National Institute for Health and Clinical Excellence

Peripheral Arterial Disease
Scope Consultation Comments Table
18.06.10 – 16.07.10

No	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1.	DOH	13.00		Thank you for the opportunity to comment on the draft scope 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.
2.	Foot in Diabetes UK	29.01		• Importance of inclusion of recognition and timely action with both critical limb ischaemia and acute limb ischaemia	Thank you for your comment. The management of acute limb ischaemia is a medical emergency and is not covered by the remit of this guidance. Evidence pertaining to critical limb ischaemia will be considered by this guidance.
3.	Foot in Diabetes UK	29.03		• Reviewing evidence on the best palliative management of ischaemic rest pain, where surgery is not possible / declined	Thank you the management of pain is covered under section 4.3.1g of the scope.
4.	Royal College of Pathologists	5.00		The Royal College of Pathologists have no comments to make at this stage in the consultation period.	Thank you.
5.	Welsh Assembly Gov	14.00		Thank you for giving the Welsh Assembly Government the opportunity to comment.	Thank you.

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				Please note that we have no comment to submit at this stage.	
6.	North of England Cardiovascular Network	30.07	All	We strongly welcome this guideline	Thank you.
7.	British Medical Association	17.01	General	While we believe that this is good outline guidance, there should be greater emphasis on the importance of seeing and treating patients holistically. While this does get a mention, it needs to be more of a central theme of the guidance.	Thank you for your comment. The guideline development group will bear a holistic approach in mind when developing the guidance.
8.	Boston Scientific Limited	22.00	General	Boston Scientific fully supports the comments submitted by ABHI. This Clinical Guideline is a great opportunity for patient outcomes to be improved and for costs to be better managed.	Thank you for your comment.
9.	British Medical Association (BMA)	17.00	General	The BMA has some concerns about the extent to which GPs and medical royal colleges were consulted in devising these guidelines, and the fact that many of the stakeholders represent drug companies.	Thank you for your comment. The Royal College of General Practitioners are registered as a stakeholder for this guideline however they did not submit any comments at the time of consultation. In addition, the guideline development group contains a general practitioner.
10.	Cook Medical	21.00	General	Cook Medical welcomes the development of a guideline on the management of lower limb PAD. We agree that there is significant variation in clinical practice, and that the emergence of new innovative endovascular therapies accentuates the need to develop clinical pathways for patients with lower limb PAD. Cook Medical obtained CE-mark for a	Thank you for your comment.

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				peripheral paclitaxel drug eluting stent in August 2009 (Zilver PTX). The stent was launched in the European market shortly after. Both randomised and non-randomised clinical studies provide clinical data on over 1,000 patients, many of them with up to 2-year follow up data. The device is awaiting FDA approval, and publication of clinical trial results is expected in the next several months. Cook Medical will be happy to share the results of both the single arm study and the randomized controlled trial with NICE, so that the technology can be appraised and included in the guideline for the benefit of the patients. This technology has proven promising in the full range of patients with superficial femoral artery disease, including diabetic patients, patients with in-stent restenosis, and patients with longer lesions who had not been well-served by more traditional endovascular treatment options.	
11.	CR Bard	20.03	General	There is concern about the difference in outcome versus other European countries which may be driven by the timing of therapy choices. If this was in the scope for review a full assessment of the patient and economic impact would be possible.	Thank you for your comment. The guideline development group will bear this in mind when reviewing evidence on outcomes.
12.	NHS Direct	8.00	General	NHS Direct welcome the guideline and have no comment on the content.	Thank you.
13.	Royal College of General Practitioners Wales	1.00	General	The scope appears fit for purpose and extensive in content	Thank you for your comment.

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14.	Royal College of Nursing	19.00	General	The Royal College of Nursing welcomes proposals to develop this guideline. The draft scope is comprehensive.	Thank you for your comment.
15.	Royal College of Physicians London	12.00	General	The Royal College of Physicians is grateful for the opportunity to respond to this draft scope consultation. We would like to make the following comments.	Thank you.
16.	Royal College of Physicians London	12.01	General	We are disappointed that diabetes does not feature more strongly in the draft. Diabetes is the biggest cause of non-traumatic lower limb amputation in the UK and we believe it should be a major part of this initiative. This should include preventive approaches to type 2 diabetes, active and vigorous management of the disease when associated with peripheral vascular disease (PVD), involvement of the diabetes care team at an early stage, and probably also screening for diabetes in PVD patients not previously known to have diabetes.	Thank you for your comment. The population of the guidance includes people with diabetes, a member of the guideline development group has been sought with expertise in this area, and the final guidance will cross-refer to a range of existing NICE guidance on the management of people who have diabetes and peripheral arterial disease.
17.	Royal College of Physicians London	12.02	General	There is not enough mention in the epidemiology or current practices sections regarding the association of diabetes and peripheral arterial disease (PAD) or the common finding of lack of symptoms of PAD in those with diabetes.	Thank you for your comment. The scope has been amended to highlight this association.
18.	Sheffield Teaching Hospitals NHS Foundation Trust	24.00	General	Suggestions are: ➢ adding referral thresholds from primary to secondary care to the list	Thank you for your comment. It is anticipated that the guideline will make recommendations about the appropriateness of referral based on

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				of items being considered ➢ automatic referral for critical ischaemia is assumed – for claudicants, a consideration of what preliminary treatment and investigations should be undertaken in primary care before referral ➢ some evaluation of symptom severity that would justify referral would be useful.	the assessment of literature on treatments and interventions provided in primary and secondary care, as well as diagnostic criteria.
19.	Cordis (Johnson & Johnson)	6.00	2	No comments	Thank you.
20.	British Medical Association	17.02	3	The information contained in Section 3 on the clinical need for guidance does not go into sufficient detail, considering the target audience, and adds little to the document in its current form.	Thank you for your comment. Without further suggestion from the stakeholder we are unable to address this point and we have augmented this section in response to other stakeholder comments where appropriate. This section is not intended to be exhaustive.
21.	MSD	31.00	3.1	Considering the large proportion of PAD patients who are asymptomatic, we feel the scope misses the opportunity to include early diagnosis of asymptomatic PAD.	Thank you for your comment. Screening is outside the remit of clinical guidance. The guidance will be considering evidence for the management of people with a finding of asymptomatic PAD.
22.	North of England Cardiovascular Network	30.00	3.1	In section 3.1a the risk of PAD is stated as a 3-4 fold increase in cardiovascular risk. In fact the risk is related in almost a linear fashion to the ABI and this should be clearly stated. The risk related to the ABI is not dependent on symptoms per se.	Thank you for your comment. The guideline development group intend to consider evidence on secondary prevention and cannot pre-judge its findings. We have amended the scope so this is reflected.
23.	North of England Cardiovascular Network	30.01	3.1	In 3.1b the risk of amputation is minimised – correctly in statistical terms – however there is a major problem with amputation in this	Thank you. We believe the epidemiological supporting text is sufficient as is currently – it is not intended to be exhaustive and details like

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				country (No decrease over the last decade) and amputations potentially will have a very large impact on cost effectiveness. This could be stressed	this may be included in the full guideline.
24.	Pfizer Limited	27.00	3.1	In reference to the line 'the incidence of peripheral arterial disease is high among people who smoke…' it is not clear why smoking cessation interventions nevertheless appear to have been omitted from the list of clinical management issues to be covered in section 4.3.1, since these would seem to be a prerequisite to subsequent treatment management in newly diagnosed PAD patients who currently smoke.	Thank you for your comment. The guideline development group will cross-refer to other NICE publications as appropriate. Please see section 5.1.2 and 4.3.1b.
25.	Society of Vascular Nurses	23.04	3.2.g	Shuttle walk often found to be more reliable measure of walking distance than treadmill walk	Thank you for your comment. This was intended as background information only with example of some commonly used investigations.
26.	Society of Vascular Nurses	23.05	3.2.h	New techniques such as cutting balloons do not have levels of evidence to support their use as yet.	Thank you for your comment. This paragraph in the scope is not intended to prejudge the evidence base for a treatment.
27.	British Society of Interventional Radiology	3.00	3.2a	This section begins by discussing intermittent claudication. Later on in section 3.2 the management of more severe disease is discussed but the term critical limb ischaemia does not appear. Should section 3.2 a) be altered to "The management of peripheral arterial disease remains controversial …." or should specific reference be made to CLI possibly in section	Thank you for your comment. The scope has been amended to read 'peripheral arterial disease' in place of 'intermittent claudication'.

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				3.2 g) ?	
28.	Royal College of Nursing	19.01	3.2a	The term "masterly inactivity" is not a widely used term in vascular practice in clinical areas.	Thank you. This has been amended.
29.	Cook Medical	21.01	3.2b	The sentence suggests that the current practice is to refer the patients experiencing more severe symptoms to secondary care. We believe that a referral is not always made when appropriate, even in patients with more severe symptoms. Therefore we recommend that the referral system for patients with intermittent claudication and with more severe symptoms is also included in section 4.3.1 as one of the clinical issues which will be addressed, after the diagnosis.	Thank you for your comment. It is anticipated that the guideline will make recommendations about the appropriateness of referral based on the assessment of literature on treatments and interventions provided in primary and secondary care, as well as diagnostic criteria.
30.	MSD	31.01	3.2b	We would kindly suggest that more clarity is required here in the definition of mild vs. severe symptoms.	Thank you for your comment. The scope is not intended to be exhaustive. This kind of detail will be included in the full guideline.
31.	Society of Vascular Nurses	23.01	3.2b	Clinical experience would suggest that patients with mild symptoms are not managed effectively in primary care and many patients receive no medical management prior to presentation to secondary care.	Thank you. This guideline will cover management in primary care and the guideline development group contains a general practitioner.
32.	Leg Ulcer Forum	4.00	3.2c	Will the guideline consider the reliability of ABPI's in patients with diabetes and whether wave form analysis, toe pressures and pulse oximetry is beneficial for this patient group.	Thank you for your comment. People with diabetes will be considered as a sub-group for this guidance and it is also being considered by the diabetic foot care guideline in development – see section 5.2.
33.	MSD	31.02	3.2c	Clopidogrel (Plavix) is indicated for the prevention of atherosclerotic events in PAD – we would suggest that is should also be	Thank you for your comment. Please see section 5.2 of the scope.

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				mentioned under current practice.	
34.	North of England Cardiovascular Network	30.02	3.2c	Treatments are not just "prescribed" as they also include dietary and lifestyle issues and an important factor is patients' compliance. There may also be socioeconomic associations – this should be acknowledged.	Thank you for your comment. The scope has been amended.
35.	Cordis (Johnson & Johnson)	6.01	3.2d	Strictly, people with intermittent claudication are encouraged to exercise. We hear anecdotally that when patients are advised to take up exercise (walking), their reaction can be 'my legs hurt when I walk, I have been told to walk, but that makes my legs hurt'. This can seem illogical to some patients and consequently, there can poor compliance with exercise advice. These patients become disheartened at the seeming lack of 'treatment' and then only re-present much later in the disease process.	Thank you for your comment. This guidance will consider both supervised and unsupervised exercise programmes as a treatment for people with PAD.
36.	Association of British Health-Care Industries	25.00	3.2d	It is normally just claudicants who are usually advised to exercise,	Thank you for your comment. The scope has been amended.
37.	Royal College of Nursing	19.02	3.2d	It may be worth adding an explanatory sentence as to why exercise is advised i.e. to promote collateral circulation	Thank you for your comment. The scope is not intended to be exhaustive.
38.	Society of Vascular Nurses	23.02	3.2d	Provision of exercise classes throughout the UK is not equitable.,not given the same credence and levels of funding enjoyed by cardiac rehab programmes, patients not always able to self fund.	Thank you for your comment. Recommendations on the use of exercise as a therapy for peripheral arterial disease will be made based on available clinical and cost-effectiveness evidence.
39.	Society of Vascular Nurses	23.03	3.2e	Reported efficacy of these drug therapies is varied..Many of them have undesirable side effects and are not well tolerated.	Thank you. Adverse effects are being considered as an outcome as listed in section 4.4h of the scope.

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40.	Association of British Health-Care Industries	25.01	3.2g	The benefits of revascularisation in mild to moderate claudicants should be considered. Revascularisation for severe short distance claudication may currently only come after patients have suffered years of pain that could have been alleviated by earlier access to revascularisation.	Thank you for your comment. Section 3.2 of the scope describes current practice. Section 4.3 states the guideline development group will consider some aspects of endovascular treatments.
41.	Cordis (Johnson & Johnson)	6.02	3.2g	We note the comment that people with severe symptoms are referred for revascularisation. The timeliness and threshold of referral for revascularisation needs to be considered in this guideline as the recent MIMIC trial has shown sustained benefit of revascularisation (specifically angioplasty in this trial) in mild to moderate claudicants.	Thank you for your comment. It is anticipated that the guideline will make recommendations about the appropriateness of referral based on the assessment of literature on treatments and interventions provided in primary and secondary care, as well as diagnostic criteria.
42.	CR Bard	20.00	3.2h	"Cutting balloon" is a product not a therapy. Bard suggest "focussed force" as a more appropriate term.	Thank you for your comment. We have amended the scope accordingly.
43.	Society of Vascular Nurses	23.00	3 .3.1b	Statement of 1-2% of pts with claudication eventually undergoing amputation seems very high	Thank you for your comment. Section 3 is not intended to be a thorough review of the literature on epidemiology or current practice. Further detail may be added into the introduction of the guideline.
44.	North of England Cardiovascular Network	30.03	4.1	Diabetics should be an explicit subgroup as should claudicants vs. those with critical ischaemia	Thank you for your comment. These sub-groups will be considered in the guidance.
45.	Royal College of Physicians London	12.03	4.1	This section should specifically include patients with diabetes and foot disease who have ulceration. It should also include patients with diabetes who are found	Thank you for your comment. People with diabetes are included as a sub-group. Management of foot ulceration is considered in CG10 and the diabetic foot care guideline – see

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				incidentally to have absent foot pulses at foot screening (screening as per NICE clinical guideline 10).	section 5.2 of the scope. This guideline will cross-refer where appropriate.
46.	Royal College of Physicians London	12.04	4.1c	It should be acknowledged that when ankle/brachial pressure index (ABPIs) are done in patients with diabetes and no symptoms of PAD that those with unusually high ABPI should also be covered (ie the patient with diabetes and calcified leg vessels).	Thank you. The scope has been amended for clarity.
47.	CR Bard	20.01	4.1.1	It is also suggested that a specific review of the diabetic lesion cohort is included in the consultation.	Thank you for your comment. We are uncertain what this term refers to but diabetic care is covered by other NICE guidance – see section 5.1 and 5.2 of the scope.
48.	Diabetes UK	18.01	4.1.1	People with diabetes should be a clearly identified subgroup within the scope given the potential impact on the health and quality of life of people with diabetes. Peripheral vascular disease is a long term complication of diabetes and according to NICE itself within its commissioning guidance, it affects 19-29 per cent of people with diabetes. [1] Furthermore it is reported up to 100 people a week have a limb amputated as a result of diabetes.[2] The draft scope for this guideline identifies that 5 per cent of people with diabetes with claudication eventually undergo an amputation. Diabetes is the most common cause of non traumatic limb amputations, with mortality rates following	Thank you for your comment. People with diabetes will be considered as a sub-group in the guidance development.

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				amputation of 50 per cent at two years and 75 per cent at six years. [3] 1. http://www.nice.org.uk/usingguidance/commissioningguides/footcare/assumptions.jsp#ref 2. Diabetes UK (2009) Putting Feet First 3. NHS Diabetes (2008) Improving emergency and inpatient care for people with diabetes	
49.	Faculty of Pain Medicine of the Royal College of Anaesthetists	26.00	4.1.1	Groups that will be covered: Section a) Should read aged 18 and older	Thank you this has been amended.
50.	Foot in Diabetes UK	29.02	4.1.1	• The importance of reviewing evidence and the NICE position on asymptomatic PAD	Thank you for your comment. This is included in 4.1.1.c.
51.	Leg Ulcer Forum	4.01	4.1.1	The leg ulcer forum would like to seek clarification regarding the application of compression therapies to patients with co-existing venous ulceration and PAD	Thank you for your comment. The management of venous ulceration is outside the remit of this guideline. If you think this should be covered by future guidance then please refer the topic to NICE's topic selection panel for consideration.
52.	Diabetes UK	18.00	4.1.1.a	Diabetes UK is seeking clarification regarding the decision to define the population as "adults aged 19 and older", instead of 18 and older.	Thank you this has been amended.
53.	ArjoHuntleigh	9.00	4.1.1a	adults aged 18 and older	Thank you this has been amended.
54.	CR Bard	20.02	4.1.1b	In the interests of considering all conditions chronic total occlusions should be reviewed.	Thank you for your comment. This section is referring to the symptomatic diagnosis rather

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					than the anatomical disease.
55.	Sanofi-Aventis	28.00	4.1.1b	Please amend to read "People who present with symptoms of lower limb peripheral arterial disease - including intermittent claudication and patients with critical limb ischaemia (ischaemic rest pain with or without tissue loss)" Sanofi-aventis believe that it is important to clearly distinguish the various stages in the natural history of symptomatic PAD. The stage of CLI, defined as a condition characterized by chronic ischemic at-rest pain, ulcers, or gangrene in one or both legs attributable to objectively proven arterial occlusive disease, is distinct from the earlier stages of PAD including intermittent claudication. Patients with CLI have an elevated risk of future myocardial infarction, stroke and vascular death, 3-fold higher than patients with intermittent claudication. Therefore, due to its negative impact on the quality of life and the poor prognosis both in terms of limb salvage and survival, critical limb ischemia is a critical public health issue and should defined and differentiated in the scope. (Novo s et al. Curr. Drug Targets Cardiovasc Haematol Disord 2004 Sep;4(3):219-25).	Thank you for your comment. We have amended the text to improve clarity.

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56.	Pfizer Limited	27.01	4.1.1d	In reference to the sentence 'subgroups based on ethnicity, socioeconomic factors, age or comorbidities, where differences in management and outcome are identified', please expand to include 'smoking status', since smokers with PAD will require smoking cessation interventions for long-term management of the disease in additional to clinical management of symptoms, hence they constitute a sub-group where bespoke clinical management is required.	Thank you for your comment. This guidance will cross refer to existing guidance on smoking cessation where appropriate.
57.	British Society of Interventional Radiology	3.01	4.3.1e	Patients with peripheral vascular disease are selected for endovascular or surgical treatment based on a number of factors including extent/site of disease and considerations regarding comorbidity, life expectancy etc. In many respects these treatment options are complementary and I feel that an important part of the guideline will be to advise on appropriate patient selection for endovascular or surgical management. I am sure that this is intended but would like to clarify that this part of the guideline will not be restricted to comparison of surgery versus endovascular treatment.	Thank you for your comment. We acknowledge that some people will need a combined approach and the guideline development group will prioritise comparisons for consideration, given it is not possible to cover all variations in the time available.
58.	Medtronic Ltd	7.00	4.3.1e	The nature of endovascular interventions is	Thank you for your comment. The guideline

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				such that in some cases a surgical approach is not possible or desirable and accordingly by stating a comparator of surgery the scope may unintentionally rule out some valuable data. Could we suggest that the point is rephrased to "endovascular treatments (for example, angioplasty and stents) compared to surgery or best medical treatment" to avoid the possibility of this exclusion?	development group will not be able to consider the literature for all comparisons however this is covered under section 4.3.1d of the scope under 'best medical management'.
59	Association of British Health-Care Industries	25.04	4.31e	Stents should not be considered as just an alternative to balloon angioplasty but also as an important bailout option. It is not as simple as 'stent versus balloon'. Patient choice will also feature in the decision as to whether endovascular or open surgery is the most appropriate revascularisation technique.	Thank you for your comment. We agree these are sometimes used in combination and that patient choice is important and will bear this in mind when reviewing the evidence.
60	Cordis (Johnson & Johnson)	6.05	4.31e	Do not assume that balloon angioplasty and stents can be simply treated as alternatives. Whilst not all patients will need primary stenting, stents are often used to improve procedural results and prevent acute/sub-acute closure after angioplasty and are thus an integral part of some procedures if complications are to be avoided.	Thank you for your comment. We recognise that balloon angioplasty and stents are not just alternatives and will bear this in mind when prioritising comparisons for inclusion in the guidance.
61.	Royal College of Nursing	19.03	4.3.2e	It is not clear the rationale for excluding use of topical treatments and dressings from this guideline. We consider that this is a key issue which should be included.	Thank you but we are unable to cover all areas relating to PAD in the time available and stakeholders at the workshop de-prioritised this for inclusion in the final scope. The guidance will refer to other NICE guidance on care for

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				In clinical practice if this is not performed correctly (e.g. a non-adherent dressing, odour absorbency for wet gangrene, etc.) it has a major outcome on the quality of the individual's life. It is not covered in other wound related NICE guidelines.	people with diabetes – please see section 5.1 and 5.2 of the scope.
62.	North of England Cardiovascular Network	30.04	4.3c	Make clear that this is assessment for possible intervention not diagnosis	Thank you. This has been amended for clarity.
63.	Association of British Health-Care Industries	25.02	4.31a	Can GPs play a bigger part in diagnosis eg assessment of ABPI? Criteria for referral to vascular specialists should also be set out.	Thank you for your comment. We do not name healthcare professionals but rather interventions in recommendations.
64.	Cordis (Johnson & Johnson)	6.03	4.31a	Diagnosis and assessment should also consider the pathway for referral to ensure that patients have access to assessment by a vascular specialist and amputation as a primary intervention is avoided wherever possible. General practitioners, if correctly trained, may be able to play a more active role such as assessment of ABPI (with the correct training), to ensure that the right patients are referred to vascular specialists.	Thank you for your comment. It is anticipated that the guideline will make recommendations about the appropriateness of referral based on the assessment of literature on treatments and interventions provided in primary and secondary care, as well as diagnostic criteria. The assessment of PAD using ABPI as a tool for diagnosis is being considered by this guideline.
65.	Association of British Health-Care Industries	25.03	4.31d	Supervised exercise is an important consideration. However, the timing of revascularisation as an adjunct to this and other conservative measures may be a more logical ordering of treatment options.	Thank you for your comment. This will be driven by the research and we cannot pre-judge the findings of an evidence review.
66.	Cordis (Johnson & Johnson)	6.04	4.31d	Following MIMIC, the scope should include revascularisation as an adjunct to supervised	Thank you for your comment. This will be driven by the research and we cannot pre-judge the

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				exercise, smoking cessation and best medical therapy. This better reflects the question of timeliness and sequencing of revascularisation relative to more conservative interventions. There may be benefit in giving specific attention to the role of below the knee/distal revascularisation in reducing amputations.	findings of an evidence review. The guideline development group are yet to prioritise comparisons for inclusion.
67.	North of England Cardiovascular Network	30.05	4.31g	It would be better to refer to critical ischaemia rather than use the term ischaemic rest pain.	Thank you the scope has been amended accordingly.
68.	British Medical Association (BMA)	17.03	4.3.1	On the key clinical issues that will be covered: - It should be reflected in the guidance that the most important clinical issues are: a) Clinical presentation b) Assessment c) Treatment i) of claudication ii) of critical ischaemia.	Thank you, we believe these areas are covered in the scope.
69.	British Medical Association (BMA)	17.04	4.3.1	On the key clinical issues that will be covered: - There should also be an explicit reference to preventable risk factors such as smoking, diet etc. as one of the clinical issues to be covered. If the intention is to include this information under 'patient information', this section needs to be expanded as it is insufficiently detailed in its current format.	Thank you the guideline will cross refer to other NICE guidance as appropriate.
70.	Action on Smoking and Health (ASH)	16.00	4.3.1	As smoking is the most important preventable risk factor for PAD, giving	Thank you the guideline will cross refer to other NICE guidance as appropriate.

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				patients advice about stopping smoking (or referring smokers to specialist advisers) should be a key component of the clinical management of PAD. For those who smoke, stopping smoking is likely to be the most effective treatment.	
71.	Diabetes UK	18.02	4.3.1	It would be useful for the guideline to cover factors associated with service organisation such as: - The professionals required at different stages of care, taking into consideration the care of population subgroups - timescales for identification, referral and treatment	Thank you for your comment. We do not name healthcare professionals but rather interventions in recommendations.
72.	Faculty of Pain Medicine of the Royal College of Anaesthetists	26.01	4.3.1	Key clinical issues that will be covered: Section a) Diagnosis may also include assessment (4.3.1c), as assessment may be part of diagnosis.	Thank you for your comment. The scope has been amended for clarity.
73.	Faculty of Pain Medicine of the Royal College of Anaesthetists	26.02	4.3.1	Key clinical issues that will be covered: Section g) For methods of pain relief: It may be better to have chronic pain specialist as expert advisor to help Guideline development group. They may be invited at a time, when guidance re methods of pain control is being developed.	Thank you for your comment. The guideline development group have appointed a pain specialist as a co-opted expert.
74.	Foot in Diabetes UK	29.00	4.3.1	• Inclusion and clarity re first line non-invasive diagnostics – history taking, symptom questioning, pulse palpation and use of handheld Doppler	Thank you for your comment. The GDG are yet to prioritise the issues for review.
75.	Leg Ulcer Forum	4.02	4.3.1	Will there be a screening programme to	Thank you for your comment. Screening is

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				identify the asymptomatic patients within the PCT's?	outside the remit of the clinical guidance programme.
76.	NHS Sheffield	15.00	4.3.1	We think that an evaluation of when a statin should be initiated in patients diagnosed with peripheral arterial disease should be considered. (SIGN suggests patients to be initiated on a statin when their total cholesterol level is >3.5mmol/L with concomitant intermittent claudication).	Thank you for your comment. We will be cross-refer and incorporate existing NICE guidance/incorporate where appropriate.
77.	NHS Sheffield	15.01	4.3.1	Lifestyle advice should be included following evaluation of its significance in the improvement of cardiovascular complications associated with peripheral arterial disease. Lifestyle modification includes smoking cessation, weight reduction, and good blood pressure and blood glucose control.	Thank you for your comment. The guideline will refer to existing guidance on secondary prevention where appropriate.
78.	Pfizer Limited	27.02	4.3.1	The list of clinical management issues to be covered should be expanded to include smoking cessation interventions, since to successfully manage the disease in the long-term, they are a prerequisite to subsequent treatment management of clinical symptoms.	Thank you for your comment. We will be cross-refer and incorporate existing NICE guidance/incorporate where appropriate.
79.	Royal College of Physicians London	12.05	4.3.1	This section should include screening for diabetes in those with PAD, who are not known to have diabetes.	Thank you for your comment but this is outside the remit of a guideline on the management of PAD.
80.	Sanofi-Aventis	28.01	4.3.1	Please include in this section before diagnosis, the *screening of patients with a history of MI or stroke for Peripheral Arterial Disease (PAD)*. The REACH Registry found overlapping manifestations of disease in patients with MI,	Thank you for your comment. Screening of at-risk populations is outside the remit of the guideline. The guidance will cover the investigation and treatment of asymptomatic PAD as identified by opportunistic case findings.

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				stroke and PAD. Out of almost 60% of patients with coronary artery disease in REACH, 6.3% of these patients also had PAD. Out of almost 30% patients with cerebrovascular disease, 2.8% of the patients had co-existing PAD. Furthermore, the REACH registry demonstrated that patients with arterial disease in more than one vascular bed were at higher risk of CV events compared to those with disease in one vascular bed. Event rates increased in a stepwise fashion with the number of symptomatic vascular beds. Endpoint of CV death, MI, stroke or hospitalisation for a CV event at one year increased from 12.58% with one, 21.14% with two, and 26.27% with three arterial bed disease locations. (p<0.001 for trend) (Bhatt et al JAMA 2006; 295: 180-189) (Steg et al JAMA 2007; 111: 1197-1206) The screening for and diagnosis of PAD in at-risk groups should be encouraged in primary care to facilitate the earlier identification and management of patients with the disease.	
81.	Sanofi-Aventis	28.02	4.3.1	d) Please include smoking cessation programmes as a recommendation. Smoking has been identified as key risk factor	Thank you for your comment. We will be cross-refer and incorporate existing NICE guidance where appropriate.

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				in the development of PAD. Furthermore, smoking cessation is associated with a decline in the incidence of IC. Results from the Edinburgh Artery Study found that the relative risk of intermittent claudication was 3.7 in smokers compared with 3.0 in ex-smokers (who had discontinued smoking for less than 5 years). (L. Norgren and W. R. Hyatt et al. Eur J Vasc Endovasc Surg Vol 33, Supplement 1, 2007)	
82.	Sanofi-Aventis	28.03	4.3.1	e) Please include the current management of patients with critical limb ischaemia (severe PAD) who are not eligible for either surgery or endovascular treatment. It would be useful to review in the scope current treatment options for patients with PAD when open or endovascular intervention is not technically possible. (L. Norgren and W. R. Hyatt et al. Eur J Vasc Endovasc Surg Vol 33, Supplement 1, 2007)	Thank you for your comment. The scope does indeed include non-interventional management of PAD – see section 4.3.1.
83.	ArjoHuntleigh	9.01	4.3.1a	diagnosis should include minimum standards of screening in primary care, subjective questioning, disease specific	Thank you for your comment. Screening is outside the remit of the clinical guidance programme, although the use of ABPI as a diagnostic tool will be considered.
84.	ArjoHuntleigh	9.02	4.3.1c	Add ABPI to assessment. An ABPI should be measured in all patients suspected of PAD.	Thank you for your comment. The use of ABPI as a diagnostic tool will be considered by the guidance.

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85.	Action on Smoking and Health (ASH)	16.01	4.3.1f	Patient information should include advice on stopping smoking.	Thank you for your comment. The guideline will cross-refer to existing NICE guidance where appropriate.
86.	British Medical Association (BMA)	17.05	4.4	Limb salvage is the most important outcome in the management of peripheral arterial disease and this should be reflected in the guidance by being placed at the head of the list. While mortality is an outcome with peripheral arterial disease, including it at the top of the list of outcomes is misleading as to its importance, and as such it should be placed further down.	Thank you for your comment. The outcomes listed are not in order of priority.
87.	Association of British Health-Care Industries	25.05	4.4	Amputation rates should be included as an outcome measure.	Thank you for your comment. Feedback at the stakeholder workshop suggested limb salvage rates are a more consistently reported outcome in the literature.
88.	Cook Medical	21.02	4.4	We suggest the inclusion of a very important clinical outcome reported on many lower limb PAD clinical studies - the Rutherford Score. The score classifies patients into one of 7 categories, and it is normally reported pre and post-intervention, providing insight into improvement of symptoms for the patient. Rutherford Categories: Class 0: Asymptomatic, no hemodynamically significant occlusive disease. Class 1: Mild claudication. Class 2: Moderate claudication. Class 3: Severe claudication. Class 4: Ischemic rest pain. Class 5: Minor tissue loss.	Thank you for your comment. The Rutherford scale is more commonly reported as a baseline characteristic than outcome such as walking distance, pain and tissue loss. If the Rutherford scale is commonly reported in a question then the guideline development group will discuss this for inclusion.

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				Class 6: Major tissue loss.	
89.	Cordis (Johnson & Johnson)	6.06	4.4	Amputation rates and absolute numbers should be an outcome measure as these are comprehensively coded and recorded in HES.	Thank you for your comment. Feedback at the stakeholder workshop suggested limb salvage rates are a more consistently reported outcome in the literature.
90.	Faculty of Pain Medicine of the Royal College of Anaesthetists	26.03	4.4	In main outcomes: For pain control studies in peripheral arterial disease, objective assessment of pain intensity should be included ie Visual analogue scale or numeric rating scale etc.	Thank you. This has been added to the list of outcomes in section 4.4 of the scope.
91.	MSD	31.03	4.4	We suggest that cardiovascular morbidity should be included as an outcome.	Thank you for your comment. This list of outcomes is not intended to be exhaustive and the guideline development group will tailored the outcomes to each question.
92.	North of England Cardiovascular Network	30.06	4.4	Since it is clear that coronary and stroke events are main causes of death/morbidity in PAD a main outcome should include the number of such events	Thank you for your comment. This list of outcomes is not intended to be exhaustive and the guideline development group will tailored the outcomes to each question.
93.	Society of Vascular Nurses	23.08	4.4e	Graft and vessel patency may be difficult to assess as not all clinicians routinely have graft surveillance programmes in place.	Thank you for your comment. We recognise that graft and vessel patency may not always be measured in clinical practice however they are considered to be important outcomes in clinical trials.
94.	MSD	31.04	4.4.g	We would kindly suggest that this point should focus on CV-related readmissions rather than all-cause readmissions. Focussing on all cause readmissions may dilute the impact that interventions, including drugs, have on the disease.	Thank you for your comment, but the intention is to capture readmissions for all causes such as those after surgical complications.
95.	Society of Vascular Nurses	23.07	4.4c	Is treadmill walking distance the most effective and reliable measure of walking distance? Shuttle walk is considered more	Thank you for your comment. This list of outcomes is not intended to be exhaustive and the guideline development group will tailored

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				reliable.	the outcomes to each question.
96.	East Lancashire Hospitals NHS Trust	10.00	General & Section 4.3.1	The Governments recent White Paper "Equity and Excellence: Liberating the NHS" promotes an NHS that is "less insular and fragmented and works much better across boundaries, including with local authorities and between hospitals and practices." assessment2.ppt LEVEL 1 ASSESSMENT1.doc The Vascular Society in "Provision of service for patients with vascular disease 2009", suggests that every patient in the country should have the opportunity to consultant with a vascular specialist at a convenient local hospital. It is not appropriate or practical to provide the full range of vascular facilities on every hospital site. The document goes on to say that in the absence of limited resources a compromise must be achieved between local access and the delivery of specialist care. There needs to be a balance between the manpower, capital and other resources required to provide an effective service. The driver for that balance must be the achievement of the best possible outcomes for individual patients. The Society acknowledges that many patients referred to a Vascular Specialist by their GP with diseases of their arteries do not require surgical or	Thank you for your comment. The guideline aims to focus on the best evidence for management. Some of the points you refer to are implementation issues once the draft guidelines have been developed. Service delivery will be looked at where appropriate but the guideline cannot go into this level of detail.

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				radiological intervention. They require simple reassurance and lifestyle advice, stop smoking, lose weight and take regular exercise, coupled with measures to reduce their future risk of heart disease and stroke, Aspirin and Lipid lowering therapy, blood pressure control. This cohort of patients forms the overwhelming majority of stable claudicants who present to the Health Services in England and Wales. In East Lancashire we have developed a system of community based levels of assessment which ensure that "stable" claudicants can be distinguished from those patients who require further investigation by vascular technologists or radiologists with a view to interventional radiology treatment, "such as balloon angioplasty or stenting". The "unstable patients" are rapidly identified and passed on immediately for further investigation. The small portion who also require urgent surgery are also identified even if they require surgery as an emergency that day. The majority of stable claudicants are safely managed in the community. The system works because the assessment of vascular patients is split into three levels. A Level 1 Assessment is undertaken by any clinician (Doctor, Nurse, Chiropodist and Podiatrist) the system involves taking a simple history, noting high risk groups and	

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				red flag symptoms which require immediate emergency care. Examination of patients must include the ascertaining that normal lower extremity pulses are present. Patients with reduced or absent foot pulses are referred on for Level 2 Assessment in the community clinics (vide infra). Patients with red flags go for immediate Level 3 assessment (The Hospital Vascular Service). Level 2 Assessment is carried out by specifically trained; community based nursing staff that run "Leg Cafes" – Healthy Leg Clinics at various settings in the community, such as in sheltered housing projects and community halls etc. Apart from taking Level 1 referrals they also provide drop in access for patients who may be worried about their lower limb (arterial) disease. I enclose a Level 2 assessment; it is essentially wave form and pulse pressure measurement to ascertain the severity of peripheral vascular disease. The Level 2 Clinics provide specialist smoking cessation, weight control, dietary advice, best medical treatment and the commencement of lipid control in combination with the referring General Practitioner. Both levels of assessment have red flags which result in direct referral to Level 3 assessment which is the Vascular Clinic at the Royal Blackburn Hospital.	

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				In this clinic all new referrals are seen by the Specialist Nurse, a full vascular assessment is carried out including treadmill testing. Patients with clearly detected physiological impairment of lower limb perfusion then undergo an anatomical assessment by duplex scanning. Once complete patients are then seen by the Consultant Surgeon and a decision is immediately made about treatment with either angioplasty and/or surgery. The unstable patient with deteriorating claudication, rest pain, gangrene and other red flag symptoms, once stabilised in the hospital by day case or in hospital treatment, are referred back to the community clinics for maintenance follow-up. We believe this system offers the best compromise between providing rapid, early intervention in unstable patients with seriously ischaemic limbs, whilst ensuring that resources for stable patients are used to keep them in the community. If the commission so wishes we can submit the detailed service specifications we have developed in conjunction with East Lancashire PCT for the Leg Café's.	

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97.	Royal College of Physicians London	12.06	4.3.2	This section should specify that the management of PAD in those with foot ulcers will be covered (the short guideline on diabetes foot care currently being developed is specifically for inpatient management)	Thank you for your comment. People with diabetes will be considered as a sub-group for this guidance. The management of foot problems is covered by CG10 and other guidance currently in development – see section 5.1 and 5.2 of the scope.
98.	Medtronic Ltd	7.01	4.3.2a	Could the Institute clarify this exclusion as often the chronic will suddenly present as acute and the same therapies are valid for revascularisation?	Thank you for your comment. We acknowledge that 'acute on chronic' is a term some people use, however this is different from an acute embolic presentation which is specifically excluded in this scope. The guideline development group will bear this in mind when developing guidance.
99.	Diabetes UK	18.03	4.3.2d	Please ensure there is clear cross referencing between this guideline and the short clinical guideline for inpatient diabetes foot care (currently under development).	Thank you for your comment. The guidance will cross-refer to this short clinical guideline where appropriate.
100.	Action on Smoking and Health (ASH)	16.02	4.5	The cost-effectiveness of giving stop smoking advice should be included in the review of the economic aspects of the guidance.	Thank you for your comment. Please refer to existing NICE guidance on smoking cessation (PH1) http://www.nice.org.uk/PHI001
101.	Sanofi-Aventis	28.04	4.6.2	We would like to bring to the Guideline Development Group's notice a pivotal phase III trial – the **T**herapeutic **A**ngiogenesis for the **M**anagement of **A**therosclerosis in a **R**andomised **I**nternational **S**tudy (TAMARIS), results of which will be presented at the American Heart Association (AHA) conference in November 2010 The TAMARIS trial is a multi-centre, randomized, double-blind placebo-controlled	Thank you for your comment. Novel areas such as this would be outside the remit of a clinical guideline. If you believe this should be considered for a technical appraisal then please refer to the NICE topic selection panel for consideration.

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				parallel group study of the efficacy and safety of 4 administrations of Non-viral (version 1) Fibroblast Growth Factor (NV1-FGF) 4mg at 2-weeks intervals on amputation or any death in Critical Limb Ischemia (CLI) patients with skin lesions. The primary objective of the study is to demonstrate the superiority of NV1FGF over placebo in the prevention of major amputation of the treated leg or of death from any cause, whichever comes first, in CLI patients with skin lesions. Non-viral (version 1) Fibroblast Growth Factor (NV1-FGF) is a plasmid-based gene delivery system for the local expression of the human FGF-1, promoting angiogenesis.	
102.	Society of Vascular Nurses	23.06	4 1.1c	This is an inaccurate statement regarding pts with venous ulceration., should this read patient with mixed aetiology or arterial ulceration.	Thank you for your comment. We are referring to those with suspected venous ulceration who are found to have a reduced ABPI pressure.
103.	ArjoHuntleigh	9.03	5.1	Add SIGN guideline 89 (2006) on Diagnosis and Management of PAD.	Thank you for your comment. Section 5.1 is referring to related guidance developed by NICE.
104.	Faculty of Pain Medicine of the Royal College of Anaesthetists	26.04	5.1.1	In section on NICE guidance to be incorporated: TA159 Pain (chronic neuropathic or ischaemic) - spinal cord stimulation: guidance published 22 October 2008, should be considered for incorporation.	Thank you for your comment. This has been added to the list of related guidance.
105.	Pfizer Limited	27.03	5.1.2	Pfizer is pleased that 'Varenicline for smoking cessation. NICE technology appraisal	Thank you for your comment. Updating Technology Appraisal 123 (2007) is outside the

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				guidance 123 (2007)' is referenced as 'other related NICE guidance' in the draft scope. However, there is new randomised controlled trial evidence for varenicline vs. placebo in a cardiovascular patient population (Rigotti, Pipe, Benowitz, Arteaga, Garza, Tonstad, 2010) that has been published since TA 123. In this multi-centre double-blind trial 179/714 (25%) of patients had PAD at baseline. The primary end point was carbon monoxide–confirmed continuous abstinence rate (CAR) for weeks 9 through 12 (last 4 weeks of treatment). CAR was significantly higher for varenicline vs. placebo during weeks 9 through 12 (47.0% vs. 13.9%; odds ratio, 6.11; 95% confidence interval [CI], 4.18 to 8.93) and weeks 9 through 52 (19.2% vs. 7.2%; OR, 3.14; 95% CI, 1.93 to 5.11). The varenicline and placebo groups did not differ significantly in cardiovascular mortality (0.3% vs. 0.6%; difference -0.3%; 95% CI, -1.3 to 0.7), all-cause mortality (0.6% vs. 1.4%; difference, -0.8%; 95% CI, -2.3 to 0.6), cardiovascular events (7.1% vs. 5.7%; difference, 1.4%; 95% CI, -2.3 to 5.0), or serious adverse events (6.5% vs. 6.0%; difference, 0.5%; 95% CI, -3.1 to 4.1). In light of Pfizer's comments made in relation to sections 3.1, 4.1.1d) and 4.3.1 above, this new evidence should be considered by the guideline development group within the relevant clinical management section of the	remit of this clinical guideline.

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				PAD guideline.	

These stakeholder organisations were approached but did not respond

3M Health Care Limited
Abbott Vascular
Abertawe Bro Morgannwg (ABM) University NHS Trust
Airedale Acute Trust
Anticoagulation Europe
Avon, Gloucestershire & Wiltshire Cardiac Network
BMJ
Bristol-Myers Squibb Pharmaceuticals Ltd
British Association for Nursing in Cardiovascular Care
British National Formulary (BNF)
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Care Quality Commission (CQC)
Commission for Social Care Inspection
Connecting for Health
Department for Communities and Local Government
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
East and North Herts NHS Trust
Faculty of Occupational Medicine
Frimley Park Hospital NHS Foundation Trust
Gloucestershire Hospitals NHS Trust
Heart UK
Insitute of Biomedical Science
Institute Metabolic Science
Kidney Research UK
Leeds PCT
Luton & Dunstable Hospital NHS Foundation Trust
Medicines and Healthcare Products Regulatory Agency (MHRA)
Ministry of Defence (MoD)

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National Patient Safety Agency (NPSA)
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NETSCC, Health Technology Assessment
NHS Islington
NHS Plus
NHS Quality Improvement Scotland
NHS Stockport
NHS Western Cheshire
NICE - CPHE Methodology - Simon for info
NICE - Guidelines Coordinator - for info
NICE - Guidelines HE for info
NICE - IMPLEMENTATION CONSULTANT Region - East
NICE - IMPLEMENTATION CONSULTANT - Region SW
NICE - IMPLEMENTATION CONSULTANT - SE/London
NICE - IMPLEMENTATION CONSULTANT Region NW/NE
NICE - IMPLEMENTATION CONSULTANT Region West Midlands
NICE - IMPLEMENTATION CO-ORDINATION for info
NICE - PPIP
NICE - R&D for info
NICE - Technical Appraisals (Interventional Procedures) FOR INFO
NICE technical lead
Norfolk and Norwich University Hospital NHS Trust
North Cumbria Acute Hospitals NHS Trust
Northumberland Hills Hospital, Ontario
Ophthalmic Pharmacy Group
Otsuka Pharmaceuticals (UK) Ltd
PERIGON Healthcare Ltd
Poole and Bournemouth PCT
Primary Care Cardiovascular Society
ReNeuron Limited
Royal Brompton & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Radiologists

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Royal Society of Medicine
Scanmed Medical
Scottish Intercollegiate Guidelines Network (SIGN)
Social Care Institute for Excellence (SCIE)
Social Exclusion Task Force
Society of Chiropodists & Podiatrists
South Tees Hospitals NHS Trust
Southport & Ormskirk Hospital NHS Trust
Target PAD
UK Clinical Pharmacy Association (UKCPA)
Vascular Society of Great Britain and Ireland
W. L. Gore & associates
Welsh Scientific Advisory Committee (WSAC)
Western Health and Social Care Trust
York NHS Foundation Trust

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