered in this NICE guideline is the most up-to-date trial evidence available. We did not include observational studies when assessing the relative efficacy of the interventions because of confounding affecting the interpretation of results. These were included in the American guidelines. Additionally, aspirin doses considered in the evidence used to inform the development of the American guidelines include those > 300mg daily which are not included in our guideline as they are not considered standard doses to use in this population in the UK.</p> <p>The committee also noted a study showing a reduced mortality rate with LMWH compared to aspirin when data were propensity score matched. While this result could be due to residual confounding it still does not suggest equivalence and makes it difficult to recommend aspirin alone given that it could lead to more deaths for what is an elective</p>

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					procedure. The GC therefore believes that RCT evidence was needed to test the effectiveness of aspirin alone and have made a research recommendation (Jameson SS, Charman SC, Gregg PJ, Reed MR, Van Der Meulen JH. The effect of aspirin and low-molecular-weight heparin on venous thromboembolism after hip replacement: A non-randomised comparison from information in the National Joint Registry. Journal of Bone and Joint Surgery - Series B. 2011; 93 B(11):1465-1470).
Chelsea and Westminster NHS Foundation Trust	Short	19	13	<i>Recommendation 1.3.61</i> Include 'intermittent pneumatic compression' as a method of mechanical thromboprophylaxis, particularly if patients have a contraindication/allergy/intolerant to anti-embolism stockings.	Thank you for your comment. The cost effectiveness analysis showed that AES are more cost effective than IPC in this population and hence, only AES are recommended. This does not preclude using IPC for people who have a contraindication/allergy/intolerant to AES, as we did not recommend against IPC use.
Chelsea and Westminster NHS Foundation Trust	Short	19	16	Consider removing 'elective' and keep as 'Knee replacement' This will provide clear thromboprophylaxis guidance for patients undergoing knee replacement surgery and consider both elective and non-elective cases	Thank you for your comment. The population specified for this review was restricted to elective cases.
Chelsea and	Short	19	End	Guidance to see NICE technology appraisal	Thank you for your comment. This will be

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Westminster NHS Foundation Trust			note – 26	guidance for apixaban and dabigatran, however these agents are not recommended for hip and knee replacement surgery – value of this endnote?	reviewed.
Chelsea and Westminster NHS Foundation Trust	Short	19	End note – 30	Guidance to see NICE technology appraisal guidance for apixaban and dabigatran, however these agents are not recommended for hip and knee replacement surgery – value of this endnote?	Thank you for your comment. This has been reviewed.
Chelsea and Westminster NHS Foundation Trust	Short	20	1 - 4	<i>Recommendation 1.3.62</i> Mechanical thromboprophylaxis to be added to each pharmacological thromboprophylaxis regimen (aspirin, and DOAC options) for clarity Mechanical thromboprophylaxis is included in line 2 but not lines 1 or 4 It will add confusion on mechanical thromboprophylaxis is indicated if not offered to all patients, when evidence supports use in reduced VTE risk	Thank you for your comment. The recommended interventions were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, the committee did not wish to recommend combinations that were not supported by evidence.
Chelsea and Westminster NHS Foundation Trust	Short	20	1	<i>Recommendation 1.3.62</i> Guidance required on aspirin dose. Full guidance mention off-label use and 'up to 300mg' but specific guidance on dosing would be helpful to clinicians and to standardise practice in healthcare organisations.	Thank you for your comment. A recommended dose has been added to the recommendation for elective knee replacement surgery.

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Chelsea and Westminster NHS Foundation Trust	Short	20	10	<i>Recommendation 1.3.63</i> Include 'anti-embolism stockings' in addition to 'intermittent pneumatic compression' as a method of mechanical thromboprophylaxis, particularly if patients have a contraindication/allergy/intolerant to a type of mechanical method.	Thank you for your comment. The cost effectiveness analysis showed that IPC was more cost effective than AES in this population. Hence, only IPC is recommended. This does not preclude using AES for people who cannot or refuse to use IPC.
Chelsea and Westminster NHS Foundation Trust	Short	20	18	<i>Recommendation 1.3.65</i> There is no or limited evidence to recommend '14 days' LMWH for people undergoing non-arthroplasty orthopaedic knee surgery – further research is required for VTE incidence in this surgical procedure. This will have financial and resource implications, with increased bleeding risks if implemented when not clinically indicated.	Thank you for your comment. The recommendation is for prophylaxis to be considered in this group based on risk assessment, not to be offered to everyone. This recommendation has been based on extrapolation from the elective total knee replacement surgery.
Chelsea and Westminster NHS Foundation Trust	Short	23	6	<i>Recommendation 1.3.77</i> 'Continue for a minimum of 7 days' – evidence is limited for offering a minimum duration of thromboprophylaxis following cranial surgery. Financial implications, resource burden and increased bleeding risks.	Thank you for your comment. The minimum duration has been specified based on the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the cost of VTE events prevented.
Chelsea and Westminster NHS Foundation	Short	24	8	<i>Recommendation 1.3.84</i> Include 'anti-embolism stockings' in addition to 'intermittent pneumatic compression' as a method of mechanical thromboprophylaxis, particularly if	Thank you for your comment. The committee considered IPCD as the mechanical method of choice given the available clinical and economic evidence to support its clinical and

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Trust				patients have a contraindication/allergy/intolerant to a type of mechanical method.	cost effectiveness. Alternative mechanical prophylaxis methods (for example anti-embolism stockings and foot impulse devices) can be used but only if IPCD is contraindicated.
Chelsea and Westminster NHS Foundation Trust	Short	24	12	<i>Recommendation 1.3.85</i> Consider changing to 'Reassess risk of VTE and bleeding whenever clinical situation changes in people with serious or major trauma'	Thank you for your comment. The recommendation has been changed as suggested.
Chelsea and Westminster NHS Foundation Trust	Short	24	16	<i>Recommendation 1.3.86</i> 'Continue for a minimum of 7 days' – evidence is limited for offering a minimum duration of thromboprophylaxis. Financial implications, resource burden and increased bleeding risks.	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
Chelsea and Westminster NHS Foundation Trust	Short	25	13	<i>Recommendation 1.3.91</i> It would be useful to offer guidance on dosing for pharmacological thromboprophylaxis e.g. dosing based on ideal body weight or actual body weight	Thank you for your comment. No evidence was identified for weight-based dosing of thromboprophylaxis, whether based on ideal or actual body weight and the Committee decided to make a research recommendation.
Chelsea and Westminster	Short	26	2	<i>Recommendation 1.3.93</i>	Thank you for your comment. The recommendation allows for longer duration of

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NHS Foundation Trust				Concern with a minimum of 7 days of pharmacological thromboprophylaxis for people undergoing bariatric surgery, when risks are up to 4 weeks post-surgery, particularly in high risk patients e.g. previous VTE event, contraception use.	prophylaxis to be used, based on risk assessment, as it only specifies a minimum of 7 days. The guideline committee acknowledged that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE.
Chelsea and Westminster NHS Foundation Trust	Short	28	11	<i>Recommendation 1.3.100</i> To remove ‘)’ after ‘anti-embolism stocking’.	Thank you this has been corrected.
Chelsea and Westminster NHS Foundation	Short	29	17 - 19	<i>Recommendation 1.3.107</i> The majority of oral and maxillofacial surgery is performed as day case surgery and under local	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using

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Trust				<p>anaesthetic and limited evidence to suggest a minimum of 7 days of LMWH. This will have financial implications, resource burden and increase bleeding risks.</p> <p>Consider changing to 'Consider pharmacology VTE prophylaxis with LMWH for a minimum of 7 days for high risk patients e.g. previous VTE undergoing oral or maxillofacial surgery whose risk of VTE outweighs their risk of bleeding'</p>	<p>prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.</p>
Chelsea and Westminster NHS Foundation Trust	Short	29	5 - 6	<p><i>Recommendation 1.3.104</i></p> <p>Consider offering thromboprophylaxis to only high risk varicose vein surgery patients e.g. previous VTE. Weak evidence to suggest offering all patients undergoing varicose vein surgery a minimum of 7 days thromboprophylaxis – this will have financial implications, resource burden and increase bleeding risks.</p> <p>Consider changing to 'Consider pharmacology VTE prophylaxis with LMWH for a minimum of 7 days to very high risk varicose surgery patients e.g. previous VTE whose risk of VTE outweighs their risk of bleeding'</p>	<p>Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from</p>

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					preventing VTE events.
Chelsea and Westminster NHS Foundation Trust	Short	30	6 - 8	<p><i>Recommendation 1.3.109</i></p> <p>ENT surgery is performed as day case surgery and under local anaesthetic and limited evidence to suggest a minimum of 7 days of LMWH. This will have financial implications, resource burden and increase bleeding risks.</p> <p>Consider changing to 'Consider pharmacology VTE prophylaxis with LMWH for a minimum of 7 days for high risk patients e.g. previous VTE undergoing ENT surgery whose risk of VTE outweighs their risk of bleeding'</p>	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
Chelsea and Westminster NHS Foundation Trust	Short	33	8	<p>Change '(HAT), covers all VTE that occurs in hospital and for 90 days after hospital admission.' to '...(HAT), covers all VTE events that occur during hospital admission and within 90 days after recent hospital admission.'</p> <p>This will comply with the national definition for hospital associated thrombosis, as outlined in the</p>	Thank you for your comment, the definition for hospital-acquired thrombosis has been amended to "covers all VTE events that occur during hospital admission and within 90 days after hospital admission".

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				NHS Acute Contract.	
Cook Medical	Full vol 1	General		There is no recommendation to refer these patients to a venous evaluation for VTE afterwards – for further treatment /follow up – venous center referral.	Thank you for your comment. This guideline is focused on primary prophylaxis of VTE. For guidance of treatment please refer to CG144.
Cook Medical	Full vol 1	P17	9	There is a recommendation for no compression stockings for patients with severe leg edema – but no recommendation to give them bandages instead to prevent PE	Thank you for your comment. This section was not updated in this guideline; recommendations were carried forward from CG92.
Cook Medical	Full vol 1	15		It appears that the committee members does not include interventional radiologists when it is likely they would be heavily involved in patients treatment.	Thank you for your comment. The need to have a radiologist on the committee was not highlighted during the scoping stage of the guideline. Additionally, this guideline's focus is on primary VTE prophylaxis rather than treatment.
Department of Health	General	General	General	Thank you for the opportunity to comment on the draft for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.

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Firstkind Ltd	Full Vol 1	207-235	All	<p>Lines 207-235 deals with the highly problematic pathway of acute stroke for which Firstkind Ltd would like to make a significant contribution to the consultation process.</p> <p>The pathway of stroke is by far the biggest in terms of where current VTE prophylaxis strategies do not provide cover at all times during the acute phase. Any strategy in the cohort is further complicated due to the uncertainties around bleed risk and the real issues of contraindication and tolerance to the NICE recommended modality of IPC.</p> <p>Firstkind Ltd acknowledge that on page 234 (2nd para) where NICE conclude that “the guideline committee noted that the evidence reported from the studies evaluating mechanical interventions [in stroke] was inconclusive but noted that the more clinically beneficially mechanical intervention is IPCD”.</p> <p>Firstkind Ltd highlight the following extension of the same statement:</p> <p>“The committee acknowledged concerns from stakeholders expressed during previous guideline public consultation that a large proportion of stroke patients, at high risk for VTE and contraindicated for</p>	<p>Thank you for your comment.</p> <p>The committee acknowledges your concern around stroke patients who are unable to use IPC devices. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				<p>pharmacological prophylaxis, may be left without protection. The guideline committee therefore agreed that the recommendation relating to the use of IPCD (from CG92 and the CG92 stroke population addendum) was still applicable.</p> <p>What this paragraph should, but doesn't acknowledge, is that a high proportion of stroke patients who are given IPC because of drug contraindication are either immediately contraindicated to IPC due to issues such peripheral arterial disease or skin damage, or begin IPC therapy and quickly become intolerant of it. Therefore this group may be left with no other protection and without any recommended alternative.</p> <p>Firstkind Ltd ask that the guidance committee reconsider this specific paragraph and make a recommendation regarding what DVT prophylaxis strategy should then be prescribed. Firstkind Ltd position is substantiated both by the CLOTS 3 trial where mean adherence to IPC was just 69% but real world audit data Collected by the NHS. It was for specific circumstances like these that MTG19 was created.</p>	

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Firstkind Ltd	Full Vol 1	207-235	All	<p>In respect to serving the unmet need in the stroke pathway, Firstkind Ltd can now share the key outcomes of an audit conducted at the Royal Stoke Hospital. This audit which began in October 2016 and has so far reported on 561 acute stroke patients of ischemic and haemorrhagic origin.</p> <p>[Data shared in confidence]</p> <p>Firstkind believe that this data demonstrates a role for the geko™ device in stroke but only when drug or IPC is contraindicated, impractical or not tolerated. Firstkind have evaluated the health economics using the same cost consequence model as NICE approved for MTG19. Adjusting the specific risk profile for stroke and assuming (as NICE previous did) at least equivalence with IPC, then this shows that the use of the geko™ device is cost saving.</p> <p>This example further highlights to the guidance committee why the updated CG92 guidance must recommend a VTE prophylaxis strategy in circumstances for patients who would otherwise have no treatment.</p>	<p>Thank you for your comment. The committee appreciates the information provided about the audit conducted at the Royal Stoke Hospital. Though this evidence is very informative, as per the agreed protocol for the stroke population this audit could not be included in the evidence review due to the inappropriate study design.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				<p>There appears to be no basis for the current guidance committee position of “do not use NMES” in stroke and more so if this recommendation refers to the geko™ device.</p> <p>Firstkind asks the guidance to committee to consider this data when addressing question 2.2.7 of the guidance scope.</p>	
Firstkind Ltd	Full Vol 1	207-235	All	<p>In respect to relevant evidence that will assist in the guidance committee deliberations regarding Stroke. Firstkind Ltd cites the following extracted from the NICE stroke addendum, Clinical Guideline Addendum 92.1 published in June 2015: Section 2. VTE risk in stroke reads:</p> <p>“Venous thromboembolism (VTE) is a collective term for deep vein thrombosis (DVT) and pulmonary embolism (PE). It is a common, potentially avoidable cause of hospital mortality. <i>A DVT is a blood clot that forms most commonly in the deep veins of the calf muscles</i> (distal DVT) and, less often, the deep veins of the thigh (proximal DVT). It can sometimes affect arm or other deep veins within the body”.</p> <p>Whilst this may seem a bland and obvious statement to many, Firstkind Ltd believe it to be of particular relevance in circumstance of stroke. In high risk stroke patients who often suffer calf pump paralysis,</p>	<p>Thank you for your comment. The committee notes the published evidence available regarding biological outcomes but are unable to include this evidence within the evidence review for the stroke population as the outcomes were not highlighted as appropriate for identifying clinical effectiveness. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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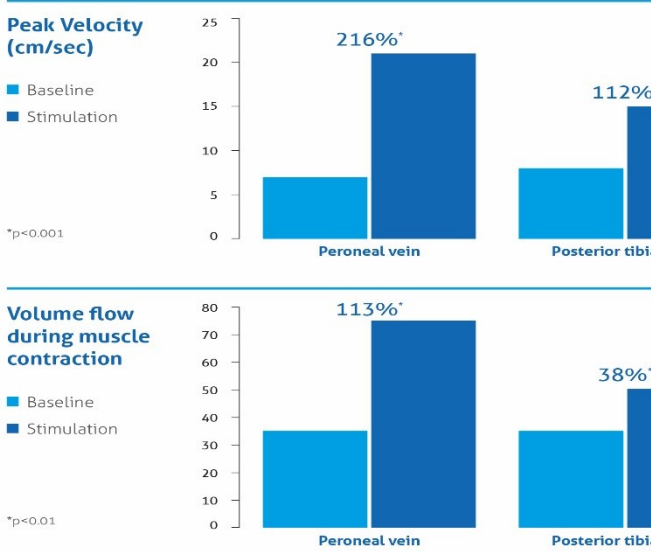
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				<p>the above risk is increased due to the unavoidable venous stasis within the deep veins of the calf.</p> <p>Accordingly, Firstkind Ltd commissioned a study with Professor Andrew Nicolaides in which the effect of the geko™ device upon blood flow velocity within the deep veins of the calf was evaluated. The study showed a statistically significant increase in blood flow velocity within the relevant deep veins that NICE refer to above. See the summary below and <i>A.Nicolaides, M Griffin, Measurement of blood flow in the deep veins of the lower limb using the geko™ neuromuscular electro-stimulation device. Journal of International Angiology August 2016-04.</i></p>	

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				 <p>Firstkind asks the guidance to committee to consider this data when addressing question 2.2.7 of the guidance scope.</p>	
Firstkind Ltd	Full Vol 1	57-60	All	Firstkind Ltd does understand that the preference of the CG92 committee is to see RCT data for any modality within this guidance and build search criteria around this preference.	Thank you for your comment. The committee appreciates your comment on the selection of outcomes within the guideline, particularly for this population. This was not identified as an area of concern during the scoping stage of

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				<p>However, when the geko™ device was reviewed by NICE under the leadership of Professor Bruce Campbell it was accepted that an RCT in a series of populations in not a practical solution. This highly relevant when designing a strategy to deal with a no treatment or unmet need scenario. Instead, the committee made clear reference that in- market data collection such via examples of clinical audits would be a suitable clinical strategy.</p> <p>Furthermore, Firstkind Ltd acknowledge that the guidance committee (page 60 line 6) felt comfort in that “it was appropriate to use DVT as an endpoint alongside PE” when adopting its data search position. However, when considering patients who have no DVT treatment available, the previous NICE committee concluded that the alterative end point of venous stasis prevention is also appropriate.</p> <p>It is clear from the conclusion of the NICE Committee that created NICE guidance MTG19, that that most important end point in this specific patient group is to prevent venous stasis until another modality can be prescribed. As such increasing blood flow, to prevent stasis, is the surrogate marker of most relevance.</p>	<p>the guideline and was thus agreed. The committee encourages comment on the scope of following updates of this guideline; if appropriate it can be addressed in the update.</p>

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				Firstkind asks the guidance to committee to consider this matter in forming any judgement for guidance scope question 2.2.7.	
Firstkind Ltd	Full Vol 1	57 - 60	All	<p>Firstkind Ltd highlight a concern that it believes seriously undermines the evidence search criteria outlined in this section. The search criteria seem to make no provision for searching against previous NICE guidance that may be relevant to this guidance scope.</p> <p>Given the above clinical need, had this search criterion been applied then the data within MTG19 would have been identified and would be meaningful to supporting question 2.2.7. Firstkind Ltd acknowledges that MTG19 is mentioned as a link within section 3.3.3 of this consultation document but there is no indication that the previous NICE recommendations and justifications have been considered in anyway by the guidance committee.</p> <p>Firstkind asks the guidance to committee to consider this matter when addressing question 2.2.7 of the guidance scope.</p>	<p>Thank you for your comment. Relevant studies that reported appropriate outcomes were searched for in the current evidence review.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>
Firstkind Ltd	Full Vol 1	232-235	22	This section discusses DVT prophylaxis in stroke patients.	Thank you for your comment. Relevant studies that reported appropriate outcomes searched for in the current evidence review.

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				<p>Firstkind Ltd acknowledges that the limited search criterion, in respect to Stroke, has created the commentary described in the tables initiated in Line 22. The subsequent debate of the guidance committee resulted in the “do not use NMES” recommendation as stated on the first line of the Stroke recommendation table.</p> <p>This appears to have resulted from a specific discussion described at the bottom of page 233 “Trade-off between clinical benefits and harms”.</p> <p>Further, this section documents that the committee <i>“discussed and stated that the potential risks of skin damage associated with the use of the devices was great enough in this highly immobile population to strongly recommend against their use”</i>.</p> <p>The above summary raises some critical points that must be clarified by the guidance committee.</p> <p>The guidance committee must appreciate that throughout this review “EMS” has been associated with “the geko™ device” and the community respect the geko™ device as a “NMES device”. It would seem reasonable therefore to assume that the guidance committee was attributing its negative</p>	<p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				<p>comments regarding skin damage to the geko™ device.</p> <p>The guidance committee will be aware that the data that Firstkind Ltd submitted to NICE as part of the geko™ review process did not cause the committee to be concerned about patients suffering skin damage as a result of using of the geko™ device. If NICE has sight of evidence indicating a risk of skin damage through use of the geko™ device we request that you share this with us forthwith.</p> <p>In the absence of such evidence any reference to skin damage is fundamentally without basis, in respect of the geko™ device. Furthermore the conclusion drawn in respect of the geko™ device should be reconsidered.</p> <p>In this regard we refer to the NICE Medical Technology Guidance MTG19, published in June 2014 (and updated in June 2016) in which NICE concluded that the geko™ device should be adopted for use in people who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. At paragraph 3.17 of</p>	

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				<p>that guidance it is stated that “<i>the Committee noted no evidence of harm to patients from the geko™ device.</i>” Furthermore the guidance references expert advice that the <i>risk of harm is very low</i>. It is clear therefore that in previous assessments NICE did not consider there to be a risk of skin damage to patients on the evidence before it. In the absence of new evidence supporting the existence of such a risk we are unclear how the statement we reference in the draft CG92 can be found to have basis.</p> <p>We invite NICE to therefore amend and clarify the draft guidance to clearly state that any risk of skin damage is not relevant to the geko™ device; and to make the necessary consequential amendments to the conclusions in the draft document, consultation responses and final versions of CG92. A failure to do so will likely cause significant loss and damage to Firstkind Ltd, the manufacturer and marketer of the geko™ device.</p> <p>A natural consequence of the above clarification and correction should therefore be the removal of the “do not use NMES” specifically related to the stroke recommendation on line 22 of this guidance.</p>	
Firstkind Ltd	Full Vol 1	169	12-26	Firstkind Ltd positively acknowledges the summary	Thank you for your comment. This update

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				<p>on line 13 which says “Venous stasis in the deep leg veins causes a decrease in the mean flow and pulsatility of the venous of the flow trace. Mechanical methods of DVT prophylaxis work to combat venous stasis”</p> <p>Line 26 concludes “...intermittent pneumatic compression devices and foot impulse devices [have been combined] and are treated as equally effective”.</p> <p>Firstkind Ltd take from this that the CG92 guidance committee are therefore fully aligned with their medical technology colleagues who issued the geko™ device guidance MTG19. It would seem that the NICE clinical guidance is effectively confirming that a device with proven anti-stasis attributes would reduce VTE risk more effectively than no treatment. This removes any differences of opinion that may exist between the two guidance groups.</p> <p>Therefore with the above correction in point 3 made to explain EMS and NMES the document will then correctly explain that all these mechanical modalities also “combat stasis”.</p> <p>If this agreed position is aligned to question 2. 2.7 of the guidance scope, then the only question remains</p>	<p>supersedes MTG19 that was published in 2014 as well as the clinical guideline addendum 92.1. No relevant evidence was identified to recommend the geko™ device in this population.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				<p>is how and by what means this effect this should be delivered in patients who have no other form of DVT prophylaxis available to them.</p> <p>Firstkind Ltd ask the guidance committee to consider that many will be surprised that the natural link between this real clinical need and the geko™ device, that is approved by NICE to deliver this required effect, isn't being made.</p>	
Firstkind Ltd	Full Vol 1	169	12-17	<p>This is Section 9 entitled "General VTE prevention for everyone in hospital".</p> <p>Given that the guideline scope suggested that "electrostimulation (including geko™ devices)" would be reviewed in terms of evidence, it would seem to be an error that electrostimulation is not described by the author under the mechanical prophylaxis option section on line 12?</p> <p>This comment is further validated because throughout the document, under the review question in many of the pathways (e.g. section 12.2 line 18 page 191), potential interventions are listed of which "electrostimulation (including geko™ devices)" is cited. However, unlike other mechanical interventions, the reader hasn't been educated as to</p>	<p>Thank you for your comment.</p> <p>This section of the guideline has been carried forward from CG92. The introductory text here is for information only and does not affect the recommendations. The NICE process is not to update any text in these sections so we have not added definitions.</p> <p>A definition for electrostimulation has been added to the glossary.</p>

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				<p>what these modalities actually are and how they deliver the desired effect of reducing venous stasis.</p> <p>Firstkind Ltd asks that this omission be corrected.</p>	
Firstkind Ltd	Full Vol 1	233	General	Furthermore and to the same point as above, NMES is also introduced as an acronym on the bottom of this page (no line number). This is again without explanation and NMES should be explained under this section 9.	Thank you for your comment. NMES is spelled out in full in this section and a definition for NMES has been added into the glossary of the guideline.
Firstkind Ltd	Full Vol 1& 2	General	General	<p>Firstkind Ltd wishes to stress to the guidance committee that it has only ever positioned the geko™ device as a prophylaxis option when current treatments are contraindicated or impractical. It wishes to make clear to the guidance committee that it has never positioned the technology within the NHS as a displacement modality in direct opposition to established chemical and mechanical therapy options. Until Firstkind Ltd have evidence to support an alternative displacement strategy that will be the position of Firstkind ltd.</p> <p>This point is made for the avoidance of doubt that may still reside within the guidance committee. The overriding permission for this marketing position has been provided by NICE themselves. It is NICE who believe that MTG19 was a required piece of guidance and it was NICE who investigated the</p>	<p>Thank you for your comment. The committee considered RCT evidence of effectiveness for all methods of prophylaxis included in the scope. No relevant evidence was identified to recommend the geko™ device in any population. Consequently, it no recommendation has been made regarding it's use.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices. The committee note that MTG19 does not provide any evidence relating to VTE outcomes. The committee also note that the</p>

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				<p>clinical, economical, safety and compliance criteria that underpinned the positive guidance recommendation for the geko™ device.</p> <p>Firstkind have invested significantly to support NICE guidance MTG19. However, CG92 is not integrating this previous NICE guidance that specifically gives an option when patients have no DVT treatment available to them.</p> <p>It is of concern, that NICE's medical technology approval for this specific use of the geko™ device for unmet need is being overlooked by the clinical guidance team. The NICE clinical guidance team appear to have resisted the reality that within the NHS established chemical and mechanical interventions do not provide full prophylactic cover all of the time. Firstkind Ltd believes that this is misplaced and contradicts a number of principles of driving adoption by the NHS of new technology.</p> <p>Firstkind Ltd believe that the guidance committee needs to take this opportunity to ensure that CG92 is a fully integrated document that reflects all relevant NICE guidance so to maximise choice for all stakeholders and patients alike.</p>	<p>external advisory committee that assessed the technology concluded that there is no evidence that Geko devices reduce the risk associated with VTE. Therefore the committee do not believe this guideline contradicts the evidence.</p>

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				The draft as it currently stands is contradictory and incomplete and as highlighted in comment 8 above, this draft document contains unsubstantiated and damaging claims and allegations in respect to the geko™ device.	
Firstkind Ltd	Full Vol 1&2	General	General	<p>On November 17th 2015, Firstkind Ltd attended the guidance scoping meeting for update of CG92. This resulted in NICE issuing a Final Version Guideline Scope. This document was posted by NICE on February 26th 2016 and was updated" on April 26th 2016.</p> <p>In both of these documents, a very pertinent question was asked on Page 6, under Section 2, titled Prophylaxis, and it reads: “Each of the following questions will investigate individual populations separately”.</p> <p>Firstkind Ltd draw the attention of the guidance committee and patient support groups to question 2.7:</p> <p>“What is the most effective prophylaxis strategy for patients in whom both mechanical and pharmacological prophylaxis are contraindicated?”</p>	Thank you for your comment. The review question about contraindication to pharmacological and mechanical prophylaxis was addressed within each population as stratification instead of evaluating this patient group within a separate question (e.g. please refer to the acute stroke clinical review protocol in the appendices A-I document; page 63-67). The committee felt that this was more appropriate.

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				<p>Firstkind Ltd highlight to the guidance committee, patient group representatives and the general public that it appears that this critical question has not been reviewed throughout Volume 1 and Volume 2 of this draft review. There are no recommendations of what to do in the when <i>all</i> the current treatment are contraindicated. This situation is very real; it varies by pathway but is prominent in areas such as Stroke.</p> <p>Firstkind Ltd therefore asks the guidance committee to consider this point.</p>	
Firstkind Ltd	Full Vol 1&2	General	General	<p>Further to the above question within the guideline scope, Firstkind Ltd believes it is important for any new member of the guidance committee to appreciate that the geko™ device, as manufactured by Firstkind Ltd, is a NICE approved medical device for this <i>specific</i> clinical scenario.</p> <p>The device is recommended by NICE guidance MTG19 for use only when current recommended mechanical or pharmacological prophylactic modalities are contraindicated or impractical.</p> <p>There is wide acceptance, which includes experts within NICE, that current prophylactic strategies do not provide full prophylactic cover all of the time.</p>	<p>Thank you for your comment. No relevant evidence was identified to recommend the geko™ device in this population. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				Firstkind asks the guidance committee to consider this reality.	
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	General	General	The current version does not have the sections in a logical order -could the risk assessment and recommendations be sectioned according to the patient group as this will make the document more user-friendly, particularly for individuals not familiar with the document.	Thank you for your comment. Once the guideline has been published online it will be easier to navigate.
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	5 - 6	1.1.12-1.1.14	<i>VTE risk assessment in pregnancy (including women who have given birth/had miscarriage/termination in last 6 weeks):</i> The sentence (1.1.13) is too vague. Although it is acknowledged that the current evidence base for VTE prophylaxis in pregnancy is of a lower grade, the RCOG recommendations are followed by obstetric units throughout the UK. As an exemplar centre, we would recommend that the NICE guidance should reflect RCOG recommendations. In addition, expert opinion from one of the authors of the RCOG guidelines suggests that the RCOG risk assessment should be utilised.	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.
Guy's and St Thomas' Hospitals	Short	4-5	1.1.3 - 1.1.10	<i>Recommendation about VTE risk assessment using published tool:</i>	Thank you for your comment. We have amended our recommendations to state:

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Foundation Trust (GSTFT)				We would recommend using the national VTE risk assessment tool, published by the Department of Health (2010) to perform the VTE risk assessment. This would ensure that there is consistency in the approach to assessing VTE risk assessment, throughout the country. Using different tools may introduce differences in VTE prophylaxis and this may have implications when performing root cause analysis of hospital-acquired VTE.	<p>“Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)”</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
Guy's and St Thomas'	Short	19 - 20	1.2.62-1.3.63	Elective hip replacement:	Thank you for your comment. The cost effectiveness analysis showed that AES are

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Hospitals Foundation Trust (GSTFT)				<p>IPC should also be included as an option for mechanical VTE prophylaxis in this group.</p> <p>It would be worth including rationale for not including the other DOACs as options for VTE prophylaxis as the current guidance will naturally raise questions by clinicians as to why they have been excluded, especially as NICE TAs available for all DOACs in elective hip replacement.</p>	<p>more cost effective than IPC in this population and hence, only AES are recommended. This does not preclude using IPC for people who cannot or refuse to use AES.</p> <p>The economic analysis also showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its main recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. The committee's rationale for recommending rivaroxaban are outlined in the Linking Evidence to Recommendation (LETR) section on page 149-154, Full guideline volume 2.</p> <p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered.</p>
Guy's and St Thomas' Hospitals Foundation	Short	19 - 20	1.2.62-1.3.63	<p><i>Elective knee replacement:</i></p> <p>It is unclear why AES is considered in combination with LMWH but not with aspirin and DOAC.</p>	<p>Thank you for your comment.</p> <p>The interventions recommended were based on the interventions in the included RCT</p>

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Trust (GSTFT)				<p>May cause confusion in areas with mixed thromboprophylaxis options. IPC should also be included as an option for mechanical VTE prophylaxis in this group.</p> <p>It would be worth including rationale for not including the other DOACs as options for VTE prophylaxis as the current guidance will naturally raise questions by clinicians as to why they have been excluded, especially as NICE TAs available for all DOACs in elective hip replacement.</p>	<p>evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, it is not possible to recommend any of these combinations.</p> <p>The cost effectiveness analysis also showed that IPC was more cost effective than AES in this population. Hence, only IPC is recommended. This does not preclude using AES for people who cannot or refuse to use IPC.</p> <p>The economic analysis also showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its first recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors.</p> <p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered .</p>

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Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	4 - 5	1.1.5, 1.1.10	<p><i>Recommendation about starting VTE prophylaxis within 14 hours of VTE risk assessment:</i></p> <p>We are concerned that this recommendation may imply that VTE prophylaxis could be delayed by 14 hours from time of admission. The current statement could be misinterpreted and result in omission of doses of VTE prophylaxis, particularly for patients admitted to one ward and transferred to another ward. It may also have implications on classification of hospital acquired VTE. The sentence should be reworded to reflect that the outcome of the VTE risk assessment needs to be actioned as soon as the VTE risk assessment has taken place.</p>	Thank you for your comment. We have amended our recommendation to state "...start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	10	1.3.22	<p><i>Recommendations for Acute Stroke</i></p> <p>This guidance does not recommend what to do in terms of VTE prophylaxis beyond 30 days, although we acknowledge that this reflects the RCP Stroke Guidelines. We would suggest that VTE risk is reassessed at 30 days to ascertain VTE risk and appropriate VTE prophylaxis is continued, as these patients would then be deemed as medical patients.</p>	Thank you for your comment. In the absence of evidence the committee decided it was best to follow the RCP Stroke Guidelines. The guideline already recommends that an individual's risk of VTE should be reassessed when their condition changes and the committee are of the opinion that this was a better recommendation rather than trying to state every occasion a person needs to be reassessed.
Guy's and St	Short	10	1.3.22	<i>Commencing IPC in acute stroke</i>	Thank you for your comment. The committee

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Thomas' Hospitals Foundation Trust (GSTFT)				Despite recommendation from the CLOTs trial that IPC is commenced within 3 days, we would suggest that IPC is started as soon as possible after admission to protect patients at the highest risk time. This is particularly as IPC companies recommend that there is a theoretical risk of VTE development if IPC is not applied as soon as possible.	discussed your comment and felt that starting IPC within 3 days of admission is appropriate as it may be difficult to judge which survival cohort the patient is in during the very early hours of a stroke, so this is a balanced recommendation. Different clinical scenarios would require different initiation times and the committee are of the opinion that this is best judged by the clinician assessing the individual.
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	11	1.3.24	<i>Offering pharmacological VTE prophylaxis for minimum of 7 days for acutely ill medical patients</i> This recommendation will be a challenging change in practice because of the practical and clinical implications for this group of patients. It would be useful for the 'acutely ill medical patient' to be defined. Recommendations for VTE prophylaxis in patients who have a genuine acute medical condition/additional VTE risk factor co-morbidity but their acute medical illness is managed in a more ambulatory care setting, without overnight stay and associated reduced mobility should be determined particularly as patient's length of stay is getting shorter and there is a drive for management of	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the evidence available and the clinical experience of the guideline committee.

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				<p>complex conditions in an ambulatory care setting. There is a risk that introducing a minimum of 7 days pharmacological VTE prophylaxis may dissuade clinicians from prescribing VTE prophylaxis as they may be guided by the length of stay rather than the patient's VTE risk.</p> <p>This could have implications for the outcome, e.g. number of hospital-acquired VTE. Moreover, there is limited evidence that a minimum of 7 days of pharmacological VTE prophylaxis would reduce the risk of VTE. We would suggest that a statement is included for patients to have VTE prophylaxis continued for a minimum of 7 days or continued until discharge (as stated in the previous NICE guidance).</p>	
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	13	1.3.31	<p><i>Patients with central venous catheters:</i></p> <p>There is limited evidence for patients with CVCs and cancer to receive pharmacological VTE prophylaxis and needs to be balanced with the additional cost burden associated with increased use of pharmacological VTE prophylaxis and potential increased risk of bleeding. The recommendation should relate to patients receiving chemotherapy, not the CVC.</p>	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed.
Guy's and St	Short	14	1.3.41-	<i>Pregnant women and women who gave birth or had</i>	Thank you for your comment.

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Thomas' Hospitals Foundation Trust (GSTFT)			1.3.47	<p><i>miscarriage or termination of pregnancy in past 6 weeks</i></p> <p>1.3.44: needs to take into account the clinical picture, particularly the bleeding risk of the patient who is admitted with labour and then requires caesarean section.</p> <p>1.3.45: Where is the evidence for minimum 7 days duration?</p> <p>1.3.46: this sentence is a double negative and could be misinterpreted. Could it be changed to: offer pharmacological and mechanical VTE prophylaxis in patients who are likely to be immobilised for 3 or more days after surgery, including caesarean section.</p> <p>1.3.46 and 1.3.47 seem to be the same sentence! What is the difference between these two sentences?</p> <p>Medical patients (pregnancy plus acute medical illness) does not seem to be covered in the summary guidance. Statement needs to be included in the guidance to reflect thromboprophylaxis in pregnancy who present with an acute medical illness.</p> <p>1.3.47: no evidence for use of anti-embolic stockings in pregnancy. Guidance should include what clinicians should do if there is continued reduced</p>	<p>In regards to your comment about recommendation 1.3.44 (now recommendation 1.6.4), taking bleeding risk has been highlighted in recommendation 1.3.41 (now 1.6.1). The guideline committee felt that it was not necessary to state this again in recommendation 1.3.44.</p> <p>The guideline committee agree that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE.</p> <p>The guideline committee agree that clarity was needed for the recommendations 1.3.46 and 1.3.47, this has been amended, (please see recommendation 1.6.6)</p>

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				<p>mobility at discharge.</p>	<p>There was limited relevant evidence available for pregnancy, evidence from abdominal surgery was extrapolated to this population (please refer to full volume 1 of the guideline, pages 326-331). This evidence presented intermittent pneumatic compression (IPC) in combination with LMWH as more clinically effective than ant-embolism stockings in combination with LMWH. Recommendation 1.6.6 states that VTE prophylaxis can be continued post-discharge if mobility is “significantly reduced relative to their normal or anticipated mobility” , combination prophylaxis should be considered. The guideline committee appreciate that IPC is not feasible post-discharge, clinicians should consider the use of anti-embolism stockings.</p>
<p>Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)</p>	<p>Short</p>	<p>16</p>	<p>1.3.48-1.3.52</p>	<p><i>People with psychiatric illness:</i></p> <p>With the limited evidence base for rate of VTE in patients with psychiatric illness, it is unclear if there is any benefit in risk assessing this cohort of patients. If NICE recommend routine risk assessment, it would be useful to cross-reference</p>	<p>Thank you for your comment. A research recommendation has been made to address this paucity of evidence and assess the burden of VTE associated disease in psychiatric inpatients.</p> <p>Recommendations for risk assessment are</p>

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				against the Department of Health National VTE risk assessment tool to guide healthcare professionals to utilising the correct VTE risk assessment tool for this cohort of patients.	included in the full guideline, volume 1 chapter 5.
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	20	1.3.64-1.3.66	<i>Non-arthroplasty orthopaedic knee surgery</i> It is unclear from current evidence where the recommendation of the duration of VTE prophylaxis of 14 days came from. There is a risk that this may be associated with an increased risk of bleeding.	Thank you for your comment. The recommendation is for prophylaxis to be considered in this group based on risk assessment, not to be offered to everyone. This recommendation has been based on extrapolation from the elective total knee replacement surgery.
Guy's and St Thomas' Hospitals Foundation Trust (GSTFT)	Short	29	1.3.104-1.3.106	<i>Varicose vein surgery:</i> This recommendation of minimum 7 days duration of VTE prophylaxis could be challenging change in practice because current practice is only to consider VTE prophylaxis in high risk patients and there would be a huge financial and cost implication if used for all patients.	Thank you for your comment. It is the aim of the guideline influence practice in a positive way. The decision as to whether someone fits the criteria for receiving prophylaxis should be based on the outcome of the initial risk assessment undertaken according to the guideline recommendations for risk assessment in surgical and trauma patients. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials

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					extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
King's College Hospital NHS Foundation Trust	Full	General	General	Orthopaedic subcommittee comprised 5 surgeons, 4 of which were orthopaedic surgeons and interpretation of evidence therefore at significant risk of bias.	Thank you for your comment. The orthopaedic subcommittee was selected for their expertise in orthopaedic surgery and ability to be in an advisory role. The guideline committee and subcommittee had the same evidence presented to them. Both were given the opportunity to evaluate and scrutinise the evidence. However, the subcommittee could only make comments and suggestions whilst the guideline committee made recommendations and were in a position to not follow suggestions made by the subcommittee. The guideline committee solely have voting rights in regards to recommendations made.
King's College Hospital NHS Foundation	Full	General	General	There is no new evidence presented or justification for reducing the age for risk assessment and thromboprophylaxis to 16 years (from 18 years). As acknowledged throughout the document, none of the anticoagulants are licenced for this age group. This	Thank you for your comment. The committee are of the opinion that some people aged 16-18 are at risk of VTE, for example girls in this age group may be taking a contraceptive pill. The current age range was in the scope and

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Trust				will have practical implications in that this patient group will require counselling regarding the use of an unlicensed medication (this is difficult to justify given the lack of evidence). Additionally, there will be significant implications in terms of implementation across hospitals, and for data collection of risk assessment rates without evidence of benefit. Strongly recommend this is removed and recommendations apply to adults (18 years and over) as previously.	the committee reiterated that all patients should be offered the same prophylaxis if considered at risk of VTE. Risk assessment would determine if an individual requires prophylaxis. If shown to be at increased risk then prophylaxis should be offered according to their condition.
King's College Hospital NHS Foundation Trust	Full	General	General	There is an inconsistent approach to recommendations in terms of basing on evidence; in some areas evidence is robustly adhered to and in others recommendations are made (with potential far-reaching for patients, carers and organisations) with no evidence base to support the recommendation.	Thank you for your comment. The recommendations are based on evidence where available and extrapolation from other similar populations where it is not available and it is possible to extrapolate. All recommendations were discussed in detail to ensure they were made from the best available evidence.
King's College Hospital NHS Foundation Trust	Full	190	1	Whilst there are no clinical studies comparing weight based thromboprophylaxis dosing with fixed doses focusing on clinical outcomes, as already acknowledged by the guideline committee, there are a number of studies, using anti-Xa activity as an outcome, demonstrating that obese patients require higher doses of LMWH to match exposure observed in normally weighted patients. We understand why the committee is unable to make a specific	Thank you for your comment. The guideline committee appreciate that some centres do use weight-adjusted doses, the wording in the recommendation discussion table will be amended to reflect this (please refer to the full volume 1 of the guideline, pages 330-335). As mentioned, the guideline committee is unfortunately unable to make an explicit recommendation about weight-adjusted doses

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				<p>recommendation on weight based LMWH dosing, given the lack of clinical outcome data, however we are concerned that the current wording in this section of guidance implies that weight based dosing is not appropriate. We feel, this could lead to confusion, particularly as other societies have recommended and continue to recommend weight-based LMWH thromboprophylaxis dosing, e.g. Royal College of Obstetrics and Gynaecologists in the antenatal and postnatal period (we note the comment made on this issue in the pregnancy section of the draft NICE guidance).</p> <p>We thank the guideline committee for making a high priority research recommendation on weight-based LMWH dose-adjustment strategies to overcome the lack of information, and we hope research studies will be executed to address this research question. However, if such studies are commenced, the results are unlikely to be available for a significant number of years, due to the large number of patients which would be required in each arm of such studies, due to the low event rate that is likely to be seen.</p> <p>Therefore, we would like the guideline committee to consider stating, that many centres do increase the LMWH in line with body-weight based on pharmacodynamic data, and that until further clinical</p>	<p>as there is insufficient evidence to do so. The guideline committee highly encourages research into weight-adjusted doses of LMWH as this is a clinical area of increasing importance.</p>

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				outcome data becomes available, such practice is considered reasonable.	
King's College Hospital NHS Foundation Trust	Full Vol 2	394	Para8	<i>Bariatric surgery</i> 'The committee also noted that all people undergoing bariatric surgery would be considered at increased risk of VTE using the risk assessment tool because they are all obese' This is dependent on the risk assessment tool utilised, for tools with weighted risk factors, not all bariatric patients will reach criteria for 'high VTE risk'.	Thank you for your comment. This sentence has been edited to reflect that this is "usually" rather than always the case.
King's College Hospital NHS Foundation Trust	Full Vol 2 Short	417 29	Box 2 5	<i>Study by Wang et al 2015</i> The intervention arms (UFH/LMWH) treatment duration in this study was 3 days, not 30 days as stated. All VTE events are assumed to be asymptomatic (detected on weekly screening) and of note PEs detected in this study were also in asymptomatic patients diagnosed with DVT on screening examinations. These events are unlikely to be clinically significant and are not usually an endpoint of 'modern' thromboprophylaxis studies. They did not report any symptomatic VTE events in this study. Symptomatic VTE likely to be much less common in this population than inferred by results presented. <i>Recommendation 1.3.104</i>	Thank you for your comment. This is an error in the report which we have corrected. The duration of the interventions was in fact 3 days; this has been amended throughout the guideline. The outcomes were measured at 30 days. We included studies that assessed DVT (symptomatic and asymptomatic) as an outcome. We acknowledge that symptomatic VTE is likely to be less common than asymptomatic VTE; however, this does not mean that asymptomatic VTE should not be considered given that it can lead to post thrombotic syndrome in the longer term, as well as the possibility of becoming symptomatic with the potential to lead to pulmonary embolism.

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				<p>There is very low quality evidence to support the need/benefit of thromboprophylaxis following varicose vein surgery. Most of this surgery is performed as day surgery and as the committee acknowledges is not open surgery (as per Wang's study which provides most of the evidence for this patient group). Suggest amend to 'Do not routinely offer pharmacological VTE prophylaxis to people undergoing varicose vein surgery' and add 'Offer pharmacological VTE prophylaxis with LMWH to those with very high VTE risk (eg previous VTE, pregnancy, cancer) and a low risk of bleeding'.</p>	
King's College Hospital NHS Foundation Trust	Short	4 5	11 5	<p><i>Recommendations 1.1.3/1.1.9</i></p> <p>The approach to VTE risk assessment and thromboprophylaxis in England is recognised internationally as innovative and effective (ISTH 2016; Raskob & Spyropoulos, 2017). The use of the NHS National risk assessment tool is recommended as an option by International Society for Thrombosis and Haemostasis. Broadening the approach to VTE risk assessment, as proposed in the draft guidance threatens the significant progress made in the National VTE prevention programme. The evidence to support such a change reviewed by the committee is limited. There will be patients who fall into neither a medical or surgical category (or where their</p>	<p>Thank you for your comment. We have amended our recommendations to state:</p> <p>"Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)"</p> <p>The committee debated risk assessment tools at length. While they noted that the</p>

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				<p>category changes during an admission) and if wrongly applied tool utilised may be left with no thromboprophylaxis. The committee argue that use of the National tool may result in over-prescription of thromboprophylaxis in medical patients but have not identified evidence to support this nor that this practice results in patient harm. Many of the alternate tools result in more than 2 risk categories (ie 'low', 'moderate' or 'high' risk) and do not incorporate assessment of bleeding risk. The subsequent draft guidance makes no recommendation as to how the 'moderate' risk group should be managed. Patients managed across multiple hospitals may experience different approaches to VTE prophylaxis when they are assessed as 'high' risk in one hospital but 'low' risk in another.</p> <p>We strongly recommend that the National tool remain the preferred means of risk assessment but agree this should be a priority area for research.</p>	<p>Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
King's College Hospital NHS Foundation Trust	Short	4 5	13 8	<p><i>Recommendations 1.1.5/1.1.10</i></p> <p>There is no evidence to support recommending administration within 14hours of risk assessment and we note this recommendation was made to coincide with timing of consultant review. Prescription of thromboprophylaxis should occur at time of risk assessment and given administration of</p>	<p>Thank you for your comment.</p> <p>We have amended our recommendation to state ".....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".</p>

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				<p>thromboprophylaxis is a nursing task there is no logical reason to amend timing to within 14hours. We therefore recommend continuing with timing 'as soon as possible' after risk assessment completed as per 2010 NICE CG 92.</p> <p>Minor comment: current wording is confusing as thromboprophylaxis is not 'treating' a condition. Suggest rewording to 'if prescribing VTE prophylaxis for medical/surgical and trauma patients, start..'</p>	<p>We have edited the wording and removed the word 'treat' from the recommendation.</p>
King's College Hospital NHS Foundation Trust	Short	10	22	<p><i>Recommendations for Acute stroke</i></p> <p>No new evidence evaluating pharmacological thromboprophylaxis following acute stroke was presented and it is therefore unclear why the previous recommendation to consider anticoagulant prophylaxis for patients at high risk of VTE and low risk of haemorrhagic transformation was removed. In the CLOTS studies pharmacological thromboprophylaxis was used in up to 35% of participants and there is significantly more evidence for benefit of anticoagulant thromboprophylaxis in this patient group than in some of the other patient groups in which this draft recommends considering its use (see later). Suggest amend to include consideration of anticoagulant thromboprophylaxis for selected high risk patients. IPC is not suitable for use in all patients particularly as mobility improves and a number of patients do not tolerate IPC. There</p>	<p>Thank you for your comment. The committee reviewed the evidence for pharmacological VTE prophylaxis and did not feel that that current evidence demonstrated a strong enough positive effect on VTE outcomes to warrant recommending pharmacological prophylaxis in this population where bleeding would have catastrophic consequences.</p> <p>It was noted that it is standard practice for stroke patients to be administered anti-platelets as part of their treatment; the committee noted that it would not be necessary to recommend additional pharmacological prophylaxis.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices</p>

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				is a need for an alternate option for patients at high risk of VTE with low bleeding risk.	has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices. Although, the committee do not recommend the use of these devices deleting this recommendation means there is no longer provides a barrier for clinicians considering other forms of prophylaxis. Please refer to full guideline volume 1; pages 238-241 for further discussion of the evidence.
King's College Hospital NHS Foundation Trust	Short	11	11	<i>Recommendation 1.3.24</i> 'for a minimum of 7 days' There is no evidence here (or for other patient groups) to offer for a minimum 7 days. The benefit of extending thromboprophylaxis beyond discharge in the presented studies was offset by an increase risk of bleeding (this is in a highly selected trial population and bleeding risk may well be higher in 'real world'). Many patients are discharged sooner than 7 days and this has both significant implications in terms of cost and for community nursing. A significant proportion of patients may be unable/unwilling to self administer. Recommend amend to continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the evidence available and clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.

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				mobility returns to baseline .	
King's College Hospital NHS Foundation Trust	Short	12	9	<i>Recommendation 1.3.28</i> Amend 'consider' to 'offer' There is significantly more evidence to support the use of thromboprophylaxis in the myeloma group receiving chemotherapy with thalidomide/lenalidomide than other groups with a 'consider' recommendation. This would also align the NICE guidance with other national guidance (BCSH) and international guidelines including ACCP and ASCO.	Thank you for your comment. It is the view of the committee that a "consider" recommendation reflects the strength of the evidence and the concern about the increased risk of bleeding in this population.
King's College Hospital NHS Foundation Trust	Short	13	1	<i>Recommendation 1.3.31</i> Change recommendation to 'do not routinely offer pharmacological prophylaxis...' The evidence considered is extremely low quality and biased by detection of early asymptomatic DVT of uncertain significance. ACCP (excluding one study) and ASCO reviewed the same evidence and do not advocate use of thromboprophylaxis in this patient group. Offering thromboprophylaxis to this patient group will incur significant costs to the NHS without clear evidence of benefit and also puts a significant burden on cancer patients to self inject for prolonged periods without known benefit based on available evidence. Of note, none of the reported studies continued LMWH for the duration the line remained in situ and the bleeding risk associated with this will	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed. A research recommendation has been made as well to assess the clinical and cost effectiveness of pharmacological prophylaxis in this population.

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				therefore be underestimated. A significant proportion of patients will be unable to self-administer and this represents a potential considerable burden on community nurses for administration.	
King's College Hospital NHS Foundation Trust	Short	16	10 - 19	<i>People with psychiatric illness</i> As identified in the NICE evidence review, there is no evidence for risk assessment or thromboprophylaxis in this patient group. Furthermore the burden of VTE remains unknown. The adoption of either a medical risk assessment or the National tool will result in up to 40% of such patients (local audit data) receiving thromboprophylaxis which will be at significant cost to the NHS. Patients would need baseline FBC and renal function prior to starting; if this is not routinely performed this will be additional risk/cost in this population. Strongly recommend that this is changed to a research priority only.	Thank you for your comment. The committee believe risk assessment is important as some psychiatric patients are considered to be at risk of VTE. We have amended our recommendations so that both risk assessment and prophylaxis only apply people admitted to an acute psychiatric ward rather than all psychiatric patients.
King's College Hospital NHS Foundation Trust	Short Full document volume 2	17 15	22	<i>Lower limb immobilisation</i> The risk of VTE in this patient group is very low and evidence for thromboprophylaxis also very low quality. The studies included since publication of 2010 version do not favour use of thromboprophylaxis. Strongly recommend reword existing recommendation to 'do not routinely offer pharmacological VTE prophylaxis...', and add 'Offer pharmacological VTE prophylaxis to highly selected	Thank you for your comment. The committee agree that overall the risk of VTE in this heterogeneous patient group can be low. However, with such a heterogeneous population the committee did not consider it appropriate to make a do not routinely offer prophylaxis recommendation. The recommendations highlight the need to assess then balance the risk of VTE and risk of

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				<p>patients with high VTE risk (eg previous VTE, active cancer, pregnancy and Achilles tendon rupture). Consider pharmacological VTE prophylaxis for patients with continued lower limb immobilisation post-operatively'. The evidence reviewed included patients managed in an ambulatory setting. In England, this will often be an urgent care centre followed by outpatient fracture clinic. This population should also be specified.</p>	<p>bleeding and the consideration of VTE prophylaxis. If the patient has been identified as low risk of VTE after risk assessment then the clinician can decide that prophylaxis is not necessary.</p> <p>We have updated our section on 'Recommendations and link to evidence' to make it clear the recommendation applies to all patients including outpatients.</p> <p>We have also made it clear in the overview of the guidance in the web version who is covered by this guidance.</p>
King's College Hospital NHS Foundation Trust	Short	19	1 - 12	<p><i>Elective hip replacement</i> We note recommendations made based on cost-effectiveness; the role of AES has not been evaluated in two of the proposed options but if they improve efficacy in conjunction with LMWH it would be logical to include for the option of LMWH followed by aspirin. Most patients post THR will be discharged prior to d10, having a switch at d10 (from LMWH to aspirin) increases the possibility of error eg patients may take both medications from discharge which will increase risk of bleeding and potentially reduce efficacy in preventing VTE, as</p>	<p>Thank you for your comment. The committee did not wish to recommend combinations that were not supported by evidence . As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, the committee did not wish to recommend any of these combinations.</p> <p>The committee anticipate that minimising errors will be addressed through implementing adequate measures to ensure patient safety</p>

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				<p>overall duration will be reduced. Suggest remove this option. Dabigatran and apixaban were not considered options based on cost effectiveness but are efficacious and approved for use in NICE TA assessments, and thus should remain options post THR. There are already three options recommended, thus restricting choice of DOAC to rivaroxaban is not likely to standardise practice (any of three listed options could be used). It may however lead to increased costs in the longer term due to reduced competition.</p>	<p>including appropriate counselling on discharge.</p> <p>The cost effectiveness analysis takes into account clinical effectiveness as well as costs. It showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its first recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. Hence, the benefits of recommending one option were considered to outweigh the risk of reducing competition.</p> <p>.</p> <p>The recommended choices are given to address the issue of contra-indications. For those in whom DOAC is the only suitable option, rivaroxaban should be considered as the preferred choice based on clinical effectiveness, safety and cost effectiveness. Apixaban and dabigatran are now included in a further recommendation that specifies the</p>

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					circumstances under which these DOACs might be considered .
King's College Hospital NHS Foundation Trust	Short	20	1 - 9	<p><i>Elective knee replacement</i></p> <p>We note again recommendations based on cost effectiveness. Whilst aspirin was most cost effective, this option had least evidence to support its use (a single underpowered study). Given AES have only been studied in LMWH population but improve cost effectiveness, it would appear logical to offer combined treatment to all options. Given apixaban and dabigatran also has NICE TA approval for use as an option, these should also be offered. As above, as there are three options available, restricting the choice of DOAC is not likely to further standardise practice and risks increasing costs due to lack of competition.</p>	<p>Thank you for your comment. The relative efficacy estimates for aspirin are based on network meta-analyses which include all relevant trials for all included interventions. This in part addresses the problem of the low analysis power resulting from the small number of trials for each of the intervention.</p> <p>The recommended interventions were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, the committee did not wish to recommend combinations that were not supported by evidence.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its main recommendation to allow for standardisation of practice. The</p>

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					committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. Apixaban and dabigatran are now also included in a further recommendation that specifies the circumstances under which these DOACs might be considered.
King's College Hospital NHS Foundation Trust	Short	20	18 - 21	<i>Non-arthroplasty orthopaedic knee surgery</i> As the authors acknowledge there was low quality evidence to inform this recommendation with only one of the including studies reporting duration that was likely to be associated with increased VTE risk. None of the reported studies evaluated the recommended duration of LMWH of 14 days. Suggest reword to consider for those with total anaesthesia time of >1 hour AND additional VTE risk factors which outweigh risk of bleeding. Suggest amend duration to 7 days in line with other areas (with greater VTE risk) given evidence for extended duration not well established.	Thank you for your comment. The recommendation is for prophylaxis to be considered in this group based on risk assessment, not to be offered to everyone. This recommendation has been based on extrapolation from the elective total knee replacement surgery.
King's College Hospital NHS	Short	21	5 - 10	<i>Foot and ankle surgery</i> Suggest add recommendation regarding duration to align with recommendation 1.3.59 ie to continue for duration of immobilisation	Thank you for your comment. The recommendation has been edited to specify the duration.

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Foundation Trust					
King's College Hospital NHS Foundation Trust	Short	22 275	18 - 19 2	<p><i>Recommendation 1.3.75</i> Suggest amend to 'continue until the person no longer has significantly reduced mobility or until discharge from the acute hospital setting'. Some of these patients may have a prolonged recovery in a rehab setting where there is no evidence for continued thromboprophylaxis and monitoring required for safe use of anti embolism stockings may not take place.</p> <p>Comment that "people undergoing cranial surgery for malignant tumours will usually be assessed as at increased risk of VTE due to the 'active cancer' risk factor". This is dependent on the risk assessment tool utilised, some published tools require >1 risk factor including cancer to reach classification of 'high VTE risk'.</p>	Thank you for your comment. The duration of prophylaxis has been specified in the recommendation to be a maximum of 30 days to reflect this, extrapolating from the evidence available for stroke patients.
King's College Hospital NHS Foundation Trust	Short	22	6 - 7	<p><i>Recommendation 1.3.72</i> Suggest amend to 'continue until the person no longer has significantly reduced mobility or until discharge from the acute hospital setting'. Some of these patients may have a prolonged recovery in a rehab setting where there is no evidence for continued thromboprophylaxis.</p>	Thank you for your comment. We have amended the recommendation to state 'Continue for 30 days or until the person is mobile or discharged, whichever is sooner'.
King's	Short	23	6	<i>Recommendation 1.3.77</i>	Thank you for your comment. The minimum

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College Hospital NHS Foundation Trust				There is no evidence to 'continue for a minimum of 7 days'. Some patients, eg those undergoing biopsy may be discharged soon after surgery and continuing post discharge places potential burden on patient/carers/community nursing to continue administration with a lack of evidence to support this. Recommend amend to continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.	duration has been specified based on the available evidence and the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
King's College Hospital NHS Foundation Trust	Short	24	3 - 6	<i>Recommendation 1.3.83</i> Suggest amend to 'continue until the person no longer has significantly reduced mobility or until discharge from the acute hospital setting'. Some of these patients may have a prolonged recovery in a rehab setting where there is no evidence for continued thromboprophylaxis.	Thank you for your comment. We have amended the recommendation to state 'Continue for 30 days or until the person is mobile or discharged, whichever is sooner'.
King's College Hospital NHS Foundation Trust	Short	24	16	<i>Recommendation 1.3.86</i> 'Continue for a minimum of 7 days'. The majority of evaluated studies did not report duration or discontinued at hospital discharge. Therefore similar to previous comments, suggest amend duration to 'continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.

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King's College Hospital NHS Foundation Trust	Short	25	3	<i>Recommendation 1.3.89</i> ...for a minimum of 7 days'. The majority of studies reviewed were included in the 2010 recommendations; of the five new studies none examined whether 7 days was superior to a shorter duration. The studies reviewed included durations of until hospital discharge, 5-7 days (or extended for cancer patients). None of the evidence presented suggests 7 days is superior to shorter durations. In line with previous comments, this will have significant implications for patients/carers/community nurses by extending duration beyond discharge. Strongly recommend revert to previous recommendation of 5 to 7 days.	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
King's College Hospital NHS Foundation Trust	Short	26	14 - 15	<i>Recommendation 1.3.95</i> There is no evidence to support continuing LMWH for a minimum of 7 days and implementation of this will have significant implications on patients/carers/community nurses where discharge occurs sooner than 7 days. As per previous comments, suggest amend to 'continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.'	Thank you for your comment. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
King's College	Short	27	12	<i>Recommendation 1.3.98</i> No clinical evidence identified for this patient group.	Thank you for your comment. The minimum duration has been specified based on the

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Hospital NHS Foundation Trust				As per previous comments to reduce burden on patients/carers/community nursing post discharge, suggest amend duration to 'continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.'	clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the cost of VTE events prevented.
King's College Hospital NHS Foundation Trust	Short	29	17 - 19	<i>Oral and maxillofacial surgery</i> As noted by the committee there was no direct evidence to inform this area, much of the surgery occurs as day case, frequently under local anaesthesia. We therefore recommend amending to 'Do not routinely offer pharmacological VTE thromboprophylaxis' and 'Consider pharmacological VTE prophylaxis in selected patients at high VTE risk (eg prolonged surgical times, cancer surgery) where VTE risk outweighs risk of bleeding. We also recommend amending duration to 'continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.' Alternatively, this subsection could be removed from guidance as we note not all types of surgery are covered by the NICE guideline eg plastics/breast/dermatology	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. Hence, the minimum duration has been specified based on committee consensus extrapolating from the abdominal surgery population. It was the view of the stakeholders during the guideline scope consultation that there is a need for specific guidance for this type of surgery. Plastics/breast/dermatology were not identified as areas needing recommendations for VTE.
King's College Hospital	Short	30	5 - 15	<i>ENT surgery</i> As noted by the committee there was no direct evidence to inform this area, much of the surgery	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak

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NHS Foundation Trust				occurs as day case, frequently under local anaesthesia. We therefore recommend amending to 'Do not routinely offer pharmacological VTE thromboprophylaxis' and 'Consider pharmacological VTE prophylaxis in selected patients at high VTE risk (eg cancer surgery) where VTE risk outweighs risk of bleeding. We note postoperative bleeding may be increased following some surgery. We also recommend amending duration to 'continue until hospital discharge, or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.' Alternatively, this subsection could be removed from guidance as we note not all types of surgery are covered by the NICE guideline eg plastics/breast/dermatology	recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. It was the view of the stakeholders during the guideline scope consultation that there is a need for specific guidance for this type of surgery.
Leeds Teaching Hospital NHS Trust	Short	General	General	We are concerned as to the impact of the recommendation that any patient considered for low molecular weight heparin (LMWH) prophylaxis should receive at least 7 days. Where does this recommendation come from? This will put people off prescribing LMWH for patients who are not likely to be in for as long as 7 days. For patients discharged before 7 days the guidance seems to suggest the LMWH should be continued at home until 7 days is reached. Many patients cannot self-inject LMWH meaning district nurses or practice nurses are required to administer the injection putting huge	Thank you for your comment. The committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study

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				pressures on this resource. I think this needs a serious re-think	population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80). The committee appreciate that there may be concerns around administering LMWH post-discharge. However, the cost-effectiveness analysis conducted for CG92, which has been included in this review, has already taken into account district nurses' time and has shown that a prophylaxis duration of 10 days is clinically effective and cost-effective.
Leeds Teaching Hospital NHS Trust	Short	General	General	The document states any published VTE risk assessment document or checklist can be used. Why are we not promoting the national VTE risk assessment?	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)" The committee debated risk assessment tools at length. While they noted that the

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					Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.
Leeds Teaching Hospital NHS Trust	Short	general	general	Elderly medical patients are not mentioned in this as a separate group and concerns have been raised in the past that general evidence is extrapolated to this group rather than there being any documented trials or research into this group. Could the evidence be reviewed for this group and specific guidance be added.	Thank you for your comment. The evidence was reviewed for all age groups and the recommendation applies to older adults admitted as acutely ill medical patients.
Leeds Teaching Hospital NHS Trust	Short	5	13	Reassessment was previously stated to be at 24 hours and whenever clinical situation changes. Why did this need to change. Should re-assessment be done at every senior review? Who is senior, consultant? Registrar? This needs defining.	Thank you for your comments. The need to risk assess every 24 hours was believed to be unnecessary for all patients. The committee believe it is only when the condition changes that the reassessment needs to be made. Consequently, we changed the previous recommendation requiring reassessment

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					We have changed "senior review" to "consultant review" so that it is in line with the document on "Seven day services in the NHS" (https://improvement.nhs.uk/resources/seven-day-services/).
Leeds Teaching Hospital NHS Trust	Short	5	17	This needs to link to the RCOG guidance for VTE prevention in pregnancy, it would be appropriate to use the RCOG risk assessment and this should be stated. This is based on demographic data and is the best risk assessment tool for this group	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.
Leeds Teaching Hospital NHS Trust	Short	6	18	It is good to see documented the issues some patients have with porcine products but it would be helpful to have more specific information on how this should be explained to patients.	Thank you for your comment. We did not identify more information specific to giving advice to patients for this topic. The committee note that general advice on communicating with patients is available in the patient

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					experience guideline available at https://www.nice.org.uk/guidance/cg138 .
Leeds Teaching Hospital NHS Trust	Short	10	9	What is the evidence for mechanical prophylaxis in medical patients? There was very little if any I was aware of.	Thank you for your comment. A single study was identified which compared LMWH + AES vs AES only. The findings of the study are presented in the full guideline, volume 1, chapter 16.
Leeds Teaching Hospital NHS Trust	Short	10	21	There is no mention of LMWH thromboprophylaxis in the acute stroke section. This needs to be added, either to delay but consider after x days if high risk or advice on type of stroke and when to start LMWH	Thank you for your comment. The committee reviewed the evidence for pharmacological VTE prophylaxis and did not feel that that evidence current evidence demonstrated a strong enough positive effect on VTE outcomes to warrant recommending pharmacological prophylaxis in this population where bleeding would have catastrophic consequences (please refer to full guideline volume 1; pages 243-241 for further discussion of the evidence).
Leeds Teaching Hospital NHS Trust	Short	12	5	This statement needs clarifying, does it mean that if a patient has cancer but has had a VTE in the past they should get prophylaxis?	Thank you for your comment. We have amended this recommendation to read "Do not offer VTE prophylaxis to people with cancer who are receiving cancer modifying treatments such as radiotherapy, chemotherapy or immunotherapy and who are mobile except as outlined in 1.4.11 and 1.4.12, unless they are also at increased risk

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					of VTE because of something other than the cancer.”
Leeds Teaching Hospital NHS Trust	Short	13	1	This is a huge change with big cost pressures, what is the evidence for this and which patients should be chosen for prophylaxis? If they have a CVC but don't have cancer should they still be considered for VTE prophylaxis	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed. A research recommendation has been made as well to assess the clinical and cost effectiveness of pharmacological prophylaxis in this population.
Leeds Teaching Hospital NHS Trust	Short	17	21	Were oral agents such as rivaroxaban considered here? There is some decent evidence and though they are not licensed none of the LMWH's are for patients who are 16.	Thank you for your comment. The guideline committee evaluated the evidence for pharmacological interventions highlighted in the protocol. There was little evidence to support a recommendation in favour of rivaroxaban and therefore rivaroxaban was not recommended for this group of patients. One study was identified – no relevant bleeding outcomes were reported. Bleeding is a major clinical concern associated with rivaroxaban.
Leeds Teaching	Short	19	1	Aspirin has long been overtaken by more appropriate VTE prevention drugs, why has it re-	Thank you for your comment. The recommended strategies are based on

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Hospital NHS Trust				<p>appeared, is there new evidence? Why are the other oral agents with a licence not listed, apixaban and dabigatran? They have been approved by NICE?</p>	<p>the results of the clinical and cost-effectiveness analysis of all the interventions considered. A recent RCT assessed the clinical efficacy of LMWH used for 10 days followed by aspirin for 28 days has been identified (Anderson 2013) and included in the analysis. This intervention was the most cost effective in our economic analysis compared to all other strategies including apixaban and dabigatran.</p> <p>Aspirin as the sole prophylaxis option, however, is not recommended as it was not found to be clinically or cost effective compared to the other options. As patient factors should be taken into account when deciding on a prophylaxis option, more than one option were recommended to cater for any possible contra-indications or patient preference considerations. The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its main recommendation to allow for standardisation of practice. The committee also believed that</p>

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					<p>recommending only one DOAC is likely to reduce costs and minimise errors.</p> <p>Apixaban and dabigatran are now also included in a further recommendation that specifies the circumstances under which these DOACs might be considered.</p>
Leeds Teaching Hospital NHS Trust	Short	19	13	Why just anti-embolism stockings until discharge if pharmacological interventions are not appropriate?	Thank you for your comment. The duration recommended was based on the duration of using AES in the trials.
Leeds Teaching Hospital NHS Trust	Short	19	16	Why aspirin and why not apixaban and dabigatran as they have been approved by NICE?	<p>Thank you for your comment. The recommended options were chosen based on the results of the clinical and cost effectiveness analysis.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its main recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors.</p>

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					Apixaban and dabigatran are now also included in a further recommendation that specifies the circumstances under which these DOACs might be considered
Leeds Teaching Hospital NHS Trust	Short	20	10	Why IPCs for knees and anti-embolism stockings for hips, what is the evidence that one type of mechanical prevention is better than another for hips or knee replacements	Thank you for your comment. The recommendations are based on the clinical and cost effectiveness evidence. The guideline committee noted that the differing recommendations for elective hip replacement surgery and elective knee replacement surgery could raise some concerns but felt that it is crucial that these populations are considered separately as there are associated with different VTE risks. The analysis of the evidence underpinning this recommendation is presented in Appendices M and P.
Leeds Teaching Hospital NHS Trust	Short	20	18	This is not clear, it states VTE prophylaxis not usually needed but then seems to include any patient whose risk of VTE outweighs risk of bleeding as needing prophylaxis. These needs to be clarified	Thank you for your comment. The first "Be aware" recommendation applies when the total anaesthesia time is less than one hour and the patient is assessed to at low risk of VTE. The second recommendation to "Consider LMWH" applies when anaesthesia time is more than one hour and the person's risk of VTE outweighs their risk of bleeding.
Leeds	Short	22	4 - 10	This is very helpful and detailed but other areas are	Thank you for your comment. In the interest of

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Teaching Hospital NHS Trust				not so detailed leading to inconsistencies. Either make all recommendations as detailed as this or consider making this more in line with the rest of the document by putting "start LMWH when haemostasis is secured at the discretion of the senior surgeon" ¹⁷	readability, we have added detail only where the committee felt that more clarification is needed.
Leeds Teaching Hospital NHS Trust	Short	25	9	Extended prophylaxis is for patients with cancer undergoing major surgery in the abdomen or pelvis, pelvis isn't mentioned in this statement, is this an oversight?	Thank you for your comment. The review related to major abdominal surgery and not surgery of the pelvis therefore the recommendation is limited to major abdominal surgery only.
Leeds Teaching Hospital NHS Trust	Short	26	1	There is evidence to suggest longer prophylaxis is required in bariatric surgery not just 7 days.	Thank you for your comment. The recommendation allows for longer duration of prophylaxis to be used, based on risk assessment, as it only specifies a minimum of 7 days. The guideline committee acknowledged that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that

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					the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE.
Leeds Teaching Hospital NHS Trust	Short	31	3	The trials involving LMWH, fondaparinux and the oral agents used creatinine clearance not eGFR. eGFR may give an over-representation of renal function in patients of low body weight	Thank you for your comment. The terminology was approved by the committee as an appropriate measure of renal impairment.
LEO Pharma	Short	12	1	It is worth clarifying the categorisation of "renal impairment" especially as many guideline users may consider 30ml/min as severe renal impairment. Including a link to CG 182 would be helpful to provide appropriate context and alignment for non-expert audience.	Thank you for your comment. We have added a link to CG182 in the guideline.
LEO Pharma	Short	12	14	The evidence review rules out increase risk with lung cancer but there is no mention of stomach cancer. The Khorana risk score (https://www.mdcalc.com/khorana-risk-score-venous-thromboembolism-cancer-patients) does identify stomach cancer as having the same risk profile as pancreatic cancer with respect to VTE, so providing clarity via its inclusion or reason for exclusion would be helpful.	Thank you for your comment. Evidence was only identified for pancreatic cancer. The guideline committee agrees that, histologically, stomach cancer is similar to pancreatic cancer. However, the guideline committee did not feel it would be appropriate to extrapolate to the stomach cancer population in the absence of evidence to assess the clinical and cost effectiveness of prophylaxis in this population.
Neurocare Europe Limited	Full	233	15, 6, 41	We comment on the statement: " Do not offer foot impulse or neuromuscular electrical stimulation devices for VTE prophylaxis to people who are admitted with acute stroke, except in the context of	Thank you for your comment. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the

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		233		<p>research. [2018]" We are unaware of any clinical evidence which would support this statement. We are, however ,aware of a broad body of research which supports the use of NMES immediately post stroke where the therapeutic objective is to maintain muscle movement and condition and, as some studies report, recover a degree of motor control of limb movement We present below clinical evidence on this clinical application below:</p> <p>Muscle Nerve. 2007 May;35(5):562-90.Neuromuscular electrical stimulation in neurorehabilitation. Sheffler LR¹, Chae J. Abstract This review provides a comprehensive overview of the clinical uses of neuromuscular electrical stimulation (NMES) for functional and therapeutic applications in subjects with spinal cord injury or stroke. Functional applications refer to the use of NMES to activate paralyzed muscles in precise sequence and magnitude to directly accomplish functional tasks. In therapeutic applications, NMES may lead to a specific effect that enhances function, but does not directly provide function. The specific neuroprosthetic or "functional" applications reviewed in this article include upper- and lower-limb motor</p>	<p>evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p> <p>Thank you for providing references. These have been checked for potential inclusion in the evidence. review. After reviewing the references they are not suitable for inclusion as they do not provide relevant outcomes, none provide RCT evidence on the effectiveness of VTE prophylaxis.</p> <p>The committee appreciates that are there are numerous studies that investigate biological outcomes but are unable to consider this evidence and therefore unable to conduct cost-effectiveness analyses for these interventions. If new evidence is published that address clinical effectiveness in terms of VTE outcomes such as rates of DVT (symptomatic and asymptomatic) and PE this may be assessed in future updates of this guideline.</p>

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				<p>movement for self-care tasks and mobility, respectively, bladder function, and respiratory control. Specific therapeutic applications include motor relearning, reduction of hemiplegic shoulder pain, muscle strengthening, prevention of muscle atrophy, prophylaxis of deep venous thrombosis, improvement of tissue oxygenation and peripheral hemodynamic functioning, and cardiopulmonary conditioning. Perspectives on future developments and clinical applications of NMES are presented.</p> <p>We comment on the following text “The guideline committee noted that there was no evidence identified for the use of foot impulse devices (FID) or neuromuscular electrical stimulation (NMES). The guideline committee discussed the lack of evidence and stated that the potential risks of skin damage associated with the use of the devices was great enough in this highly immobile population to strongly recommend against their use outside of the VTE prophylaxis.”</p> <p>We are unaware of any clinical evidence which would support the assertion that NMES brings potential great risk of skin damage We have little knowledge of FID and therefore confine our comments to electrotherapy in general and NMES in</p>	

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				<p>particular .</p> <p>Electrotherapy in all forms has a very good safety record evidenced by a very large number of clinical trials in many different clinical applications most of which make precisely this point about the inherent safety of electrotherapy. Earlier devices using poorly designed skin contact electrodes running at 60/70 milliamps plus may have been uncomfortable when adjusted to such high intensity but any suggestion that permanent damage in the form of burn marks or blistering is a commonly experienced outcome which is implied by the expression "great risk" is simply not supported by any evidence.</p> <p>The paragraph also speaks of "this highly immobile population" as a contributor to the risk profile of the therapy.</p> <p>NMES (outside the UK) is frequently used to maintain muscle condition in immobilised patients often in an ICU setting and the following clinical trials document this application and present the very positive results obtained In none of these trials is there any evidence documented of adverse events in the form of burn injuries. In the interests of brevity we have confined our presentation of clinical trial</p>	

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				<p>results to those trials which in our judgement are the most relevant.</p> <p>Clin Sci (Lond). 2015 Mar;128(6):357-65. doi: 10.1042/CS20140447. Neuromuscular electrical stimulation prevents muscle wasting in critically ill comatose patients. Dirks ML(1), Hansen D(2), Van Assche A(2), Dendale P(2), Van Loon LJ(1).</p> <p>RESULTS: In the CON leg, type 1 and type 2 muscle-fibre-CSA decreased by 16 ± 9% and 24 ± 7% respectively (P<0.05). No muscle atrophy was observed in the stimulated leg. NMES increased mammalian target of rapamycin (mTOR) phosphorylation by 19 ± 5% when compared with baseline (P<0.05), with no changes in the CON leg. Furthermore, mRNA expression of key genes involved in muscle protein breakdown either declined [forkhead box protein O1 (FOXO1); P<0.05] or remained unchanged [muscle atrophy F-box (MAFBx) and muscle RING-finger protein-1 (MuRF1)], with no differences between the legs. In conclusion, NMES represents an effective and feasible interventional strategy to prevent skeletal muscle atrophy in critically ill comatose patients.</p>	

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				<p>Cochrane Database Syst Rev. 2013 Jan 31;1:CD009419. doi: 10.1002/14651858.CD009419.pub2. Neuromuscular electrical stimulation for muscle weakness in adults with advanced disease. Maddocks M¹, Gao W, Higginson IJ, Wilcock A.</p> <p>NMES significantly improved quadriceps strength by a SMD of 0.9 (95% confidence interval (CI) 0.33 to 1.46), equating to approximately 25 Newton metres (Nm) (95% CI 9 to 41). Mean differences across various walking tests, favouring NMES, were 40 m (95% CI -4 to 84) for the six-minute walk test, 69 m (95% CI 19 to 119) for the incremental shuttle walk test and 160 m (95% CI 34 to 287) for the endurance shuttle walk test.</p> <p>J Crit Care. 2014 Dec;29(6):1082-8. doi: 10.1016/j.jcrc.2014.06.024. Epub 2014 Jun 30. Feasibility of neuromuscular electrical stimulation in critically ill patients. Segers J¹, Hermans G², Bruyninckx F³, Meyfroidt G⁴, Langer D¹, Gosselink R⁵. In the early phase of critical illness, a large proportion of patients are unable to participate in any</p>	

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				<p>active mobilization. Neuromuscular electrical stimulation (NMES) could be an alternative strategy for muscle training. The aim of this study was to investigate the safety and feasibility of NMES in critically ill patients. RESULTS: In 50% of the patients, an adequate quadriceps contraction was obtained in at least 75% of the NMES sessions CONCLUSIONS: Critically ill patients having sepsis, edema, or receiving vasopressors were less likely to respond to NMES with an adequate quadriceps contraction. Neuromuscular electrical stimulation is a safe intervention to be administered in the ICU.</p> <p><u>Med Intensiva</u>. 2014 Oct;38(7):444-54. doi: 10.1016/j.medin.2013.12.003. Epub 2014 Jul 22. Application and effects of neuromuscular electrical stimulation in critically ill patients: systematic review. <u>Wageck B</u>¹, <u>Nunes GS</u>², <u>Silva FL</u>³, <u>Damasceno MC</u>³, <u>de Noronha M</u>⁴. To investigate the applications and effects of neuromuscular electrical stimulation (NMES) in critically ill patients in ICU by means of a systematic review. CONCLUSIONS: The selected studies showed that NMES has good results when used for the maintenance of muscle mass and strength in critically ill patients in ICU.</p>	

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				<p>J Crit Care. 2013 Aug;28(4):536.e1-7. doi: 10.1016/j.jcrc.2013.02.010. Epub 2013 Apr 3. The effect of electrical muscle stimulation on the prevention of disuse muscle atrophy in patients with consciousness disturbance in the intensive care unit. Hirose T¹, Shiozaki T, Shimizu K, Mouri T, Noguchi K, Ohnishi M, Shimazu T.</p> <p>Results :We were able to limit the rate of muscle atrophy as measured in the cross-sectional areas to within 4% during the period of EMS (days 7-42) in 5 patients. The difference between the control and the EMS groups was statistically significant (P < .001).</p> <p><i>Conclusion Electrical muscle stimulation is effective in the prevention of disuse muscle atrophy in patients with consciousness disorder.</i></p> <p>Your requirement for this consultation also seeks comment on the following point under the headings: Make sure you consider: The areas that will have the biggest impact on practice and be challenging to implement .How to help users overcome challenges.</p> <p>We comment as follows</p> <p>We submit that the clinical trial data presented above constitutes a convincing body of evidence in</p>	

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				<p>favour of the use of NMES as a mechanical prophylactic in the avoidance of venous thromboembolism</p> <p>It is simple to apply in a clinical setting and very suitable for self treatment at home. The most effective modern devices are comfortable in operation and largely risk free. It is inexpensive: the most expensive component being the Gell Electrodes which are patient specific, cost around £8-10 per pack of four and can be used on around 10 occasions.</p> <p>Comparative tests have shown it to be of superior performance to ICDs and most important are the further effects of its mechanism of action as compared to ICDs.</p> <p>Whereas ICDs achieve blood displacement by means of compressive force applied to local tissue, NMES achieves superior and more natural arterial and venous circulation by mechanical activation (contraction and relaxation) of local musculature which apart from replicating normal circulation also achieves improvement in muscle condition which may be critical to the prospects of rehabilitation in these patient populations.</p>	

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				Taken together .the combination of avoiding thromboembolism whilst simultaneously improving muscle condition offers a major positive impact on current practice. Minimal changes to either the training of clinical staff or substantial changes to working practices will be required to adopt this therapy.	
Neurocare Europe Limited	Full Vol 1 and 2 and Summary	General	General	We note that in documents with a combined total number of pages exceeding 2600 ,Neuromuscular Electronic Stimulation is mentioned , on only 4 occasions and each time very briefly. Treatment recommendations for mechanical VTE prophylaxis overwhelmingly reference anti-embolism stockings, and intermittent pneumatic compression yet there is convincing and recent evidence that electrical stimulation of (usually) calf muscles is a significantly more effective prophylactic than these limited alternatives. We comment on the use of NMES devices in” reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism “ and include some summary evidence as follows: Nmes devices have been used in a very wide variety of clinical applications since their emergence as a	Thank you for your comment and the references provided. A literature search was conducted and studies were reviewed based on agreed clinical evidence protocols (please refer to appendix C of the guideline). No relevant evidence was identified to recommend neuromuscular electrical stimulation. The committee notes the published evidence available regarding biological outcomes but is unable to include this evidence within the evidence reviews as these outcomes were not highlighted as appropriate for identifying clinical effectiveness. The recommendation against using foot impulse or neuromuscular stimulation devices

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				<p>distinctly separate form of electrotherapy in the USA in the early 1990s. According to FDA they have 6 indications (which are usually considered to be clinically proven applications) which are , 1). Increase of Local circulation; 2) Muscle re-education; 3) Relaxation of muscle spasms; 4) Maintaining or increasing range of motion; 5) Prevention or retardation of disuse atrophy; 6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.</p> <p>Specific examples of clinical evidence which supports the use of NMES in this and similar applications is presented below. We have highlighted in RED those pieces of text directly relevant to assertions made in the consultation documents</p> <p>In 1970, Browse and Negus, both Surgeons at St Thomas' in London carried out a clinical trial (1) as described in the following summary: "In a prospective trial of preventing deep vein thrombosis electrical stimulation of the calf muscles of one leg was used in 110 patients undergoing major surgery. Deep vein thrombosis was detected by means of the I-fibrinogen uptake test in nine of the stimulated legs and in 23 of the unstimulated legs. It is suggested that this technique, which is both simple</p>	<p>in the stroke population has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices.</p>

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				<p>and effective, should be used on all patients undergoing major surgery.”</p> <p>The following passages are taken as direct quotations from the discussion section of the report of this trial</p> <p>“This study, using an objective method of detecting deep vein thrombosis, has confirmed Doran and White's (1967) observations that stimulation of the calf muscles during a surgical operation significantly reduces the incidence of deep vein thrombosis. Though the method of stimulation that we used significantly reduced the incidence of deep vein thrombosis it did not completely abolish it. We feel that the method of repeated brisk contractions of the calf muscles as described by Doran and White (1967) is more effective in promoting the "pump action" of the calf muscles and in increasing the velocity of venous blood flow than the technique of slower contractions described by Moloney and Fell (1968). We have not, however, compared the two methods.</p> <p>We have experienced no skin blistering or burning when adhering to the precautions already mentioned. On two occasions the corner of one plate became uncovered and pressed hard into the skin,</p>	

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				<p>and small (1 cm. diameter) blisters appeared next day. This complication is completely avoidable by ensuring good, even contact through a protective covering and would be still less likely if the direction of the current was reversed with each stimulation.</p> <p>The precise mechanism by which muscle stimulation reduces the incidence of deep vein thrombosis remains an unanswered question. Though simple abolition of venous stasis, by increasing the velocity of venous blood flow, may be important, other possible factors are the increase in arterial inflow-normally depressed during operation (Browse, 1962)-induced by the muscle contractions, and an increase in blood fibrinolytic activity which is known to be stimulated by muscle activity (Feamley, 1965).</p> <p>The venous thrombosis which most often gives rise to fatal pulmonary embolism develops in the upper femoral or iliac veins (Mavor and Galloway, 1967). No such thrombi have been detected in this trial. The ¹²⁵I-fibrinogen uptake test is not accurate above the groin, but no patient has shown clinical evidence of either iliac vein occlusion or pulmonary embolism. It is reasonable to suppose that the twofold increase in the velocity of venous blood flow in the upper femoral vein produced by calf muscle stimulation will inhibit thrombus formation at this site if it does so in</p>	

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				<p>the more distal veins of the thigh and calf.</p> <p>The high incidence of deep vein thrombosis during surgery and the serious effects of thrombus propagation and fragmentation make effective prophylaxis mandatory. This study has shown the simplicity and effectiveness of calf muscle stimulation, and we believe that this method should be used on all patients undergoing a major surgical operation.”</p> <p>In 1997,Faghri et al (2) undertook a clinical trial entitled “ electrical stimulation-induced contraction to reduce blood stasis during arthroplasty.” Their results and conclusions are summarised as follows “The results show stroke volume and cardiac output to be higher throughout surgery in the electrical stimulation group as compared with the sequential compression device group. The heart rate was consistently lower during electrical stimulation for both groups. Total peripheral resistance did not change in the electrical stimulation group; but increased in the sequential compression device group. The data suggest that continuous electrical stimulation-induced contractions could improve lower leg circulation by eliciting the physiologic muscle pump. This will lead to improved venous</p>	

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				<p>circulation and reduction of blood stasis during total hip and/or knee surgery. This technique may offer greater protection against DVT and PE during surgery than the commonly used sequential compression device.</p> <p>In 2010 Tucker et al (3)undertook a clinical trial entitled "Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve".</p> <p>The results were summarised as follows :"During neuromuscular stimulation, significant increases in blood volume flow and velocity and skin capillary blood flow were found; transdermal skin oxygen levels were maintained. No changes were observed in heart rate, blood pressure, oxygen saturation or femoral vein vessel diameter."</p> <p>In 2010 Czyrny et al (4) carried out a clinical trial entitled "Electrical foot stimulation: A potential new method of deep venous thrombosis prophylaxis ." and concluded "Short-term electrical foot stimulation is at least as effective as knee high intermittent pneumatic compression in</p>	

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				<p>increasing popliteal and femoral blood flow velocity. Electrical foot stimulation has the potential to be an effective method of deep venous thrombosis prophylaxis.</p> <p>In 2010 Broderick et al (5) carried out a trial which consisted of: "A pilot evaluation of a neuromuscular electrical stimulation (NMES) based methodology for the prevention of venous stasis during bed rest." Their results and conclusions were that, "The stimulated groups maintained a significantly higher venous blood flow and heart rate. Volume flow in contralateral limb remained constant throughout the study and was comparable to that of the stimulated limb's recovery flow. The results suggest that even short periods of bed rest can significantly reduce lower limb blood flow which could have implications for DVT development. Electrically elicited calf muscle contractions significantly improve lower limb blood flow and can alleviate some debilitating effects of bed rest.</p> <p>And also in 2011 Broderick and other colleagues (6) undertook a further trial of NMES to</p>	

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				<p>investigate the “Hemodynamic performance of NMES in the early post operative period following orthopaedic surgery.” They presented the following results, “ The effect of calf muscle NMES on peak venous velocity and volume flow were compared to resting values. Comfort was assessed using a 100 mm non-hatched visual analogue scale taken before application of NMES, once NMES was initiated and before NMES was withdrawn. Results of the study showed that NMES produces a beneficial hemodynamic response in patients in the early postoperative period following orthopaedic surgery. This patient group found extended periods of calf-muscle NMES tolerable.</p> <p>In 2014 Broderick et al (7) conducted a trial which directly compared the performance of IPC and NMES entitled “Comparative lower limb hemodynamics using neuromuscular electrical stimulation (NMES) versus intermittent pneumatic compression (IPC)” They concluded that “ Calf-IPC and NMES produced significant increases in venous blood velocity (cm/s) and volume of blood ejected per cycle (1 cycle of NMES expels 23.22 ml compared to the baseline ejected</p>	

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				<p>Please insert each new comment in a new row</p> <p>volume of 2.52 ml, measured over 1 s ($p < 0.001$ versus baseline).Improving lower limb hemodynamics is vital in preventing DVT. NMES resulted in larger ejected volumes compared to IPC (x3 greater than foot-IPC and x1.7 greater than calf-IPC) more effectively emptying the veins and soleal sinuses. This is an important finding as DVT occurs predominantly in the soleal sinuses. NMES is silent and portable and thus does not suffer many of the issues associated with IPC. This work supports the potential widespread application of NMES in hospital and home settings where the risk of DVT formation is high.</p> <p>In 2017 Ojima et al (8) carried out a trial to explore the “Hemodynamic effects of electrical muscle stimulation in the prophylaxis of deep vein thrombosis for intensive care unit patients: a randomized trial” and commented as follows :“Deep vein thrombosis (DVT) is a major complication in critical care. There are various methods of prophylaxis, but none of them fully prevent DVT, and each method has adverse effects. Electrical muscle stimulation (EMS) could</p>	<p>Please respond to each comment</p>

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				<p>be a new effective approach to prevent DVT in intensive care unit (ICU) patients. We hypothesized that EMS increases the venous flow of the lower limbs and has a prophylactic effect against the formation of DVT. Conclusions:EMS increased the venous flow of the lower limbs. EMS could be one potential method for venous thromboprophylaxis.”</p> <p>REFERENCES</p> <p>1) Prevention of post operative leg vein thrombosis by electrical muscle stimulation. An evaluation with I-Labelled Fibrinogen V.L. Browse, D. NegusBMJ, 1970,3,615-618</p> <p>2) IEEE Trans Rehabil Eng. 1997 Mar;5(1):62-9. Electrical stimulation-induced contraction to reduce blood stasis during arthroplasty. Faghri PD¹, Van Meerdervort HF, Glaser RM, Figoni SF.</p> <p>3) Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve.AT Tucker, PhD,1,2 A Maass, PhD,1,2 DS Bain, PhD,2</p>	

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				<p>L-H Chen, MSc,2 M Azzam, MD, 1H Dawson,1 and A Johnston, PhD2 Int J Angiol. 2010 Spring; 19(1): e31–e37. PMID: PMC2949997</p> <p>4) Electrical foot stimulation: A potential new method of deep venous thrombosis prophylaxis Czyrny JJ, Kaplan RE, Wilding GE, Purdy CCH, Hirsh J Vascular 2010 Jan-Feb;18(1):20-7</p> <p>5) Med Eng Phys. 2010 May;32(4):349-55. doi: 10.1016/j.medengphy.2010.01.006. Epub 2010 Feb 18.A pilot evaluation of a neuromuscular electrical stimulation (NMES) based methodology for the prevention of venous stasis during bed rest. Broderick BJ¹, O'Briain DE, Breen PP, Kearns SR, Olaighin G</p> <p>6) Conf Proc IEEE Eng Med Biol Soc. 2011;2011:7630-3. doi: 10.1109/IEMBS.2011.6091880. Hemodynamic performance of NMES in the early post operative period following orthopaedic surgery. Broderick BJ¹, Breathnach O, Masterson E, Breen PP, ÓLaighin G.</p> <p>7) Physiol Meas. 2014 Sep;35(9):1849-59. doi:</p>	

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				<p>10.1088/0967-3334/35/9/1849. Epub 2014 Aug 26. Comparative lower limb hemodynamics using neuromuscular electrical stimulation (NMES) versus intermittent pneumatic compression (IPC). Broderick BJ¹, O'Connell S, Moloney S, O'Halloran K, Sheehan J, Quondamatteo F, Quinlan LR, OLaighin G.</p> <p>8) J Intensive Care. 2017 Jan 13;5:9. doi: 10.1186/s40560-016-0206-8. eCollection 2017. Hemodynamic effects of electrical muscle stimulation in the prophylaxis of deep vein thrombosis for intensive care unit patients: a randomized trial. Ojima M¹, Takegawa R¹, Hirose T¹, Ohnishi M¹, Shiozaki T¹, Shimazu</p> <p>Further comment:</p> <p>The Guideline Development Group for this document will be aware that there is a Cochrane Systematic Review in the course of preparation entitled "Neuromuscular electrical stimulation for the prevention of venous thromboembolism." Publication is imminent but unfortunately not yet available for its conclusions to be incorporated within these comments on the draft guideline</p>	
NHS	All versions	General	General	Given the inclusion of mental health units and the	Thank you for your comment. Mental health

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England				emphasis on continuing treatment after discharge, is 'hospital-acquired' still the right title of the guideline? Would 'healthcare-associated' better describe its reach?	units are no longer referred to in the guideline recommendation. The recommendations have been changed to apply only to psychiatric patients admitted to an acute psychiatric ward. This change is in response to stakeholder comments.
NHS England	All versions	General	General	The guideline does not appear to contain any recommendations for people not admitted (e.g. trauma patients assessed in A&E who go home in plaster casts). It would be very helpful to for the guidance, including short version, to be very clear on whether this lack of recommendation is because it was out of scope, or because the guideline does not think these patients need assessment and prophylaxis based on the evidence considered.	<p>Thank you for your comment. The lower limb immobilisation recommendation applies to all patients including outpatients treated in A&E. It is stated in the scope as such and we have made this clear in the section on 'Recommendations and link to evidence'.</p> <p>We have also made it clear at the beginning of the guidance who the guideline applies to. The text reflects the scope and states "This guideline covers assessing and reducing the risk of venous thromboembolism (VTE or blood clots) and deep vein thrombosis (DVT) in over 16s in hospital. It aims to help healthcare professionals identify people most at risk of VTE. It describes treatments and interventions that can be used to reduce the risk of VTE. It includes people admitted to hospital, people discharged from hospital (including from A&E) with lower limb devices such as plaster casts and braces, people</p>

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					attending hospital for day procedures including cancer treatment and surgery, and pregnant women admitted to hospital or a midwife unit including up to 6 weeks after giving birth.”
NHS England	All versions	Multiple pages	Multiple sections	Mechanical Prophylaxis: would like to see a recommendation that mechanical prophylaxis is ‘prescribed’ or at least clearly documented in notes – often not and so difficult to ascertain if used and for how long on audit or incident review.	Thank you for your comment. The guideline committee agrees that documentation is important but a recommendation about this is outside of the remit/scope of the guideline.
NHS England	General	General	General	The content of the guideline is so complex and nuanced that I doubt clinicians will be able to implement in practice unless they have an associated clinical decision support tool. This is an important practical consideration that should be addressed as part of the guideline, otherwise there is very little hope of the guideline being followed effectively.	Thank you for your comment. The committee acknowledge that this is a complex document which is a reflection of the complexity of VTE prophylaxis. We have tried to address this by providing further clarification within the guideline in response to your and other stakeholder comments. Clarifications include: <ul style="list-style-type: none"> • definition for admission and how this relates to inpatients and day procedures such as surgery and chemotherapy in the short and full versions of the guideline • definitions for significantly reduced mobility and discharge in the short and full versions of the guideline • defining more clearly which published tools can be used for VTE risk

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					assessment using the words requested by you <ul style="list-style-type: none"> • providing a time limit for risk assessment within the recommendations • more detail in the “Recommendations and link to evidence” sections • more detail in recommendations for some recommendations
NHS England	Short	General	General	We are keen the document is as specific as possible in its language, especially to support consistent measurement of compliance with VTE assessment and prevention. Areas where language is potentially ambiguous and could affect clinical implementation and national measures of compliance are: <ul style="list-style-type: none"> • ‘admission to hospital’/ ‘people admitted to hospital’ – is this intended only to encompass ordinary admission i.e. those intended to stay at least one night, or does it encompass day surgery? If day surgery, does it also encompass admission to other types of day unit, such as interventional radiology or for chemotherapy? How would it be defined in relation to pregnant women, where brief admission for assessment may take place? A clear definition, perhaps 	Thank you for your comments. Admission – We have added the following definition to the guideline: Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay. Timescale for assessing on admission: we have amended our recommendation to state that assessment should happen “as soon as possible after admission to hospital or by the time of the first consultant review”.

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				<p>through a footnote to avoid repetition, would be most helpful</p> <ul style="list-style-type: none"> • 'assess on admission' – a clear timescale would be very helpful e.g. 'assess as soon as possible or within x hours of admission at the latest'. If NICE does not provide this, there is a risk it gets defined by others in order to make consistent measurement possible. • 'published tool or checklist' – published is an ambiguous term and could mean local, personal or private publication. Clearer wording such as 'published by a national UK body, professional network or peer review journal' would be helpful <p>'discharge' – seems to be used to mean sent home from inpatient care, but clarity helpful given likely to still be under care of some sort during prophylaxis at home</p>	<p>Published tool or checklist: Thank you. We have amended the recommendation to state "published by a national UK body, professional network or peer review journal" as suggested.</p> <p>Discharge – We have added the following definition for discharge: "Discharge in the context of this guideline refers to discharge from hospital as an inpatient or after a day procedure." When recommendations state "until discharge" in relation to duration of prophylaxis this is when the committee advise prophylaxis to be stopped.</p>
NHS England	Short	General	1.1.12	Wording seems ambiguous – does it mean all pregnant women or only pregnant women who have been admitted to hospital?	Thank you for your comment. The guidance covers pregnant women who have been admitted to hospital or due to be admitted for elective surgery. We have restructured our recommendations so that the wording relating to admission comes first. The recommendations now read as ".....all women who are admitted to hospital or midwife-led unit if they are pregnant or gave

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					birth, had a miscarriage or had a termination of pregnancy in the past 6 weeks.....”
NHS England	Short	General	1.3.16	It would be good if there was a strong message that anticoagulants must be restarted, if stopped, and must be within range, if on warfarin, before discharge. This is a significant area of patient safety concern.	Thank you for your comment. The committee agree this is an important issue. The guideline has not made any recommendation on this as no evidence was identified in relation to stopping prophylaxis. The committee noted this would need to be judged by the clinicians managing the admission. We have noted in the section on 'Recommendations and link to evidence' that anticoagulation should be restarted as soon as possible. We have also noted that clinicians would need to ensure that therapeutic levels of warfarin are reached or bridging is arranged post-discharge until the INR is therapeutic with appropriate arrangements for follow up for the monitoring of INR.
NHS England	Short	General	1.3.48	People with psychiatric illness – this does not have a requirement for reassessment when condition changes. Because admissions can be long and see marked changes in mobility (e.g. from a hyperactive to depressed phase of bipolar illness) a requirement to reassess seems vital.	Thank you for your comment. The guideline committee discussed your comment and agreed that this should be re-emphasised. The following recommendation has now been added to this section: “Reassess all people admitted to an acute

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					psychiatric ward for risk of VTE and bleeding at the point of consultant review or if their clinical condition changes.”
NHS England	Short	General	1.3.57	Guidance offers range of 28-35 days. In terms of cost efficiencies and to prevent confusion on transfer between trusts and GPs it would be better to state a fixed number.	Thank you for your comment. We have taken your view on board and specified that the recommended duration of prophylaxis is a month. This is in line with the durations reported in the trial evidence (28 to 31 days).
NHS England	Short	General	1.3.62	Offering a range of interventions with such a wide disparity of costs with no rationale for choice will cause issues in practice. Needs rationale for when to choose which option	Thank you for your comment. Recommended options are based on the results of the economic analysis and all recommended options are considered cost-effective. No evidence was available to distinguish between these options and therefore the committee left it to the clinician to decide which the most appropriate method is for the patient in front of them taking into account patient's VTE and bleeding risks, their preference and any contraindications.
NHS England	Short	33	General	It would be helpful also to cite these data on deaths with VTE in part 1 of death certificate within 90 days of a hospital admission https://indicators.hscic.gov.uk/download/Outcomes%20Framework/Specification/NHSOF_5.1_I00675_Q.pdf	Thank you for your comment. The document provided refers to how data should be recorded rather than the actual data. We have cited recent data on deaths in the introduction of the guideline.
Orthopaedic	Full Vol 1	23	General	We are concerned that these recommendations will	Thank you for your comment. Clinical

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Trauma Society				<p>lead to further uncertainty in the clinical community. Our main concern is that most of the recommendations offer 'advice' while acknowledging that there is little strong evidence to support the recommendations. In the absence of evidence, the OTS believes that NICE should be making research recommendations only.</p> <p>This would encourage the clinical community to work together to create a strong evidence base, rather than spending it's time trying to interpret 132 different recommendations based on incomplete evidence. The OTS believes that the current NICE recommendations will lead to further uncertainty and variation in interpretation across the NHS.</p>	<p>guideline recommendations are provided guidance to clinicians and are not meant to be prescriptive or replace clinicians' judgment. We agree that most of the evidence reviewed for this guideline was of low quality; however, it is the role of the guideline committee to scrutinise this evidence and supplement it with their expert clinical knowledge to assess the benefit-harm balance of the interventions considered and ensure that evidence-informed decisions are made regarding whether practice or research recommendations would be the most appropriate, and whether a practice recommendation should be a strong or weak one. The expert input from the committee will ensure that decisions reflect both the evidence and the collective experience of the committee members.</p> <p>The committee has already made a number of research recommendations in the areas of highest uncertainty and where research is feasible to be undertaken in a scientifically robust and unbiased way. We believe these research recommendations will encourage the clinical community to strengthen the evidence base in the areas of highest uncertainty; where the value of collecting further</p>

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					information outweighs the value of making a practice recommendation.
Orthopaedic Trauma Society	Full Vol 1	30	19	It states treatment reduces risk of DVT. It should also say whether it affects PE rates. In addition it should state the risk of major bleeding (2-3%) on patients having anticoagulants to make it clear the pharmaceutical treatments are not without risk	The importance of considering risks of prophylaxis are mentioned in the paragraph following this sentence. The introduction is only meant to be brief and not go into all detail around evidence.
Orthopaedic Trauma Society	Full Vol 1	139	General	NICE recommends risk assessment for all trauma patients yet acknowledge that there are no valid assessment tools – this recommendation will lead to further confusion and adds no clarity to what should be done on the ground. If the risk of a major bleed is unknown and the risk of PE unknown, then how can clinicians make a valid risk assessment? Surely this should be a research recommendation until the risks are quantified and a validated risk assessment tool is available..	Thank you for your comment. The GC are of the opinion that major trauma patients could be at risk of VTE as all other hospital patients and therefore should be risk assessed and given prophylaxis if considered at risk. The recommendation has been updated to state “Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)” Clinicians will need to make a judgement on balancing risks.

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Orthopaedic Trauma Society	Full Vol 1	183	General	It is recommended to use IPCs yet there is no evidence referenced it made a difference to VTE rates in trauma patients. The daily costs of these for every trauma operative case needs to be considered against any potential clinical gain	Thank you for your comment. Cost effectiveness has been taken into account in all of the guideline recommendations. The economic evidence presented supported the cost effectiveness of IPCD and showed that it was a cost saving option compared to vena cava filters in people who have contraindication to pharmacological prophylaxis. This is discussed further in the 'recommendations and link to evidence' section for this population, full volume 2, chapter 34, page 315
Orthopaedic Trauma Society	Full Vol 1	186	General	In 2017 do we really need a recommendation that we need to encourage patients to be mobile? This is standard practice in the NHS	Thank you for your comment. These are general recommendations that reinforce good practice and ensure that all the required information is available in one place for clinicians to refer to.
Orthopaedic Trauma Society	Full Vol 2	11	General	The recommendations of one type of anaesthesia over another is derived from elective surgical trials from over 20 years ago – this recommendation should be for elective surgery is unlikely to be applicable to trauma surgery	Thank you for your comment. This recommendation has been carried over from CG92 as it was not part of the remit of this guideline committee to update this review.
Orthopaedic Trauma Society	Full Vol 2	27	General	Recommendation 78 "Consider pharmacological VTE prophylaxis with LMWHb or fondaparinux sodiumc for people with lower limb immobilisation whose risk of VTE outweighs their risk of bleeding. Continue until lower limb immobilisation is stopped.	Thank you for your comment. Risk of VTE versus risk of bleeding should be balanced using a risk tool. It is important that healthcare professionals use expertise to assess patient's individual characteristics/risk factors to

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				<p>[2018]" Please see comment above; how can we do this when we have no idea of their risk of VTE versus bleeding?</p> <p>Also the use of IPCD has been assessed for lower limb embolization, what about in theatre when thousands are used every day at great cost to NHS</p>	<p>determine VTE prophylaxis.</p> <p>The committee discussed the overlap with the lower limb immobilisation section of the guideline and two orthopaedic sections: non-arthroplasty knee surgery and foot and ankle surgery. The use of IPCD has been evaluated in those populations as for all of the guideline populations. Relevant studies that evaluated IPCD were identified and included in the different evidence reviews. For more information about the effectiveness and cost effectiveness of IPCD in those please refer to the knee surgery or foot and ankle surgery sections of the guideline.</p>
Orthopaedic Trauma Society	Full Vol 2	57	General	Recommendation 79 states give prophylaxis for 28-35 days - could we just chose one time frame as there will be wide variability around country (currently 28 days)	Thank you for your comment. We have taken your view on board and specified that the recommended duration of prophylaxis is a month. This is in line with the durations reported in the trial evidence (28 to 31 days).
Orthopaedic Trauma Society	Full Vol 2	241	General	Recommendation 86 Consider VTE prophylaxis for people undergoing other knee surgery (for example, osteotomy or fracture surgery) whose risk of VTE outweighs their risk of bleeding -	Thank you for your comment. The committee discussed risk assessment at length. There are not tools that advise a clinician on how to balance risks the recommendations made by

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				again with fracture surgery how can we do this when we have no idea of their risk?	the committee reflect this. We have amended the VTE and bleeding risk assessment recommendations to acknowledge that the Department of Health tool is the most widely used risk assessment tool in the NHS.
Orthopaedic Trauma Society	Full Vol 2	246	General	Recommendation 89 again this phrase of “risk of VTE outweighs risk of bleeding” can we not use this as we do not know why the risk of clinical VTE. There is a large recent RCT on ankle fracture which showed no benefit – this should be added otherwise the guidelines are out of date before publication N Engl J Med 2017;376:515-25. DOI: 10.1056/NEJMoa1613303	<p>Thank you for your comment.</p> <p>The guideline committee decided that it is important to risk assess patients to those at increased risk of VTE. The committee also noted that any identified risk needs to be balanced against that patient’s risk of bleeding. There is no tool to give a quantified answer to this and it needs to be a clinical judgement. This is why the committee made this recommendation.</p> <p>This trial has been included under the population of people discharged with lower limb immobilisation in the full guideline, volume 2 chapter 24, as patients were treated with casting of the lower leg (lower limb/s were immobilised).</p>
Orthopaedic Trauma Society	General	General	General	Please do not use the term “risk of VTE outweighs the risk of bleeding” – you do not quote the risk of bleeding throughout the report , this phrase means little and will create huge debate (including in the	Thank you for your comment. The committee believe this is an important part of risk assessment which in turn is important to help reduce the risk of VTE in hospital patients.

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				courts – if there is no evidence please state that, if there is then we need hard figures to assess this risk.	The committee acknowledge that defining risk of bleeding in relation to the risk of VTE is difficult. It is a reflection of the lack of evidence showing how to do this. Even the risk tools which provide some quantification of risk for VTE and bleeding do not give a method of weighing up the results to state whether VTE risk is outweighed by bleeding. The committee are of the opinion that clinicians need to decide on a case by case basis whether an individual is more at risk of VTE of bleeding.
Portola Pharmaceuticals	Full Vol 1	18 19	11 – 455 1 - 2	Same comment as above	Thank you for your comment.
Portola Pharmaceuticals	Short	11	11 - 13	Section 1.3.24 states to offer pharmacological VTE prophylaxis for a minimum of 7 days to acutely ill medical patients whose risk of VTE outweighs their risk of bleeding: - Use low-molecular-weight heparin (LMWH) as first-line treatment - If LMWH is contraindicated use fondaparinux sodium. [2018] Portola comment: It has been shown that medically ill patients continue to be at risk for much longer than 7 days. The way the statement is worded could imply 10 days prophylaxis would be enough but in	Thank you for your comment. The recommendation states that LMWH should be administered for a minimum of 7 days. LMWH can be administered for an extended duration, if it is clinically appropriate (i.e. if patients are higher risk). However, the evidence identified shows that extended duration prophylaxis has limited clinical effectiveness for the patient groups analysed. Betrixaban was not included in protocols as it

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				<p>reality several observational studies have shown that acute medically ill patients remain at high risk of VTE for at least 30 days and up to three months after hospital discharge with the majority of VTE events occurring during this period.1-7 Of patients who developed VTE in the IMPROVE study, the majority (69%) developed VTE one to 42 days after hospital admission, and 45% had post-discharge VTE.2 In the analysis by Pendergraft et al (2013), 57% of patients had evidence of VTE following hospital discharge.4 Among patients with evidence of post-discharge VTE, 58% developed it within the first 90 days after hospital discharge, and 42% developed VTE from days 91 to 180. Amin et al (2012) conducted a retrospective, observational study to assess the incidence and time course of symptomatic VTE events during and after hospitalisation in a large population of 11,139 US medical patients.1 Of the 11,139 patients, 366 (3.3%) experienced a symptomatic VTE event during the 180-day observation period. At 40 days, the symptomatic VTE rate was greater than 2.0%. The majority of events occur after hospital discharge and standard prophylaxis. In total, 56.6% of all VTE events occurred after discharge.1 The findings of these studies emphasise that the risk of VTE extends beyond the in-hospital period and</p>	<p>is not licenced and therefore does not form part of this guideline. However, the committee noted that the patient group included in the Betrixaban trial is a very specific set of patients who are at a very high risk of VTE. The recommendation included in the guideline applies to a much wider group of people.</p>

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				<p>demonstrates the need to consider extending VTE prophylaxis after hospital discharge. Global audits have shown underutilisation of thromboprophylaxis by clinicians in hospitalised at-risk medical patients, mainly due to the perceived higher risk of bleeding or lower risk of VTE than that reported in the clinical trials.⁸ Among acute medically ill patients in the UK at risk of VTE in the ENDORSE study, only 37% received appropriate in-hospital prophylaxis.⁹ Reasons for the underutilisation of in-hospital prophylaxis may include decreasing lengths of hospitalisation in this patient population, with the average length of stay being 5 to 6 days, or concerns about the use of anticoagulants due to bleeding risk.^{1,10,11} As hospital stays shorten, many medical patients who are prescribed inpatient prophylaxis alone are unlikely to receive the prophylaxis for more than 6 days.¹ Patient compliance with the current therapies is impacted by pain/discomfort from injections, potential injection site hematoma,¹² and patient refusal of injections.^{13,14} Furthermore, the large population-based studies in medically ill patients suggest that use of an in-hospital only thromboprophylactic strategy does not reduce the community burden of VTE in this population.^{9,15} In addition to the underutilisation of in-hospital VTE</p>	

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				<p>prophylaxis, acute medically ill patients are also not currently receiving prophylaxis for VTE post-discharge. As discussed above, acute medically ill patients remain at highest risk of VTE from the beginning of hospitalisation and through at least 30 days after hospital discharge. Moreover, real-world studies have shown that the majority of VTE events in this population occur within 30 days after hospital admission.^{1,3,5,6}</p> <p>Previous clinical studies of extended prophylaxis in the medically ill population with other fXa inhibitors (EXCLAIM/enoxaparin, ADOPT/apixaban and, MAGELLAN/rivaroxaban) have failed to demonstrate a net clinical benefit (reduction in VTE vs increased major bleeding).¹⁶⁻¹⁸ Betrixaban is unique among the direct and indirect fXa inhibitors in this patient population. The APEX study has clearly shown that in patient populations at the highest risk for VTE extended thromboprophylaxis with oral betrixaban administered for 35 to 42 days compared to enoxaparin (at a dose of 40 mg) for 10±4 days resulted in a 25% relative risk reduction (RR = 0.75; 95% CI, 0.61–0.91; p = 0.003; NNT = 63) in the primary efficacy endpoint (composite of adjudicated asymptomatic proximal DVT, symptomatic proximal or distal DVT, non-fatal PE, or VTE-related death) in the modified intent to</p>	

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				<p>treat (mITT) population, without an increase in bleeding.¹⁹ This result was more pronounced in the high dose cohort (80 mg dose), with a 32% relative risk reduction (RR = 0.68; 95% CI, 0.55–0.86; p = 0.0008; NNT = 50) in the primary efficacy endpoint and reduced rates of VTE in the mITT population, without an increase in bleeding.</p> <p>Post-hoc analyses of the mITT population have shown important and significant reductions in symptomatic VTE events (Exploratory efficacy endpoint – composite of symptomatic proximal or distal DVT, fatal PE or VTE related death),²⁰ VTE related rehospitalisation²¹ (NNT = 127 through day 77) and fatal or irreversible outcomes (non-haemorrhagic cardiopulmonary death + non-fatal PE + MI + ischemic stroke + ICH), with a NNT = 56 through day 77.²²</p> <p>Based on the evidence above and comparing this with the statement in Section 1.3.24 we are concerned that by only stating thromboprophylaxis should be administered for a minimum of 7 days to medically ill patients there will be the tendency to administer around 7 days. This would leave patients at the highest risk without appropriate prophylaxis to reduce VTE for the critical period from hospital admission through 35 to 42 days when a substantial percentage of the VTE events occurred in medically</p>	

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				<p>ill patients.</p> <p>Question 1: This recommendation may lead to an inadequate duration of thromboprophylaxis to be administered in medically ill patients. Can the wording be amended to make clear that in patient populations at the highest risk for VTE the minimum ideal duration should be 35 days rather than 7 days?</p> <p>Question 2: How will a recommendation (if positive) for betrixaban which will be reviewed via a NICE STA be incorporated into the Clinical Guideline in timely way especially if the NICE Clinical Guideline is published before NICE concludes its STA?</p> <p>1. Amin AN, Varker H, Princic N, et al. Duration of venous thromboembolism risk across a continuum in medically ill hospitalized patients. J Hosp Med 2012. 7: 231–238.</p> <p>2. Spyropoulos AC, Anderson FA, FitzGerald G, et al. Predictive and associative models to identify hospitalized medical patients at risk for VTE. Chest 2011. 140: 706–714.</p> <p>3. Spyropoulos AC, Hussein M, Lin J, et al. Rates of venous thromboembolism occurrence in medical patients among the insured population. Thromb Haemost 2009. 102: 951–957.</p>	

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				<p>4. Pendergraft T, Atwood M, Liu X, et al. Cost of venous thromboembolism in hospitalized medically ill patients. Am J Health-Syst Pharm AJHP Off J Am Soc Health-Syst Pharm 2013. 70: 1681–1687.</p> <p>5. Spencer FA, Lessard D, Emery C, et al. Venous thromboembolism in the outpatient setting. Arch Intern Med 2007. 167: 1471–1475.</p> <p>6. Amin AN, Lin J, Thompson S, et al. Real-world rates of in-hospital and postdischarge deep-vein thrombosis and pulmonary embolism in at-risk medical patients in the United States. Clin Appl Thromb Off J Int Acad Clin Appl Thromb 2011. 17: 611–619.</p> <p>7. Beckman MG, Hooper WC, Critchley SE, et al. Venous thromboembolism: a public health concern. Am J Prev Med 2010. 38: S495-501.</p> <p>8. Spyropoulos AC & Raskob GE. New paradigms in venous thromboprophylaxis of medically ill patients. Thromb Haemost 2017. 117: 1662–1670.</p> <p>9. Cohen AT, Tapson VF, Bergmann J-F, et al. Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. Lancet Lond Engl 2008. 371: 387–394.</p> <p>10. Lauzier F, Muscedere J, Deland E, et al. Thromboprophylaxis patterns and determinants in critically ill patients: a multicenter audit. Crit Care</p>	

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				<p>Lond Engl 2014. 18: R82.</p> <p>11. Vardi M, Dagna L, Haran M, et al. Attitudes towards and practice of venous thromboembolism prevention in general internal medicine wards: a multinational survey from member countries of the European Federation of Internal Medicine. <i>Thromb Res</i> 2012. 129: 573–576.</p> <p>12. LOVENOX [package insert]. Bridgewater, NJ:sanofi-aventis U.S. LLC.</p> <p>13. Shermock KM, Lau BD, Haut ER, et al. Patterns of non-administration of ordered doses of venous thromboembolism prophylaxis: implications for novel intervention strategies. <i>PloS One</i> 2013. 8: e66311.</p> <p>14. Newman MJ et al. Nonadministration of thromboprophylaxis in hospitalized patients with HIV: a missed opportunity for prevention? <i>J Hosp Med</i>. 2014 Apr;9(4):215-20</p> <p>15. Mahan CE, Fisher MD, Mills RM, et al. Thromboprophylaxis patterns, risk factors, and outcomes of care in the medically ill patient population. <i>Thromb Res</i> 2013. 132: 520–526.</p> <p>16. Goldhaber SZ, Leizorovicz A, Kakkar AK, et al. Apixaban versus Enoxaparin for Thromboprophylaxis in Medically Ill Patients. <i>N Engl J Med</i> 2011. 365: 2167–2177.</p> <p>17. Cohen AT, Spiro TE, Büller HR, et al. Rivaroxaban for Thromboprophylaxis in Acutely Ill</p>	

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				<p>Medical Patients. N Engl J Med 2013. 368: 513–523. Hull RD, Schellong SM, Tapson VF, et al. Extended-duration venous thromboembolism prophylaxis in acutely ill medical patients with recently reduced mobility: a randomized trial. Ann Intern Med 2010. 153: 8–18.</p> <p>18. Hull RD, Schellong SM, Tapson VF et al. Extended-duration venous thromboembolism prophylaxis in acutely ill medical patients with recently reduced mobility: a randomized trial. Ann Intern Med. 2010 Jul 6;153(1):8-18</p> <p>19. Cohen AT, Harrington RA, Goldhaber SZ, et al. Extended Thromboprophylaxis with Betrixaban in Acutely Ill Medical Patients. N Engl J Med 2016. 375: 534–544.</p> <p>20. Gibson CM, et al Full-Dose Betrixaban Reduces Venous Thromboembolism-Related Mortality: An APEX Trial Substudy Circulation. 2017;136: A20393</p> <p>21. Chi G, et al Extended-Duration Betrixaban Reduces the Risk of Venous Thromboembolism-Related Rehospitalization Among Acutely Ill Hospitalized Patients: An APEX Trial Substudy Circulation. 2017;136:A20322</p> <p>22. Gibson CM, Korjian S, Chi G, et al. Comparison of Fatal or Irreversible Events With Extended-Duration Betrixaban Versus Standard Dose Enoxaparin in Acutely Ill Medical Patients: An APEX</p>	

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				Trial Substudy. J Am Heart Assoc 2017. 6:	
RCP	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to formally endorse the response submitted by the British Thoracic Society	Thank you for your comment.
Royal College of Emergency Medicine	Full	General	General	The guidance does not specifically mention CDU / Observation ward patients, but the overriding principle seems to be risk assessment on admission.	Thank you for your comment. That is right the principle is risk assessment on admission as it was with the last version of the guideline. We have added a definition for admission to the guideline to make this clear. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient, where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
Royal College of Emergency Medicine	Full	General	General	From our perspective the biggest impact will be the expectation that patients admitted to a CDU / Observation Ward will effectively have to be risk assessed and treated on admission. The current understanding is that if the patient is likely to be in hospital for less than 24hr then the risk assessment can be deferred.	Thank you for your comment. That is right the principle is risk assessment on admission as it was with the last version of the guideline. If after risk assessment the patient is likely to be in hospital for less than 24 hours then it is also likely that the patient is not at risk of VTE and VTE prophylaxis is not required. However, the committee are of the opinion that only the clinicians seeing the patient can make the

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					<p>judgement on a case by case basis.</p> <p>We have added a definition for admission. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.</p>
Royal College of General Practitioners	General	General	General	The piece re palliative care needs family involvement as starting injections some months before death may be a burden not wanted.	Thank you for your comment. This is mentioned in the recommendation which states: "Take into account temporary increases in thrombotic risk factors, risk of bleeding, likely life expectancy and the views of the person and their family members or carers (as appropriate)".
Royal College of General Practitioners	General	General	General	<p>what about 'flight socks' are these now recommended to be 'fitted' as opposed to buying over the counter?</p> <p>The 14 hr window suggest that if seen in an evening nothing needed till following day.</p>	<p>Thank you for your comment. The use of flight socks is outside of the scope of this guideline.</p> <p>We have amended our recommendation to state ".....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations" to align with the NHS England standards on "Seven day services in the NHS" (https://improvement.nhs.uk/resources/seven-</p>

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					day-services/).
Royal College of General Practitioners	Short	General	General	This is an odd document. There is a great deal of repetition. For instance, paragraphs 1.1.1 to 1.1.5 are repeated almost verbatim in 1.1.6 to 1.1.10, then again not quite verbatim 1.1.12 to 1.1.4 and 1.3.48 to 1.3.52. There are other examples throughout all the specialist sections of the guideline. This seems unnecessary and makes the document feel much more substantial than it really is. There must be a much more succinct way of presenting the recommendations that will make it easier for anyone wanting to refer to it.	Thank you for your comment. The committee felt that repetition in places was necessary to emphasise the importance of an action.
Royal College of General Practitioners	Short	7	26	Para 1.2.8 - This is very sensible advice. I have looked in the full guideline, and can find no evidence cited to support it, but the authors presumably think that no evidence is required. I agree with the advice, but it skates around the question of what 'notify' means. This is one example where a standard discharge letter is not really good enough. If the statement is to be included (and, again, I think it should) then it should be suggested that a phone call to the practice should be the standard of communication.	Thank you for your comment. It is the committee's view that the choice of the communication method will be dependent on local arrangement already in place in each trust.
Royal	Short	9	5	Para 1.3.7. This guideline looks onerous. It is not	Thank you for your comment. It is the

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College of General Practitioners				clear whether the advice is too difficult to be followed (therefore risking setting a rule that will be impossible to follow), or meaning that some patients will not be given stockings when they might have benefited, because of the fear of damage. It might help to express the intention in more permissive terms.	committee's view that it is important to highlight these precautions to avoid any untoward events that could arise as a result of using stockings. The committee consider that removing stockings to check a person's legs is important.
Royal College of General Practitioners	Short	9	21	Para 1.3.12 - The advice here again is sound. However, it appears that the job of giving alternative contraceptive advice is to fall to the surgeons, and in that sense looks a bit unlikely. Should the guideline be more open – so that patients are advised to seek other advice if necessary.	Thank you for your comment. The wording of this recommendation cannot be changed as it is carried over from CG92 and the review underpinning it has not been updated.
Royal College of Nursing	General	General	General	The Royal College of Nursing welcome proposals to update the venous thromboembolism in over 16s guideline. The RCN invited members who care for people with venous thrombosis to review the draft document on its behalf. The comments below reflect the views of our reviewers.	Thank you for your comment.
Royal College of Nursing	General	General	General	We welcome the 2018 additions which seem appropriate and add clarity to the guidelines.	Thank you for your comment.
Royal	General	General	General	It is welcome that this particular guideline has	Thank you for your comment.

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College of Nursing				emphasised nurses' roles in prevention of HAT.	
Royal College of Nursing	General	General	General	It is welcome that this guideline reemphasises the importance of continuing with the work done in individual hospitals.	Thank you for your comment.
Royal College of Nursing	General	General	Questions	<p>The following are answers to the specific questions NICE asked for this guideline:</p> <p><i>1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why?</i></p> <p>The guideline had to be updated from 2010. The current guideline is more specific.</p> <p><i>2. Would implementation of any of the draft recommendations have significant cost implications?</i></p> <p>There is a national Freedom of Information (FOI) requirement that hospitals are expected to complete and this highlights to individual trusts where they are in terms of their performance.</p> <p>Clinical Commissioning Groups (CCGs) implement penalties for organisations that</p>	Thank you for comment and responses to the specific questions asked.

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				<p>have increased HATs and who have no measures to prevent HATs.</p> <p>3. <i>What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</i></p> <p>Prevention of hospital-acquired 7 thrombosis (HAT) has been in place since 2010 therefore we do not envisage there is a need for national campaign.</p> <p>Hospitals have implemented VTE prevention and continuing to improve the process and data collection</p>	
Royal College of Nursing	Short	6	18	Section 1.2.3: We welcome the inclusion of the statement that heparins are of animal origin and the acknowledgment that this may be of concern for some people. We welcome the suggestion to discuss alternatives with people who may have concerns about using animal products.	Thank you for your comment.
Royal College of Nursing	Short	7	1.2.5 1.2.6	We welcome the advice and general information to people regarding using VTE prophylaxis and that of wearing anti-embolism stockings.	Thank you for your comment.

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Royal College of Obstetricians and Gynaecologists	Full Vol 1	General	General	Typo page 326 (full version, volume 1), 2 nd paragraph of text – ‘when the ubiquity og AES in many settings ...’ should be ‘when the ubiquity of AES in many settings ...’	Thank you for your comment, this has been amended.
Royal College of Obstetricians and Gynaecologists	Full Vol 1	Chapter 7, section 7.7	Pages 153-155	There is some interesting discussion in this section regarding risk assessment tools. Reference is made to the risk assessment outlined in RCOG Green-top Guideline 37a (“In discussion with the obstetric sub-group, the committee believed that basing assessment of risk on the current (2015) RCOG guidelines ¹⁶⁶ results in offering an unnecessarily large proportion of pregnant and postpartum women VTE prophylaxis (35% according to the included study ¹⁸¹ ”). It is acknowledged that the one risk model identified was based on low quality evidence and NICE offers no other risk assessment model or checklist. The list of risk factors for VTE in pregnancy and the puerperium provided in CG92 has been removed from this version. I would therefore urge NICE to recommend the use of the risk assessment checklists provided in RCOG Green-top Guideline 37a .	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.
Royal College of	Full Vol 1	Section 21	General	Consider appropriate reference to the RCOG Green-top Guideline 37a in regards to assessment of risk	Thank you for your comment. Following guideline committee discussion, the risk

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Obstetricians and Gynaecologists				factors and dosage of LMWH.	assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.
Royal College of Obstetricians and Gynaecologists	Full Vol 2	General	General	I have no comments to make.	Thank you for your response.
Royal College of Obstetricians and Gynaecologists	General	General	General	Thank you for asking us to review this guideline. Please see below a number of comments from our reviewers.	Thank you for your comment.
Royal College of	General	General	General	Comments focussed on: <ul style="list-style-type: none"> • Short version, pages 1–42 	Thank you for your comments. We have responded to these within each row.

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Obstetricians and Gynaecologists				<ul style="list-style-type: none"> Full guideline, volume 1, chapter 7 – Risk assessment for pregnant women and women up to 6 weeks post-pregnancy Full guideline, volume 1, chapter 21 – Pregnant women and women up to 6 weeks post-pregnancy	
Royal College of Obstetricians and Gynaecologists	General	General	General	Reviewing the guideline would have been easier if the numbering system on the summary guideline (short version) was the same as the main guideline.	Thank you for your comment. The two documents are separate from each other. It was not possible to number the recommendations in the same way.
Royal College of Obstetricians and Gynaecologists	Short	General	General	The document is very generalised in terms of pregnancy management and does not provide specific information which is of real value to practising clinicians. The recommendation for pregnant women is to follow a published tool or checklist.	Thank you for your comment. As with other patient groups, the guideline committee is unable to make highly specific recommendations that cover every clinical scenario in relation to VTE prophylaxis. If evidence identified from a literature search and/or clinical expertise expresses a strong concern about clinical harm associated with a specific intervention, guidance would be provided. The recommendations regarding risk assessment tools has been discussed by the guideline committee have been amended to introduce clarity (please refer to recommendations 1.1.9-1.1.10).

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Royal College of Obstetricians and Gynaecologists	Short	Recommendations that have been deleted or changed	26, 5 th row in table	IVC filters are useful in pregnant women at high risk of VTE where anticoagulation has to be interrupted. These women are otherwise at increased risk of haemorrhage. I appreciate that secondary prevention is not part of the scope of this guideline, but this could be useful for guideline users, therefore consider including.	Thank you for your comment. The guideline committee agree that IVC filters are useful in pregnant women at high risk of VTE. However, as this guideline is for primary prevention of VTE, this cannot be included. It is out of the scope of the guideline. Please refer to the NICE guideline CG144 which evaluates management using interventions such as IVC filters.
Royal College of Obstetricians and Gynaecologists	Short	1.1.3	9	Consider adding examples of validated tools in this stem e.g. National VTE Risk Assessment Tool	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)"
Royal College of Obstetricians and Gynaecologists	Short	1.3.15	1	Consider changing 'antiplatelets' to 'anti-platelets' to be in line with the rest of the document OR to 'antiplatelet agents'	Thank you for your comment. We have changed the terminology in the short and full guidelines to 'antiplatelet therapy' wherever appropriate (unchanged in evidence)

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sts					tables or in legacy text from previous guideline).
Royal College of Obstetricians and Gynaecologists	Short	1.3.47	General	This section suggests medical and mechanical thromboprophylaxis postpartum without being specific about the indications and clinicians would have to check the RCOG guideline for specifics (i.e. previous VTE, women with 4 risk factors antenatally or more than 2 risk factors postnatally etc.). I think that, in practice, this document is of limited value for the management of pregnant women, as there are no recommendations about dosage, risk factors, duration of therapy etc.	Thank you for your comment. The guideline committee has made risk assessment recommendations (please see recommendations 1.1.9-1.1.10) which present the importance of taking individual patient characteristics using a risk assessment tool. The guideline committee is unable to present highly specific details unless there is a strong clinical need to do so. The committee acknowledges that the RCOG risk tool is currently used in practice (see recommendation 1.1.9). Further discussion and advice can be found in the full volume of the guideline (please refer to full volume 1 of the guideline, pages 330-335).
Royal College of Obstetricians and Gynaecologists	Short	1.3.47	General	<i>Consider combined prophylaxis with LMWH plus mechanical prophylaxis for pregnant women or women who gave birth or had a miscarriage or termination of pregnancy in the past 6 weeks and who have significantly reduced mobility relative to their normal or anticipated mobility for 3 or more days after surgery, including caesarean section:</i> <ul style="list-style-type: none"> • <i>Use intermittent pneumatic compression as first-line treatment.</i> • <i>If intermittent pneumatic compression is</i> 	Thank you for your comment. There was limited relevant evidence available for pregnancy, evidence from abdominal surgery was extrapolated to this population (please refer to full volume 1 of the guideline, pages 325-329).The guideline committee noted that this population is high risk of VTE due to significantly reduced mobility and the presence of the risk factor of pregnancy itself. The committee also noted that prothrombin

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				<p><i>contraindicated use antiembolism stockings. Continue until the woman no longer has significantly reduced mobility relative to her normal or anticipated mobility or until discharge from hospital. [2018]</i></p> <p>This is really quite a vague statement and, given that it is not evidence based (as agreed by the committee) and has major resource implications in terms of intermittent pneumatic compression provision, it should perhaps be reconsidered. It would be seem appropriate to state that there is no evidence that prophylaxis additional to LMWH is of benefit but, in this higher risk group, it may be reasonable to offer some form of additional method, for example antiembolic stockings or intermittent pneumatic compression.</p>	<p>state continues post-partum. The extrapolated evidence presented intermittent pneumatic compression (IPC) in combination with LMWH as more clinically effective than ant-embolism stockings in combination with LMWH.</p>
Royal College of Obstetricians and Gynaecologists	Short	1.1.12 – 1.1.14	Page 5 of 42, lines 17-28 Page 6 of 42, lines 1-3	These [2018] recommendations are in line with RCOG Green-top Guideline 37a, published 2015	Thank you for your comment.
Royal College of Obstetricians and	Short	1.3.41 – 1.3.47	14 of 42, lines 16-21 Page 15	Recommendation 1.3.43 (short version), recommendation 65 (long version, volume 1) says “stop VTE prophylaxis when women are in labour”. Presumably this applies only to chemical	Thank you for your comment. We have amended this recommendation (now recommendation 1.6.3) to state ‘Stop

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Gynaecologists			of 42, lines 1-18 Page 16 of 42, lines 1-9	<p>thromboprophylaxis – antiembolism stockings can be worn during in labour in women at particular risk who have been using LMWH prior to the onset of labour.</p> <p>Recommendations 1.3.45 (short version), recommendation 67 (long version, volume 1) says that LMWH should be continued for a minimum of 7 days. The discussion on pages 326-327 of the long version (volume 1) acknowledges that there is a lack of evidence to support duration of thromboprophylaxis and that clinical judgement and individual assessment is required (which is good). RCOG Green-top Guideline 37a recommends a duration of at least 10 days; in view of the lack of evidence to support practice, it would be really helpful for clinicians if NICE and the RCOG were saying the same thing. Thanks for considering this.</p>	<p>pharmacological VTE prophylaxis.....”.</p> <p>There was limited relevant evidence available for pregnancy, evidence from abdominal surgery was extrapolated to this population (please refer to full volume 1 of the guideline, pages 325-329). The guideline committee noted that this population is high risk of VTE due to significantly reduced mobility and the presence of the risk factor of pregnancy itself. The committee also noted that prothrombin state continues post-partum. The extrapolated evidence presented intermittent pneumatic compression (IPC) in combination with LMWH as more clinically effective than ant-embolism stockings in combination with LMWH.</p> <p>The guideline committee agree that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group.</p>

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					Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE.
Royal College of Pathologists/ British Society of Haematology	Full Vol 1	Section 1.1	General	2. VTE risk assessment There is no recommended risk assessment tool for VTE risk and bleeding risk within the guideline. Sections 1.1.3/1.1.8 refer to assessing VTE risk 'using a published tool or checklist' i.e. not even recommending a validated one. This could lead to great variability nationally and hamper health improvements and data collection.	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)" The committee did not make a recommendation for a specific tool because no evidence was identified to show one tool was more effective than another.
Royal College of Pathologists/ British Society of	Full Vol 1	Section 1.1	General	Timing of interventions These could be clearer and with evidence base. What is the basis for sections 1.1.5 and 1.1.10 "start [LMWH] within 14 hours of risk assessment", and	Thank you for your comment. The initiation of VTE prophylaxis within 14 hours of risk assessment is in line with 7-day working standards. Risk assessment recommendations have been amended to

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Haematology				<p>1.3.45 for delivery “start 6-8 hours”</p> <p>On the other hand a recommendation on timing of re-introduction of chemical thromboprophylaxis after surgery would be helpful. Eg if only the minimum time suitable.</p> <p>“Minimum of 7 days” is a frequently used recommendation. eg 1.3.24, 1.3.45, 1.3.86, 1.3.89, 1.3.98 This requires clarification. Does this mean if someone remains an inpatient it must be for at least 7 days, or is the expectation that patients who are admitted for 48 hours should be discharged with another 5 days of LMWH: a massive undertaking</p>	<p>ensure that VTE prophylaxis is initiated as soon as possible. The guideline committee appreciate that there is limited evidence for initiation of LMWH and recommended the timeframe based on consensus expert opinion.</p> <p>In regards to re-introduction of pharmacological thromboprophylaxis, clinicians should refer to population specific recommendations for further details.</p> <p>The committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80). The committee appreciate that there may be concerns around administering LMWH post-discharge.</p>

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					However, the cost-effectiveness analysis conducted for CG92, which has been included in this review, has already taken into account district nurses' time and has shown that a prophylaxis duration of 10 days is clinically effective and cost-effective.
Royal College of Pathologists/ British Society of Haematology	Full Vol 1	Section 1.1.	General	5. Antiembolism stockings Section 1.1.1-1.1.5: removal of considering AES for medical patients with a CI to LMWH is an important change compared to previous guideline. It is important to make a clear statement in the summary of recommendations with regards to this as it represents a significant change from previous recommendation	Thank you for your comment. Specific recommendation regarding the choice of thromboprophylaxis for the acutely ill medical patients has been given in 1.4.7 and also in the full guideline, volume 1, chapter 16.
Royal College of Pathologists/ British Society of Haematology	Full Vol 1	Section 1.3.104	General	Would be a big change in practice for varicose vein surgery. Again can they provide a guideline for who fits criteria of 'risk of VTE outweighing risk of bleeding'?	Thank you for your comment. It is the aim of the guideline influence practice in a positive way. The decision as to whether someone fits the criteria for receiving prophylaxis should be based on the outcome of the initial risk assessment undertaken according to the guideline recommendations for risk assessment in surgical and trauma patients.
Royal College of Pathologists/	Full Vol 1	Section 1.3.12	General	One would hope 'fully anticoagulated' and "taking vit K antagonists who are within their therapeutic range" are the same thing	Thank you for your comment. The recommendation wording has been edited accordingly.

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British Society of Haematology					
Royal College of Pathologists/ British Society of Haematology	Full Vol 1	Section 1.3.27	General	Not clear in summary that this refers to cancer patients coming to day units (rather than inpatients or OPD)	Thank you for your comment. The recommendation covers both inpatients and those attending day units. The recommendation avoids stating hospital patients for this purpose. We have added a definition for admission in the guideline to make it clear which people undergoing day procedures are included. We have added a definition for admission to the guideline to make this clear. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient, where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
Royal College of Pathologists/ British Society of Haematology	Full Vol 1&2	General	General	The guidelines refer to hospital acquired thrombosis throughout the guideline but hospital associated thrombosis is a better description.	Thank you for you your comment. We have used the term "Hospital acquired thrombosis" because this is what the guideline seeks to reduce the risk of. 'Hospital acquired thrombosis' is also the term used in the title and scope of the guideline so it is better to use this term for consistency.

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Royal College of Pathologists/ British Society of Haematology	Full Vol 2	Section 26.6 and 27.6	General	We are particularly concerned regarding the recommendations for total hip and total knee replacements (THR and TKR). The sections 26.6 and 27.6 "Recommendations and link to evidence" do not clearly represent the network meta-analyses (NMA) presented in appendix M. In particular the LMWH for 10 days followed by aspirin does not appear in any of the ranking charts in appendix M. Moreover, LMWH clearly ranked better than aspirin, for PE LMWH (SD; ed) ranked best and aspirin not ranked, for bleeding LMWH ranked best, aspirin not ranked. The only justification for continuing to include aspirin appears to be that it is very cheap (27.6) and so scores well in cost-benefit analyses. Section 26.6 notes "The committee noted that LMWH was often amongst the top ranked interventions when assessing only the clinical data for all three critical outcomes, particularly when used for an extended duration and often when combined with anti-embolism stockings" but goes on to say "The economic model showed lack of cost effectiveness, with aspirin ranking last and worse than no prophylaxis. However, the experience of the orthopaedic surgeons in the orthopaedic subgroup suggests that aspirin may be a suitable prophylaxis options for some individuals". The evidence base for LMWH followed by aspirin is	Thank you for your comment. THR and TKR populations are treated separately due to the difference in the baseline risk of VTE. Hence, the recommendations are different for these two populations. LMWH for 10 days followed by aspirin for 28 days is a different intervention from aspirin alone and LMWH alone. It appears in the ranking plot in figure 830 (for PE) ranked as the best intervention. It also appears in figure 832 (for major bleeding) ranked as the best intervention. It was assumed that the same relative effectiveness for the PE outcome will apply to the DVT outcome, and hence this intervention does not appear in the NMA ranking plot for DVT. This assumption has been agreed with the committee a priori. The preferable cost effectiveness of this intervention is a result of its superiority in terms of clinical effectiveness and is not solely based on its cost. The evidence for this intervention was indeed based on a single trial. This has been acknowledged in the guideline. However, the

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				<p>noted by “the evidence of efficacy for this intervention is based on a single trial”. Hence for recommendations 82 and 84 we are concerned that the evidence for aspirin as an effective substitute for LMWH or DOAC in extended prophylaxis is not good enough to support the recommendation. TKR and THR appear to be the only situations in which this substitution is proposed. We are concerned that the guidelines often lack specific direction.</p>	<p>relative effectiveness estimates used in the analysis are based on network meta-analyses that include all the trials for all interventions, which increase the power of the analysis.</p>
<p>Royal College of Pathologists/ British Society of Haematology</p>	<p>General</p>	<p>Section 1.1</p>	<p>General</p>	<p>4. Clarity The summary recommendations are often vague with limited help for the practitioner. For example (88) the guidance: ‘whose risk of VTE outweighs their risk of bleeding’ is not very helpful. We would expect the guideline to be clearer on giving an assessment of balance of risk. OR 76 ‘plan the timing of pharmacological VTE prophylaxis to minimise the risk of epidural haematoma’ Again we would expect an analysis of the relationship between time and risk.</p>	<p>Thank you for your comment.</p> <p>The committee did look to provide clearer guidance for this but found no evidence to show how the risk of VTE is balanced against the risk of bleeding. Even the risk tools which provide some quantification of risk for VTE and bleeding do not give a method of weighing up the results to state whether VTE risk is outweighed by bleeding. The committee are of the opinion that clinicians need to decide on a case by case basis whether an individual is more at risk of VTE or bleeding.</p> <p>The evidence has not been reviewed for these areas and no changes to the meaning of the</p>

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					recommendations have been made. Therefore recommendations related to anaesthesia have been carried forward from NICE clinical guideline CG92, the previous version of the guideline. .
Royal College of Physicians and Surgeons of Glasgow	Full	General	General	The Royal College of Physicians and Surgeons of Glasgow welcomes this update on Venous thromboembolism in over 16s	Thank you for your comment.
Royal College of Physicians and Surgeons of Glasgow	Full	General	General	The College recommends that consideration should be given to the creation of a national standardised risk assessment form for VTE prophylaxis to replace individual hospitals creating their own. The numerous different risk assessments serves to confuse staff particularly when moving hospitals.	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)"
Royal College of Physicians	Full	General	General	It must be stressed for all indications the risk of bleeding must be balanced against the risk of venous thromboembolism. This should mean that	Thank you for your comment. The committee did not identify any evidence to show how to balance the risk of VTE against bleeding.

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and Surgeons of Glasgow				the relative risks should be given equal weighting.	Even the risk tools which provide some quantification of risk for VTE and bleeding do not give a method of weighing up the results to state whether VTE risk is outweighed by bleeding.
Royal College of Physicians and Surgeons of Glasgow	General	General	General	The guideline committee had only a limited number of medical and surgical specialities covered. In particular there was no cardiologist, gastroenterologist, stroke specialist or neurologist or rheumatologist. In surgery only vascular surgery, orthopaedic and trauma surgery were included.	Thank you for your comment. Unfortunately it was not possible to have specialist clinicians for all population groups evaluated in this guideline. The committee appreciate that this would have been very valuable. However, committee members were recruited for their knowledge in various population groups.
Royal College of Physicians and Surgeons of Glasgow	Short	4	4	With respect to risk of thromboembolism, consideration should be give to the future pharmacological needs of the patient for treatment of newly diagnosed diseases. For instance certain important drug therapies are contraindicated in patients on anticoagulants. Alternative compatible therapies should be considered. Certain diseases are associated with thrombosis and it is as important to treat the predominant disease rather than risk of thrombosis e.g. Systemic Lupus Erythematosus. There is no section on these conditions.	Thank you for comment. Specific diseases associated with thrombosis such as Systematic Lupus Erthythematosus were not highlighted during the scoping stage of the guideline. However, guidance has been provided for those who are using anticoagulants (please refer to recommendation 1.3.17)
Royal College of Physicians and	Short	18	3	Fragility fractures particularly of the pelvis are known to bleed heavily with considerable loss of blood. This carries risk for elderly patients. The paragraph needs to be clearly written whether the consideration is pre-	Thank you for your comment. The guideline committee agrees that bleeding risk is significant in the fragility fractures population. The recommendation has been amended to

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Surgeons of Glasgow				<p>operative or post operative. There is no discussion on the real risks of haemorrhage in these individuals.</p> <p>In the longer version, evidence is reviewed from volume 2 page 30 onwards. The majority of the studies when assessed had very low or low quality of evidence. Further justification of the advice is required.</p>	<p>reflect the balance of risk of bleeding and VTE.</p> <p>The guideline committee appreciate that the majority of the evidence identified as been graded as very low or low in this patient group (as well as many other patients groups). The guideline committee noted the quality of the evidence, expert opinion and practical/feasibility considerations when making recommendations. They believe the risk of VTE warrants making recommendations with this level of evidence. The uncertainty is reflected in the numerous occasions when a softer recommendation has been made for prophylaxis to be 'considered' rather than automatically 'offered'.</p>
Society of British Neurological Surgeons (SBNS)]	Full Vol 2	262	4	Amend this to read ' including craniotomies for brain tumours and haemorrhages including ruptured vascular lesions'.	Thank you for your comment we have amended this accordingly.
Society of British Neurological Surgeons (SBNS)]	Full Vol 2	262	6	Change intracranial to cranial	Thank you for your comment we have amended this accordingly.

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Society of British Neurological Surgeons (SBNS)]	Full Vol 2	262	9	Uncertain as to why previous history of neurosurgery is included ?	Thank you for your comment. We have removed this from the introduction.
Society of British Neurological Surgeons (SBNS)]	Full Vol 2	272	7	Paragraph should start with 'When' etc	Thank you for your comment. This has been edited.
Society of British Neurological Surgeons (SBNS)]	Full Vol 2	272	12	Full stop after Thrombocytopenia. However etc to follow	Thank you for your comment. This has been edited.
Society of British Neurological Surgeons (SBNS)]	Full Volume 2	262	general	The title of the Section should be CRANIAL SURGERY rather than Intracranial to encompass the range of operations performed by neurosurgeons including those done jointly with other specialists	Thank you for your comment we have amended this accordingly.
Society of British Neurological Surgeons (SBNS)]	General	General	General	Q1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. Q2. Would implementation of any of the draft recommendations have significant cost implications? Q3. What would help users overcome any challenges? (For example, existing practical	Thank you for your comments. The committee hope this will not require much change as the recommendations related risk assessment and methods of prophylaxis for patients undergoing cranial surgery are similar in this update to the recommendations in the

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				<p>resources or national initiatives, or examples of good practice.)</p> <p>Q 1. The main challenge will be to ensure that every patient has an assessment on admission and at regular intervals thereafter. The compliance for wearing and providing AED stockings needs education of clinical teams. The other major area to quantify the risk of VTE and risk of bleeding. There is very little evidence to decide and it is often qualitative.</p> <p>Q 2. The cost of PCC devices will be an issue.</p> <p>Q 3. Risk assessment tools should be easily available and the best for purpose recommended for use.</p>	previous version of the guideline.
Society of British Neurological Surgeons (SBNS)]	Short	7	11	1.2.6 – add a bullet point specifically to highlight the importance of ensuring that groin length stockings have to be properly fitting and the risk of the device acting as a tourniquet rather than a support if it is too tight as it has a frequently a tendency to roll downwards	Thank you for your comment. This information has been given in the full guideline, volume 1, chapter 9, section 9.1.2.1.
Society of British Neurological	Short	23	4, 5, 6	The Executive of the SBNS discussed this recommendation and concluded that the time of commencement of LMWH after cranial surgery	Thank you for your comment. The recommendation has been changed to be in line with the recommendation for elective

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Surgeons (SBNS)]				should be with the treating surgeon and the wording should be the same as for Elective spinal surgery (1.3.72 and 1.3.73) with a time line of 24-48 hours being indicated but according to clinical judgement and taking into account patient characteristics and surgical procedure. The recommendation of 1.3.73 in the Spinal section should be added to the Cranial section to allow clinicians to commence LMWH earlier than 24 hours in specific situations and the decision to involve MDT or senior opinion or agreed local protocols. Also, the continuation of the treatment for a minimum of 7 days is acceptable but the issue about impaired mobility is equally applicable for spinal and cranial surgery patients and the wording should include the duration of reduced mobility.	spinal surgery. A window of 24-48 hours has been specified. The same recommendation allowing surgeons to start earlier than 24 hours in specific situations has also been added as has the duration of reduced mobility has been stated.
Society of British Neurological Surgeons (SBNS)]	Short	23	7, 8	The Executive Council of the SBNS concluded that recommendation 1.3.78 should be deleted because there was no evidence to support this and there was a wide variation of current practice among neurosurgeons whether to give or withhold LMWH in this group of patients.	Thank you for your comment. This has now been removed.
Society of British Neurological	Short	23	18, 19	Add to 1.3.81 that the assessments should be repeated at regular intervals after the initial assessment.	Thank you for your comment. Reassessment of risk has been covered in a general chapter in the Full Guideline, Volume 1, Chapter 6.

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Surgeons (SBNS)]					
The British Orthopaedic Foot and Ankle Association	Full Vol 2	246	14	The British Orthopaedic Foot and Ankle Society have a current position statement on VTE prevention in patients that have undergone foot and ankle surgery which agrees with the general recommendations of this document.	Thank you for your comment. The guideline committee welcomes this.
The Clinical Leaders of Thrombosis	CG92	207	General	: The Clinical Leaders of Thrombosis have received information in relation to a audit carried out in the an Acute Stroke Unit and would like to make the following recommendations. Contact Huw Rowswell (Chair)	Thank you for your comment.
The University Hospital of the North Midlands	CG 92	232	15.6	Our trust has had experience of a audit in VTE prevention post stroke and we are happy to share this approach and would be willing to submit its experiences to the NICE shared learning database. Contact jodie.williams@uhnm.nhs.uk	Thank you for your comment. NICE encourage stakeholder to submit their experiences. More information on how to communicate with NICE is available from https://www.nice.org.uk/get-involved/contact-us
Thrombosis UK	Full Vol 1	15	1, 3, 4, 6,8,9,11, 12, 13, 14	Since 2010 NICE Guidance included recommendation to risk assess using the Department of Health VTE Risk Assessment Tool . This risk assessment tool had received NICE recommendation within previous guidelines (CG92) since 2008/2010, has been incorporated into clinical practice and shown to effectively work in all UK settings.	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment

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				<p>No other VTE risk assessment tool has been validated for this specific population, or to the extent the Department of Health VTE Risk assessment tool has been.</p> <p>Furthermore, work is progressing towards implementation of a national VTE audit programme. The use of a single, validated VTE risk assessment tool, tested and validated for the intended population, is a critical factor in being able to ensure efficacy of the planned audit programme.</p> <p>We strongly urge NICE and the guidelines Committee to review this omission and move to include recommendation of use of the tested and evidenced in the UK population, the Department of Health National VTE Risk Assessment Tool indicated in all other related NICE VTE guidance.</p>	<p>tool for medical patients is the Department of Health National risk assessment tool (see appendix)"</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence they also discussed that it can lead to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
Thrombosis UK	General	General	General	<p>Thrombosis UK would like to than NICE for bringing this guidance to Committee for review and update. There are several new recommendations that will increase the comprehensive reach of this Guideline and thus both safe-guard and bring benefit to patient care and patient outcome.</p> <p>However, we would draw the Committee's attention</p>	<p>Thank you for your comment. We have responded to the further points where they appear in subsequent rows.</p>

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Thrombosis UK	Short	19	2 – 1.3.60	<p>Procedure specific: Elective THR and TKR: Dose of aspirin recommended? 75mg and 300mg available in the UK. In view of the increased risk of GI bleed, we would welcome the Committee including advice regarding stomach protection for the duration of therapy (PPI show significant reduction in GI bleed)</p>	<p>Thank you for your comment. We have added potential doses to the recommendation.</p> <p>None of the trials that assessed aspirin as a prophylaxis strategy specified combining it with a PPI; hence, it is not possible to recommend this combination.</p>
		19	17 – 1.3.62	<p>The use of aspirin eliminates a major analgesic class (COX2 or short course of Ibuprofen/Naproxen) which might have an impact on LOS for elective patients.</p> <p>Does elective knee replacement include uni-compartmental replacement? If so, please can this be specified within the Guideline?</p> <p>Would it be possible for the Committee to include a comment regarding AF patients already prescribed a DOAC, and reference to NICE CG180 AF Guidelines, in order to support the calculation of CHADSVASc /HAS-BLED to decide whether to restart immediately on AF dose or have a few days</p>	<p>We did not include COX2 inhibitors as a method of prophylaxis. The included studies may have included patients using these but this was not identified as a factor to report when the protocols were developed and therefore the data were not extracted. Consequently, we cannot make a recommendation or comment on these medications.</p> <p>Elective knee replacement does not include uni-compartmental replacement.</p> <p>VTE prophylaxis for patients already receiving anticoagulation for other indications has been</p>

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				of prophylactic dose? In practice, this causes uncertainty, and can be confusing in particular for surgeons/anaesthetists having to consider this issue. Clarification with reference to relevant assessment tool in CG180 would be helpful.	covered in a separate chapter in the guideline (Chapter 13)
Thrombosis UK	Short	5	4 - 1.1.8	<p>The draft updated short document has recommended <i>“Assess all surgical and trauma patients for their risk of VTE using a published tool or checklist”</i></p> <p>For reasons given in response ‘2’, Thrombosis UK strongly urge the Committee to review this wording and suggest only recommending risk assessment using the validated and tested Department of Health VTE Risk Assessment tool- (as referenced in all other related NICE VTE risk assessment guidance) for all VTE risk assessment.</p>	<p>Thank you for your comment. We have amended our recommendations to state:</p> <p>“Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)”</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially</p>

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					<p>incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
Thrombosis UK	Short	6	7 - 1.2.2	<p>The draft guidelines indicate: <i>“for people admitted to hospital who are at increased at VTE, give them.....written and verbal information...”</i></p> <p>Whilst some patients can be identified as ‘at increased risk’ on admission, a significant number have risk changes during their hospitalisation and their VTE risk will often increase.</p> <p>We feel it is very important that all patients (carers and/or close family member) admitted to hospital should be given written and verbal information about VTE in order to increase and empower prevention, and awareness supporting early detection.</p>	<p>Thank you for your comment. This applies to all patients. Wording has been amended to make this clearer.</p>
Thrombosis UK	Short	6	5 – 1.2.1	<p><i>Giving information: The greatest risk for developing VTE is admission to hospital.</i></p> <p><i>Whether elective or not, admission to hospital understandably is accompanied by levels of anxiety.</i></p>	<p>Thank you for your comment. This applies to all patients. Wording has been amended to make this clearer.</p>

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				<p><i>Verbal communication alone, has a low level of retention. Given that individuals being admitted to hospital, will either be in poor health or concentrating on the elective procedure they have been admitted to undergo, verbal communication alone about VTE and VTE risk assessment alone is insufficient. This has also been advocated by hundreds of enquiries to Thrombosis UK, who have little or no recollection of VTE assessment and shared information on admission to hospital, even when an elective admission.</i></p> <p>Thrombosis UK would ask the Committee to include in the guideline, recommendation that on admission to, and discharge from hospital all individuals should be given verbal and written information on VTE risk assessment and VTE.</p>	
Thrombosis UK	Short	10	2 – 1.5.15	Settings and services vary tremendously. To support safe implementation of recommendations, Thrombosis UK would suggest the Committee considers including a comment/recommendation, reminding service providers to measure platelets before initiation of UFH/LMWH, and then weekly during commencement of treatment for the first two weeks.	Thank you for your comment. The committee are of the opinion that this would be done as standard and have therefore not made any statement relating to this.

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Thrombosis UK	Short	17	6	Orthopaedics: We would suggest that the Committee include recommendation for all licensed direct acting oral anticoagulants (DOACs) to be considered in orthopaedic surgery, guided by current license/UK marketing authorisation and NICE STA guidance – as indicated in: TA245, TA157, TA170	Thank you for your comment. It is the view of the guideline committee members that these DOACs are not clinically equivalent and should not be considered to have a class effect. Dabigatran and apixaban are now included in this recommendation. However, as both were not cost effective compared to rivaroxaban, the committee decided that these options could only be considered if all the three recommended options are not suitable for the person (for example due to contraindications or issues related to patient preference).
Thrombosis UK	Short	21 21	1 - 1.3.66 4 - 1.3.67	Non-arthroplasty: Please can the Committee include the same narrative as 1.3.65? This would support clarification (LMWH 14/7) regarding ACL (crucial ligaments) who receive LMWH 10/14 days. Foot and ankle: Please can the guidelines include the same narrative as 1.3.65?	Thank you for your comment. These recommendations are worded in a different way as the committee are of the opinion that they are a more heterogeneous group than the recommendation for arthroscopic knee surgery.
Thrombosis UK	Short	24	1 - 1.3.88	Guidance has indicated: 'Until the person no longer has significantly reduced mobility relative to their normal anticipated mobility'	Thank you for your comment. We have added a definition to the guideline. Significantly reduced mobility refers to people who are bed

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				Please would the Committee include a definition of this phrase, relevant for the whole guidelines document to clarify and avoid any misinterpretation or misunderstanding.	bound, unable to walk unaided or likely to spend a substantial proportion of their day in bed or in a chair. Clinicians will need to assess how this compares to their normal anticipated mobility.
Thrombosis UK	Short	29	16	Oral surgery: <i>Please can the Committee include clarification whether this includes multiple tooth extraction under conscientious sedation? For example: total clearance (all teeth), procedure time about 45 minutes in a dental surgeon chair and mobile immediately. These patients are not usually assessed for VTE risk assessment.</i>	Thank you for your comment. If the patient is admitted then they would fall into the remit of the guideline and need to be risk assessed as all other admitted patients. If not, then they are outside of the scope of the guideline and the committee have made no statement on their need for VTE prophylaxis. We have added a definition for admission to the guideline. Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient, where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
Thrombosis UK	Short	35	21	LMWH and obese patients: The recommendations / comments regarding dose related to weight for obese individuals, lacks clarity. The UK National Medicines Directory (UKMI) sets out clear dosage guidance. Is this not a valid document that could be	Thank you for your comment. The committee considered the evidence on effectiveness of dose-adjusted strategies for LMWH but did not identify any so have proposed research in this area. The suggested document refers to

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				referenced? (See link: LMWH and body weight: https://www.sps.nhs.uk/wp-content/uploads/2016/10/QA414_2-2016-final-version-Oct-16.pdf	treatment of venous thromboembolism rather than prophylaxis.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Full	General	General	We are not aware of any strong evidence to support changing the remit of the guideline from >18 yrs to >16 yrs. We anticipate that risk assessing this age group may result in overuse of prophylaxis in a group of patients in whom VTE is very rare. It will also have implications for our unify risk assessment data submissions.	Thank you for your comment. The committee are of the opinion that some people aged 16-18 are at risk of VTE, for example girls in this age group may be taking a contraceptive pill. The current age range was in the scope and the committee reiterated that all patients should be offered the same prophylaxis if their risk of VTE outweighs their risk of bleeding. Risk assessment would determine if an individual's risk of VTE outweighs their risk of bleeding and they require prophylaxis. If this is shown to be the case then prophylaxis should be offered according to their condition.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis	Full Vol 1	153	19	Recommendation 13: we are concerned at the very general recommendation to assess "using a published tool or checklist". There are numerous published tools and checklists available, the majority of which are not pregnancy-specific. The committee acknowledge later in this section ("Trade-off between clinical benefits and harms" and "Other	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and

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Group				considerations”) that age, Body Mass Index, hyperemesis, multiple pregnancy etc are likely to be risk factors for pregnancy but in the effort to equate the pregnancy recommendations with those for medical and surgical patients, this important distinction is lost. We feel a more appropriate recommendation would be to use a tool or checklist “based on Royal College of Obstetrics and Gynaecologists (RCOG) thromboprophylaxis guidance”, which allows tailoring to local circumstances but includes pregnancy-specific measures.	Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Full Vol 1	321 onwards	Section 21	The draft refers to the surgical risks associated with pregnancy but appears to downplay the medical risks that may be associated with the current pregnant/recently delivered population who the committee acknowledge to be older and have higher BMIs than previously. Women are entering pregnancy with more significant medical complications than in the past. These women may be at greater risk of VTE than non-pregnant women when admitted for medical reasons and consideration of this should be built in to risk assessment. This may be a suitable topic for research.	Thank you for your comment. The guideline committee acknowledges that medical risks associated with pregnancy are important in contributing to risk of VTE. However, evaluating individual medical risks associated with pregnancy was not highlighted as a topic within the scope of guideline. The guideline committee is therefore unable to make an explicit research recommendation regarding this. A research recommendation evaluating risk assessment tools in pregnancy has been presented (please see Appendix R1, full volume 2, page 696-697). The guideline committee encourage research into medical risk factors that can be incorporated in a

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					clinically-effective and cost-effective validated risk tool in this population.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Full Vol 1	323	18 Recommendations	Recommendation 66: the recommendation to administer Low Molecular Weight Heparin (LMWH) within 14 hours of risk assessment does not appear to be evidence-based (a criticism of many recommendations in eg RCOG guidance which are therefore discounted in this draft). Introducing a target time for administration may add to risk as healthcare professionals strive to meet a time target and forget the wider context for the patient eg potential need for neuraxial analgesia in women admitted for induction of labour.	Thank you for comment. The guideline committee felt that a timeframe is useful, as it provides an auditable goal which is safe, sensible and achievable. As highlighted in the 'recommendations and link to evidence' section, in the full volume 1, chapter 21, pages 331-336, "The committee recommend a time point that is in line with current NHS policy on time to consultant review of acute inpatients. This standard states that all emergency admissions must be seen and have a thorough clinical assessment by a suitable consultant as soon as possible but at the latest within 14 hours from the time of admission to hospital. The committee agreed that recommending a similar timeframe within which pharmacological prophylaxis should be given (if indicated by risk assessment) makes logical clinical sense and will ensure clinical care is not delayed".
UK Clinical Pharmacy Association (UKCPA) Haemostasis	Full Vol 1	323	18 Recommendations	Recommendation 67: We are concerned that the proposed duration of treatment is reduced compared with RCOG. Numerous centres have adapted practice to supply a 10 day course of postnatal LMWH. This is a pragmatic duration, covering the	Thank you for your comment. The guideline committee agree that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration

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and Thrombosis Group				period of greatest risk, allowing original packs to be supplied (either over-labelled or dispensed). With a recommendation of a minimum of 7 days treatment, centres may assume they will save money on drug costs if they reduce the duration supplied from 10 days, but unless the drug companies make available suitable packs to the NHS at an equivalent cost per syringe to that quoted in the draft (Appendix Q), much time, effort and money will be spent on repacking LMWH and any financial savings envisaged from the reduced duration may not materialise.	presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE. The guideline committee felt that evidence should be followed rather than current usage of drug packs.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Full Vol 1	324	18 Recommendations	Recommendation 67: "start 6–8 hours after the event unless contraindicated". National guidance for regional anaesthesia (Obstetric Anaesthetists Association /Association of Anaesthetists of Great Britain & Ireland) states that LMWH can be given 4 hours after epidural catheter removal. This has been implemented without apparent increase in postnatal bleeding. Timing of first dose LMWH heparin postnatally and impact on bleeding would be a suitable research topic, and review of the suggested timing of dosing is requested.	Thank you for your comment. The recommendation has been amended with the lower value in the range has been lowered to 4 hours instead of 6 hours. The guideline committee appreciate that there is limited evidence for initiation of LMWH and recommended the timeframe based on consensus expert opinion.
UK Clinical Pharmacy Association	Full Vol 1	324	18 Recommendations	Recommendations 68 & 69: we feel that these would be more easily understood if combined into one statement as they appear to be suggesting the same	Thank you for your comment. The two recommendations have been combined to state:

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(UKCPA) Haemostasis and Thrombosis Group			ons	outcome but 68 is phrased as "Do not" and 69 is phrased as "Consider". We would propose deletion of 68 and amendment of 69 to the following "who gave birth or had a miscarriage or termination of pregnancy in the past 6 weeks and who are likely to be immobilised, or have significantly reduced mobility relative to their normal or anticipated mobility, for 3 or more days after surgery including caesarean section:"	Consider combined prophylaxis with LMWH plus mechanical prophylaxis for pregnant women or women who gave birth or had a miscarriage or termination of pregnancy in the past 6 weeks and who are likely to be immobilised, or have significantly reduced mobility relative to their normal or anticipated mobility for 3 or more days after surgery, including caesarean section: <ul style="list-style-type: none"> • Use intermittent pneumatic compression as first-line treatment. • If intermittent pneumatic compression is contraindicated use antiembolism stockings.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Full Vol 1	327	18 Other considerations	The draft states "The committee believed there was no evidence to change current accepted practice of no adjustment in dose for pregnant women". Centres are routinely adjusting thromboprophylaxis doses for weight in pregnancy and the puerperium (as per RCOG 37a) whereas this states the opposite. Could the committee review the statement please – we would be able to collate information on this on an adhoc basis, if required.	Thank you for your comment. The guideline committee agree that some centres do use weight adjusted doses, but noted that there is inadequate evidence to recommend this. The committee discussion section has been amended to acknowledge that weight-adjusted doses are used by some centres.
UK Clinical Pharmacy Association (UKCPA)	Short	General	General	Many of the recommendations advise to give thromboprophylaxis for a minimum of 7 days. There is no evidence to offer for a minimum 7 days. The benefit of extending thromboprophylaxis beyond	Thank you for your comment. The committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was

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Haemostasis and Thrombosis Group				discharge in the presented studies was offset by an increased risk of bleeding (this is in a highly selected trial population and bleeding risk may well be higher in 'real world'). Many patients are discharged sooner than 7 days and this has both significant implications in terms of cost and for community nursing. A significant proportion of patients may be unable/unwilling to self-administer. Recommend amend to continue until hospital discharge or whilst hospitalised for a minimum of 7 days and until mobility returns to baseline.	recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80). The committee appreciate that there may be concerns around administering LMWH post-discharge. However, the cost-effectiveness analysis conducted for CG92, which has been included in this review, has already taken into account district nurses' time and has shown that a prophylaxis duration of 10 days is clinically effective and cost-effective.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	15-16	P15,11-P16, 9	1.3.46 and 1.3.47 Consider rewording or removing 1.3.46 as this is covered by 1.3.47 and results in unnecessary repetition.	Thank you for your comment. Recommendations 1.3.46 and 1.3.47 have been combined for clarity (please see recommendation, now numbered 1.6.6).

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UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	4 5	11 5	<p><i>Recommendations 1.1.3/1.1.9</i></p> <p>We strongly recommend that the National VTE risk assessment tool remains the main tool in England for several reasons: Much of the success and progress of the National VTE Prevention Programme has been due to the consistent approach taken throughout the country. Some of the alternative tools have more than two risk categories which will mean that there are groups of patients (i.e. moderate risk) who do not fall under any NICE guidance for thromboprophylaxis. Patients may find their risk is assessed differently at different hospitals if different tools are used. This may result in different thromboprophylaxis being given and further complicate the process of root cause analysis of hospital associated thrombosis. Junior doctors who rotate frequently are most commonly responsible for completing the risk assessment, if each trust has a different tool it may lead to inaccurate completion. The committee's feeling that the current tool results in too many medical patients receiving anticoagulation is not evidenced but should be a priority area for research.</p>	<p>Thank you for your comment. We have amended our recommendations to state:</p> <p>"Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)"</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis</p>

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					risk assessment.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	4 5	13 8	<i>Recommendations 1.1.5/1.1.10</i> Thromboprophylaxis should be prescribed as soon as is practically possible, ideally after the risk assessment. There is no evidence to support this and it made lead to delays in prophylaxis prescription. It may also have implications on the classification of hospital associated thrombosis. This presumable relates to a recent standard that a patient must be reviewed by a consultant within 14 hours, however it is not necessary for a patient to be seen by a consultant to be risk assessed and for thromboprophylaxis to be prescribed.	Thank you for your comment. We have amended our recommendation to state ".....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	5	21 - 23	<i>1.1.13</i> Recommend use of risk assessment tool based on RCOG guidelines as is used in most trusts.	Thank you for your comment. Following guideline committee discussion, the risk assessment in pregnancy recommendations have been amended (please refer to recommendations 1.1.9-1.1.10). The guideline committee is aware and acknowledges that the Royal College of Obstetricians and Gynaecologists (RCOG) risk assessment tool is commonly used in clinical practice to assess risk of VTE in pregnancy. There was a lack of evidence for the RCOG risk tool; therefore the guideline committee could not specifically recommend it.

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04/10/2017 to 15/11/2017

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UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	5	13	<i>1.1.11</i> Clarify what a 'senior' review is. Open to interpretation. Suggest changing to 'clinical review'.	Thank you for your comment. We have changed "senior review" to "consultant review" so that it is in line with the document on "Seven day services in the NHS" (https://improvement.nhs.uk/resources/seven-day-services/).
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	10	25 - 26	<i>IPC in acute stroke</i> We acknowledge that the CLOTs trials commenced IPC within 3 days but feel that the guidance should state as soon as possible after admission in order to protect the patient at the highest risk time, particularly as it is not associated with any risk to patients. Most IPC companies recommend that caution is used if IPC is left off for a certain amount of time (i.e. 3 hours) in case of VTE development due to the theoretical risk of embolization with IPC so if IPC is not applied as soon as possible after admission, concerns regarding VTE development may prevent or further delay IPC application.	Thank you for your comment. The committee acknowledges your concern but feel that starting IPC within 3 days of admission is appropriate as it may be difficult to judge which survival cohort the patient is in during the very early hours of a stroke, so this is a balanced recommendation. Different clinical scenarios would require different initiation times and the committee are of the opinion that this is best judged by the clinician assessing the individual.
UK Clinical Pharmacy Association (UKCPA)	Short	10	22	<i>Recommendations for Acute stroke</i> Anticoagulant thromboprophylaxis is used safely in many acute stroke patients with careful consideration of the bleeding vs thrombosis risk	Thank you for your comment. The committee reviewed the evidence for pharmacological VTE prophylaxis and did not feel that that current evidence demonstrated a strong

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Haemostasis and Thrombosis Group				balance. IPC isn't indicated or tolerated by some patients which may leave them vulnerable if NICE advise against chemical prophylaxis as well. Suggest that this be amended to 'consider anticoagulant thromboprophylaxis in high risk patients after careful assessment of bleeding risk'.	<p>enough positive effect on VTE outcomes to warrant recommending pharmacological prophylaxis in this population where bleeding would have catastrophic consequences.</p> <p>It was noted that it is standard practice for stroke patients to be administered anti-platelets as part of their treatment; the committee noted that it would not be necessary to recommend additional pharmacological prophylaxis.</p> <p>The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices. Although, the committee do not recommend the use of these devices deleting this recommendation means there is no longer provides a barrier for clinicians considering other forms of prophylaxis.</p> <p>Please refer to full guideline volume 1; pages 238-241 for further discussion of the evidence.</p>

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UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	12	6	<i>1.2.27</i> Clarify 'oncological treatment'. Does this apply to radiotherapy/chemotherapy/immunotherapy/all?	Thank you for your comment. The recommendation has been edited to clarify that oncological treatments are "cancer modifying treatments such as radiotherapy, immunotherapy or radiotherapy".
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	13	1	<i>Recommendation 1.3.31</i> Again, this will be expensive and consume a lot of resources without a clear evidenced based benefit to patients and potential increased risk of bleeding.	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed. A research recommendation has been made as well to assess the clinical and cost effectiveness of pharmacological prophylaxis in this population.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	16	10 - 19	<i>People with psychiatric illness</i> There is no evidence that people with psychiatric illness should be risk assessed and the incidence of VTE in this patient group is still unknown. Until more is known about VTE in this patient group, routine risk assessment should not be implemented as it may result in increased risk to patients from bleeding and will be a huge economic burden.	Thank you for your comment. A research recommendation has been made to address this paucity of evidence and assess the burden of VTE associated disease in psychiatric inpatients. However, the guideline committee was of the opinion that as some patients are at risk of developing VTE, these patients should still be assessed and offered prophylaxis. It is the

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					committee's view that the incremental cost of prophylaxis in this population is likely to be offset by the cost saving achieved from the averted VTE events.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	17	22	<i>Lower limb immobilisation</i> There is limited evidence that these patients would benefit from receiving thromboprophylaxis, it is likely that only the highest risk patients would benefit and these should be risk stratified. Recommend amending to 'consider pharmacological thromboprophylaxis in patients at high VTE risk'.	Thank you for your comment. The guideline committee agree that overall the risk of VTE in this heterogeneous patient group can be low. The recommendations highlight the need to assess then balance the risk of VTE and risk of bleeding and the consideration of VTE prophylaxis. If the patient has been identified as low risk of VTE after risk assessment then the clinician can decide that prophylaxis is not necessary.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	19	1 - 12	<i>Elective hip replacement</i> We note recommendations made based on cost-effectiveness; the role of AES has not been evaluated in two of the proposed options but if it improves efficacy in LMWH would be logical to include for option of LMWH followed by aspirin. Most patients post THR will be discharged prior to day 10, therefore having a switch at day 10 increases the possibility of error e.g. patients may take both from discharge which will increase risk of bleeding and potentially reduce efficacy as duration will be reduced. If it is not clear, on discharge that aspirin is for short-term use it is very likely to be	Thank you for your comment. The committee did not wish to recommend combinations that were not supported by evidence . As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, the committee did not wish to recommend any of these combinations. The committee anticipate that minimising errors will be addressed through implementing adequate measures to ensure patient safety including appropriate counselling on

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				<p>continued long term in the community. Suggest remove this as an option.</p> <p>Include dabigatran and apixaban as options for pharmacological thromboprophylaxis since NICE approved them through technology appraisals, costs may well fluctuate so may not always be more cost effective to use rivaroxaban</p>	<p>discharge.</p> <p>The cost effectiveness analysis takes into account clinical effectiveness as well as costs. It showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its first recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. Hence, the benefits of recommending one option were considered to outweigh the risk of reducing competition.</p> <p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered . Any change in prices that is likely to impact the relative cost effectiveness of these DOACs will be taken into account when the guideline is considered for updating in the future.</p> <p>The recommended choices are given to address the issue of contra-indications. For</p>

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					those in whom DOAC is the only suitable option, rivaroxaban should be considered as the preferred choice based on clinical effectiveness, safety and cost effectiveness.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	20	1 - 9	<p><i>Elective knee replacement</i></p> <p>As above recommendations based on cost effectiveness. Whilst aspirin was most cost effective, this option has the least evidence to support its use (single underpowered study).</p> <p>Given AES have only been studied in LMWH population but improve cost effectiveness, it would appear logical to offer combined treatment to all options.</p> <p>Given apixaban and dabigatran also has NICE TA approval for use as an option, these should also be offered.</p>	<p>Thank you for your comment. The relative efficacy estimates for aspirin are based on network meta-analyses which include all relevant trials for all included interventions. This in part addresses the problem of the low analysis power resulting from the small number of trials for each of the intervention.</p> <p>The recommended interventions were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, it is not possible to recommend any of these combinations.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its recommendation to allow for standardisation of practice. The committee</p>

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					also believed that recommending only one DOAC is likely to reduce costs and minimise errors.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	20	18 - 21	<i>Non-arthroplasty orthopaedic knee surgery</i> Limited evidence to recommend giving patients having arthroscopic knee surgery 14 days of LMWH, under current guidelines most wouldn't receive any prophylaxis at all and we don't see hospital associated thrombosis in this patient group. Suggest amending to consider for those with total anaesthesia time of >1 hour AND additional VTE risk factors which outweigh risk of bleeding. Suggest amend duration to 7 days in line with other areas (with greater VTE risk) given evidence for extended duration not well established.	Thank you for your comment. The recommendation is for prophylaxis to be considered in this group based on risk assessment, not to be offered to everyone. This recommendation has been based on extrapolation from the elective total knee replacement surgery.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	29	17 - 19	<i>Oral and maxillofacial surgery</i> As a lot of oral and maxillofacial surgery is performed in day surgery and often under local anaesthetic, we recommend that patients are only offered thromboprophylaxis if their risk is very high, i.e. previous VTE. As before, this should be for the length of hospital stay or 7 days, whichever is shorter. There is no evidence to support this patient group routinely receiving prophylaxis and again the resource and financial burdens are potentially	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials

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				significant.	extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
UK Clinical Pharmacy Association (UKCPA) Haemostasis and Thrombosis Group	Short	29	5	<i>Recommendation 1.3.104</i> Suggest only offer thromboprophylaxis to very high risk varicose vein surgery patients such as those with previous VTE as the evidence to offer all patients prophylaxis is very weak and will again result in a large financial and resource burden as well as potentially increasing the risk of bleeding.	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. The decision as to whether someone fits the criteria for receiving prophylaxis should be based on the outcome of the initial risk assessment undertaken according to the guideline recommendations for risk assessment in surgical and trauma patients. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
UK Clinical Pharmacy Association (UKCPA) Haemostasis	Short	30	5 - 15	<i>ENT surgery</i> As a lot of ENT surgery is performed in day surgery and often under local anaesthetic, we recommend that patients are only offered thromboprophylaxis if their risk is very high, i.e. previous VTE. As before,	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE.

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and Thrombosis Group				this should be for the length of hospital stay or 7 days, whichever is shorter. There is no evidence to support this patient group routinely receiving prophylaxis and again the resource and financial burdens are potentially significant.	We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
University College London Hospitals NHS Foundation Trust	Short	General	Beginning	Would state (and re-iterate throughout), the need for general VTE risk reduction measures for all patients ie maintaining good hydration and early mobilisation	Thank you for your comment. These general recommendations have been included in the full guideline, volume 1, chapters 9 and 10 and short version as recommendations 1.3.14 and 1.3.15.
University College London Hospitals NHS Foundation Trust	Short	General	Beginning	Are there any NICE clinical audit standards?	Thank you for your comment. The quality standard associated with this guideline will be updated.
University	Short	General	General	If there is a lack of evidence regarding the most	Thank you for your comment. We have

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College London Hospitals NHS Foundation Trust				appropriate VTE risk assessment tool (and the National VTE risk assessment tool is not being recommended by NICE), then could a suggestion be included as to possible alternative published options? Trusts already use the 'National tool' in order to be compliant with the requirement in the NHS Standard Contract of '95%'adults patients VTE risk assessment on admission to hospital'. The question will be asked (as it already is by clinicians), as to the clinical benefit of using a tool where evidence is lacking and not endorsed by NICE, but against which individual Trust performance is rated.	amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix)" The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.

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University College London Hospitals NHS Foundation Trust	Short	4	13 - 15	Thromboprophylaxis for medical patients within 14 hours of <i>risk assessment</i> . This assumes that all patients receive timely risk assessment on admission to hospital (definitions of 'timely' and 'on admission' have not been formally defined and are variably interpreted within the NHS). In routine clinical practice, 'within 14hours of risk assessment' could actually be highly variable depending on the time of the initial VTE risk assessment. If the 14hour time frame is taken from the current NHS policy on time to consultant review of acute inpatients (as soon as possible but at the latest within 14 hours from the time of admission to hospital), then thromboprophylaxis should be started within 14 hours of <i>admission</i> (assuming appropriateness) and not within 14hours of risk assessment. HOWEVER , 'time of admission' has not been defined.	Thank you for your comment. We have amended our recommendation related to pharmacological prophylaxis for medical patients to state "...start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations". We have amended our recommendation related to risk assessment to state that assessment should happen "as soon as possible after admission to hospital or by the time of the first consultant review".
University College London Hospitals NHS Foundation Trust	Short	4	5	A time limit for 'admission to hospital' needs to be defined, otherwise there could be tremendous variability	Thank you for your comment. We have amended our recommendation to state that assessment should happen "as soon as possible after admission to hospital or by the time of the first consultant review".
University College London	Short	4	17	A time limit for 'admission to hospital' needs to be defined, otherwise there could be tremendous variability	Thank you for your comment. We have amended our recommendation to state that assessment should happen "as soon as

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Hospitals NHS Foundation Trust					possible after admission to hospital or by the time of the first consultant review".
University College London Hospitals NHS Foundation Trust	Short	5	8 - 11	See comment 5. Same question for surgical and trauma patients regarding starting pharmacological thromboprophylaxis within 14hours after the VTE risk assessment	Thank you for your comment. We have amended our recommendation to state ".....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".
University College London Hospitals NHS Foundation Trust	Short	5	18 - 19	A time limit for 'admission to hospital or midwife-led unit' needs to be defined, otherwise there could be tremendous variability	Thank you for your comment. Admission – We have added the following definition to the guideline: Admission in the context of this guideline refers to admission as an inpatient, where a bed is provided for one or more nights or admission as a day patient where a bed will be provided for a procedure including surgery or chemotherapy but not for an overnight stay.
University College London Hospitals NHS Foundation	Short	5	5	See comment 3 re 'published tool / checklist'	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a

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Trust					<p>tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)”</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
University College London Hospitals NHS	Short	5	23	See comment 3 re ‘published tool / checklist’	Thank you for your comment.

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Foundation Trust					
University College London Hospitals NHS Foundation Trust	Short	5	26	If the risk assessment is to be completed within 6 hrs, then the start of thromboprophylaxis could be considerably delayed. At UCLH postpartum LMWH is started within 6 hrs of delivery or termination of pregnancy	Thank you for your comment. The guideline committee noted that there is a lack of evidence for reassessment within 6 hours but felt that following expert opinion, recommending reassessment within 6 hours of giving birth, having a miscarriage or having a termination of pregnancy or when clinical condition changes is practical.
University College London Hospitals NHS Foundation Trust	Short	6	9	Could NICE provide standardized information for use across trusts ?	Thank you for your comment. The information will need to be specific to the patient.
University College London Hospitals NHS Foundation Trust	Short	6	23	Could NICE provide standardized information for use across trusts?	Thank you for your comment. The information will need to be specific to the patient.
University	Short	7	4	Could NICE provide standardized information for use	Thank you for your comment. The information

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College London Hospitals NHS Foundation Trust				across trusts ?	will need to be specific to the patient.
University College London Hospitals NHS Foundation Trust	Short	7	11	Could NICE provide standardized information for use across trusts ?	Thank you for your comment. The information will need to be specific to the patient.
University College London Hospitals NHS Foundation Trust	Short	9	27	Would amend wording – <i>'do not allow people to become dehydrated unless clinically indicated'</i> !!	Thank you for your comment. The wording of this recommendation cannot be changed as it is carried over from CG92 and the review underpinning it has not been updated.
University College London Hospitals NHS Foundation Trust	Short	10	12-13	Note that patients may be undergoing warfarin 'bridging' therapy (eg peri-procedurally) and be intentionally under anticoagulated with sub therapeutic doses of LMWH depending on thrombosis vs bleeding risk of procedure. The draft statement, does not acknowledge these patients and VTE thromboprophylactic doses may not be	Thank you for your comment. We have updated the recommendation and removed reference to patients who are fully anticoagulated. We have also referenced in the section on 'Recommendations and link to evidence' the British Committee for Standards for Haematology document on perioperative

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				appropriate. The reader should be referred to local Trust guidelines for the management of these patients	management of anticoagulation and antiplatelet therapy for information. The committee thought they could not mention every scenario on this issue and therefore linking to further guidance would be helpful.
University College London Hospitals NHS Foundation Trust	Short	10	15-16	Some warfarin inpatients may have slightly subtherapeutic INRs ; the implication of this paragraph (lines 14-17), is that patients should be offered VTE prophylaxis in this situation. Reader should be referred to local Trust guidance for the management of anticoagulated patients.	Thank you for your comment. This recommendation has now been removed to avoid confusion. The recommendation related to acute coronary syndromes has also been changed to note this group do not usually require prophylaxis. The section on 'Recommendations and link to evidence' provides a link to British Society for Haematology guidance on this topic (14.6 of full version).
University College London Hospitals NHS Foundation Trust	Short	10	19 (which refers to lines 12-13)	Acute coronary syndrome (ACS): patients treated with fondaparinux 2.5mg od or rivaroxaban 2.5mg BD as part of their ACS treatment are not fully anticoagulated. Could lines 12/13 be misinterpreted and VTE prophylaxis added to ACS rivaroxaban therapy in error? (Unlikely for fondaparinux, as 2.5mg od is a licensed dose for VTE prophylaxis). Would suggest careful rewording of ACS paragraph (line 19) to make it explicit that VTE prophylaxis should not be concomitantly added to patients	Thank you for your comment. This recommendation has been edited to note that prophylaxis is not usually required in this group.

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				receiving anticoagulant drugs as part of their ACS treatment (even though the level of anticoagulation with rivaroxaban/fondaparinux is not therapeutic)	
University College London Hospitals NHS Foundation Trust	Short	11	11	Duration of pharmacological VTE prophylaxis for medical patients (minimum 7 days) - please clarify whether prophylaxis is just as an in-patient or whether it should be continued beyond discharge (and until patient back to baseline mobility). Discharging medical patients on LWMH injections will be a change to routine clinical practice and will likely significantly impact on primary care with regards to administration and secondary care costs.	Thank you for your comment. Prophylaxis should be continued after discharge, if discharge occurs before 7 days. We did not find any evidence to support the efficacy of shorter duration of LMWH prophylaxis. Hence, the minimum duration has been specified based on the evidence available and the clinical experience of the guideline committee. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
University College London Hospitals NHS Foundation Trust	Short	12	16 - 17	Thrombotic risk is often driven by the disease and not just by chemotherapy, in which case it may not be appropriate to stop thromboprophylaxis just because chemo has stopped.	Thank you for your comment. There was not enough evidence to recommend prophylaxis for people with cancer alone. The evidence relates to the treatment of chemotherapy and therefore the committee based the recommendations on the treatment and not the disease. With this in mind once the chemotherapy is stopped the committee believe the prophylaxis should also be stopped.
University	short	12	6	Should the reference read 1.3.28 (and not 1.3.29)?	Thank you for your comment, we have

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College London Hospitals NHS Foundation Trust					corrected this.
University College London Hospitals NHS Foundation Trust	Short	12	7	Should the reference read 1.3.29 (and not 1.3.10)?	Thank you for your comment, we have corrected this.
University College London Hospitals NHS Foundation Trust	Short	12	7	Suggest give examples of 'increased VTE risks' such as cancer type/stage of disease, previous VTE, immobilisation, hormonal therapies, angiogenesis inhibitors (thalidomide, lenalidomide, pomalidomide) as per ACCP 2012.	Thank you for your comment. The committee did not want to add examples within recommendations. They have however amended the main risk assessment recommendations to highlight that the Department of Health tool is the most commonly used tool. This is also included in the guideline appendices. See risk assessment recommendations in section 1.1 of the short version of the guideline.
University College	Short	12	9	For myeloma patients, should probably state that (1) patient VTE risk factors (e.g. previous VTE, obesity,	Thank you for your comment.

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London Hospitals NHS Foundation Trust				co-morbidities) (2) myeloma factors (e.g. at diagnosis, hyperviscosity) and (3) treatment factors (e.g. concurrent use of high-dose steroids), all be taken into consideration when assessing VTE risk and the need for pharmacological thromboprophylaxis. Evidence for using aspirin as thromboprophylaxis for thalidomide? The Current London Cancer network multiple myeloma guidelines 2015, advise that patients taking thalidomide with additional risk factors receive LMWH (dose depending on number risk factors) rather than aspirin, due to poor evidence of the latter.	All populations should be risk assessed in line with the recommendations in section 1.1. of the short version of the guideline. For myeloma patients the committee are of the opinion that all these patients should be considered for VTE prophylaxis because of the treatment factors in conjunction with their cancer add to their risk of VTE. The recommendation to use aspirin was based on the cost effectiveness evidence identified (Chalayer 2016). There was no evidence to distinguish between aspirin and LMWH heparin hence the committee recommend either option.
University College London Hospitals NHS Foundation Trust	Short	12	10	Include pomalidomide as well?	Thank you for your comment. The committee agree and the recommendation wording has been edited to add pomalidomide to the types of chemotherapy.
University College London Hospitals	Short	13	2 - 4	This says to consider pharmacological VTE thromboprophylaxis for patients with central venous catheters receiving chemo; note that many of these patients will be outpatients and fully mobile.	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous

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NHS Foundation Trust				However, pg 12, lines 5-8 states that patients having oncological treatment and who are mobile, should <i>not</i> be offered VTE prophylaxis. In the two sections contradict each other – clarity needed.	catheters who are having chemotherapy should be removed. A research recommendation has been made as well to assess the clinical and cost effectiveness of pharmacological prophylaxis in this population.
University College London Hospitals NHS Foundation Trust	Short	15	11 - 15	Re choice of mechanical thromboprophylaxis (if deemed appropriate); section 1.3.46 is not explicit re choice. Assuming this section also relates to the choices listed on page 16, lines 3 and 4, then would suggest cross-referencing i.e. ' <i>LWMH plus mechanical prophylaxis (see section 1.3.47 for choice)</i> '	Thank you for your comment. Recommendations 1.3.46 and 1.3.47 have been amended/combined for clarity (please see recommendations in section 1.6)
University College London Hospitals NHS Foundation Trust	Short	15	8 - 10	A significant number of women giving birth will have regional anaesthesia peri-delivery. We feel that there should be some reference to this fact, as the timing of the catheter insertion/removal will impact on the both the timing of the last thromboprophylactic dose of LMWH given pre catheter insertion and the first thromboprophylactic dose of LMWH given post catheter removal (as per the Royal College of Obstetricians and Gynaecologists, RCOG). Regional anaesthesia is already mentioned on pg 17 Lines 13-17 NB: There will also be women who are at higher risk of thrombosis (VTE, cardiac etc) requiring specialist	Thank you for your comment. The guideline committee agree with your point about catheter insertion and removal, a statement will be added into the discussion for the recommendation (please refer to full volume 1 of the guideline, pages 330-335).

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				haematological input (ie those requiring intermediate intensity / therapeutic anticoagulation with LMWH during pregnancy). In these cases, the 'usual' timings of LMWH around catheter insertion / removal will not apply and specific peri-delivery anticoagulation plans re needed.	
University College London Hospitals NHS Foundation Trust	Short	15	4	'Starting LMWH within 14 hours of VTE RA being completed' – same comment re point 5 above re definition of timelines for risk assessment etc	Thank you for your comment. We have amended our recommendation to "If using LMWH in pregnant women, start within 14 hours of the risk 4 assessment being completed...."
University College London Hospitals NHS Foundation Trust	Short	15	9	Practical rationale behind when to start thromboprophylaxis acknowledged from NICE 2018 Vol 1. Locally we use 6hours	Thank you for your comment. The guideline committee are glad that recommendation reflects current clinical practice.
University College London Hospitals NHS Foundation	Short	15	10	Duration of thromboprophylaxis; rationale for minimum 7 days noted. But RCOG Green top guideline No 37a, 2015, states 10 days	Thank you for your comment. The guideline committee agree that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout

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Trust					the guideline. It was also noted that studies such as the Million Women Study (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80) have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE.
University College London Hospitals NHS Foundation Trust	Short	16	7 - 9	Should there be a minimum duration? (ie 7 days if post routine c-section)	Thank you for your comment. The committee did not identify evidence for a time point for the duration of mechanical prophylaxis in this group of patients. They noted that it is most effective in any group when the patient is immobile. Furthermore IPC devices cannot be used when an individual is mobile. Consequently, the committee are of the opinion that once a patient is mobile there is no evidence to continue using mechanical methods of prophylaxis. This recommendation is in line with other surgical recommendations.
University College London Hospitals NHS	Short	18	7 - 8	Fragility fractures, pelvis, hip and femur – likely a high risk patient group (elderly with probable degree of renal impairment). Would suggest highlighting caution with the fondaparinux statement – ie add 'refer to SPC for higher risk patients (≥75 years, <50	Thank you for your comment. The guideline committee agree that SPC should be referred for patients and encourage clinicians to do so. However, the guideline committee felt that it was not appropriate to include this within the

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Foundation Trust				kg and/or renal impairment CrCL 20 - 50 ml/min). Or perhaps advise avoid fondaparinux completely?	recommendation, Prophylaxis should be in line with the SPC for all medications and the committee did not think it was appropriate to specify it just for this case and not others.
University College London Hospitals NHS Foundation Trust	Short	18	1	Lower limb immobilisation – ‘continue until lower limb immobilisation is stopped’. Should baseline mobility be acknowledged? (ie ... <i>and back to baseline mobility, whichever is the longer</i>)	Thank you for your comment. The guideline committee are of the opinion that baseline mobility can be difficult to assess and that the risk of VTE associated with lower limb immobilisation is most easily defined by the duration of immobilisation. However, we have amended this recommendation to state Consider stopping prophylaxis if lower limb immobilisation continues beyond 42 days” .
University College London Hospitals NHS Foundation Trust	Short	18	11	‘Consider pre-op VTE prophylaxisstopping 12 hours before surgery’ – a frequently misunderstood statement in routine practice. Does it mean that it is acceptable to take the last dose 12 hours before surgery, or that the dose should be omitted 12 hours before surgery. Would advise clarification of wording	Thank you for your comment. The guideline committee felt that people undergoing surgery for fragility fractures of the pelvis, hip and proximal femur should not have their last dose of prophylaxis within 12 hours of surgery. The recommendation has been edited to state “Consider pre-operative VTE prophylaxis for people with fragility fractures of the pelvis, hip or proximal femur if surgery is delayed beyond the day after admission. Give the last dose no less than 12 hours before surgery for LMWH or 24 hours before surgery for fondaparinux sodium.”

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University College London Hospitals NHS Foundation Trust	short	18	11	'Consider pre-op VTE prophylaxis stopping 12 hours before surgery' – please review this statement. SC fondaparinux has a significantly longer half-life than SC LMWH (17hrs in healthy young, 21 healthy elderly vs ~3.5-4 hours for dalteparin) – the timing advice will be different for the two drug classes.	Thank you for your comment. The recommendation has been changed to reflect the different timing advice required for the two drugs.
University College London Hospitals NHS Foundation Trust	Short	19	4	For confirmation please re LMWH followed by aspirin: this is <u>38 days</u> post-op thromboprophylaxis in total ?	Thank you for your comment. Yes, we confirm that this is the recommended intervention. This has been clarified in the wording of the recommendation which now reads “LMWH for 10 days followed by aspirin for a further 28 days”.
University College London Hospitals NHS Foundation Trust	Short	19	13	Elective hip replacement: ' <i>consider AES until discharged from hospital if pharmacological interventions are contraindicated</i> '. Should this be AES until back to baseline mobility? The push for early discharge means that patients may be discharged 5-7 days post-op and may not be fully mobile, especially if going to 'rehab' rather than home. This group would otherwise receive less thromboprophylaxis compared to the other 3 groups receiving thromboprophylaxis for approx. 28-38 days	Thank you for your comment. The committee recommended stockings until discharge because they consider this a good proxy for mobility. There was no evidence for stockings alone for long periods. The committee believe that LMWH alone once discharged would be sufficient prophylaxis and a similar level of protection as the other two recommended options of aspirin and rivaroxaban which offer single rather than combined prophylaxis after hospital discharge.
University College	Short	20	16 - 17	Would re-iterate need for general VTE risk reduction measures such as maintenance of good hydration	Thank you for your comment. These are general considerations that have to be

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London Hospitals NHS Foundation Trust				and early mobilisation, especially if patient not receiving thromboprophylaxis	followed in all patients. They have been covered in the Full Guideline, Volume 1, Chapters 9 and 10.
University College London Hospitals NHS Foundation Trust	Short	20	1	<ul style="list-style-type: none"> • What dose of aspirin is proposed? • What about patients at higher VTE risk (eg additional VTE risk factors such as a previous history of VTE, but not on longterm anticoagulation), where aspirin may insufficient as VTE thromboprophylaxis (unless NICE has additional information for this patient group)? A risk stratified approach is surely needed? What about patients taking longterm aspirin? Are additional thromboprophylactic precautions required? 	<p>Thank you for your comment. A recommended dose has been added to the recommendation for elective knee replacement surgery. We did not find evidence to be able to make recommendations based on risk stratification.</p> <p>The recommended options include other prophylaxis strategies than aspirin that can be used, they are LMWH in combination with stockings or rivaroxaban. If a clinician does not feel aspirin is appropriate they can consider using one of these instead. There wasn't the evidence to recommend a tiered approach to the recommendations.</p> <p>The guideline includes a section on patients who are already receiving anti-platelets, including aspirin, for other indications (chapter 12).</p>
University College	Short	20	12	Elective knee replacement: For intermittent pneumatic compression device (IPCD) use, what is	Thank you for your comment. By mobile the committee mean once the patients is up and

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London Hospitals NHS Foundation Trust				the definition of 'mobile'? As stated in Vol 2, IPCD will likely delay mobilisation and so the recommendations is counter-intuitive.	moving about. We have made this clear in the section on 'Recommendations and link to evidence' and added a definition for significantly reduced mobility to the glossary of the full version and 'Terms used in the guideline' of the short version.
University College London Hospitals NHS Foundation Trust	Short	21	8	Is the reference back to 1.3.59 correct?	Thank you for your comment. It should cross refer to the lower limb immobilisation recommendation. We have corrected this.
University College London Hospitals NHS Foundation Trust	Short	26	5	Is there any evidence for the use of thromboprophylactic doses of fondaparinux in bariatric patients	Thank you for your comment. One study was included in this review (EFFORT trial (Steele 2015)). It compared LMWH (standard dose pre-op, high dose post-op; standard duration) versus fondaparinux (see Full guideline, volume 2, page 393-397).
University College London Hospitals NHS Foundation Trust	Short	26	16	Cardiac patients may be receiving single or dual antiplatelet therapy; need to consider risks of bleeding with additional thromboprophylaxis vs thrombosis in this context	Thank you for your comment. The guideline recommends that bleeding risk assessment should be undertaken before prescribing pharmacological VTE prophylaxis to balance the risk of bleeding against the risk of VTE. This risk assessment should take into account any concomitant medication that the person is

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					receiving for their cardiac condition.
University College London Hospitals NHS Foundation Trust	Short	28	2	Depending on the thrombosis risk of the vascular procedure and patient, therapeutic anticoagulation may be required.	Thank you for your comment. The guideline recommends that risk assessment should be undertaken before prescribing any VTE prophylaxis. This risk assessment should take all these factors into account to guide the decision as to whether to prescribe pharmacological VTE prophylaxis.
University College London Hospitals NHS Foundation Trust	Short	29	20 - 22	Is mechanical thromboprophylaxis proposed if pharmacological thromboprophylaxis contraindicated? (implied but not specifically stated, unlike other surgery types)	Thank you for your comment. It could be in combination or when pharmacological prophylaxis is contraindicated. Although the committee agreed most of this group would not require prophylaxis there may be some high risk patients where combined could be beneficial.
University College London Hospitals NHS Foundation Trust	Short	30	9 - 11	Is mechanical thromboprophylaxis proposed if pharmacological thromboprophylaxis contraindicated? (implied but not specifically stated, unlike other surgery types)	Thank you for your comment. This is correct, mechanical VTE prophylaxis should be used if pharmacological VTE prophylaxis is contraindicated. The wording has been amended to add clarity.
University Hospital Southampton NHS Foundation	Short	General	General	<i>The guideline now includes >16 to <18 years olds.</i> We are concerned that there is currently no validated VTE risk assessment tool available for people under 18. Therefore it is likely that young	Thank you for your comment. The committee acknowledge that there are no validated risk assessment tools for people under 18. The committee discussed that despite this they are of the opinion that some people aged 16-18

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Trust				<p>people <18 will be risk assessed with risk assessment tools designed for adult patients. This in turn would possibly result in over use of prophylaxis in this age group, with significant cost implications as well as putting patients at increased risk of bleeding. We are also concerned that there are currently no medicines licensed for VTE prophylaxis in under 18s and that the proposed guidance will put prescribers in a difficult situation trying to obtain consent for prescribing medicines off-label without strong supporting evidence.</p> <p>We would recommend to include risk assessment and VTE prophylaxis for >16 to <18 years olds to the recommendations for research section.</p>	<p>are at risk of VTE, for example girls in this age group may be taking a contraceptive pill. The current age range was in the scope and the committee reiterated that all patients should be offered the same prophylaxis if considered at risk of VTE. Risk assessment would determine if an individual requires prophylaxis. If shown to be at increased risk then prophylaxis should be offered according to their condition. The committee did not believe that age alone is the only risk factor for this group. The other factors commonly associated with risk of VTE in adults could also increase the risk of VTE in under 18s. In the absence of an appropriate tool the committee aer of the opinion that this group should be risk assessed in the same way that adults.</p>
University Hospital Southampton NHS Foundation Trust	Short	General	General	<p><i>Recommendation to start pharmacological VTE prophylaxis within 14 hours after the risk assessment, unless otherwise stated.</i></p> <p>We welcome the intention to give guidance on the appropriate time to initiate prophylaxis. However, we believe that it is essential to also give guidance on the timeframe for completion of risk assessment. – see above. We are concerned that a 14 hour time frame for starting thromboprophylaxis may lead to</p>	<p>Thank you for your comment. We have amended our risk assessment recommendation to state that risk assessment for VTE and bleeding should be done “.....as soon as possible after admission to hospital or by the time for the first consultant review” to emphasise the importance of doing this early. The committee believe there still needs to be some room for maneuver with the start time</p>

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				delays in starting prophylaxis. We believe that thromboprophylaxis should be prescribed as soon as possible after the risk assessment, with the first dose given as soon as practical.	of pharmacological prophylaxis so the risks can be discussed with the consultant if that is appropriate. We have also edit the recommendation on when to start prophylaxis to "...as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".
University Hospital Southampton NHS Foundation Trust	Short	General	General	<p><i>Duration of prophylaxis with LMWH for a minimum of 7 days for various patient groups (acutely ill medical patients, cranial surgery, abdominal surgery, bariatric surgery, thoracic surgery, oral and maxillofacial surgery, ENT surgery).</i></p> <p><i>In the full version (Vol 1 p326) the guideline committee notes the lack of evidence to support recommendation of a specific duration of prophylaxis with LMWH. It was acknowledged that this will require clinical judgement and individual assessment. Longer duration of prophylaxis will be more costly but might be considered essential. We are concerned that a minimum duration, likely extending beyond the hospital stay, is included in the guideline despite the lack of evidence in many patient groups. This is likely to lead to a significant cost pressure. We are also concerned about the additional work load due to the need for teaching patients to self-administer LMWH. There will also be</i></p>	<p>Thank you for your comment. The committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted that studies such as the Million Women Study have shown that the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80). The committee appreciate that there may be concerns around administering LMWH post-discharge. However, the cost-effectiveness analysis conducted for CG92, which has been included in this review, has already taken into account</p>

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				an additional pressure on councils needing to dispose of sharps waste in the community. We would suggest continuing prophylaxis until discharge unless there is good evidence for certain patient groups to extend prophylaxis beyond discharge.	district nurses' time and has shown that a prophylaxis duration of 10 days is clinically effective and cost-effective.
University Hospital Southampton NHS Foundation Trust	Short	4	4 16	Risk assessment. The recommendations for risk assessing medical and surgical and trauma patients appear identical. Splitting the recommendation adds unnecessary complexity to the guideline. We would recommend combining these sections under the heading "People admitted to hospital" unless the recommendations for these patient groups differ in the final document.	Thank you for your comment. It was decided to keep these separate as there are different risk tools for both groups. We have now updated our risk assessment recommendation to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)"
University Hospital Southampton NHS Foundation Trust	Short	4 5	9 5	Risk assessment tool. Given the lack of good quality evidence for any risk assessment tool, we are concerned that this recommendation will introduce significant variability in VTE risk assessment and prophylaxis nationally. Junior doctors who rotate frequently are most	Thank you for your comment. We have amended our recommendations to state: "Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a

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				<p>commonly responsible for completing the risk assessment, if each trust has a different tools for different patient groups, it may lead to inaccurate completion and incorrect VTE prophylaxis. Patients may find their risk is assessed differently at different hospitals if different tools are used. This may result in different thromboprophylaxis being given. Some of the published tools include more than two risk categories which means there will be groups of patients (ie moderate risk) where it is not clear if prophylaxis is required or not.</p> <p>We recommend that the same risk assessment tool should be used for the same patient groups across the country. The current National Risk assessment tool already prompts clinicians to note the risk assessment for VTE is not just a checklist of risk factors that once ticked automatically mean prophylaxis, it is a balance between VTE risk and bleeding risk which requires clinical judgement before the decision to offer prophylaxis is made. We would encourage modification of the national tool to incorporate documentation of the outcome of the risk assessment.</p>	<p>tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)”</p> <p>The committee debated risk assessment tools at length. While they noted that the Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
University Hospital Southampton NHS	Short	4	17	<p><i>Risk assessment for surgical and trauma patients.</i></p> <p>In addition to risk assessment on admission, surgical and trauma patients should be reassessed as part of</p>	<p>Thank you for your comment. At this point it is likely that the person's clinical condition would have changed and therefore the risk reassessment recommendation would apply.</p>

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Foundation Trust				the WHO safer surgery check-list process, ideally during the sign out phase in theatre as this is the golden moment to agree a VTE prophylaxis plan, and unless done then the moment is lost to balance bleeding and clotting risks properly with senior input. The assessment on admission can't fully address this, as not until the operation is done is the bleeding risk fully established. The reassessment should be done jointly by surgeon and anaesthetist.	The committee did not think they could write a recommendation for every scenario when a person's condition might change so have just made one recommendation to cover all scenarios. The committee are of the opinion that the WHO checklist is an opportunity to check and confirm but not the "golden time" to do it.
University Hospital Southampton NHS Foundation Trust	Short	4	5 14	Risk assess on admission. We would welcome a definition for "on admission" as this may be interpreted as within 24 hours of admission, potentially resulting in a significant delay to starting prophylaxis. We would suggest a recommendation in line with the NHS England standard for Seven Day Services "Risk assess as soon as possible during the initial patient assessment on admission, but at the latest within 14 hours from the time of admission to hospital."	Thank you for your comment. We have amended our recommendation to state that assessment should happen "as soon as possible after admission to hospital or by the time of the first consultant review". This aligns with the NHS England standard for 7 day services.
University Hospital Southampton NHS Foundation Trust	Short	10	21	Acute stroke patients We are concerned that pharmacological prophylaxis is not included in the recommendations of acute stroke patients. We feel pharmacological prophylaxis should be considered, taking into account bleeding risk and risk of haemorrhagic transformation.	Thank you for your comment. The committee reviewed the evidence for pharmacological VTE prophylaxis and did not feel that that current evidence demonstrated a strong enough positive effect on VTE outcomes to warrant recommending pharmacological prophylaxis in this population where bleeding would have catastrophic consequences

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					(please refer to full guideline volume 1; pages 238-241 for a further discussion of the evidence).
University Hospital Southampton NHS Foundation Trust	Short	10	27	<i>Intermittent pneumatic compression (IPC) in acute stroke patients</i> We acknowledge that the CLOTs trials commenced IPC within 3 days but feel that the guidance should state that IPC should be started as soon as possible after admission as there is a risk of clots forming in the interim and the potential of clot breaking off leading to pulmonary embolism once IPC is commenced.	Thank you for your comment. The committee discussed your comment and felt that starting IPC within 3 days of admission is appropriate as it may be difficult to judge which survival cohort the patient is in during the very early hours of a stroke, so this is a balanced recommendation. Different clinical scenarios would require different initiation times and the committee are of the opinion that this is best judged by the clinician assessing the individual.
University Hospital Southampton NHS Foundation Trust	Short	12	10	<i>VTE prophylaxis for people with myeloma.</i> This should also include pomalidomide.	Thank you for your comment. The committee agree and the recommendation wording has been edited to add pomalidomide.
University Hospital Southampton NHS Foundation	Short	13	2	<i>Patients with central venous catheters.</i> This recommendation might be seen to contradict 1.3.27 (p12 line5) <i>Do not offer VTE prophylaxis to people with cancer who are having 5 oncological treatment and who are mobile except as outlined in</i>	Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy

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Trust				Please insert each new comment in a new row <i>1.3.29 6 and 1.3.30</i>	Please respond to each comment should be removed.
University Hospital Southampton NHS Foundation Trust	Short	14	4	<i>LMWH only option for pharmacological prophylaxis for people admitted to critical care</i> We are concerned that unfractionated heparin (UFH) is not included in the recommendations for this patient group. We use UFH instead of LMWH as an overall risk management strategy for several reasons: <ul style="list-style-type: none"> • a significant proportion of patients admitted to critical care have significant renal impairment • UFH allows procedures with bleeding risk (e.g. line insertion) to be carried out without undue delay due to the shorter duration of UFH compared to LMWH UFH can be fully reversed with protamine	Thank you for your comment. The guideline committee discussed your comment and agreed that UFH would be an appropriate option to recommend for those with renal impairment. Hence, the recommendation was edited, adding a cross reference to the recommendation for people with renal impairment which specifies UFH as the recommended prophylaxis option. We have also added text to the section on 'Recommendations and link to evidence' of the critical care section in relation to your comment to describe when UFH may be preferred to LMWH.
University Hospital Southampton NHS Foundation Trust	Short	14	6	<i>Mechanical prophylaxis for people admitted to critical care only if pharmacological prophylaxis is contra-indicated</i> We are extremely concerned that this recommendation will lead to suboptimal prophylaxis in a patient group that is at high risk of VTE. Patients admitted to critical care are often surgical or trauma patients who should have mechanical prophylaxis as well as pharmacological prophylaxis unless contra-indicated. This recommendation could lead to	Thank you for your comment. The evidence identified for combined prophylaxis did not show it to be any better than single prophylaxis therefore the committee did recommend combined prophylaxis.

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				mechanical prophylaxis being discontinued on admission to critical care.	
University Hospital Southampton NHS Foundation Trust	Short	19	1	<p><i>Elective hip replacement</i> Although pharmaco-economic considerations favour the listed options, we feel that patient specific factors should also be taken into account when deciding on the best option for prophylaxis in this patient group. Dabigatran and Apixaban also have received NICE technical appraisal approval and should be included as an option. We are concerned about the inconsistent use of antiembolism stockings as this may lead to confusion and insufficient prophylaxis. IPC should also be given as an option for mechanical prophylaxis in this group.</p>	<p>Thank you for your comment. We agree that patient factors should be taken into account when deciding on a prophylaxis option. This is why more than one option was recommended to cater for any possible contra-indications or patient preference considerations.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its first recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors.</p> <p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered .</p> <p>The interventions recommended were based</p>

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					<p>on the interventions in the included RCT evidence. The committee did not wish to recommend any interventions that have not been tested in a trial. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, to the committee did not wish to recommend any of these combinations.</p> <p>The cost effectiveness analysis also showed that AES are more cost effective than IPC in this population and hence, only AES are recommended. This does not preclude using IPC for people who cannot or refuse to use AES.</p>
University Hospital Southampton NHS Foundation Trust	Short	20	1 - 9	<p><i>Elective knee replacement</i> Although pharmaco-economic considerations favour the listed options, we feel that patient specific factors should also be taken into account when deciding on the best option for prophylaxis in this patient group. Dabigatran and Apixaban also have received NICE technical appraisal approval and should be included as an option. We are concerned about the inconsistent use of antiembolism stockings as this may lead to</p>	<p>Thank you for your comment. We agree that patient specific factors should be taken into account. For this reason, we have provided four options to address issues of contraindications, allergies and patient preference rather than solely recommending the most cost effective option.</p> <p>The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost</p>

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				confusion and insufficient prophylaxis. IPC should also be given as an option for mechanical prophylaxis in this group.	effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors. IPC is already recommended for this population.
University Hospital Southampton NHS Foundation Trust	Short	22	14 - 19	<i>Mechanical prophylaxis in cranial surgery patients</i> We believe that there is good evidence for combined mechanical prophylaxis with antiembolism stockings and intermittent pneumatic compression in this patient group.	Thank you for your comment. We have identified only one study that assessed the efficacy of combined mechanical prophylaxis in this population. However, the quality of this evidence was very low due to risk of bias, indirectness and imprecision. Additionally, no economic evidence was identified to support the cost effectiveness of this combined prophylaxis strategy. Consequently, the committee have only made a weaker 'consider' recommendation.
University of Nottingham	Appendix R	698	General	The document states that in the section on evidence base that " <i>While there are several published risk assessment tools for venous thromboembolism in a variety of populations none have been validated in</i>	Thank you for comment. The QThrombosis tool was evaluated and has been excluded from the evidence review as the population was not applicable as it relates to the general

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				<p><i>an NHS population or compared to each other". This is incorrect. The QThrombosis tool has been developed in an NHS population and also validated several times in NHS patients^{1 2}. The QThrombosis tool predicts risk of VTE in the general population taking account of multiple factors in men and women (age, body mass index, smoking status, varicose veins, congestive cardiac failure, chronic renal disease, cancer, chronic obstructive pulmonary disease, inflammatory bowel disease, hospital admission in past 6 months and current prescriptions for antipsychotic drugs.). Additionally, in women it includes combined oral contraceptives, tamoxifen and hormone replacement therapy.</i></p> <p>QThrombosis includes all the risk factors in the DH VTE risk assessment tool which were independently predictive of VTE. The crucial difference is that the risk assessment is based on a principled on a multivariate model which takes account of multiple risk factors simultaneously to give an absolute risk of thrombosis. In contrast, the national VTE risk assessment tool has not been tested or validated and gives equal weighting to all risk factors which is simply too crude an approach. This is presumably why 90% of people are considered to be at high risk. The QThrombosis tool is available as a free publicly</p>	<p>population and not to people admitted to hospital. The committee believe the additional factor of being admitted to or treated in hospital means that the patients would be at a different level of risk to those covered in the QThrombosis tool and therefore it is right that this tool is excluded from the guideline review.</p>

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				<p>available website (www.qthrombosis.org) and can also be integrated into clinical computer systems. It will provide more individualised and accurate assessment of risk for a patient attending the hospital prior to an operation. QThrombosis could also be adapted to include risk estimates following different types of surgery although even in its current form it will be able to distinguish between high and low risk people with a good degree of accuracy. I think the research question is to compare performance of current VTE assessment with the QThrombosis assessment. This could either be done using</p> <ul style="list-style-type: none"> (a) an existing database of GP records linked to HES and mortality (such as CPRD or QResearch) (b) as a cluster RCT eg randomised by hospital (c) combination of (a) and (b) <p>1. Hippisley-Cox J, Coupland C. Development and validation of risk prediction algorithm (QThrombosis) to estimate future risk of venous thromboembolism: prospective cohort study. <i>BMJ</i> 2011;343:d4656. doi: 10.1136/bmj.d4656 [published Online First: 2011/08/19]</p>	

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				2. Hippisley-Cox J, Coupland C, Brindle P. The performance of seven QPrediction risk scores in an independent external sample of patients from general practice: a validation study. <i>BMJ Open</i> 2014;4(8):e005809. doi: 10.1136/bmjopen-2014-005809 3. Hippisley-Cox J, Coupland C. Predicting risk of upper gastrointestinal bleed and intracranial bleed with anticoagulants: cohort study to derive and validate the QBleed scores. <i>BMJ</i> 2014;349:g4606. doi: 10.1136/bmj.g4606	
University of Nottingham	Full Appendix I	77 593	General	The document states in table N.1 that the two papers which present the development and external validation of QThrombosis ^{1 2} have both been excluded because “the target condition does not match the protocol”. It is unclear why it does not match since QThrombosis predict risk of VTE and the outcome of VTE is stated in many places to be the target condition of interest. The original papers make it clear that the VTE outcome is a recorded diagnosis of VTE (either DVT or pulmonary embolism) on GP or ONS mortality records. Whilst the tool was evaluated at 1 and 5 years, the model is able to predict risk at 90 days also. So, we think these studies should be included especially as they	Thank you for comment. The QThrombosis tool was evaluated and has been excluded from the evidence review as the population was not applicable as it relates to the general population and not to people admitted to hospital. The committee believe the additional factor of being admitted to or treated in hospital means that the patients would be at a different level of risk to those covered in the QThrombosis tool and therefore it is right that this tool is excluded from the guideline review.

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				<p>are likely to be better than the DH VTE risk assessment tool which has not been validated and which seems to identify everyone as high risk.</p> <p>1. Hippisley-Cox J, Coupland C. Development and validation of risk prediction algorithm (QThrombosis) to estimate future risk of venous thromboembolism: prospective cohort study. <i>BMJ</i> 2011;343:d4656. doi: 10.1136/bmj.d4656 [published Online First: 2011/08/19]</p> <p>2. Hippisley-Cox J, Coupland C, Brindle P. The performance of seven QPrediction risk scores in an independent external sample of patients from general practice: a validation study. <i>BMJ Open</i> 2014;4(8):e005809. doi: 10.1136/bmjopen-2014-005809</p>	
University of Nottingham	107	General	General	Has the panel overlooked this BMJ paper which predicts risk of major bleeding in people starting anticoagulation taking account of multiple factors? ³ again this tool (known as QBleed) includes all the relevant risk factors from the DOH risk assessment tool which remained significant on multivariate analysis. It gives an absolute risk of bleeding which	Thank you for comment. The QBleed tool is related to the QThrombosis tool which was evaluated and excluded from the evidence review. It was excluded because the population was considered not applicable as it relates to the general population and not to people admitted to hospital. The committee

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				can be compared with the absolute risk of VTE to get an idea of the trade-off between risks and benefits for anticoagulation. It is available as a simple web calculator at www.qbleed.org and is likely to be more sensitive and specific than the DOH risk assessment tool which gives equal weighting to all the risk factors.	believe the additional factor of being admitted to or treated in hospital means that the patients would be at a different level of risk to those covered in the QThrombosis tool and therefore it is right that this tool is excluded from the guideline review.
VTE National Network for Nursing and Midwifery	Full	General	General	We are not aware of any strong evidence to support changing the remit of the guideline from >18 yrs to >16 yrs. We anticipate that risk assessing this age group may result in overuse of prophylaxis in a group of patients in whom VTE is very rare. It will also have implications for our unify risk assessment data submissions.	Thank you for your comment. The committee are of the opinion that some people aged 16-18 are at risk of VTE, for example girls in this age group may be taking a contraceptive pill. The current age range was in the scope and the committee reiterated that all patients should be offered the same prophylaxis if their risk of VTE outweighs their risk of bleeding. Risk assessment would determine if an individual's risk of VTE outweighs their risk of bleeding and they require prophylaxis. If this is shown to be the case then prophylaxis should be offered according to their condition.
VTE National Network for Nursing and Midwifery	Short	General	General	Many of the recommendations advice to giving thromboprophylaxis for a minimum of 7 days. There isn't any evidence to support this and it could have huge financial and resource implications. Suggest that thromboprophylaxis is continued until discharge or for a minimum of 7 days. If it is to remain at 7 days, please clarify if this means continuing after	Thank you for your comment. The guideline committee agrees that there is limited evidence for the most effective duration of LMWH for VTE prophylaxis. The duration of 7 days was recommended as it is the average duration presented in the trials evaluated throughout the guideline. It was also noted

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				discharge if the inpatient stay is less than 7 days.	that studies such as the Million Women Study have shown the risk of VTE extends post-discharge, shorter doses of LMWH are less likely to reduce risk of VTE (The Million Women Study: design and characteristics of the study population. The Million Women Study Collaborative Group. Breast Cancer Research. 1999; 1(1):73-80). The course of LMWH would need to be continued after discharge if hospital stay is less than 7 days.
VTE National Network for Nursing and Midwifery	Short	4 5	11 5	<p><i>Recommendations 1.1.3/1.1.9</i></p> <p>We strongly recommend that the National VTE risk assessment tool remains the main tool in England for several reasons:</p> <ul style="list-style-type: none"> • Much of the success and progress of the National VTE Prevention Programme has been due to the consistent approach taken throughout the country. • Some of the alternative tools have more than two risk categories meaning that there will be groups of patients (ie moderate risk) who do not fall under any NICE guidance for thromboprophylaxis. • Patients may find their risk is assessed 	<p>Thank you for your comment. We have amended our recommendations to state:</p> <p>“Assess all medical patients on admission to hospital to identify the risk of venous thromboembolism (VTE) and bleeding using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health National risk assessment tool (see appendix A)”</p> <p>The committee debated risk assessment tools at length. While they noted that the</p>

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				<p>differently at different hospitals if different tools are used. This may result in different thromboprophylaxis being given and further complicate the process of root cause analysis of hospital associated thrombosis.</p> <ul style="list-style-type: none"> Junior doctors who rotate frequently are most commonly responsible for completing the risk assessment, if each trust has a different tool it may lead to inaccurate completion. <p>The committee's feeling that the current tool results in too many medical patients receiving anticoagulation is not evidenced but should be a priority area for research.</p>	<p>Department of Health VTE risk assessment tool has been embedded in practice for 7 years with a high level of adherence several committee members were of the opinion that the tool leads to over prescribing of prophylaxis, particularly in medical patients, without clear evidence of benefit, potentially incurring a significant cost to the NHS. Additionally, there was no evidence to suggest another tool would perform better. Consequently, the committee decided not to endorse a particular tool for VTE prophylaxis risk assessment.</p>
VTE National Network for Nursing and Midwifery	Short	4 5	13 8	<p><i>Recommendations 1.1.5/1.1.10</i></p> <p>Thromboprophylaxis should be prescribed as soon as is practically possible, ideally after the risk assessment rather than allowing 14 hours. There is no evidence to support this and it made lead to delays in prophylaxis prescription. It may also have implications on the classification of hospital associated thrombosis.</p>	<p>Thank you for your comment. We have amended our recommendation to state ".....start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations".</p>
VTE National Network for Nursing and Midwifery	Short	10	25 - 26	<p><i>IPC in acute stroke</i></p> <p>We acknowledge that the CLOTs trials commenced IPC within 3 days but feel that the guidance should state as soon as possible after admission in order to</p>	<p>Thank you for your comment. The committee acknowledges your concern but feel that starting IPC within 3 days of admission is appropriate as it may be difficult to judge</p>

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				protect patients at the highest risk time. Most IPC companies recommend that caution is used if IPC is left off for a certain amount of time (ie 3 hours) in case of VTE development due to the theoretical risk of embolization with IPC, so if IPC is not applied as soon as possible after admission, concerns regarding VTE development may prevent or further delay IPC application.	which survival cohort the patient is in during the very early hours of a stroke, so this is a balanced recommendation. Different clinical scenarios would require different initiation times and the committee are of the opinion that this is best judged by the clinician assessing the individual.
VTE National Network for Nursing and Midwifery	Short	10	22	<i>Recommendations for Acute stroke</i> Anticoagulant thromboprophylaxis is used safely in many acute stroke patients with careful consideration of the bleeding vs thrombosis risk balance. IPC isn't indicated or tolerated by some patients which may leave them vulnerable if NICE advice against chemical prophylaxis as well. Suggest that this be amended to 'consider anticoagulant thromboprophylaxis in high risk'.	Thank you for your comment. The committee reviewed the evidence for pharmacological VTE prophylaxis and did not feel that that current evidence demonstrated a strong enough positive effect on VTE outcomes to warrant recommending pharmacological prophylaxis in this population where bleeding would have catastrophic consequences. It was noted that it is standard practice for stroke patients to be administered anti-platelets as part of their treatment; the committee noted that it would not be necessary to recommend additional pharmacological prophylaxis. The recommendation against using foot impulse or neuromuscular stimulation devices has now been removed because on re-

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					<p>examining the evidence the committee agreed that as well as no evidence of benefit there is no evidence of harm with these devices. Although, the committee do not recommend the use of these devices deleting this recommendation means there is no longer provides a barrier for clinicians considering other forms of prophylaxis.</p> <p>Please refer to full guideline volume 1; pages 238-241 for further discussion of the evidence.</p>
VTE National Network for Nursing and Midwifery	Short	13	1	<p><i>Recommendation 1.3.31</i> Again, this will be expensive and consume a lot of resources without a clear evidenced based benefit to patients and potential increased risk of bleeding.</p>	<p>Thank you for your comment. The guideline committee discussed your comment and agreed that the recommendation to consider prophylaxis for people with central venous catheters who are having chemotherapy should be removed. A research recommendation has been made as well to assess the clinical and cost effectiveness of pharmacological prophylaxis in this population.</p>
VTE National Network for Nursing and Midwifery	Short	16	10 - 19	<p><i>People with psychiatric illness</i> There is no evidence that people with psychiatric illness should be risk assessed and the incidence of VTE in this patient group is still unknown. Until more is known about VTE in this patient group, routine risk</p>	<p>Thank you for your comment.</p> <p>The guideline committee agree that it would be difficult to apply the recommendations to all psychiatric patients. However they are also of</p>

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				assessment should not be implemented as it may result in increased risk to patients from bleeding and will be a huge economic burden.	the opinion that some patients are still at risk of developing VTE and these patients should still be assessed and offered prophylaxis. Consequently, the recommendations have been changed to apply only to psychiatric patients admitted to an acute psychiatric ward.
VTE National Network for Nursing and Midwifery	Short	17	22	<i>Lower limb immobilisation</i> There is limited evidence that these patients would benefit from receiving thromboprophylaxis, it is likely that only the highest risk patients would benefit and these should be risk stratified. Recommend amending to 'consider pharmacological thromboprophylaxis in patients at high VTE risk'.	Thank you for your comment. The guideline committee agree that overall the risk of VTE in this heterogeneous patient group can be low. The recommendations highlight the need to assess then balance the risk of VTE and risk of bleeding and the consideration of VTE prophylaxis. If the patient has been identified as low risk of VTE after risk assessment then the clinician can decide that prophylaxis is not necessary.
VTE National Network for Nursing and Midwifery	Short	19	1 - 12	<i>Elective hip replacement</i> Include dabigatran and apixaban as options for pharmacological thromboprophylaxis since NICE approved them through technology appraisals, costs may fluctuate so may not always be more cost effective to use rivaroxaban. Include AES in the DOAC and aspirin options since it seems unlikely that they would be effective when used with LMWH but not aspirin and a DOAC, also may cause confusion and errors in areas with mixed	Thank you for your comment. The cost effectiveness analysis showed that, on average, rivaroxaban was the most cost effective of the three DOACs considered. Hence, the guideline committee specified rivaroxaban in its recommendation to allow for standardisation of practice. The committee also believed that recommending only one DOAC is likely to reduce costs and minimise errors.

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				<p>thromboprophylaxis practice. IPC should also be given as an option for mechanical prophylaxis in this group.</p>	<p>Apixaban and dabigatran are now included in a further recommendation that specifies the circumstances under which these DOACs might be considered. Any change in prices that is likely to impact the relative cost effectiveness of these DOACs will be taken into account when the guideline is considered for updating in the future.</p> <p>The interventions recommended were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, these forms of prophylaxis were not recommended. The committee anticipate that minimising errors will be addressed through implementing adequate measures to ensure patient safety.</p> <p>The cost effectiveness analysis also showed that AES are more cost effective than IPC in this population and hence, only AES are recommended. This does not preclude using IPC for people who cannot or refuse to use AES.</p>

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VTE National Network for Nursing and Midwifery	Short	20	1 - 9	<i>Elective knee replacement</i> We would recommend including AES in the DOAC and aspirin options since it seems unlikely that they would be effective when used with LMWH but not aspirin and a DOAC, also may cause confusion and errors in areas with mixed thromboprophylaxis practice. IPC should also be given as an option for mechanical prophylaxis in this group.	Thank you for your comment. The interventions recommended were based on the interventions in the included RCT evidence. As there were no trials that assessed the efficacy of AES combined with any of the DOACs or with aspirin, the committee did not wish to recommend combinations that were not supported by evidence. IPC is already recommended for this population.
VTE National Network for Nursing and Midwifery	Short	20	18 - 21	<i>Non-arthroplasty orthopaedic knee surgery</i> There isn't any evidence to recommend giving patients having arthroscopic knee surgery surgery 14 days of LMWH, under current guidelines most wouldn't receive any prophylaxis at all and we don't see hospital associated thrombosis in this patient group. Fourteen days seems excessive, particularly in the absence of any evidence. .	Thank you for your comment. The recommendation is for prophylaxis to be considered in this group based on risk assessment, not to be offered to everyone. We have made a recommendation highlighting that prophylaxis is generally not needed for arthroscopic surgery. However, the committee noted that some procedures have a high risk of VTE for example; periarticular osteotomy and therefore prophylaxis should be considered. The duration of prophylaxis has been based on extrapolation from the elective total knee replacement surgery which was considered to

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					be the most similar population.
VTE National Network for Nursing and Midwifery	Short	29	17 - 19	<i>Oral and maxillofacial surgery</i> As a lot of oral and maxillofacial surgery is performed in day surgery and often under local anaesthetic, we recommend that patients are only offered thromboprophylaxis if their risk is very high, ie. previous VTE. As before, this should be for the length of hospital stay or 7 days, whichever is shortest. There is no evidence to support his patient group routinely receiving prophylaxis and again the resource and financial burdens are potentially significant.	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration specified is based on the mean duration of LMWH reported in the trials - extrapolated from the abdominal surgery population. The average duration of trials was between 7-10 days in the abdominal surgery population, trials predominantly evaluated 7-days of LMWH. Consequently, the committee believed recommended 7 days duration was the most accurate reflection of the evidence. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
VTE National Network for Nursing and	Short	29	5	<i>Recommendation 1.3.104</i> Suggest only offer thromboprophylaxis to very high risk varicose vein surgery patients such as those	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak

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Midwifery				with previous VTE as the evidence to offer all prophylaxis is very weak and will again result in a large financial and resource burden as well as potentially increasing the risk of bleeding.	recommendation was made to consider using prophylaxis only for those at high risk of VTE. The decision as to whether someone fits the criteria for receiving prophylaxis should be based on the outcome of the initial risk assessment undertaken according to the guideline recommendations for risk assessment in surgical and trauma patients. Cost effectiveness has been considered when making this recommendation. It was the committee's view that this cost will be off-set by the saving from preventing VTE events.
VTE National Network for Nursing and Midwifery	Short	30	5 - 15	<i>ENT surgery</i> As a lot of ENT surgery is performed in day surgery and often under local anaesthetic, we recommend that patients are only offered thromboprophylaxis if their risk is very high, ie. Previous VTE. As before, this should be for the length of hospital stay or 7 days, whichever is shorest. There is no evidence to support his patient group routinely receiving prophylaxis and again the resource and financial burdens are potentially significant.	Thank you for your comment. We agree that prophylaxis should not be routinely used in this population. Hence, a weak recommendation was made to consider using prophylaxis only for those at high risk of VTE. We did not find any evidence to support the efficacy of durations shorter than 7 days of LMWH prophylaxis. The minimum duration has been specified based on the average duration of prophylaxis in the trials extrapolating from the abdominal surgery population. Cost effectiveness has been considered when making this recommendation. It was the committee's view

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					that this cost will be off-set by the saving from preventing VTE events.

No tobacco link was declared.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

[Registered stakeholders](#)

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