NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Peripheral arterial disease

Date of Quality Standards Advisory Committee post-consultation meeting:
11 October 2013

2 Introduction

The draft quality standard for peripheral arterial disease was made available on the NICE website for a 4-week public consultation period between 6 August and 4 September 2013. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 21 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include overarching outcomes, thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Stakeholders were also invited to respond to the following statement specific questions:

3. For draft quality statement 1: Is it clear that there are two quality improvement areas addressed in this statement, identifying people who should have an assessment and ensuring the assessment is high quality?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Support for the development of the quality standard on PAD.
- Stakeholders suggested amputation rates are an important overarching outcome measure and the objective of identification and improved treatment of PAD.

Consultation comments on data collection

- Data collection possible and a common template would enhance the usefulness.
- If specific clinical service for assessment, diagnosis and management were redesigned and commissioned it would be relatively easy. If there was no redesign to integrate key PAD services is would be almost impossible.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with suspected peripheral arterial disease (PAD) are offered an assessment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Assessment and ABPI
  - Suggested assessment should be in two stages; initial assessment on foot pulses and symptoms by practice nurse and further assessment examining popliteal and femoral pulses by particular clinics
  - Concern that the use of ABPI is effectively a screening programme
  - Concern over the quality of performance of ABPI (not covered in QOF for this reason)
  - More emphasis on history and clinical examination (there appears to be an overemphasis on ABPI) and training in all types of examination
  - How is the quality of training assessed to ensure quality and accuracy?
- Measures
  - Clarification needed on how definitions correspond to the process measures.
  - More information on ‘time to diagnosis’ including a baseline
  - Training needs to comply with accepted best practice and include in the structure measure.
  - Issues with trying to categorise PAD in outcome measures

- Concern with the feasibility of data collection, practicalities as it will include people in different settings and volume of data.
- Definitional issues:
  - Expand the definition of people who should be offered an assessment to include people with suspected asymptomatic PAD where co-morbidities such as diabetic neuropathy, musculoskeletal mobility problems, communication difficulties or sedentary lifestyles may mask symptoms
  - Expand assessment to include the establishment of the baseline use of analgesics and control of symptoms
  - Use of compression hosiery.
  - People with suspected PAD and diabetes
- Concern over the number of referrals to secondary care and the need for a clear referral pathway from GP to MDT.

Consultation question 3

Stakeholders made the following comments in relation to consultation question 3:

- Some stakeholders felt it was clear that the statement was aiming to address 2 key improvement areas.
- Other stakeholders did not think it was clear. The rationale makes reference to high quality assessment however this is not made clear until the definitions, late in the information

5.2 Draft statement 2

People with intermittent claudication are offered a supervised exercise programme (SEP).

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Concern about the cost implications as many areas do not offer SEP.
- Concern over the sequence of treatment. Suggestion that SEP should be given before angioplasty with concerns on the long term benefits and quality of the underlying evidence.

- Include support and encouragement in the statement and audience descriptors.
- Stakeholders queried what would happen to people who declined?
- Measures
  - Should they include completion of SEP when it is not included in statement?
  - Suggested measures on who provides the SEP, how it is accessed and what the SEP is
  - Recommend an appropriate tool for the quality of life outcome measure
- Clarification on what a SEP is, how long it should be given for and where.

5.3 Draft statement 3

People with peripheral arterial disease (PAD) being considered for revascularisation are offered appropriate imaging.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Statement
  - Important to highlight the order of imaging in the statement itself.
  - Waiting times for imaging important. Concern that people with critical limb ischaemia were waiting too long for imaging and delaying treatment.
- Negative consequences of having to offer duplex. Stakeholders highlighted that having to offer duplex ultrasound may slow down treatment leading to poor outcomes e.g. people admitted in need of emergency treatment with for example diabetic foot complications. In some cases going to straight to other types of imaging would be appropriate and it was reported in some areas they have stopped ultrasound altogether, other areas were suggested to have good vascular services with ultrasound.
- Additional measure for practices to be audited to ensure consistent results.
- Imaging should be carried out by a fully accredited vascular scientist.

5.4 Draft statement 4

People with intermittent claudication are offered angioplasty in accordance with NICE guidance.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Link between statements 2 and 4 needed to be clearer to show the pathway.
- Pain relief options would be important for people where angioplasty or amputation is not appropriate.
- Method of angioplasty used may affect the amount of restenosis

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Stakeholders suggested that a separate statement on secondary prevention of cardiovascular disease and its assessment and management is needed as it is an important issue for this group. This should include smoking cessation and increased exercise as well as controlling of lipids, blood pressure and blood sugar if appropriate.

- Stakeholders suggested timely referral to the most appropriate clinic and the monitoring and recording of where people with PAD are being referred is important. Sub-optimal outcomes remain if people are not referred to centres with MDTs and people are often referred to late when little can be done to prevent amputation.

- Stakeholders suggested all people with critical limb ischaemia should be assessed by a vascular MDT before treatment decisions are made.

- Stakeholders suggested not offering major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular MDT is an important issue.

- Stakeholders suggested prevention strategies for PAD as a key area for quality improvement.

- Stakeholders suggested no patient with intermittent claudication should be offered angioplasty or surgery if they continue to smoke or have smoked in the last 3 months.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
1	Bard Limited	General	Reassuring to see earlier referral of people with intermittent claudication for vascular imaging and intervention
2	Boston Scientific	General	This guidance does not consider all available Endovascular choices. No reference is made to current available technology –Drug eluting PTA. Chronic Total Occlusion Crossing devices [CTO] .Both of which have been commercially available since 2011.So this document is limited in its publication-and any Quality standards based on this –will have limitations.
3	Boston Scientific	General	We are surprised and disappointed that that none of the quality statements and standards use the reduction of amputation rates as a measure for improved outcomes, the overarching objective of identification and improved treatment of lower limb PAD - to reduce amputation numbers.
4	British Cardiovascular Society	General	Overall very good.
5	Department of Health	General	The Department of Health has no substantive comments to make, regarding this consultation
6	Merck Sharp & Dohme	General	Merck Sharp & Dohme (MSD) appreciates the opportunity to comment on the NICE consultation on the draft peripheral arterial disease quality standard. MSD has no comments on the draft quality standard
7	NHS England	General	I notice in the original briefing paper for the 12th June a number of other areas were discussed but they don't seem to have been picked up in the draft consultation document. I don't know if that is because they were thought to have been addressed by other areas e.g. amputation rate reporting?
8	Pfizer Limited	General	Pfizer would like to thank NICE for the opportunity to respond to the draft quality standard (QS) for PAD and we very much support its development. This is an important document to help ensure that PAD patients are appropriately diagnosed and managed. In order to improve PAD patient management Pfizer have recommended the following addition to the QS (see references).
9	Royal College of Nursing	General	There are no comments to submit on behalf of the Royal College of Nursing to inform on the draft quality standard for peripheral arterial disease.
10	Royal College of Physicians	General	The RCP wishes to endorse the response submitted by the British Cardiovascular Society
11	The All Party Parliamentary Group on Vascular Disease	General	The Quality Standard should monitor and record in more detail about where patients are referred. There has been a clear direction of travel in the treatment of cardiovascular and vascular diseases in developing centres of excellence. Sub-optimal outcomes will remain if patients are referred for treatment at centres without multi-disciplinary teams – especially if the disease is complicated by diabetes. Too often lower limbs are amputated before any attempt to save the limb. It is therefore crucial that the number of patients referred – and considered for referral – to multi-disciplinary teams should be measured as part of this Quality Standard.

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			The APPG are currently conducting an inquiry in order to ascertain referral patterns and outcomes for patients with peripheral arterial disease, and we would welcome sharing our findings with NICE
12	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	General	Guideline 147 is a 300 page document which by its own assessment is based on what the Guideline Group has almost exclusively described as “low” or “very low” quality data. There are occasional studies listed which NICE considers to be of “moderate” quality. This is either a very harsh assessment of the peer reviewed literature, or a situation where such restrictive guidance is unjustified. An example of the limitation of such conclusions is the guidance that all patients with intermittent claudication should be offered supervised exercise before revascularization is offered. NICE recognises that many areas of the country do not offer this. Thus there are significant cost implications to commissioners, based on low quality data. In addition the MIMIC Trial (a prospective randomized trial described as low quality) shows clearly that patients offered revascularization at the same time as an exercise programme have a significantly better outcome. Add to this, supervised programmes alone show a benefit, only as long as the supervision continues. Further Guideline 147 has not considered all of the endovascular options, even those that were available at that time (the field has progressed since then). There is no mention made at all of technology and techniques, such as drug eluting balloon angioplasty. In addition the cost effectiveness calculations assume that drug eluting stents are more expensive than bare metal stents. This is not necessarily the case. Almost all of the data, that NICE assessed as considered low quality, indicates that drug eluting stents are more effective at revascularization than bare metal. There is no mention that if the costs are similar then drug eluting stents would be preferable. NICE recommends that only bare metal stents are used. Thus Guidance 147 had considerable limitations at the time of publication, and is already out of date. Thus quality standards based on such guidance is inevitably going to have significant limitations.
13	The Royal College of Surgeons of Edinburgh	General	The introductory part (pages one to four) of the document is reasonably well written but from there on, the standard becomes less succinct and difficult to follow with the impression that there has been an overuse of ‘cutting and pasting’.
14	The Royal College of Surgeons of Edinburgh	General	From the peripheral arterial disease (PAD) briefing paper, NICE clinical guidance 147 (2012) on lower limb peripheral arterial disease, and this present draft NICE quality standard statement, it is clear that the major cause in premature death with PAD occurs as a result of an increase in cardiovascular events (myocardial infarction and stroke). ‘Approximately 10 – 15% will die of cardiovascular causes within 5 years and a further 20% will have a non-fatal cardiovascular event.’

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			'PAD is also a marker for an increased risk (3–4 fold) of cardiovascular morbidity (heart attack and ischaemic stroke) and mortality, even while it is asymptomatic.' Both the NHS Outcome Framework 2013/14 and the Public Health Outcomes Framework for England, 2013 -2016 mentioned have indicated that reducing premature death is a major goal. However, particularly from the Cardiothoracic SSG's point of view, there is no clear reflection of this in the Quality Statements, particularly one and two.
15	The Royal College of Surgeons of Edinburgh	General	Within this draft, the focus seems to be on the isolated diagnosis, assessment and treatment of PAD but given the introductory statements and one of the aims of the Frameworks mentioned above, there should be more guidelines on the global cardiovascular assessment of patients with PAD. This is because it would mainly be through the prevention of myocardial infarction and stroke that the reduction in premature death could potentially be achieved. Therefore, the focus of assessment should extend to that of the heart (presence of ischaemic heart disease (IHD), atrial fibrillation) and carotid artery disease. It is worth noting that up to 60% of patients with PAD may have IHD. Many of these will not have symptoms of angina as their exercise tolerance is limited by intermittent claudication. Similarly patients with PAD may also have asymptomatic severe carotid artery disease. The current NICE guidelines focus on assessing patients with symptomatic disease either with respect IHD or stroke (acute coronary syndrome (CG94), chest pain of new onset (CG95), patients with angina (CG126) or Stroke (CG68)). Therefore, there is no clear guidance as to how patients with PAD, who may have other asymptomatic cardiovascular disease, should be fully assessed. Making a diagnosis of PAD and measuring ankle and brachial pressures are probably insufficient indicators of 'high quality'. Another aim of the quoted Frameworks is the reduction in premature death caused by lung cancer. This again reflects the importance of a global 'high quality' assessment of the patient with PAD.
16	Boston Scientific	Question 1	Management of critical limb ischemia • Ensure that all people with critical limb ischemia are assessed by a vascular multidisciplinary team before treatment decisions are made. • Do not offer major amputation to people with critical limb ischemia unless all options for revascularisation have been considered by a vascular multidisciplinary team. Ensure that there is an understanding between the acute differences between Critical Limb ischemia –and intermittent claudication, and the urgency of a timeline and a treatment pathway for Critical Limb ischemia
17	British Cardiovascular Society	Question 1	Yes

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
18	British Medical Association	Question 1	Increased exercise and smoking cessation are both very important in the assessment and treatment of Peripheral Arterial Disease (PAD). The draft Quality Standard states “Smoking is the most important risk factor for PAD”, yet it is not mentioned again in the document; without specifically addressing smoking, this document is seriously devalued. There should be equal emphasis on referral for supervised exercise and smoking cessation programmes. In addition, controlling blood pressure, lipids and blood sugar if diabetic should be given more prominence.
19	British Medical Association	Question 1	People with PAD need comprehensive cardiovascular risk factor reduction (as they will all give a risk level above the intervention threshold there is no need for a formal assessment).
20	Diabetes UK	Question 1	It would be helpful for NICE to consider the inclusion of a quality statement on the need for a locally agreed pathway to ensure people are being sent to the most appropriate clinic.
21	Dialog Devices Ltd	Question 1	It is noted in the section “Why this quality standard is needed” that PAD is a marker for increased risk of cardiovascular morbidity and mortality. Additionally, the briefing paper for this Quality Standard states that secondary prevention of cardiovascular disease (CVD) in patients diagnosed with PAD is an area for improvement. However, it is disappointing that none of the Quality Statements reference improving the management of secondary prevention of CVD in patients diagnosed with PAD.
22	Foot in Diabetes UK	Question 1	FDUK welcomes the specific quality statements in that they will help draw attention to key areas of PAD diagnosis and management, in people with co existing diabetes. Overall the statements seem too focused on claudication and angioplasty. We think that to best serve the population with diabetes and PAD, who make up a large proportion of all people with PAD, it would be essential to ensure there were additional statements, to focus on 3 other key areas for quality improvement in the NHS. All 3 additional areas are taken from the PAD NICE Guidance; 1. People with suspected asymptomatic PAD are offered assessment, where co-morbidities such as diabetic neuropathy, musculoskeletal mobility problems, communication difficulties or sedentary lifestyles may mask symptom presentation 2. All people with PAD are targeted for aggressive cardiovascular risk factor identification, medicines management, lifestyle modification around exercise and quit smoking strategies and defined periodic monitoring of disease state / progress. 3. All people with suspected critical limb ischaemia are provided with rapid PAD assessment and if CLI is found, they are referred urgently for multidisciplinary diabetes and vascular team management
23	Leg ulcer forum	Question 1	Yes the standards reflect the key areas for quality improvement as stated although prevention strategies for PAD are not featured in the quality standards.
24	Medtronic	Question 1	The Quality Standard should also record the overall reduction in the number (and percentage wise) of lower limb amputations as a driver for success. Lowering mortality during carotid procedures for stroke, and abdominal aortic aneurysms is seen as a sense of professional pride at many centres – the same should be done for lower limb amputation from peripheral arterial disease.
25	Medtronic	Question 1	Many critical limb ischemia patients are referred too late to vascular specialists when little can be done to prevent

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			lower limb amputation. A referral pathway for patients (with moderate intermittent claudication before critical limb ischemia sets in) from primary care to vascular specialists would help.
26	Medtronic	Question 1	The role of multi-disciplinary teams in improving outcomes for patients with peripheral arterial disease – often complicated by diabetes – is well regarded. Models of best practice already exist in parts of the country – Kings, Southampton and Ipswich. However, too many hospitals do not have these teams in place or have not included interventional radiology as part of the team. Recording the number of referral to these teams will help drive up performance and should be included in the Quality Standard.
27	Pfizer Limited	Question 1	Pfizer request that the PAD QS include a quality statement stating that people with PAD who smoke should be identified and managed in accordance with the final smoking cessation quality standard quality statements 2-5. The quality statements 2-5 from the smoking cessation quality standard state the following: 2. People who smoke are offered a referral to an evidence-based smoking cessation service 3. People who smoke are offered behavioural support with pharmacotherapy by an evidence-based smoking cessation service. 4. People who seek support to stop smoking and who agree to take pharmacotherapy are offered a full course. 5. People who smoke who have set a quit date with an evidence-based smoking cessation service are assessed for carbon monoxide levels 4 weeks after the quit date. Rationale for QS One of the key priorities for implementation of CG147 “Lower limb PAD: diagnosis and management” is the secondary prevention of cardiovascular disease in people with peripheral arterial disease. The guideline recommends that all people with peripheral arterial disease are provided information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance including guidance on smoking cessation In the UK, the prevalence of current smoking in PAD patients ranges from 40-53% (Khan 2007; Price 1999). A study in England found that 50% of PAD patients who smoked had tried to stop in the 6 months prior to the study, with the most common methods being either ‘cold turkey’ or using NRT (Khan 2007). A study conducted in Wales found that only 25% of PAD patients received anti-smoking advice (D’Souza, 2008). The above evidence illustrates that current management of smoking cessation in PAD patients in the UK is sub-optimal Existing QOF (QoF 2013/2014) indicators (SMOK002, SMOK 005) covering PAD patients who smoke are on their own insufficient to guarantee that these patients will receive the most appropriate smoking cessation interventions,

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			and will have their smoking cessation outcomes appropriately measured, as the indicators are limited to the identification of PAD patients who smoke and the recording of an offer of smoking cessation support or treatment in PAD patients who smoke. • QOF SMOK002 - The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the preceding 12 months. • QOF SMOK005 - The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses who are recorded as current smokers who have a record of an offer of support and treatment within the preceding 12 months A key area for quality improvement in the management of PAD is to ensure that PAD patients are screened for smoking status and are offered treatment in line with published NICE guidance. The smoking cessation quality statements 2-5 provide a comprehensive quality framework for smoking cessation management and outcome measurement. A quality statement stating that people with PAD who smoke should be identified and managed in accordance with the final smoking cessation quality standard quality statements 2-5, will help ensure that PAD patients who smoke are managed appropriately and in line with NICE guidance .
28	The Royal College of Surgeons of Edinburgh	Question 1	In relation to this statement, it is very much aimed at improving localised symptoms, which although important in itself, does not reflect the aim of the Frameworks mentioned above. The importance of secondary prevention (smoking cessation, treatment of hypertension, lipid management etc.) was stated in the original guidance on lower limb peripheral arterial disease (CG147) and this together with the treatment of prognostically important cardiac and carotid artery disease, will be important factors in reducing the mortality related to patients with PAD. As such, Quality Standard statements regarding the treatment in patients with PAD should reflect this
29	The Vascular Society	Question 1	Consider the guidance that no patient with intermittent Claudication should be offered angioplasty or surgery if they continue to smoke or have smoked within the past 3 month.
30	The Vascular Society	Question 1	I am concerned that adequate risk factor modification does not feature as a quality statement. I suggest Statement 1 should be expanded so that it reads; “People with suspected peripheral arterial disease (PAD) are offered an assessment and appropriate risk factor modification interventions (i.e. anti-platelet, lipid-lowering and anti-hypertensive therapies and help with smoking cessation) in line with existing NICE guidelines”. I know these items are covered in NICE Guidelines, but they are significantly more effective than supervised exercise classes in preventing major morbidity and premature death, and therefore deserve (at least) equal prominence.
31	British Cardiovascular Society	Question 2	Yes
32	Foot in Diabetes UK	Question 2	If specific clinical services for assessment, diagnosis and management of PAD are redesigned and commissioned (non surgical diagnosis and management services in community / primary care settings and vascular surgical

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			services in hospital settings with diabetes and vascular teams working in close proximity) it would be relatively easy to collect the data for the quality measures. If there are no clinical service redesigns to integrate key existing potential PAD services (e.g. Specialist Podiatrist and Specialist Nurse led services working close to patients and GP Practices), the task of agreeing, coordinating and collating common data around the PAD statements will be virtually impossible. Additional QOF indicators linked to the quality statements may help improve data collection.
33	Leg ulcer forum	Question 2	It would be possible to collect the data but the quality and usefulness of this would be enhanced by having a common template.
34	Bard Limited	Quality statement 1	Addresses and meets the criteria of the 3 questions
35	Bard Limited	Quality statement 1	Time to diagnosis and referral onto a patient centred care pathway which includes a multi-disciplinary team, specifically a diabetic foot team where appropriate, 7 days per week
36	British Pain Society	Quality statement 1	Regarding pain due to limb ischaemia – assessment should also include the establishment of the baseline use of analgesics and control of symptoms. It could also include an assessment of the use of further analgesic strategies in the short term whilst a definitive management plan is being formulated.
37	Diabetes UK	Quality statement 1	We support the inclusion of local arrangements to ensure that local health and social care practitioners receive training to recognise the symptoms suggestive of PAD. However, it is important that the quality standard clarifies how the quality of the training will be assessed to ensure quality and accuracy. All subsequent steps of a treatment plan are dependant on an initial accurate assessment of PAD. Furthermore, we would suggest that assessments are conducted in two stages. The initial assessment could be conducted by a practice nurse (as the most likely first point of care) to focus on foot pulses and symptoms. Further assessment, examining the popliteal and femoral pulses, could then be conducted in podiatry clinics, diabetic foot clinics or vascular triage clinics.
38	Diabetes UK	Quality statement 1	We are concerned about the feasibility of collecting data on the number of people with symptoms suggestive of PAD who have received an assessment. It would be very difficult to gain this information from podiatry records and link this with other data sources
39	Diabetes UK	Quality Statement 1	Please can you provide further information on what is meant by ‘time to diagnosis’ in the outcome section?
40	Diabetes UK	Quality Statement 1	We would like further clarification on the decision to focus on the need to use compression hosiery in relation to PAD in this Quality Standard. We are concerned that this is more often indicative of a venous problem than PAD. The definition used does not include people with asymptomatic PAD, where early intervention may prevent people presenting with tissue loss.
41	Dialog Devices Ltd	Quality statement 1	It is noted in the section “Why this quality standard is needed” that PAD increases the risk of cardiovascular morbidity and mortality, even while it is asymptomatic, and in the rationale for Quality Statement 1 it is acknowledged that many

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			people with PAD will have no symptoms. The American Heart Association (AHA) guidelines refer to patients with 'suspected PAD' and define a group of patients that includes those who may not be symptomatic for PAD but who are at high risk of having asymptomatic PAD. Both AHA and NICE include diabetics (who are not necessarily symptomatic for PAD) in the recommendations for PAD assessment but, in contrast to the NICE guidelines, the AHA guidelines also include age and smoking as key selection criteria for assessment for PAD. The section on "Why this quality standard is needed" acknowledges smoking and age as risk factors in the incidence of PAD, but they are not taken into account in the definition of "suspected PAD". Therefore, this Quality Statement - whilst acknowledging the existence and risk arising from asymptomatic PAD - does not reference improving the diagnosis and management of asymptomatic PAD.
42	Dialog Devices Ltd	Quality statement 1	This references "all healthcare practitioners undertaking hand held Doppler ultrasound assessments of ABPI….". Work commissioned by NICE at the time that PAD was being considered for inclusion in the QOF (Development feedback report on piloted indicator (indicator area, PAD), Apr – Sep 2010. http://www.nice.org.uk/nicemedia/live /13521/55462/55462.pdf) indicated that "The majority of practices do not perform ABPI in practice" and the use of ABPI in the diagnosis of PAD was not included in the QOF indications. It is understood that this decision was influenced by concerns regarding the quality of performance of ABPI even where it is used. Therefore, whilst this indicator addresses the issue of quality and need for training in the performance of ABPI, it does not address the fact that many practices still do not use ABPI and hence this measure will not be applicable to all practices and is not wholly inclusive. In the interests of improving the quality of detection of PAD in primary care, Dialog Devices Ltd. has a CE marked device trademarked VEWS (vascular early warning system) which provides a fast, automated and reliable method for assessing patients for the presence of PAD. VEWS is an automated system that does not require the use of pressure cuffs or the location of arteries. It gives a consistent index with no operator technique variations and can be used with minimal training. Testing can be performed by a healthcare assistant as opposed to more expensive practice personnel. It is quick to perform, a bilateral test takes approximately 10 minutes, meaning that the impact on practice resources and facilities is further minimised. It can be used to assess all patients, including those with highly calcified, incompressible arteries since it relies on photoplethysmography to detect blood flow, rather than on pressure cuffs. It can also be used on patients with swollen and/or ulcerated legs without significant discomfort VEWS has high sensitivity and specificity for detecting PAD, as confirmed by the gold standard assessment method of colour duplex ultrasound (CDU) or magnetic resonance angiography (MRA) in clinical trials. Dialog have plans to submit VEWS for technical review by NICE
43	Dialog Devices Ltd	Quality	Process a) addresses people with symptoms suggestive of PAD

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
		statement 1	Process b) references people receiving intervention to the leg and foot Process c) references people using compression hosiery When this is compared to the definition of people with suspected PAD (bottom of page 8) the following groups of people with suspected PAD are not covered by this process i) People who have diabetes, (and / or) non-healing wounds on the legs or feet (and) or unexplained pain ii) People being considered for interventions who do not go on to have such an intervention Therefore this process is not fully inclusive of the defined population of interest.
44	Dialog Devices Ltd	Quality statement 1	Time to diagnosis – what is the baseline for this measure going to be? For patients with symptoms suggestive of PAD it could be the time from when the patient says they first experienced symptoms but for diabetics etc. what is the baseline?
45	Dialog Devices Ltd	Quality statement 1	Incidence of IC and CLI – if these measures are intended to drive improvement of detection and management of PAD, we suggest that they should be measured against a reference standard such as the incidence that would be expected based in the practice population. There are sufficient published data on expected incidence to provide this guidance.
46	Dialog Devices Ltd	Quality statement 1	Our interpretation of the definition of people with suspected PAD includes: • diabetics who have non-healing wounds on the legs or feet or unexplained leg pain • diabetics (by implication, without non-healing wounds on the legs or feet or unexplained leg pain) • non diabetics with non-healing wounds on the legs or feet or unexplained leg pain Please confirm / clarify.
47	Leg ulcer forum	Quality statement 1	It may be challenging to ascertain the number of people with symptoms suggestive of PAD as a denominator as they will, by definition have been assessed for PAD, so it would be easy to demonstrate 100% agreement here.
48	Leg ulcer forum	Quality statement 1	It is not clear what point is being made about hosiery. Generally this would not be used or lower levels used depending on the extent of PAD. Is the purpose of this question to ascertain how many people are wearing hosiery who have not had a PAD assessment? If this is the case should the statement be more overt?
49	Medtronic	Quality statement 1	Medtronic welcome in particular measures that will quickly diagnose peripheral arterial disease as occurs with other forms of vascular/cardiovascular disease – early diagnosis is crucial as symptoms are often ignored by patients but the disease can progress quickly. It is crucial that education and training is offered to GPs and other professionals (such as social care workers) and it is good that the Quality Standard will monitor this and record performance data. However, this cannot be a tick-box exercise and the 'local arrangements' should be defined as to comply with accepted best practice
50	NHS England	Quality Statement 1	I would be strongly supportive of the suggestion that anyone suspected of PAD should be assessed. I am concerned that the current wording of the document seems to focus on ABPI rather than emphasising it is history, clinical examination and ABPI. This is important as it is really the history of leg pain in walking which is going to trigger the assessment and if that isn't dome many people will be missed. Terms such as assessment using Doppler should not

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			appear. Many people incorrectly hold that assessment of the waveform is helpful. In everyday practice this is not true and so nothing to suggest that it is should appear. I have some concerns about the quality measures. How can you measure the number of people with PAD offered an assessment unless you know the number of people with PAD? I think collecting data on people having interventions to their legs who have had an assessment will be difficult and not very informative. What constituents an intervention? Orthopaedic surgery is obvious but varicose vein injections?? Also as the interventions will occur in a range of environments from primary care, secondary care and the independent sector how would they be collated? The NICE recommendation was intended not as a way of increasing the overall diagnosis of PAD (many of the patients having leg interventions will be young and you would expect the prevalence of PAD to be low) it is a patents safety issue as a small but significant number of patients who have interventions to their leg run into problems because of undiagnosed PAD. I don't think it would be a good quality measure. The same applies to compression stockings. These are used for a range of conditions but in the community largely for venous disease and lymphedema. In secondary care largely for thromboprophylaxis where the majority of hospitalised patients will receive them. While an important safety issue I am not sure it is a good quality marker for the increased diagnosis of PAD. I think the best would be a PAD registry as suggested. Any patient with diagnosed PAD would be neutered onto it (this would cover primary and secondary care). You would not expect the prevalence to vary widely across the country so I think like amputation rates it would be possible to identify areas not performing. A registry would also be an excellent way of ensuring secondary prevention is offered. Some specific comments on this section: The diagnosis of critical limb ischaemia is very difficult and always causes problems clinically because there are so many caveats. I think trying to identify different categories of patients with PAD will be fraught with problems and be very time consuming. I would suggest what really matters as a quality indicator is the number of people in the community with identified PAD and the amputation rate in that community. On page * I think anyone with a wound on their foot or leg should have an assessment of their circulation. When is a wound non-healing? By the time someone thinks it is it is often too late. If the initial assessment suggest PAD the patient needs urgent referral.
51	Society for Vascular Technology of Great Britain and Ireland	Quality Statement 1	The follow point is made after seeing these assessments carried out, but carried out poorly in both community and hospital settings. PAD assessment – we need to ensure practitioners are properly trained to carry out these assessments. That they fully understand the symptoms pertaining to claudication and rest pain. That they have full and proper training for taking ABPIs, understand when ABPIs should not be taken and when an ABPI is unreliable. Although ABPI is a good indicator of disease status, there are many ways to get wildly inaccurate results.
52	The All Party	Quality	The All Party Parliamentary Group welcomes measures to ensure that those involved in primary care are trained in

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
	Parliamentary Group on Vascular Disease	statement 1	identifying the symptoms of peripheral arterial disease – and the tests required to make an official diagnosis. Our report 'Putting Vascular Disease at the Heart of Government Thinking' was compiled after hearing evidence from clinicians, patients and NHS staff – it heard evidence from Professor Mike Edmonds, the Professor of Kings College Hospital who stated the: 'GP is often the first line of defence against "diabetic foot attack"' See the report here - http://www.appgvascular.org.uk/media/reports/2012-10-putting_vascular_disease_at_the_centre_of_government_thinking.pdf
53	The All Party Parliamentary Group on Vascular Disease	Quality statement 1	It is welcome that the proportion of people receiving interventions to the leg or foot will be recorded. This will be crucial data – as will the type of intervention. Patients with critical limb ischemia need urgent intervention and to be referred to specialist clinics (as often will patients with moderate intermittent claudication as the disease can progress quickly). Many secondary clinicians have reported to inquiry that they are often seeing patients too late when little can be done to save legs. This requires GPs to improve their understanding not only of the symptoms but also treatment options and the services available. Our inquiry heard that less than half of those patients who require amputation in England and Wales have benefitted from any attempt to treat poor circulation to their leg.
54	The All Party Parliamentary Group on Vascular Disease	Quality statement 1	There is a need for a clear pathway from the GP to multi-disciplinary foot teams and vascular specialists for patients presenting with moderate intermittent claudication, as peripheral arterial disease becomes more severe. It has been estimated in patients with diabetes that 85% of amputations could be avoided by earlier intervention The number of patients referred – and considered for referral – to multi-disciplinary teams should be measured as part of this Quality Standard.
55	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	Quality statement 1	This recognizes that many patients with peripheral arterial disease (PAD) do not have symptoms. Early identification is aimed at slowing disease progression and reducing the cardiovascular risk profile. The recommendation that ABPIs are regularly performed in primary care will identify patients at an earlier phase, but effectively this is recommending a PAD screening programme. I am not aware of any data that suggest that this is an effective or cost effective intervention in primary care.
56	The Vascular Society	Quality statement 1	If they are asking for such widespread assessment by ABPI, need some guidance on what primary care should refer on to us, otherwise we'll be inundated with patients who have been in stockings for years with no problems but who have slightly low ABPI, or asymptomatic patients who are having their toenails trimmed.
57	British Cardiovascular Society	Question 3	Yes
58	Dialog Devices Ltd	Question 3	It is not clear to us that there are two areas addressed in this statement. The Rationale makes mention of a "high quality assessment" but the quality element is only implied in the definition of the assessment which comes "late in

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			the day" (on page 9) The fact that it should be a high quality assessment is not explicitly stated either in this Quality Statement or as an individual quality statement e.g. "The assessment performed is a high quality assessment in line with NICE guidance"
59	Foot in Diabetes UK	Question 3	With quality statement 1, it is not at all clear to the intended audience (general clinicians, commissioners, people with possible PAD) who needs to be targeted for PAD assessment, particularly considering the significant majority percentage of the total PAD population who are asymptomatic, but still at increased modifiable risk of heart attacks, strokes and early mortality. Also with quality statement 1, it is not clear that the high quality of the assessment for people with suspected PAD needs to include cardiovascular risk assessment & review, symptom history, pulse examination for foot to groin and ABPI. Even in people with diabetes where ABPI results can be affected by arterial vessel calcification, this standard, structured clinical approach to quality assessment, if provided routinely in the NHS would significantly improve the likelihood of early diagnosis, severity assessment and best clinical management for all people with PAD. FDUK strongly recommends that with quality statement 1, it is made clear which people need to be targeted for PAD assessment and what the minimum clinical diagnostic assessment must include.
60	Leg ulcer forum	Question 3	It is clear that two quality improvement areas are being addressed; identification and high quality assessment
61	Bard Limited	Quality statement 2	Address and meets the criteria of both questions
62	Boston Scientific	Quality statement 2	Supervised exercise programmes - are advocated for all patients as first line treatment These are not currently available to all patients in England and Wales. Level 1 data shows that exercise programmes in conjunction with endovascular treatment have a statistically increased patency at 1 year –[MIMIC & BASIL trials]
63	British Cardiovascular Society	Quality statement 2 (and 3)	Main issues are:- a) Length of time of supervised exercise programme? I think a minimum of 6 months. b) Think duplex should be offered not considered in those patients in whom intervention is considered c) Does MRA have any role, duplex should be sufficient to plan intervention
64	British Medical Association	Quality statement 2	It would be helpful if NICE could explain what "supervised exercise programme" means in practice.
65	Diabetes UK	Quality statement 2	It would be helpful to have further information provided on what will be offered to people with claudication who decline to take up these exercise classes.
66	Dialog Devices Ltd	Quality statement 2	This is based on the number of people who complete a supervised exercise programme but no mention is made of completion as an element of the Quality Statement e.g. "People with intermittent claudication are offered a supervised exercise programme and provided with the support and encouragement to complete this".
67	Dialog Devices Ltd	Quality	The need for healthcare practitioners to support / encourage patients to complete the programme is not mentioned in

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
		statement 2	this section
68	Dialog Devices Ltd	Quality statement 2	The need for patients to be supported / encouraged to complete the programme is not mentioned in this section
69	Foot in Diabetes UK	Quality statement 2 (and 4)	With the current wording, these statements do not complement each other well, as they do not specify the sequencing of exercise vs angioplasty and the term 'in accordance with NICE guidance' is not consistently used, perhaps biasing towards angioplasty being chosen over exercise. It needs to be made explicitly clear that supervised exercise should be the intervention of choice for all people with IC initially and even if people are referred for consideration of angioplasty, supervised exercise is still offered as a key ongoing intervention (as is antiplatelet and lipid lowering therapy). With quality statement 2, it may be beneficial to state the aim of the supervised exercise programmes in protecting or improving maximum walking distance in people with IC. It may also be beneficial to clarify that a supervised exercise programme is to be offered alongside individually tailored education and information on PAD, taking into account patient attitudes and belief systems, as in isolation, exercise therapy may be a very misunderstood, under utilised and poorly adhered to intervention.
70	Leg ulcer forum	Quality statement 2	Does there need to be guidance/recommendation about an appropriate tool for measuring quality of life locally and more universally for consistency and meaningful data.
71	NHS England	Quality Statement 2	Totally agree with statement. I think the quality indicators are a bit confusing. To me it should be simple. Each community needs clear identification of who provides supervised exercise, how is it accessed by patients and what the programme is. I think the numbers starting and completing the programme are fine together with the measured improvement. I am not sure where "group" based programmes came from. This might be the way the programme is delivered but there are many problems with group based programmes. Many patients do not like them, it means you have to wait until you have a group of appropriate size so some patients will not get exercise for some time. I also am unaware of the rational for the comments about 2 hours exercise per week and walking to maximal pain neither of which has evidence to support them and is nor what many programmes do. The optimum method of exercise is unknown hence why NICE made a research recommendation for this area.
72	The All Party Parliamentary Group on Vascular Disease	Quality statement 2	The APPG welcome the focus on supervised exercise programmes – with a distinct measurement on the number of patients who complete such a programme. Our inquiry heard that too often GPs have offered to lifestyle advice to patients with intermittent claudication without following up to check whether it has had a positive impact on the patient.
73	The Royal College of	Quality	As indicated above there is little or no evidence that supervised exercise programmes produce a durable beneficial

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
	Radiologists in collaboration with The British Society of Interventional Radiology	statement 2	effect on symptoms, particularly after the supervision has stopped. Whilst the data indicate an increase in walking distance, perhaps by a statistically significant proportion, there is little to indicate that this is sufficiently useful to the individual. Again the NICE assessed evidence is considered to be low quality, but yet the standard indicates that it should be offered to all symptomatic patients.
74	The Vascular Society	Quality statement 2	Needs more detail on what a supervised exercise program looks like and where should it be done (close to patients home or at hospital) - what is the evidence?
75	Bard Limited	Quality statement 3	Address and meets the criteria of both questions. To ensure that healthcare professionals are trained in the appropriate use of imaging equipment , will the standard include a requirement that practice is audited in image interpretation to ensure consistent accurate results
76	Boston Scientific	Quality statement 3	The terminology surgery should be replaced with Revascularisation.
77	Boston Scientific	Quality statement 3	All patients should be offered Duplex. Sometimes when a patient is admitted in need of emergency treatment i.e. Diabetic foot complications by recommending Duplex you would actually slowdown the patient pathway-and may cause poor clinical outcomes, due to the time delay in a patient receiving endovascular treatment.
78	British Cardiovascular Society	Quality statement 3 (and 2)	Main issues are:- a) Length of time of supervised exercise programme? I think a minimum of 6 months. b) Think duplex should be offered not considered in those patients in whom intervention is considered c) Does MRA have any role, duplex should be sufficient to plan intervention
79	Leg ulcer forum	Quality statement 3	It would be useful to have indication of waiting times for imaging especially given the comment about local variation in equipment and skills.
80	NHS England	Quality statement 3	I found this puzzling as while it is very important for patients having interventions it is probably unlikely to make a major impact on patient outcomes compared with some of the other areas. To me this area is more about service organisation and efficiency. Some the variations in this area I would suggest are based on established local practice rather than lack of equipment or personal. Duplex ultrasound is widely available and is the first line investigation for DVT so I don't think availability is the problem. Many clinicians think it is superfluous and go straight for MR or CT imaging. To me the real issues are showing that all patients with PAD who are being considered for intervention have a Duplex first and then if needed an MR. I think these easiest way to do this is to expect vascular services to have a care pathway that indicates this and they audit against compliance. There is still a large group of radiologists who do not believe that MR should be used in preference to CT angiograpy. This really needs to be tackled at national level and this may be a role for the specialists bodies e.g. BSIR. If this isn't tackled there will be some areas who will refuse to comply.

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
81	Society for Vascular Technology of Great Britain and Ireland	Quality Statement 3	Where possible duplex ultrasound scans should be carried out by a fully accredited vascular scientist or by a trainee vascular scientist that has supervision or by a person that has completed full training in vascular ultrasound and practices vascular ultrasound on a regular basis.
82	The All Party Parliamentary Group on Vascular Disease	Quality statement 3	The APPG understand the importance of imaging and recognise the statement that training, expertise and availability of imaging equipment may be variable. However, as peripheral arterial disease progresses quickly a lack of imaging equipment should not be an excuse for a failure to refer to a multi-disciplinary team. Patients being referred to high capacity regional centres will help address this.
83	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	Quality statement 3	This indicates that all patients should be offered duplex ultrasound. There are clinical situations where duplex is unnecessary and may delay further investigation, such as MRA or CTA. Particularly in patients in need of urgent treatment (such as diabetic foot problems). This delay may result in a poor outcome. I would agree that catheter angiography as a diagnostic procedure should rarely be performed, however, there remains a tariff benefit to performance of traditional angiography, and Trusts should be encouraged, with a suitable tariff for MRA/CTA, with a penalty for unjustified catheter angiography. The denominator for MRA should include a reduction for those patients where MRA is contraindicated (e.g. those at risk of Nephrogenic Systemic Fibrosis), or the denominator should be MRA and CTA.
84	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	Quality statement 3 (and 4)	With respect to the Quality Standards proposed: The standards repeatedly use “surgery” for invasive treatment. This should be referred to as “intervention” or “revascularization”. Similarly rather than use the rather limited term “angioplasty”, “endovascular” would be much more contemporary.
85	The Vascular Society	Quality statement 3	My main comment will be on the first line imaging. This implies that all should have Duplex then followed by MRA. Why not go straight to MRA if intervention is contemplated? We have just ditched Duplex in favour of going straight to MRA as less operator dependent, quicker and it produces images clinicians can interpret themselves. We found that we were wasting a week or more by using Duplex as a first investigation. We now use Duplex U/S only if patients can't have an MRA and there is no clinical evidence of proximal arterial disease. If femoral pulses are weak/absent we go for CTA unless renal impairment, in which case it's back to Duplex U./S. We also use Duplex for vein mapping, checking the CFA and distal landing zones and for vein graft surveillance. We have a great duplex service available at the first consultation in a one-stop clinic with easy to read pictures we can all interpret. In contrast our MRAs take ages and are full of artefact! This suggests the document should allow some latitude for locally available expertise? The speed of investigation and treatment is what matters for CLI. I see to many claims where feet are lost because of such delays. We run on a duplex first service, with duplex on the same day for hot feet. It saves a lot of time as getting MRA can be slow and if they have renal failure our radiologists get terribly excited about the (small) risk of nephrogenic

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			systemic fibrosis. We then have to wait while a CTA is booked. We can get rapid CTA, but only for emergencies presenting to the emergency site, otherwise we wait a bit. So it's duplex in the week and CTA at night and weekends. Local Imaging quality and speed of access varies a lot so difficult to make definitive statement for each unit. My impression is that patients with CLI are now subjected to multiple non-invasive imaging modalities and take far too long to come to intervention. They are now managed as outpatients as beds are scarce and prioritising them with radiology remains an issue (out of site is out of mind. Sensible guidelines on wait times for imaging would be useful . On a purely personal note I often think MRA and CTA are pretty poor for distal run off and we only get decent images when TFA is performed for attempted angioplasty!
86	Bard Limited	Quality statement 4	Address and meets the criteria of both questions
87	Boston Scientific	Quality statement 4	The terminology angioplasty describes balloon PTA - this should be replaced by Endovascular treatments to encompass the wealth of options available technologies to revascularise - Bare metal stents, Drug eluting stents, Drug eluting balloons, Chronic Total Occlusion [CTO] and Re-entry devices.
88	Boston Scientific	Quality statement 4	This states that all endovascular treatment is outside these standards unless a supervised exercise programme has failed. As documented in statement 2 not all patients have access to a supervised exercise programme. Two Level 1 RCT demonstrated that supervised exercise programmes in conjunction with endovascular treatment -had significantly better outcomes. BASIL 1 trial –Bradbury et al. Heartlands, Birmingham UK. Lancet 2005 Dec 3 .336. MIMIC trial –Greenhagh, et al-Imperial College, –London UK. Eur.j.Vasc.Endovasc.Surg.2008 Dec 36[6]
89	British Pain Society	Quality statement 4	There are a group of patients with severe ischaemic limbs that are not amenable for revascularisation or angioplasty. These patients may have very poor quality of life due to the pain and may also be not keen for limb amputation. There has been poor evidence for improvement of perfusion following lumbar sympathetic blockade be it with local anaesthetics or neurolytic agents; however this is an option that could be considered for managing the pain and improving quality of life and pain services can play a role in not only contributing to this, but also involve in the multidisciplinary management of the complex pain.
90	Foot in Diabetes UK	Quality statement 4 (and 2)	With the current wording, these statements do not complement each other well, as they do not specify the sequencing of exercise vs angioplasty and the term 'in accordance with NICE guidance' is not consistently used, perhaps biasing towards angioplasty being chosen over exercise. It needs to be made explicitly clear that supervised exercise should be the intervention of choice for all people with IC initially and even if people are referred for consideration of angioplasty, supervised exercise is still offered as a key ongoing intervention (as is antiplatelet and lipid lowering therapy). With quality statement 2, it may be beneficial to state the aim of the supervised exercise programmes in protecting or improving maximum walking distance in people with IC.

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			It may also be beneficial to clarify that a supervised exercise programme is to be offered alongside individually tailored education and information on PAD, taking into account patient attitudes and belief systems, as in isolation, exercise therapy may be a very misunderstood, under utilised and poorly adhered to intervention.
91	Medtronic	Quality statement 4	The Quality Standard only refers to 'angioplasty' but not the use of stents or drug eluting balloons. A major challenge for patients following an angioplasty is the risk of restenosis and associated lower limb amputation. The use of a drug-delivery agent to prevent restenosis is commonly used in coronary interventions. The role of drug eluting balloons has been widely accepted in the treatment of peripheral arterial disease. There is considerable efficacy data for the use of the technology both below the knee (BTK) and in the superficial femoral artery (SFA). Evidence taken from In.Pact BTK registry (as well as In.Pact BTK Leipszig registry) demonstrated a low restenosis rate in patients who underwent an angioplasty with a drug-eluting balloon with long BTK lesions and occlusions at 3 months. Moreover, the same data also showed a reduction in restenosis rate and burden at 12 months when compared to patients who had an angioplasty using a standard balloon in patients with critical limb ischemia and diabetes. The Quality Standard should reflect the risk of restenosis – and the subsequent need for amputation or a repeat procedure – and record and monitor the number of patients with peripheral arterial disease treated through angioplasty using a drug eluting balloon as a driver to improve performance and patient outcomes.
92	NHS England	Quality Statement 4	There are a number of reasons for not using angioplasty as a first line treatment. Only a proportion of patients are suitable and durability of angioplasty below the groin is moderate to poor. I think quality indicators are important but the need to be easy to measure. I think the numbers of angioplasty carried out for intermittent claudication and variability between units would have a major impact. Compliance with NICE guidelines is vital but when patients moving between primary and secondary care can be difficult to identify. If referral to secondary care was only for patients who fulfilled the NICE criteria this would make it much easier. There could even be a standardised referral form (this ties in with one of the areas I think that has been left out and is addressed below namely referral guidelines). What puzzles me is the omission of some really important areas. Increasing the diagnosis rate is of little value without improving patients and professionals understanding of the significance and importance of PAD (Education). There is nothing about this. We know that secondary prevention is still not utilised as well as it should be and again this is not addressed. Some of this is due to lack of awareness but some is due to confusion e.g. there is confusion about the role of statins in PAD with some doctors only advising them in people with elevated cholesterols and other giving them to all patients with PAD.

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
			The other thing that came up consistently following the NICE guidelines is the need for a nationally agreed template for referral (Referral Guidelines). A bit like the MI thrombolysis referral. This would clarify which patients need to be referred to secondary care and in what time base. For example you could argues that patients with intermittent claudication should be treated in primary care unless they fulfill the criteria for intervention in which case they should be seen and treated within 6-8 weeks. A patient's with an ulcer and PAD should be seen with 24 hours etc. At present one of the problems with implementation of the NICE Guideline is that is depends on the HCPs understanding of PAD which we know is generally poor. Too many patients are referred to secondary care when it is not necessary and many are referred too late.
93	The All Party Parliamentary Group on Vascular Disease	Quality statement 4	While it is important that patients with early stage peripheral arterial disease receive lifestyle change advice and pharmacological management – as the condition rapidly deteriorates, early revascularisation procedures are crucial to avoid major amputation and associated morbidity and mortality. This would require a clear pathway from the GP to multi-disciplinary foot teams and vascular specialists for patients presenting with moderate intermittent claudication
94	The All Party Parliamentary Group on Vascular Disease	Quality statement 4	The APPG believe that monitoring and collecting data on the number of patients offered and treated through angioplasty is important and will help drive up performance. However, we would ask that NICE consider breaking this down even further. The Quality Standard should monitor and record the number of patients treated through angioplasty using particular technologies such as stents and drug eluting balloons.
95	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	Quality statement 4	This statement indicates that all angioplasty (endovascular revascularization) is outside these standards unless supervised exercise has failed. As noted above, this makes the majority of UK practice below standard, with significant cost implications for setting up such programmes (which as noted above may offer little or no benefit). Trials show that if endovascular revascularisation is offered alongside the exercise programme significantly improved outcomes can be achieved.
96	The Royal College of Radiologists in collaboration with The British Society of Interventional Radiology	Quality statement 4 (and 3)	With respect to the Quality Standards proposed: The standards repeatedly use "surgery" for invasive treatment. This should be referred to as "intervention" or "revascularization". Similarly rather than use the rather limited term "angioplasty", "endovascular" would be much more contemporary.
97	The Vascular Society	Quality statement 4	Perhaps should state that primary care should not refer a patient with intermittent Claudication until they have tried risk modification and supervised exercise program so that only those patients who need treatment are referred on (with the outcome standard that 90% of secondary care referrals should be considered for intervention to improve QOL)

Pfizer references

1. Lower limb peripheral arterial disease (CG147) http://www.nice.org.uk/CG147. Accessed August 2008

2. D'Souza J, Patel NN, Lewis MH. Management of cardiovascular risk factors by primary care physicians in patients with peripheral arterial disease. Surgeon. 2008 Jun; 6(3):144-7.
3. Khan S, Flather M, Stansby G.Characteristics and treatments of patients with peripheral arterial disease referred to UK vascular clinics: results of a prospective registry. Eur J VascEndovasc Surg. 2007 Apr; 33(4):442-50.
4. Price JF, Mowbray PI, Fowkes FG. Relationship between smoking and cardiovascular risk factors in the development of peripheral arterial disease and coronary artery disease: Edinburgh Artery Study. Eur Heart J. 1999 Mar; 20(5):344-53.
1. NICE public health guidance 10. Smoking cessation services in primary care, pharmacies, local authorities and workplaces. http://guidance.nice.org.uk/PH10
2. Quality and Outcomes Framework (QOF) for 2013/14. http://www.nhsemployers.org/Aboutus/Publications/Pages/qof-2013-14.aspx