[Peripheral arterial disease: diagnosis and management (standing committee update)]

Consultation on draft guideline - Stakeholder comments table
[16/11/17 to 14/12/17]

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Organisation name	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Action on Smoking and Health	All	General	General	The risk factors to PAD and diabetes caused by smoking need to be managed. There is substantial evidence that stopping smoking reduces the risk of disease progression amongst patients with PAD and dramatically reduces the need for limb amputation and the risk of premature death. We recommend highlighting the important role that smoking plays in PAD treatment as there are many beneficial outcomes to quitting smoking, especially if surgery is needed. *1. Armstrong EJ, Wu J, Singh GD, et al. Smoking cessation is associated with decreased mortality and improved amputation-free survival among patients with symptomatic peripheral artery disease. J Vasc Surg. 2014 Dec;60(6):1565-71.* *2. ASH. Research Report: Smoking and Peripheral Arterial Disease. December 2017.*	Thank you for your comment. This guideline update focused on the use of diagnostic tools in determining diagnosis and severity of PAD. Therefore the potential impact of smoking cessation is outside the scope of this update. The full protocol of this evidence review can be found in Appendix A of the Addendum. The current recommendations 1.1.1 and 1.2.1 provide guidance on offering information and support on smoking cessation. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
Action on Smoking and Health	Short	18	18	Smoking is the most important, preventable risk factor for PAD. By age 90, the lifetime risk for PAD in England is 2.6% for non-smokers and 8.9% for smokers. Smokers have a significantly greater risk of developing PAD than people who have never smoked. We recommend expanding the information available on the risk that smoking poses to PAD. *Pujades-Rodriguez M, George J, Shah AD, et al. Heterogeneous associations between smoking and a wide range of initial presentations of cardiovascular disease in 1937360 people in England: lifetime risks and implications for risk prediction. Int J Epidemiol. 2015 Feb;44(1):129-41.*	Thank you for your comment. This guideline update focused on the use of diagnostic tools in determining diagnosis and severity of PAD. The context section in short version (page 17, line 10) has been amended to highlight risk of PAD in people who smoke. Current recommendation 1.2.1 provides guidance on offering all people with PAD information on smoking cessation.

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Action on Smoking and Health	Short	18	18	A dose-dependent relationship between smoking and PAD has been reported with a greater cigarette consumption associated with increased risk. Duration of smoking is also a predictor of disease development and progression. We recommend including information about lifestyle changes, such as smoking cessation, in the section on treatment options to manage PAD symptoms. *1. Willigendael EM, Teijink JA, Bartelink ML, et al. Influence of smoking on incidence and prevalence of peripheral arterial disease. J Vasc Surg. 2004 Dec;40(6):1158–65. 54. Vavra AK, Kibbe MR. Women and peripheral arterial disease. Womens Health (Lond). 2009 Nov;5(6):669-83.* *2. Fowkes FG, Housley E, Riemersma RA, et al. Smoking, lipids, glucose intolerance, and blood pressure as risk factors for peripheral atherosclerosis compared with ischemic heart disease in the Edinburgh Artery Study. Am J Epidemiol 1992;135:331-40.* *3. Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Conte MS, Pomposelli FB, et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. J Vasc Surg. 2015 Mar;61(3 Suppl):2S-41S.* *4. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:S1-75.* *5. The health consequences of smoking – 50 years of progress: a report of the Surgeon General. – Atlanta, GA. : U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.*	Thank you for your comment. This guideline update focused on the use of diagnostic tools in determining diagnosis and severity of PAD. The context section in short version (page 17, line 10) has been amended to highlight risk of PAD in people who smoke. Current recommendation 1.2.1 provides guidance on offering all people with PAD information on smoking cessation.
Association	Short	General	General	We welcome the opportunity to comment on this	Thank you for your comment. Management of critical

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of British Healthcare Industries, Vascular Special Interest Section				guideline and we are pleased to see that you have considered the guideline for review. We are concerned and disappointed to see that this review is still not addressing the lack of specific guidance around drug eluting technologies. ***Appendix A: summary of new evidence from surveillance*****,** which was published alongside the surveillance review detailing new evidence available since the 2012 review recognises that "there is an increasing body of evidence which supports the use of drug eluting technologies in the management of femoropoliteal disease and it would be incorrect if NICE was to continue with the existing recommendations", nevertheless, NICE has made the decision not to update the Management section of the guidance to reflect this. The use of such technologies following publication of such evidence is now widespread within the NHS, and it is concerning that NICE has left this guidance unchanged, leaving it out of step with standard practice. We ask NICE to reconsider this position and change the guidance to reflect this already substantial body of evidence demonstrating reduction in likelihood of restenosis, good cost-effectiveness and patency rates as compared to bare metal stents. Appendix A also states that "Topic experts indicated that a review of this area is necessary to establish whether there are benefits associated with the use of drug-eluting stents for treating people with intermittent claudication", and we would urge NICE to act on this recommendation, rather than wait for the BASIL – 3 trial. We also reiterate our request that NICE investigates the current situation with recruitment of BASIL -3 to further inform its previously stated conclusion that "reviewing the question now could potentially impact on the recruitment process'.	limb ischemia including the use of drug eluting technologies was outside the scope of this guideline update. A decision was made during surveillance review that the question should be considered for inclusion after the completion of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for further consideration.
Boston	Short	General	General	We welcome the opportunity to comment on this	Thank you for your comment. Management of critical

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Scientific				guideline and we are pleased to see that you have considered the guideline for review. We are concerned and disappointed to see that this review is still not addressing the lack of specific guidance around drug eluting technologies. ***Appendix A: summary of new evidence from surveillance***, which was published alongside the surveillance review detailing new evidence available since the 2012 review recognises that "there is an increasing body of evidence which supports the use of drug eluting technologies in the management of femoropoliteal disease and it would be incorrect if NICE was to continue with the existing recommendations", nevertheless, NICE has made the decision NOT to update the Management section of the guidance to reflect this. The use of such technologies following publication of such evidence is now widespread within the NHS, and it is concerning that NICE has left this guidance unchanged, leaving it out of step with standard practice. We strongly urge NICE to reconsider this position and change the guidance to reflect this already substantial body of evidence demonstrating reduction in likelihood of restenosis, good cost-effectiveness and patency rates as compared to bare metal stents. Appendix A also states that "Topic experts indicated that a review of this area is necessary to establish whether there are benefits associated with the use of drug-eluting stents for treating people with intermittent claudication", and we would urge NICE to act on this recommendation, rather than wait for the BASIL – 3 trial. We also respectfully request that NICE investigates the current situation with recruitment of BASIL -3 to further inform its previously stated conclusion that "reviewing the question now could potentially impact on the recruitment process".	limb ischemia including the use of drug eluting technologies was outside the scope of this guideline update. A decision was made during surveillance review that the question should be considered for inclusion after the completion of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for further consideration.

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Cook Medical	short	General	general	Cook welcomes this opportunity to comment on the NICE guidelines. We are disappointed that the decision has been made not to update the *Management* section of the PAD guidance. Current practice is not recognised within the guidance, which has potentially significant negative implications on future access to treatments and technologies which could save limbs and lives. We would encourage NICE to re-consider its decision not to update the *Management* section of the guidance.	Thank you for your comment. Management of critical limb ischaemia was outside the scope of this guideline update. In relation to the use of drug eluting technologies, a decision was made during surveillance review that the question should be considered for inclusion after the completion of the BASIL-3 trial. In relation to management of intermittent claudication, a decision was made during the surveillance review that new evidence identified was unlikely to change current guideline recommendations Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
Cook Medical	short	11	23	Results recently published by Hicks et al. (https://www.ncbi.nlm.nih.gov/pubmed/27928034) show that peripheral endovascular interventions lead to significantly better results than bypass surgery in patient with CLI caused by below the knee in terms of one-year primary patency: endo: 81% vs. bypass: 73% (p<0.001). No significant differences in one-year major amputation (endo: 12% vs bypass: 14% (p=0.18)) and mortality rates (endo: 4% vs. bypass: 6% (p=0.15)) in the two treatment groups were observed. The authors of the study conclude: Infrageniculate PAD resulting in critical limb ischemia can be treated successfully with both open surgical bypass or endovascular interventions. Endovascular revascularization may provide better mid-term primary patency rates than an open approach, especially in diabetic patients and in patients presenting with tissue loss, with similar risks of major amputation and death. Thus, endovascular techniques are a viable treatment approach for limb salvage in patients with infrageniculate	Thank you for your comment. Management of critical limb ischaemia was outside the scope of this guideline update. During the surveillance review, a decision was made that new evidence was unlikely to change guideline recommendations. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.

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				critical limb ischemia, and can be considered as a first-line approach in patients presenting with diabetes and/or tissue loss.	
Department of Health	General	General	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation	Thank you for your comment.
GreenVits	Guideline	General	General	Refer patient to a Dietitian to reduce their weight and their Diabetes	Thank you for your comment. Weight and diabetes management was outside the scope of this guideline update. Offering all people with PAD information, advice, support and treatment regarding weight management and diabetes is referred to in recommendation 1.2.1.
GreenVits	Guideline	General	General	Consider what Interventions might be useful to reduce arterial blockages	Thank you for your comment. Reducing arterial blockages was outside the scope of the current guideline update. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
GreenVits	Guideline	General	General	There is good evidence that increasing Vitamin D blood levels reduces the severity of Peripheral Arterial Disease https://www.vitamindwiki.com/Overview+Cardiovascular+and+vitamin+D	Thank you for your comment. This guideline update focused on the use of diagnostic tools in determining diagnosis and severity of PAD. During the surveillance review, no new evidence was identified in relation to providing all people with PAD, information on modifiable risk factors including diet. Therefore a decision was made that this area of the guideline would not be updated. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
GreenVits	Guideline	General	General	There is good evidence that increasing Vitamin K2 blood levels reduces the severity of Peripheral Arterial Disease http://vitamink2.org/relationship-vitamin-k-peripheral-arterial-disease-vissers-le-et-al/	Thank you for your comment. This guideline update focused on the use of diagnostic tools in determining diagnosis and severity of PAD. During the surveillance review, no new evidence was identified in relation to

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					providing all people with PAD, information on modifiable risk factors including diet. Therefore a decision was made that this area of the guideline would not be updated. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Full	General	General	The research relating to the BASIL 2 and 3 trials remain important questions to answer. (SVC)	Thank you for your comment. Management of critical limb ischemia including the use of drug eluting technologies was outside the scope of this guideline update. A decision was made during surveillance review that the question should be considered for inclusion after the completion of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Full	General	General	Supervised exercise programmes have been researched and the data remains in doubt. However, despite the poor evidence of benefit they have been part of NICE guidance for 5 years, but CCGs are not generally funding them. Therefore if further research is recommended and funded, even if this concludes that supervised exercise does give useful benefit, this will result in NICE recommending their use. Given that this has already been the case for 5 years, there is a question as to the cost effectiveness of further research (as the recommendations have not been followed in this regard). (SVC)	Thank you for your comment. During the development of the previous guideline, the committee noted that research on the long terms effects of supervised exercise programmes was required. During the surveillance review, no new evidence was identified that was likely to change current recommendations. During the consultation phase, stakeholders highlighted that this review question should be retained. Stakeholders highlighted that consideration should be given regarding the optimisation of analgesia to determine its effectiveness.

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					Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Full	General	General	Chemical sympathectomy is not considered standard clinical practice, and those who used to practice this are not likely to still do so. (SVC)	Thank you for comment. Chemical sympathectomy was outside the scope of this guideline update. Having received comments from other stakeholders, it has been agreed that the research recommendation on chemical sympathectomy will be retained. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Full	General	General	The review of the assessment of diabetic patients makes little mention of the use of clinical history, examination and pulse palpation. In practice these are usually clinically very useful, particularly in experienced hands. (SVC)	Thank you for your comment. Recommendation 1.3.1 to 1.3.2 offer guidance on assessing clinical history and examining the femoral, popliteal and foot pulses.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Short	4	15	Recommendation to provide support for management of Anxiety and Depression has not been carried forward to management of pain particularly when considering referral to chronic pain clinic. (MJ)	Thank you for your comment. Management of anxiety and depression was outside of the scope of the guideline update. Current recommendation 1.1.1 does offer guidance on offering all people with PAD information of how they can access support for dealing with depression and anxiety.
NHS England - Specialised Commissioning – Specialised Vascular CRG	Short	6	23	It would be useful to distinguish the care facilities that the recommendations relate to for example offer of MRA or CTA are most relevant to the secondary care services. We are concerned that this recommendation may imply that general practitioners should undertake these investigations. (MJ)	Thank you for your comment. Imaging for revascularisation was outside the scope of this guideline update. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
NHS England - Specialised Commissioni	Short	7	14	The recommendation for supervised exercise programme will be challenging to implement in the primary care and community settings due to lack of resources.	Thank you for your comment. Recommendation and research recommendation made in the previous guideline were carried over but were not part of the

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ng – Specialised Vascular CRG				This recommendation is in contrast with line 26 on page 12 which suggest there is lack of robust evidence on long-term effectiveness. (MJ)	scope for the current update. During the development of the previous guideline, the committee took into consideration the quality of the evidence and cost effectiveness of supervised exercise programme when forming the recommendation. The committee also noted that the availability of such programmes varied geographically and research was required with regards to the long term effects of supervised exercise testing. During the surveillance review, new evidence was identified that was consistent with the current recommendations and decision was made that new evidence was unlikely to change the current recommendation. Your comments have been forwarded to NICE's surveillance team for consideration.
Novo Nordisk	short	general	general	We welcome the update to this guideline and the focus on diabetes and linking this with the importance of early and accurate diagnosis of PAD to manage and prevent complications	Thank you for your comment.
Novo Nordisk	short	6	10	This section currently only provides guidance on what not to do in diagnosing PAD in people with diabetes. It would be useful to start this section with an introductory paragraph as the first point, outlining how people with diabetes are at high risk of cardiovascular disease and of peripheral arterial disease and therefore the importance of diagnosing PAD early and managing the risk factors for this and for secondary prevention of CVD. This is only otherwise mentioned as part of the recommended research on page 10	Thank you for your comment. This information has now been included in the context section of the short guideline (page 17, line 12).
United Lincolnshire Healthcare	Short	6	17	6 Item 1.4 MR angiogram is suggested to be the investigation following Duplex studies. However MRA does not reveal	Thank you for your comment. Imaging for revascularisation was outside the scope of this guideline update.

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NHS Trust				calcification that plays an important role in deciding on appropriateness of surgery or angioplasty. Also, a significant proportion of acute / acute on chronic ischaemia is due to popliteal artery aneurysm occlusion / embolization from popliteal artery aneurysm and this is not shown on MR angiogram. Better would be a CT angiogram. Otherwise, there is risk of excessive investigation with both MRA and CT angiogram. I believe that it should be left to the treating consultant to decide on which of these modalities to use as secondary investigation prior to treatment.	Your comment has been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
Vascular and Venous Disease - APPG	General	General	General	**Executive summary** The APPG responded to the previous NICE Consultation on Peripheral arterial disease: diagnosis and management and have published separate reports on the issue. The APPG believes that there are a number of steps that still need to be taken to tackle Peripheral Arterial Disease (PAD) and that the decision to only update the 'management' section of the guidance has overlooked an opportunity to improve care for patients and significantly improve outcomes. The guidance as it stands does not reflect the current realities of how patients with PAD are treated, and therefore the Group believes that the review could have gone further. Of what has been added to the Guidelines on diagnosis, APPG is broadly supportive.	Thank you for your comment. Management of PAD was outside the scope of this guideline update. In relation to management of intermittent claudication, a decision was made during the surveillance review that new evidence identified was unlikely to change current guideline recommendations. In relation to management of critical limb ischemia and use the of bare metal stents compared to drug eluting stents, a decision was made during the surveillance review that this review should not be updated at this current time, but should be considered for a future update after the publication of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
Vascular and Venous Disease - APPG	General	General	General	**Response to consultation** The new guidelines, launched for consultation in November 2017, have added a section for the diagnosis of PAD and expanded areas for research. The APPG approve of these changes as they are in line with clinical best practice and look to improve the time and accuracy of diagnosis in **section 1.3.4.**	Thank you for your comment.

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				Early diagnosis of arterial disease is crucial to prevent worsening of PAD, often resulting in Critical Limb Ischemia (CLI) and other complications. A key component of ensuring effective and fast referral is ensuring that all commissioners and providers have a clear pathway in place for patients suspected of increased risk of PAD. Using an ankle brachial pressure index has the benefit of identifying patients with PAD so that effective treatment or referrals can be made to prevent escalation of the condition and the APPG are supportive of the use of technology for the diagnosis and management of PAD. The APPG however recognises that other factors can and should be taken into account when diagnosing PAD and welcome the addition of **lines 1.3.4.11-13**.	
Vascular and Venous Disease - APPG	General	General	General	**Management of PAD** The APPG remains disappointed that the decision has been made not to update the 'management' section of the PAD guidance. The realities of current practice are not recognised within the guidance, which has potentially significant negative implications on future access to treatments and technologies which could save limbs and lives. The Group would encourage NICE to re-consider its decision not to update the 'management' section of the guidance.	Thank you for your comment. Management of PAD was outside the scope of this guideline update. In relation to management of intermittent claudication, a decision was made during the surveillance review that new evidence identified was unlikely to change current guideline recommendations. In relation to management of critical limb ischemia and use the of bare metal stents compared to drug eluting stents, a decision was made during the surveillance review that this review should not be updated at this current time, but should be considered for a future update after the publication of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.
Vascular and Venous Disease -	General	General	General	**Further comments** The APPG on Vascular and Venous disease are keen to stress that more can and needs to be done to provide	Thank you for your comment. Management of PAD was outside the scope of this guideline update. In relation to management of intermittent claudication, a decision

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APPG				patients with treatment pathways and access to technology. Our most recent inquiry and report found significant variation across England, with services failing patients with PAD. We believe that by not consulting further on management of PAD NICE has missed an opportunity to tackle these variations and would welcome the opportunity to feed in further to the guidelines.	was made during the surveillance review that new evidence identified was unlikely to change current guideline recommendations. In relation to management of critical limb ischemia and use the of bare metal stents compared to drug eluting stents, a decision was made during the surveillance review that this review should not be updated at this current time, but should be considered for a future update after the publication of the BASIL-3 trial. Your comments have been forwarded to NICE's surveillance team for consideration at the next review for the guideline.