NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2023 surveillance of NG89 Venous Thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (2018)

Consultation dates: 17th to 30th November 2022

1. Do you agree with the proposal not to update the guideline? Please could let us know if you agree or disagree (yes/no) and provide details to support your answer.			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Arjo UK Ltd	Yes	Yes. We agree that NICE should not update the guideline on Venous thromboembolism in over 16s (NG89) on VTE prevention as a result of the GAPS trial (Shalhoub et al. 2020) of graduated compression (anti-embolism) stockings. We agree that the guideline generally refers to mechanical prophylaxis as an alternative to low molecular-weight heparin, not an addition, therefore this publication should not affect the guideline. However, we believe that the more important reason why the guideline should not be changed is that the GAPS trial was only of one type of mechanical prophylaxis which is passive. Results of the trial should not change a	Thank you for your comment.

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		recommendation that also includes active methods of prophylaxis. As the full guideline states: 'Venous stasis in the deep leg veins causes a decrease in the mean flow and pulsatility of the venous flow trace. Mechanical methods of DVT prophylaxis work to combat venous stasis and include: Anti-embolism stockings/ Graduated compression stockings (GCS) Intermittent pneumatic compression devices (IPCD) • Foot impulse devices, also known as foot pumps (FID) In the previous guideline for surgical patients125 these three methods were combined into one 'mechanical' category as the evidence did not indicate that there was a difference in effectiveness between the devices. For this guideline, anti-embolism stockings have been separated out from the other methods on the basis that they used a passive mechanism for reducing the risk of VTE whereas the other two methods used 'active' methods. Additionally, the distinction between IPCD and FID is not always clear and therefore in this guideline, intermittent pneumatic compress' Our view is that this proposal only should have been to affect recommendations on graduated compression (anti-embolism) stockings specifically, and not mechanical prophylaxis as a whole.	
UK Clinical Pharmacy Association (Haemostasis & Thrombosis Committee)	No	No, we do not agree with the proposal not to update the guideline. • Specific clarification on the first VTE risk assessment completion time point i.e. on admission within 14 hours, within 24 hours from inpatient admission (to exclude A&E admission with no inpatient bed request)	Thank you for your comments and information about the trial on aspirin as prophylaxis for hip and knee replacement. We will evaluate the impact of the trial on the related recommendations and assess whether an update is required. NICE does not routinely make recommendations about doses, or recommendations about thresholds in special populations such as

		• Re-introduce reassessment for all patient groups and with a specific time point e.g. at 48 hours following hospital inpatient admission and whenever clinical situation changes • Introduce VTE risk assessment for pregnant women with hyperemesis that may present on gynaecological clinical areas/ambulatory emergency care as an opportunity to review VTE score and thromboprophylaxis management (pregnancy, hyperemesis, dehydration are all VTE risk factors affecting antenatal VTE score) • Review and removal of offering thromboprophylaxis for a minimum of 7 days to: o acutely ill medical patients o thoracic surgery o oral and maxillofacial surgery o ENT surgery o cardiac surgery o open vascular surgery or major endovascular procedures o lower limb amputation o varicose vein surgery • Pregnancy: o If using LMWH in pregnant women, start it as soon as possible and within 14 hours of the risk assessment being completed and continue until the woman is no longer at increased risk of VTE or until discharge from hospital or the midwife-led unit. § Consideration for antenatal women in labour and starting LMWH within 14 hours of risk assessment is not appropriate § Not in line with RCOG recommendations as thromboprophylaxis based on VTE score for women to continue following discharge and not 'until discharge'	renal failure. When a medication is recommended, it is expected that the professionals will prescribe it based on the terms of the marketing authorisation for the UK. This information are available on the BNF and electronic medicines compendium. See Prescribing Medicines for more information about NICE recommendations. As the scope of this exceptional review is whether the new evidence (GAPS) trial should trigger an update of the guideline for the relevant sections, we are unable to address other suggestions not related to this new evidence. However, we acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. These suggestions will be logged for considerations in future surveillance and will be feedback to the NICE implementation teams. If you are aware of specific published evidence related to any of these issues, please email us at nice@nice.org.uk.

		o If using LMWH in women who gave birth or had a miscarriage or termination of pregnancy, start 4 to 8 hours after the event unless contraindicated and continue for a minimum of 7 days. § Surgical termination of pregnancy is VTE score 3 – duration of thromboprophylaxis to be defined and in line with RCOG guidance. Useful to specify which VTE risk assessment tool to use e.g. RCOG or DOH post surgical termination of pregnancy under general anaesthesia to guide on thromboprophylaxis post-procedure including duration of thromboprophylaxis due to varying practice across hospitals. • Relaxation on the timing of when prescribing pharmacological thromboprophylaxis is started – from 14 hours to 24 hours to reflect clinical practice, ward rounds, return of blood tests, working diagnosis, next scheduled administration doses, admission times, workforce • Specific recommendations on when pharmacological thromboprophylaxis (if clinically indicated) should be prescribed and administered rather than grouping together – 'start it' should be specified as either 'prescribed' or 'administered' for clarification. 'Start it' is misinterpreted amongst hospitals, and not clear if related to first prescription or first administration. • Pharmacological thromboprophylaxis – include dosing as per actual body weight and renal function assessed by creatinine clearance for appropriate dosing of LMWH thromboprophylaxis for clear clarification. • Consistency with RCOG on mechanical thromboprophylaxis and use of anti-embolism stockings (GAPS study excluded pregnant/postpartum women) • Specify patient groups on when to offer AES or IPC, with an update on cautions and contraindications for use	

		• Surgery: o Review and update the following recommendation as only certain oestrogen contraceptives/HRT are affected - 1.3.13 Advise people to consider stopping oestrogen-containing oral contraceptives or hormone replacement therapy 4 weeks before elective surgery. If stopped, provide advice on alternative contraceptive methods. o Hip and knee replacement surgery and pharmacological thromboprophylaxis: removal of aspirin as an option as per attached JAMA publication: JAMA. 2022;328(8):719-727. doi:10.1001/jama.2022.13416. Recommendations on pharmacological thromboprophylaxis not clear e.g. LMWH for 14 days combined with anti-embolism stockings until discharge (1.11.8) to avoid confusion separate pharmacological and mechanical thromboprophylaxis and duration periods. o 'Interventions for people having orthopaedic surgery' for lower limb immobilisation – specify that hospital should prescribe, continue if applicable and supply LMWH in full for duration of immobilisation period to facilitate access and medication supply in patients who have reduced mobility, and primary care refuse to prescribe LMWH. Guidance for Urgent Care Centre and Emergency Departments, with reference to the Royal College of Emergency Medicine VTE risk assessment tool for assessment of patients in lower limb immobilisation seen in outpatient setting. • Include recommendations/guidance for patients refusing pharmacological thromboprophylaxis with specific recommendations e.g. refusing heparins due to animal origin • Review and update with specific recommendations and guidance for 'people using antiplatelet agents'	

		• Review and update with specific recommendations and guidance for 'Interventions for people with renal impairment' e.g. define thresholds for LMWH and UFH	
VTE National Nursing and Midwifery Network	No	No, the VTE National Nursing and Midwifery Network is in favour of a review and update of NG89, particularly with regards to the following: 1. Clarity is needed around the use of anti-embolism stockings. Clinicians find the recommendations around anti-embolism stockings confusing and uphelpful as the advice differs for different surgical specialities. Since the GAPS study (doi: https://doi.org/10.1136/bmj.m1309) and subsequent VTE GIRFT report, many centres have stopped stocking usage in medical and obstetrics specialities and some have also stopped in surgery as the evidence for stockings is mostly very old and GAPS did not support the use of stockings in the surgical specialities included in the study. Clinicians would like clear guidance around when they should and shouldn't use stockings. Using 'consider' without any qualifying information throughout the guideline leads to ambiguity and variation in practice across the country. 2. Seven days of thromboprophylaxis for acutely ill medical patients requires review as most Trusts are not routinely delivering this (VTE GIRFT 2021) due to safety, cost and practicality pressures combined with a lack of faith in the outdated evidence the recommendation is based on. 3. Following the CRISTAL study (doi: https://doi.org/10.1136/bmj.m1309), aspirin should be removed as an option for thromboprophylaxis following elective hip and knee replacement.	Thank you for your comments and information about the trial on aspirin as prophylaxis for hip and knee replacement (CRISTAL Study). The GAPS trial assessed the effect of adding AES to LMWH compared to LMWH in non-orthopaedic surgical patients who do not have specific risk factors which put them at a high risk of VTE (see report for the exclusions). It shows that adding AES to LMWH is not necessary (which is in line with the current NICE guideline). The GAPS trial does not suggest AES is inferior to LMWH as it is not a head-to-head trial between the two. The current guideline no longer recommends AES for medical and obstetrics patients due to the lack of evidence. For non-orthopaedic surgery patients, the use of mechanical prophylaxis is also limited to situations where patient has a contraindication to LMWH (as a single prophylaxis) and only in patients with higher VTE risks which who may benefit from combination prophylaxis. Therefore, there is no need to update the guideline based on this study. We will feedback to the NICE implementation teams regarding implementation issues and misinterpretation of the GAPS trial. The scope of this exceptional review is whether the new evidence (GAPS) trial should trigger an update of the guideline in the affected population. However, we acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. These suggestions will be logged for

		4. The VTE GIRFT study found that 80% of respondents are using weight based LMWH for thromboprophylaxis, to ensure consistency, NICE guidance needs to be updated to reflect this. 5. Timing of risk assessment completion and thromboprophylaxis administration needs to be clarified; at what point does the 14 hours start if patients are admitted via ED? As many patients are not able to receive thromboprophylaxis within 14 hours due to surgery, labour, trauma, awaiting results of investigations to determine if safe to give, this target is very difficult to audit and comply with. Starting it 'as soon as possible after admission and within 24 hours where indicated' is far more practical and auditable.	considerations in future surveillance and will be feedback to the NICE implementation teams. If you are aware of specific published evidence related to any of these issues, please email us at nice@nice.org.uk.
Thrombosis UK	No	No, we do not agree with the proposal to not update the guideline. While mentioning the GAPS Trial, the proposal has failed to consider important points: The proposal argues that the GAPS study will not change clinical practice because it will not affect their current guideline recommendations patients use either (not both) pharmacological or mechanical thromboprophylaxis, the latter in those at risk of bleeding, for surgical patients. However, it has not considered that the GAPS study is hard evidence showing the anti-embolism stockings (AES) have NO clinical benefit. We strongly urge the committee to reconsider their evidence on “mechanical thromboprophylaxis”, to reflect that the benefits of intermittent pneumatic compression	Thank you for your comments. As described in the report, we did not consider the GAPS study as evidence that AES has “no clinical benefit”; the study compared the effect of *addition* of stockings to LWMH versus LMWH in patients without risk factors which put them at a particularly high risk of VTE. Therefore, the evidence is specific to drawing conclusions that AES is not beneficial in addition to LMWH in population that is not at high risk, the GAPS study does not suggest AES is inferior to LMWH as it is not a head-to-head trial between the two, nor that it is ineffective as a single prophylaxis. Equally, the GAPS study has a lower risk profile of study population and that it does not apply to patients who have higher risks of VTE. NICE does not currently recommend using a combination of AES and LWMH for most type of elective, non-orthopaedic surgery patients. Therefore, it is reassuring to find that the GAPS trial did

		(IPC) are clear but that there is NO evidence to support AES. Until NICE addresses this we are very concerned that patients will continue to be offered AES, denying them effective mechanical thromboprophylaxis. With little to no evidence of AES reducing the risk of VTE, patients are more likely to be placed at harm from poorly fitting AES as well as sub-optimally managed in reducing risk of VTE and harm. We also recommend that NICE abandon the term 'mechanical thromboprophylaxis' and should instead use the term IPC when they recommend prophylaxis in those with bleeding risk. It is essential that this guidance is clear if patients are to be managed in line with good evidence of reducing risk from VTE and reducing risk of avoidable harm.	not find a significant benefit of using a combination prophylaxis in most elective surgery patients who do not have specific VTE risks or requiring extended prophylaxis (these patients were excluded from the GAPS trial). This is evident from the relatively low incidence of VTE in the intervention arm receiving LMWH as a single prophylaxis. The scope of this exceptional review is whether the new evidence (GAPS) trial should trigger an update of the guideline in the affected population. However, we acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. These suggestions will be logged for considerations in future surveillance and will be feedback to the NICE implementation teams. If you are aware of specific published evidence related to any of these issues, please email us at nice@nice.org.uk..
Bayer plc	Yes	Yes. Bayer support the conclusion that the guideline does not need to be updated at this time **Re Tobacco Links:** Current Situation • Bayer does not have direct or indirect links with, or funding from, manufacturers, distributors or sellers of smoking products but Bayer provides pesticides for crops, which would therefore include tobacco crops. • Bayer is a member of the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) (http://www.coresta.org/) within the scope of	Thank you for your comments.

		recommendations of pesticides used for protection of tobacco plants. • It is also a member of country and EU business federations such as the Confederation of British Industry (CBI) and 'Business Europe', which include tobacco companies. Past Situation In 2006, Bayer and its subsidiary Icon Genetics piloted a new process for producing biotech drugs in tobacco plants. Icon Genetics was acquired by Nomad Bioscience GmbH from Bayer in 2012.	
Leeds Teaching Hospitals NHS Trust	No	No There have been new studies published especially in the area of orthopaedics around VTE prevention since the guideline was published. Covid-19 wasn't included in the last guideline and should be added. The guidance to consider 7 days prophylaxis in all areas extrapolated from surgical data should be reviewed. Clarification on risk assessment and prophylaxis for patients with lower limb immobilisation should be a priority. It would be helpful if guidance on the first dose within 14 hours of admission to be clarified. Use of DOACs for VTE prophylaxis in non licensed areas would also be helpful for patients	Thank you for your comments. The other areas mentioned are beyond the scope of this surveillance review. However, we acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. These suggestions will be logged for considerations in future surveillance and will be feedback to the NICE implementation teams. If you are aware of specific published evidence related to any of these issues, please email us at nice@nice.org.uk.
British Pregnancy Advisory Service	No	No. Current guidance does not adequately address risk	Thank you for your comments.

		assessment and preventative measures for people terminating a pregnancy. Section 1.1.9 refers health care professionals to the RCOG: Risk assessment for venous thromboembolism tool. However, this guidance refers specifically to pregnant people in the context of a continuing pregnancy and makes no mention of termination of pregnancy. There is currently a lack of good evidence on risk assessment and preventative measures that should be taken in termination of pregnancy settings and abortion providers, such as BPAS, are required to extrapolate evidence from RCOG guidance that is not designed for termination of pregnancy settings. Guideline NG89 should be opened for consultation to allow for the collection of evidence relating to how to effectively risk assess people having terminations and what preventative measures abortion providers should take. A specific tool should be developed for termination of pregnancy settings to enable abortion providers to develop services on the basis of evidence and guidance that is specifically targeted to screen people for VTE in termination of pregnancy settings.	VTE prophylaxis in the context of pregnancy termination is beyond the scope of this surveillance review. However, these comments will be logged for considerations in future surveillance. We acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. If you are aware of specific published evidence related to any of these issues, please email us at nice@nice.org.uk.
British Society for Haematology	Yes	I would support a review, particularly considering: • the 7-day duration recommendation for most medical/surgical patients. This is based on old RCTs which are not applicable to the current population receiving thromboprophylaxis. The recommendation has not been widely implemented (Will/BSHT have previously commented on this) • review of antiembolism recommendations - there is v little	Thank you for your comments and information the CRISTAL trial. As the scope of this surveillance review is whether the new evidence (GAPS) trial should trigger an update of the guideline for the relevant sections, we are unable to whether an update should be considered for topics not addressed by the evidence provided by this trial, such as duration of prophylaxis.

		evidence to support their use generally and stronger statements would facilitate withdrawal of use (with consequent cost savings) • review of aspirin post major orthopaedic surgery - new evidence suggesting reduced efficacy compared with LMWH (CRISTAL Study Group. JAMA. 2022;328(8):719–727. doi:10.1001/jama.2022.13416!	The GAPS trial evaluates the impact of adding AES to patients who are already on LMWH (AES plus LMWH vs LMWH) and showed that there is no benefit. The current NICE guideline is already recommending considering LMWH for most non-orthopaedic elective surgery, and a suitable mechanical option if there is a contradiction. The use of combination therapy is only considered for certain surgical procedures among patients who are at a higher risk of VTE, or procedures where bleeding considerations would make it more logical to consider a mechanical option, and then consider LMWH added if the risk of VTE outweighs the risk of bleeding in an individual patient. We will evaluate the impact of the CRISTAL study on the related recommendations and assess whether an update is required.

1. Do you have any comments on equality issues?

Stakeholder	Overall response	Comments	NICE response
Arjo UK Ltd	No	No comments at this time	Thank you for your comments.
UK Clinical Pharmacy Association (Haemostasis & Thrombosis Committee)	No	No	Thank you for your comments.

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VTE National Nursing and Midwifery Network	No	No	Thank you for your comments.
Thrombosis UK	Yes	The 2021 NHS GIRFT Thrombosis Report (https://thrombosisuk.org/downloads/TUK-GIRFT-REPORT.pdf) evidenced that in the 98 responding NHS Trusts, only 69% had a dedicated VTE prevention role in place. In 2022, Thrombosis UK carried out a Freedom of Information across NHS Trusts in which just 22.33% of responding Trusts (103) confirmed they had funding for a dedicated VTE prevention team. Given the pressures on NHS staff and in light of the stark variation in VTE prevention posts across NHS England, we feel that unless the proposal is re-assessed to include and reflect evidence from the GAPS Trial, the current guidelines will cause inequality in care, patient safety and patient outcomes. We strongly urge the committee to review and work to update the current NG89 guidelines in light of strong evidence from the GAPS Trial.	Thank you for your comments and information about the GIRFT thrombosis report. As noted in the previous response, the GAPS trial did not provide new evidence which suggest a change in the current recommendations is necessary. We acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity. The concerns highlighted will be logged and considered for a future surveillance review.
Bayer plc	No	No There have been new studies published especially in the area of orthopaedics around VTE prevention since the guideline was published. Covid-19 wasn't included in the last guideline and should be added. The guidance to	Thank you for your comments. The areas mentioned are beyond the scope of consideration for this review but will be logged and considered in future surveillance review.

		consider 7 days prophylaxis in all areas extrapolated from surgical data should be reviewed. Clarification on risk assessment and prophylaxis for patients with lower limb immobilisation should be a priority. It would be helpful if guidance on the first dose within 14 hours of admission to be clarified. Use of DOACs for VTE prophylaxis in non licensed areas would also be helpful for patients	We acknowledge that other areas of the guideline are cause for concern and will be undertaking a full review at earliest opportunity.
Leeds Teaching Hospitals NHS Trust	No	No	Thank you for your comments.
British Pregnancy Advisory Service	NA	*No answer provided*	Thank you for your comments.
British Society for Haematology	NA	*No answer provided*	Thank you for your comments.