NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Peripheral arterial disease - lower limb peripheral arterial disease in adults aged 18 years and over

Output: Prioritised quality improvement areas for development.

Date of Quality Standards Advisory Committee meeting: 12 June 2013

Contents

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for peripheral arterial disease. It provides the Committee with a basis for discussion and prioritising quality improvement areas for developing quality statements and measures, which will be drafted for public consultation.

Structure

The structure of this briefing paper includes a brief overview of the topic followed by a summary of each of the suggested quality improvement areas followed with supporting information.

Where relevant, guideline recommendations selected from the key development source below are presented to aid the Committee when considering specific aspects for which statements and measures should be considered.

Development source

Unless otherwise stated, the key development source referenced in this briefing paper is as follows:

- Lower limb peripheral arterial disease. NICE clinical guideline 147 (2012).

Where relevant, guideline recommendations from the key development source are presented alongside each of the suggested areas for quality improvement within the main body of the report.

2 Overview[1]

2.1 Focus of quality standard

This quality standard will cover the diagnosis and management of lower limb peripheral arterial disease in adults aged 18 years and over. It will exclude acute ischaemia in the lower limb.

2.2 Definition

Peripheral arterial disease is a condition in which the arteries that carry blood to the limbs are narrowed or blocked, most often because of atherosclerosis.

The most common initial symptom of peripheral arterial disease is leg pain when walking, known as intermittent claudication. Critical limb ischaemia is a severe

[1] Sections 2.1 to 2.4 are taken from Lower limb peripheral arterial disease: Diagnosis and management. NICE Clinical Guideline 147. August 2012.

manifestation of peripheral arterial disease, and is characterised by severely diminished circulation, ischaemic pain, ulceration, tissue loss and/or gangrene.

2.3 Incidence and prevalence

The incidence of peripheral arterial disease increases with age. Population studies have found that about 20% of people aged over 60 years have some degree of peripheral arterial disease. Incidence is also high in people who smoke, people with diabetes and people with coronary artery disease. In most people with intermittent claudication the symptoms remain stable, but approximately 20% will develop increasingly severe symptoms with the development of critical limb ischaemia. Overall approximately 1-2% of people with intermittent claudication will eventually undergo amputation, although the risk is higher (about 5%) in people with diabetes.

Of those presenting with intermittent claudication over a 5-year period approximately 70 - 80% will remain with stable claudication, 10 – 20% will go on to have worsening symptoms and 5 – 10% will go on to develop critical limb ischaemia. Approximately 10 – 15% will die of cardiovascular causes within 5 years and a further 20% will have a non-fatal cardiovascular event. Of those who develop critical limb ischaemia there is a high mortality with approximately 25% dying within a year and about 1/3 will require a major lower limb amputation within a year.

Lower limb peripheral arterial disease is a marker for increased risk of cardiovascular events including myocardial infarction and stroke, even when it is asymptomatic. Symptomatic peripheral arterial disease can significantly impair quality of life through reduced mobility, severe pain, ulceration and gangrene, and it the largest single cause of lower limb amputation in the UK.

2.4 Management

Mild symptoms are generally managed in primary care, with referral to secondary care when symptoms do not resolve or deteriorate. There are several treatment options for people with intermittent claudication. These include advice to exercise, management of cardiovascular risk factors (for example, with aspirin or statins) and vasoactive drug treatment (for example, with naftidrofuryl oxalate).

People with severe symptoms that are inadequately controlled are often referred to secondary care for assessment for endovascular treatment (such as angioplasty or stenting), bypass surgery, pain management and/or amputation.

See appendix 1 for key priority for implementation recommendations from NICE clinical guideline 147.

2.5 National Outcome Frameworks

The table below shows the outcomes, overarching indicators and improvement areas from the framework that the quality standard could contribute to achieving:

NHS outcomes framework 2013–14	
Domain 1: Preventing people from dying prematurely	**Overarching** 1a Potential years of life lost (PYLL) from causes considered amenable to healthcare i) Adults **Improvement areas** *Reducing premature mortality from the major causes of death* 1.1 Under 75 mortality rate from cardiovascular disease
Domain 2: Enhancing quality of life for people with long-term conditions	**Overarching** 2 Health-related quality of life for people with long-term conditions **Improvement areas** *Ensuring people feel supported to manage their condition* 2.1 Proportion of people feeling supported to manage their condition
Domain 4: Ensuring that people have appositive experience of care	**Overarching indicators** 4a Patient experience of primary care (i) GP services 4b Patient experience of hospital care
Public Health outcomes framework 2013-16	
Domain 4: Healthcare public health and preventing premature mortality	**Indicator** Mortality from all cardiovascular diseases (including heart disease and stroke)

3 Summary of suggestions

3.1 Responses

In total 13 stakeholders responded to the 2-week engagement exercise 15/04/2013 – 29/04/2013, 12 of which submitted suggestions for quality improvement. Suggestions were also provided by specialist committee members.

Table 1 Summary of suggested quality improvement areas

Stakeholders were asked to suggest up to 5 areas for quality improvement. These have been merged and summarised in the table below for further consideration by the Committee (incorporating stakeholder and specialist committee member suggestions). The full detail of the suggestions is provided in appendix 2 for information.

Suggested area for improvement	Stakeholder
Secondary prevention of CVD	Pfizer, Heart UK, FD-UK, SCM
Diagnosis • Diagnosis • Public awareness • PAD register	ABHI, BS, FD-UK, PSF, SCM
Imaging	BSIR, BS, SCM
Supervised exercise programmes	BSIR, FD-UK, SCM
Surgical management • Revascularisation • Amputation	BSIR, ABHI, BS, Medtronic, J&J, SCM
PAD services • Access to PAD services • Referral to PAD services • Vascular MDT	ABHI, BPS, BS, FD-UK, Medtronic, SCM
Pain management • Timely access • Assessment of pain relief • Pain relief options	BPS, BTUH, FD-UK, RCA

Table 2 Stakeholder details (abbreviations)

The details of stakeholder organisations who submitted suggestions are provided in the table below.

Abbreviation	Full name
ABHI	Association of British Healthcare Industries
BTUH	Basildon and Thurrock University Hospitals NHS Foundation Trust
BS	Boston Scientific
BSIR	British Society of Interventional Radiology
BPS	British Pain Society
RCA	Faculty of Pain Medicine of the Royal College of Anaesthetists
FD-UK	Foot in Diabetes UK
HeartUK	Heart UK
J&J	Johnson and Johnson Medical
Medtronic	Medtronic Ltd
Pfizer	Pfizer Limited
PSF	NHS commissioning board patient safety function
SCM	Specialist Committee Member

4 Suggested improvement area: Secondary prevention of CVD

4.1 Summary of suggestions

Stakeholders suggested access to lifestyle modification support (e.g. smoking, obesity, alcohol etc.) was important. People with diabetes and PAD were highlighted as a specific group who should be offered regular review for modifiable cardiovascular risk factors and if found, must be targeted for individual education and support to recognise and minimise risk.

Stakeholders highlighted particular areas of secondary prevention, specifically screening for smoking status and offering treatment in line with the smoking cessation QS; cigarette smoking is one of the most important risk factors for PAD which increases the risk of PAD several fold[2]. Improvements in lipid management could be made by undertaking a full lipid profile and treating as appropriate.

4.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

NICE CG147 Recommendation number 1.2.1 (KPI)

> Offer all people with peripheral arterial disease information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance (see Related NICE guidance; section 6) on:
>
> - smoking cessation
> - diet, weight management and exercise
> - lipid modification and statin therapy
> - the prevention, diagnosis and management of diabetes
> - the prevention, diagnosis and management of high blood pressure
> - antiplatelet therapy.

[2] Lu JT, Creager MA. The relationship of cigarette smoking to peripheralarterial disease. Rev Cardiovasc Med. 2004 5(4):189-93.

4.3 Current UK practice

Stakeholders drew attention to the current 2013/14 Quality and Outcomes Framework (QOF) indicators listed below:

QOF PAD002 - The percentage of patients with peripheral arterial disease in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less.

QOF PAD003 - The percentage of patients with peripheral arterial disease in whom the last measured total cholesterol (measured in the preceding 12 months) is 5 moll/l or less.

QOF PAD004 - The percentage of patients with peripheral arterial disease with a record in the preceding 12 months that aspirin or an alternative anti-platelet is being taken.

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.

PAD indicators were added to the QOF for the first time in 2012-13, the results of which are not yet available.

No recent published reports relating to current practice were highlighted by stakeholders for this quality improvement area.

5 Suggested improvement area: Diagnosis

5.1 Summary of suggestions

Stakeholders suggested improvements in diagnosis in primary care which could be addressed through increased measuring of ankle brachial pressure index, symptom history and clinical examination including considering PAD in people with non-healing wounds. Earlier diagnosis and recognising the signs of PAD earlier in the pathway were highlighted to potentially reduce amputation rates.

Stakeholders suggested that very often the patient needs to be persuaded into accepting they have the disease and seeking advice and treatment.

Stakeholders suggested the use of PAD registers as per QOF with a particular focus on people with diabetes who, at their annual diabetes foot screening, are found to have non-palpable foot pulses, smoking history and presenting leg symptoms that limit walking.

The following specific areas for quality improvement and potential development by the QSAC were highlighted, shown in table below alongside recommendations that have been provisionally selected from the development source to support potential statement development.

Suggested quality improvement area	**NICE CG147 recommendation**
Diagnosis	Recommendations 1.3.1, 1.3.2 and 1.3.3
Public awareness	Not directly covered in NICE CG147 and no recommendations are presented
PAD register	Not directly covered in NICE CG147 and no recommendations are presented

5.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

Diagnosis

NICE CG147 Recommendation number 1.3.1 (KPI)

> Assess people for the presence of peripheral arterial disease if they:

- have symptoms suggestive of peripheral arterial disease **or**
- have diabetes, non-healing wounds on the legs or feet or unexplained leg pain **or**
- are being considered for interventions to the leg or foot **or**
- need to use compression hosiery.

NICE CG147 Recommendation number 1.3.2 (KPI)

Assess people with suspected peripheral arterial disease by:

- asking about the presence and severity of possible symptoms of intermittent claudication and critical limb ischaemia
- examining the legs and feet for evidence of critical limb ischaemia, for example ulceration
- examining the femoral, popliteal and foot pulses
- measuring the ankle brachial pressure index (see recommendation 1.3.3 below).

NICE CG147 Recommendation number 1.3.3 (KPI)

Measure the ankle brachial pressure index in the following way:

- The person should be resting and supine if possible.
- Record systolic blood pressure with an appropriately sized cuff in both arms and in the posterior tibial, dorsalis pedis and, where possible, peroneal arteries.
- Take measurements manually using a Doppler probe of suitable frequency in preference to an automated system.
- Document the nature of the Doppler ultrasound signals in the foot arteries.
- Calculate the index in each leg by dividing the highest ankle pressure by the highest arm pressure.

Public awareness

Public awareness is not directly covered in NICE clinical guideline 147 and no recommendations are presented relating to the suggested area for quality improvement area.

PAD registers

PAD registers are not directly covered in NICE clinical guideline 147 and no recommendations are presented relating to the suggested area for quality improvement area.

5.3 Current UK practice

Diagnosis

As part of the engagement process assessing people for the presence of PAD was highlighted as a potential safety consideration by the NHS commissioning board patient safety function.

The cardiovascular disease outcomes strategy[3] highlights that PAD is not well recognised and is under diagnosed in both primary and secondary care.

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Public awareness

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

PAD registers

Stakeholders drew attention to the current QOF indicator on PAD registers:

QOF PAD001 - The contractor establishes and maintains a register of patients with peripheral arterial disease.

PAD indicators were added to the QOF for the first time in 2012-13, the results of which are not yet available.

[3] Cardiovascular disease outcomes strategy (2013)

6 Suggested improvement area: Imaging

6.1 Summary of suggestions

Stakeholders suggested local access to high quality non-invasive imaging for confirmation of diagnosis which may prevent unnecessary invasive procedures could be improved.

Stakeholders reported there is good evidence in the literature that non-invasive imaging provides sufficient information for management, with MRA being the most sensitive and specific, followed by CTA and then duplex. This avoids unnecessary invasive angiography which has a small but finite significant risk of patient harm.

6.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

NICE CG147 Recommendation number 1.4.1

> Offer duplex ultrasound as first-line imaging to all people with peripheral arterial disease for whom revascularisation is being considered.

NICE CG147 Recommendation number 1.4.2 (KPI)

> Offer contrast-enhanced magnetic resonance angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) before considering revascularisation.

NICE CG147 Recommendation number 1.4.3

> Offer computed tomography angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) if contrast enhanced magnetic resonance angiography is contraindicated or not tolerated.

6.3 Current UK practice

Stakeholders reported there was under provision of MRI meaning patients are investigated using potentially harmful ionising radiation. Some hospitals around the UK are reported to be offering access to duplex scanning within 24/48 hours of admission. There needs to be faster access to diagnostics such as Doppler scanning to allow faster access to revascularisation.

The NHS atlas of variation (2010)[4] showed there is fourfold variation among PCTS in the rate of MRI activity per 1000 population. When the five PCTs with the highest rate and the five with the lowest rate were excluded, the variation was twofold. The report concluded 'Although some of this variation can be attributed to the availability of both equipment and workforce, much of the variation could be due to local clinical practices that have evolved over time, which may need re-assessing'.

During development of the NICE clinical guideline 147 the GDG expert opinion was that recommendations on imaging are likely to reflect current practice in some centres, although not all centre will offer imaging techniques in the order set out in the recommendations[5].

No other published reports relating to current practice were highlighted by stakeholders for this quality improvement area.

[4] NHS Atlas of Variation (2010) Rate of magnetic resonance imaging (MRI) activity per 1000 population by PCT
[5] NICE clinical guideline 147 costing report (2012)

7 Suggested improvement area: Supervised exercise programmes

7.1 Summary of suggestions

Stakeholders suggested improved access to supervised exercise programmes to improve quality of life for people with claudication where interventional procedures or surgery were not indicated. This is reported as a cost effective intervention which in some instances may avoid surgery.

7.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

NICE CG147 Recommendation number 1.5.1 (KPI)

> Offer a supervised exercise programme to all people with intermittent claudication.

NICE CG147 Recommendation number 1.5.2

> Consider providing a supervised exercise programme for people with intermittent claudication which involves:
>
> - 2 hours of supervised exercise a week for a 3-month period
> - encouraging people to exercise to the point of maximal pain.

7.3 Current UK practice

Stakeholders reported in most NHS organisations supervised exercise programmes for people with PAD do not currently exist. There is however many cardiac rehabilitation programmes which could be opened up to receive people diagnosed with PAD.

Stakeholders highlighted that during the development of the NICE clinical guideline 147 it was recognised that no more than 30% of people are being offered the opportunity to participate in a supervised exercise programme. Of those who do have the opportunity, less than half choose to join an exercise programme[6].

[6] NICE clinical guideline 147 costing report (2012)

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder’s knowledge and experience.

8 Suggested improvement area: Surgical management

8.1 Summary of suggestions

Stakeholders suggested access to interventional radiologists for angioplasty and stenting and increasing the use of vascularisation and endovascular approaches can lower morbidity and mortality and limit the extent of or prevent amputations.

Stakeholders suggested reducing amputation rates and reducing variation across the country. Limb salvage should be the goal of lower limb PAD.

The following specific areas for quality improvement and potential development by the QSAC were highlighted, shown in table below alongside recommendations that have been provisionally selected from the development source to support potential statement development.

Suggested quality improvement area	**NICE CG147 recommendation**
Revascularisation	Recommendations 1.5.3, 1.5.7 and 1.6.2
Amputation	Recommendation 1.6.11

8.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

Revascularisation

NICE CG147 Recommendation number 1.5.3

Offer angioplasty for treating people with intermittent claudication only when:

- advice on the benefits of modifying risk factors has been reinforced (see recommendation 1.2.1[7]) **and**
- a supervised exercise programme has not led to a satisfactory improvement in symptoms **and**

[7] NICE CG147 recommendation 1.2.1 - Offer all people with PAD information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance on: smoking cessation, diet, weight management and exercise, lipid modification and statin therapy, prevention, diagnosis and management of diabetes and high blood pressure, antiplatelet therapy.

- imaging has confirmed that angioplasty is suitable for the person.

NICE CG147 Recommendation number 1.5.7

Offer bypass surgery for treating people with severe lifestyle-limiting intermittent claudication only when:

- angioplasty has been unsuccessful or is unsuitable **and**
- imaging has confirmed that bypass surgery is appropriate for the person.

NICE CG147 Recommendation number 1.6.2

Offer angioplasty or bypass surgery for treating people with critical limb ischaemia who require revascularisation, taking into account factors including:

- comorbidities
- pattern of disease
- availability of a vein
- patient preference.

Amputation

NICE CG147 Recommendation number 1.6.11 (KPI)

Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team.

8.3 Current UK practice

Revascularisation

Stakeholders reported that regional variation in access to interventional techniques exists. There is evidence that hospitals providing high levels of interventional treatment also perform significantly fewer amputations (6 per 100,000 per annum vs. 10 per 100,000 per annum, P=0.02 in one example). They also perform a higher proportion of below knee compared to above knee amputations; this is beneficial because around 50% of below knee amputees become independently mobile with an artificial leg, compared to only 25% of above knee amputees[8].

[8] The Vascular society of Great Britain and Ireland (2012) The provision of services for patients with vascular disease.

No other published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Amputation

Stakeholders reported wide regional variations in rates of lower limb amputation are recognised within England and there are particular concerns regarding the diabetic population. This is recognised by HES data and by heath care professionals. Stakeholders reported there are too many instances where amputation is part of the treatment options rather than the last resort. People with diabetes are predisposed to developing foot ulcers primarily because of an increased risk of both PAD and peripheral neuropathy. The NHS Atlas of Variation in Healthcare for People with Diabetes[9] reported approximately half of the major lower limb amputations are in people with diabetes.

This reflects not only delays and difficulties in diagnosis and referral, but under-provision of services such as interventional radiology.

Stakeholders reported evidence from Kings College Hospital London shows that 80% of amputations (complicated by diabetes) could be avoided.

[9] The NHS Atlas of Variation in Healthcare for People with Diabetes (2012)

9 Suggested improvement area: PAD services

9.1 Summary of suggestions

Stakeholders highlighted access to PAD services was important as current outcomes are relative to which region the patient is domicile.

Stakeholders suggested people with diabetes and new foot problems should be referred to a vascular service within 24 hours for a full vascular assessment by an experienced diabetes or vascular clinician. Prompt referral to a vascular service for further management where appropriate was also suggested.

Stakeholders suggested the use of vascular MDT teams with better coordination between specialities is associated with improved outcomes and people entering secondary care should be assessed by an MDT to determine the most appropriate treatment. Stakeholders suggested a MDT should consist of diabetic foot experts, podiatrists and diabetologists, vascular experts including vascular surgeons and interventional radiologists and pain specialist.

The following specific areas for quality improvement and potential development by the QSAC were highlighted, shown in table below alongside recommendations that have been provisionally selected from the development source to support potential statement development.

Suggested quality improvement area	**NICE CG147 recommendation**
Access to PAD services	Not directly covered in NICE CG147 and no recommendations are presented
Referral to PAD services	Not directly covered in NICE CG147 and no recommendations are presented
Vascular MDT	Recommendation 1.6.1

9.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

Access to PAD services

Access to PAD services is not directly covered in NICE clinical guideline 147 and no recommendations are presented relating to the suggested area for quality improvement area.

Referral to PAD services

Referral to PAD services is not directly covered in NICE clinical guideline 147 and no recommendations are presented relating to the suggested area for quality improvement area.

Vascular MDT

NICE CG 147 - Recommendation 1.6.1 (KPI)

> Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made.

9.3 Current UK practice

Access to PAD services

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Referral to PAD services

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Stakeholders reported people are commonly perceived to be referred late either to the diabetic foot protection team, MDT diabetic foot or vascular MDT. This can often be due to geographical, organisational or cultural barriers or a lack of working local integrated care pathways.

Vascular MDT

Stakeholders reported that given the regional variation in access to interventional techniques can be high ensuring patients entering secondary care are seen by a MDT, would create an incentive for providers to ensure all patients are assessed by the appropriate care givers prior to treatment plans being confirmed.

The Vascular Society report on the Provision of Services for Patients with Vascular Disease[10] reported there remains evidence of inequality in both provision and outcome according to geographical area in the UK. Inferior and often more costly outcomes occur where patients do not have timely access to a vascular specialist opinion at their local hospital.

[10] The Vascular society of Great Britain and Ireland (2012) The provision of services for patients with vascular disease.

10 Suggested improvement area: Pain management

10.1 Summary of suggestions

Stakeholders suggested early and appropriate use of medication to control pain following pain clinic assessment would avoid unnecessary use of very high dosages.

Stakeholders suggested a pain specialist should be involved sooner in the process than is currently recommended in the guideline.

Stakeholders suggested people should have an assessment of pain relief need taking into account patient choice.

Stakeholders suggested it was important that people with severe or critical ischaemia were regularly reviewed for pain management and where people were found to have significant pain refer to pain service

Stakeholders suggested the use of spinal cord stimulation (SCS) in chronic critical limb ischaemia to reduce pain and prevent tissue loss and amputation. Currently pain services are restricted in offering SCS and neurolytic sympathectomy when medication fails. Stakeholders suggested greater use of chemical sympathectomy for people with limited options for pain management even though its use has been limited to clinical trials by NICE. Stakeholders suggested the use of ketamine as a pain option.

The following specific areas for quality improvement and potential development by the QSAC were highlighted, shown in table below alongside recommendations that have been provisionally selected from the development source to support potential statement development.

Suggested quality improvement area	**NICE CG147 recommendation**
Timely access	Not directly covered in NICE CG147 and no recommendations are presented
Assessment of pain relief	Recommendation 1.6.9
Pain relief options	Not directly covered in NICE CG147 and no recommendations are presented (links to recommendation 1.6.10)

10.2 Selected recommendations from development source

Recommendations from the development source relating to the suggested improvement areas have been provisionally selected and are presented below in inform QSAC discussion.

Timely access

Timely access is not directly covered in NICE clinical guideline 147 and no recommendations are presented relating to the suggested area for quality improvement area. This area could be covered by recommendation number 1.6.9 below.

Assessment of pain relief

NICE CG147 Recommendation number 1.6.9

> Refer people with critical limb ischaemic pain to a specialist pain management service if any of the following apply:
>
> - their pain is not adequately controlled and revascularisation is inappropriate or impossible
> - ongoing high doses of opioids are required for pain control
> - pain persists after revascularisation or amputation.

Pain relief options

Pain relief options are not directly covered in NICE clinical guideline 147. This area could be covered by recommendation number 1.6.9 above. Stakeholders highlighted greater use of chemical sympathectomy above and beyond the guideline recommendation below.

NICE CG 147 - Recommendation number 1.6.10

> Do not offer chemical sympathectomy to people with critical limb ischaemic pain, except in the context of a clinical trial.

10.3 Current UK practice

Timely access

The National Pain Audit 2012[11] found significant variation in access to pain clinics for various chronic pain conditions. The audit reported for the 18 weeks key standard, 80% of clinics in England reported meeting the standard, 2.5% explicitly did not meet

[11] British Pain Society (2012) National Pain Audit 2012

the standard, and the remainder did not answer the question. There was significant variation in wait times in England. Where waiting times were more than 18 weeks the median wait was 20 weeks in England and 33 weeks in Wales. The audit reported patients rated ease of access as moderately difficult. Most had been through traditional routes i.e. GP or consultant. This audit is not specific to people with PAD.

Assessment of pain relief

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Pain relief options

No published reports relating to current practice were highlighted by stakeholders for this quality improvement area; this area is based on stakeholder's knowledge and experience.

Appendix 1 Key priorities for implementation recommendations (CG147)

Key priorities for implementation recommendations which have been referred to in the main body of this report are highlighted in grey.

Information requirements

- Offer all people with peripheral arterial disease oral and written information about their condition. Discuss it with them so they can share decision-making, and understand the course of the disease and what they can do to help prevent disease progression. Information should include:
    - the causes of their symptoms and the severity of their disease
    - the risks of limb loss and/or cardiovascular events associated with peripheral arterial disease
    - the key modifiable risk factors, such as smoking, control of diabetes, hyperlipidaemia, diet, body weight and exercise (see also recommendation on the secondary prevention of cardiovascular disease below)
    - how to manage pain
    - all relevant treatment options, including the risks and benefits of each
    - how they can access support for dealing with depression and anxiety.

      Ensure that information, tailored to the individual needs of the person, is available at diagnosis and subsequently as required, to allow people to make decisions throughout the course of their treatment.

Secondary prevention of cardiovascular disease in people with peripheral arterial disease

- Offer all people with peripheral arterial disease information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance (see Related NICE guidance; section 6) on:
    - smoking cessation
    - diet, weight management and exercise
    - lipid modification and statin therapy
    - the prevention, diagnosis and management of diabetes
    - the prevention, diagnosis and management of high blood pressure
    - antiplatelet therapy.

Diagnosis

- Assess people for the presence of peripheral arterial disease if they:
    - have symptoms suggestive of peripheral arterial disease **or**
    - have diabetes, non-healing wounds on the legs or feet or unexplained leg pain **or**
    - are being considered for interventions to the leg or foot **or**
    - need to use compression hosiery.
- Assess people with suspected peripheral arterial disease by:
    - asking about the presence and severity of possible symptoms of intermittent claudication and critical limb ischaemia
    - examining the legs and feet for evidence of critical limb ischaemia, for example ulceration
    - examining the femoral, popliteal and foot pulses
    - measuring the ankle brachial pressure index (see recommendation below).
- Measure the ankle brachial pressure index in the following way:
    - The person should be resting and supine if possible.
    - Record systolic blood pressure with an appropriately sized cuff in both arms and in the posterior tibial, dorsalis pedis and, where possible, peroneal arteries.
    - Take measurements manually using a Doppler probe of suitable frequency in preference to an automated system.
    - Document the nature of the Doppler ultrasound signals in the foot arteries.
    - Calculate the index in each leg by dividing the highest ankle pressure by the highest arm pressure.

Imaging for revascularisation

- Offer contrast-enhanced magnetic resonance angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) before considering revascularisation.

Management of intermittent claudication

- Offer a supervised exercise programme to all people with intermittent claudication.

Management of critical limb ischaemia

- Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made.

- Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team.

Appendix 2 Suggestions from stakeholder engagement exercise

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
001	Basildon and Thurrock University Hospitals NHS Foundation Trust	Key area for quality improvement 1	There is some evidence that SCS in CCLI can reduce pain	Current PAD standards direct CCLI patients with Pain to a Specialist Pain service. However Specialist pain service are currently restricted in offering both SCS and even neurolytic sympathectomy when medication fails	SCS for Non-Reconstructable Chronic CLI Review Ubbink 2013, Cochrane Collaboration
002	Basildon and Thurrock University Hospitals NHS Foundation Trust	Key area for quality improvement 2	There is some evidence that SCS in CCLI can prevent tissue loss and amputation	Amputation of limb is both costly and a tragedy for an individual patient. SCS in selected patients appears to prevent that. No patient should have an amputation purely for pain control without an attempt at SCS	SCS for Non-Reconstructable Chronic CLI Review Ubbink 2013, Cochrane Collaboration
003	Basildon and Thurrock University Hospitals NHS Foundation Trust	Key area for quality improvement 3	There is some evidence that SCS can improve ulcer healing and reduce Fontaine classification	Amputation of limb is currently advised for patients with chronic ulceration. Providing these ulcers are not too deep or wide, SCS can promote healing and improvement in limb	SCS for Non-Reconstructable Chronic CLI Review Ubbink 2013, Cochrane Collaboration
004	British Society of Interventional Radiology	Key area for quality improvement 1 Ensure that there is local access to high quality non-invasive imaging for confirmation of diagnosis of PAD including Duplex, MRA, CTA and angiography	To ensure that patients are not exposed to unnecessary risk or harm in the diagnosis of PAD.	There is good evidence in the literature that non-invasive imaging provides sufficient information for patient management with MRA as the most sensitive and specific, followed by CTA and then Duplex. This avoids unnecessary invasive angiography which has a small but finite significant risk of patient harm.	Lower limb peripheral arterial disease. NICE guideline 147 (2012)
005	British Society of Interventional Radiology	Key area for quality improvement 2 Access to local interventional radiologists able to undertake	To ensure that patients are offered a choice and there is no unnecessary surgery and with the expectation of best possible outcomes.	Much of the treatment for PAD is carried out by interventional radiologists (so called endovascular). This has significantly lower morbidity and mortality and can treat PAD and in critical ischaemia delay, limit the extent of or prevent amputations.	Lower limb peripheral arterial disease. NICE guideline 147 (2012) Interventional Radiology :Improving Quality and outcomes for patients.

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
		angioplasty and stenting including distal infra-inguinal interventions to revascularize vessels in PAD.			Department of Health. Gateway ref 12788 The provision of services for patients with vascular disease. The Vascular society of great Britain and Ireland. Towards Best Practice in Interventional Radiology. NHS Improvement-Diagnostics British Society of Interventional Radiologists
006	British Society of Interventional Radiology	Key area for quality improvement 3 Patients are offered a local exercise program	To improve the quality of life of patients with claudication where interventional or surgery is not indicated.	There are several studies demonstrating the benefit of supervised exercise programs in improving walking distance and many instances avoiding surgery. It is also shown to be cost effective.	Lower limb peripheral arterial disease. NICE guideline 147 (2012)
007	Faculty of Pain Medicine of the Royal College of Anaesthetists	Key area for quality improvement 1 **Timely access for pain relief to Pain Clinic**	Early and appropriate use of neuropathic agent and / or strong opioids or non-pharmacological options to control pain following Pain Clinic assessment will avoid unnecessary use of very high dosages of opioids and the associated risks in elderly population.	The National Pain Audit has found significant variation in access to Pain Clinic for various chronic pain conditions. Patients should have equal access to Pain services in England.	Please see the results of National Pain Audit report publish in December, 2012. http://www.britishpainsociety.org/members_articles_npa_2012.pdf
008	Faculty of Pain Medicine of the Royal College of Anaesthetists	Key area for quality improvement 2 **Assessment of pain relief need and risks of treatment options**	Inappropriate use of strong opioids without detailed assessment and the risks may expose elderly population with uncontrolled pain to risks of opioids including falls and injuries. Pain specialists must be part of multidisciplinary teams managing pain in these patients.	Many pain clinics in England have noticed a trend of overprescribing of opioids in patients with Chronic pain in primary care, exposing patients to the risks associated with use of strong opioids. We suggest that a pain specialist is an integral part of the assessing MDT. That pain treatment options should be discussed and individualised similar to surgical therapeutic options. As it stands the guidance runs the risk	Please see neuropathic pain guideline published by NICE. http://www.nice.org.uk/cg96 Please see opioids guidelines developed by British Pain Society http://www.britishpainsociety.

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				of driving patients to very high dosed of opioids before they are allowed to see a pain specialist who would then have to manage insurmountable difficulties related to tolerance and hyperlagesia.	org/book_opioid_main.pdf
009	Faculty of Pain Medicine of the Royal College of Anaesthetists	Key area for quality improvement 3 **Patient choice for pain control options.**	Care should be patient centred based on their preference following information about available options. Patient Pathway should act as a general guidance.	There is concern that patient's choice of pain control options has been unfairly limited in recent guidelines, based on erroneous NHS figures and costing of Chemical sympathectomy and neuropathic pain drugs including strong opioids.	Please refer to stake holder's comments in response to Lower limb peripheral arterial disease guidelines. (on file with NICE GDG.) http://www.nice.org.uk/nicemedia/live/13856/60428/60428.pdf
010	Faculty of Pain Medicine of the Royal College of Anaesthetists	Key area for quality improvement 4 **Availability of pain relief options**	Current guidance advises referring patients at a later stage to pain clinic, possibly after starting strong opioids. However, Pain clinics may be able to offer education and general advice to patients, but, specific pain control options i.e. spinal cord stimulation cannot be offered.	There is high quality data from European multicentre trial that spinal cord stimulation improves limb salvage and offer better pain relief in comparison to conservative medical management. Despite good evidence in this field, this treatment is being withheld for a small number of patients who may benefit.	Amann, W, Berg, P, Gersbach, P, Gamain, J, Raphael, JH, Ubbink, DT. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). Eur J Vasc Endovasc Surg 2003; 26: 280–286. Ubbink, DT, Vermeulen, H. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia. Cochrane Database Syst Rev 2003; 3: CD004001. http://vmj.sagepub.com/content/13/3/281.full.pdf+html

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					Colini Baldeschi G, Carlizza A. Spinal cord stimulation: predictive parameters of outcome in patients suffering from critical lower limb ischemia. A preliminary study. Neuromodulation. 2011 14(6):530-2 , Available at: http://www.ncbi.nlm.nih.gov/pubmed/21854490
011	Faculty of Pain Medicine of the Royal College of Anaesthetists	Key area for quality improvement 5 **Pain relief interventions**	NICE guidance has banned chemical sympathectomy. However there is good evidence that it can be very effective a carefully selected patients who are intolerant of opioids and anticonvulsants.	The limitation of the offer of a chemical sympathectomy to a trial adds a further limitation to the therapeutic options for pain relief in a difficult group of patients. While evidence is lacking for chemical sympathectomies we note it is also lacking for opioids as well as anticonvulsants and antidepressants. Those have not been banned. We urge strongly a reconsideration of the ban on chemical sympathectomies especially in view of the costs quoted for an amputation procedure. The cost of a chemical sympathectomy quoted in the tariff is a gross exaggeration of the actual procedure cost. The solution should be to revise the tariff rather than ban the intervention based on a false cost. We would suggest chemical sympathectomy should be considered after discussion between surgeons and pain consultants on a case by case basis. A trial of local anaesthetic sympathectomy is always an option first prior to neurolytic.	*No additional information provided by stakeholder*
012	Pfizer Limited	Pfizer welcomes the development of a quality	Cigarette smoking is one of the most important risk factors for PAD, and	Existing QOF indicators covering PAD patients who smoke are on their own insufficient to	References

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		standard (QS) for PAD, and notes the inclusion on p.3 of the NICE topic overview of the following QOF smoking indicators that target 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.	increases the risk of PAD by several fold (Lu & Creager, 2004). 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. The quality statements 2-4 and 6 from the draft smoking cessation quality standard state the following: People who smoke are referred to an evidence-based stop smoking service People who have been referred to an evidence-based stop smoking service are offered behavioural support with pharmacotherapy. People who smoke are offered a full course of nicotine replacement therapy (NRT), varenicline or bupropion. People who smoke who have set a quit date are offered carbon	guarantee that PAD patients who smoke will receive the most appropriate smoking cessation interventions, and will have their smoking cessation outcomes appropriately measured. Therefore 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 2-4, and 6.	Lu JT, Creager MA. The relationship of cigarette smoking to peripheralarterial disease. Rev Cardiovasc Med. 2004 5(4):189-93. 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. 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 Vasc Endovasc Surg. 2007 Apr; 33 (4):442-50. 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

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		The NICE topic overview on p.3 also cites the smoking cessation quality standard in development as being related to the proposed PAD QS. 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 the draft smoking cessation QS quality statements 2-4, and 6. These statements provide a more comprehensive quality framework for smoking cessation management and outcome measurement of PAD patients than that contained within the two abovementioned existing QOF indicators.	monoxide testing 4 weeks after the quit date With regard to statements 2-4, there is UK evidence suggesting that NHS specialist support (includes medication) is associated with 3.14 times the odds of quitting smoking compared with unaided quit attempts, and use of NRT on prescription with minimal behavioural support is associated with 1.67 times the odds of quitting compared with an unaided quit attempt (West 2012). NRT bought over the counter does not result in improvement in smoking cessation success rates compared with unaided quit attempts (West 2012). NHS smoking cessation services have to date therefore offered smokers the best chance of quitting smoking. Quality statement 4 is particularly important as it reflects NICE guidance contained in PH 10 Smoking cessation services in primary care, pharmacies,local authorities and workplaces, and will facilitate access to all types of smoking cessation prescription medicine for PAD patients who are offered a stop smoking intervention. With regard to quality statement 6, there is evidence from the UK smoking cessation service that self-		Artery Study. Eur Heart J. 1999 Mar;20(5):344-53. West R, Brown J (2012) Smoking and Smoking Cessation in England 2011. London.www.smokinginengland.info) April 2012 NICE public health guidance 10. Smoking cessation services in primary care, pharmacies, local authorities and workplaces. http://guidance.nice.org.uk/PH10 Ferguson J, Bauld L, Chesterman J, Judge K. The English smoking treatment services: one-year outcomes. Addiction. 2005 Apr;100 Suppl 2:59-69.

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			reported quitting at 4 weeks after target quit date is associated with higher failure rates at 1 year after the attempt than patients with a CO2-validated 4-week quit outcome (Ferguson, 2005). Therefore a CO2-validated 4-week quit is a desirable quality indicator to measure smoking cessation outcome in PAD patients who are offered a smoking cessation intervention. There is also evidence from the UK smoking cessation service that 75% of smokers initiating a quit attempt will be smoking again 1 year after the attempt, with 39% of quit failures responding that they relapsed within 12 weeks of the 4-week quit date (Ferguson, 2005). This suggests that a follow-up appointment to assess smoking status at 12 weeks may motivate a significant number of potential quit failures (more than one third) to remain smoke-free until this time-point which may in turn facilitate a longer-term quit for many of these individuals. Pfizer have therefore proposed during the NICE smoking cessation quality standard consultation that QS 6 be amended to the following: 'People who smoke who have set a quit date are offered carbon		

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			monoxide testing 4 weeks and 12 weeks after the quit date'		
013	HEART UK	Key area for quality improvement 1: Improve lipid management	PAD patients should have full lipid profile and be treated as for other secondary prevention cardiovascular disease (CVD) patients i.e. high intensity statin up titration unless TC<4 LDLC<2.0 (non-HDLc<2.8).	The current QOF indicator PAD003 requires Total Cholesterol of <5 for patients with PAD, and only a 90% threshold, which are inadequate. HEART UK understands that QOF is the only data source routinely looking at cholesterol in PAD patients.	As for all patients with established CVD, the Joint British Societies' Guidelines (II) recommends an optimal level of TC of <4. JBS II guidelines: http://heart.bmj.com/content/91/suppl_5/v1.full.pdf+html
014	British Pain Society	Early and coordinated Pain Relief	The CG acknowledges the importance of pain relief and its effects on QoL. Overall however we feel that the involvement of the pain specialist is delayed according to the guidance. Also the options available to the therapist are unfairly limited. It would be wise to emphasize the importance of early involvement of a pain specialist	Pain relief is a humanitarian issue, there is clear evidence that pain relief impacts profoundly on the quality of life as well as the survival in some disease areas	*No additional information provided by stakeholder*
015	British Pain Society	Chemical and Diagnostic Sympathectomy use for pain relief	The limitation of the offer of a chemical sympathectomy to a trial adds a further limitation to the therapeutic options for pain relief in a difficult group of patients. While evidence is lacking for chemical sympathectomies we note it is also lacking for opioids as well as anticonvulsants and antidepressants. Those have been recommended by the CG. We urge strongly a reconsideration of the ban on	Sympathectomy is a 5th or possibly 6th line intervention in a group of patients with few options While we acknowledge that further RCT evidence is required to prove the case for sympathectomy in the management of pain. Clinical circumstances of the patient group will make the design and delivery of such a trial very unlikely. The cost of a chemical sympathectomy remains a small fraction of the costs quoted for an amputation	I the absence of strong RCT supporting evidence we would suggest chemical sympathectomy should be considered after discussion between surgeons and pain consultants on a case by case basis A trial of local anaesthetic sympathectomy is always an option first prior to neurolytic.

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			chemical sympathectomies		
016	British Pain Society	When to offer an amputation	Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team. This assessment team should include a pain specialist particularly for patients where pain is a major issue	Where pain is a major issue a pain specialist is able to advise on improvements to the drug regime and other techniques in pain relief which may need to the avoidance of an amputation	*No additional information provided by stakeholder*
017	British Pain Society	Pain Drug treatment in PAD	We note that no cost effectiveness data was available for any of the drug options for pain however, were strong opioids were prioritised before cheaper options such as antidepressants. We notice that ketamine has not been considered as a therapeutic option.	We feel that caution in the prescribing of strong opioids should be exercised and other options such as anticonvulsants and antidepressants should be considered within a treatment algorithm rather than a strict therapy ladder. The prescriber of opioids should be experienced in managing tolerance, opioid induced hyperalgesia and other side effects such as hypogonadotrophic hypogonadism that can occur with high doses of strong opioids? We feel that there is enough evidence to justify use of Ketamine in ischaemic leg pain	British Pain Society Guidelines: Opioids for persistent pain: Good practice (2010) Graham Hocking, Michael J. Cousins. Ketamine in Chronic Pain Management: An Evidence-Based Review. Anesth Analg 2003;97:1730–9 The authors concluded that ketamine has a potent dose-dependent analgesic effect in clinical ischemic pain but with a narrow therapeutic window. Alison C. Mitchell, Marie T. Fallon. A single infusion of intravenous ketamine improves pain relief in patients with critical limb ischaemia: results of a

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					double blind randomised controlled trial. Pain 2002; 97 (3): 275-281
018	British Pain Society	Peri-operative analgesia for arterial bypass surgery and amputation	Poorly controlled acute pain is inhumane and also a known risk factor for chronic post-op pain	The acute pain team and anaesthetic teams need to be closely involved to guide optimal multi-modal analgesia and consideration for regional analgesia/anaesthesia technique. Regional techniques may improve surgical outcomes. A large trial is about to commence (http://clinicaltrials.gov/ct2/show/NCT01803165)	**Kehlet** H, Jensen TS, Woolf CJ: Persistent postsurgical pain: Risk factors and prevention. **Lancet 2006;** 367:1618–25 Malinzak EB, Gan TJ. Regional anesthesia for vascular access surgery. Anesth Analg. 2009 Sep;109(3):976-80. doi: 10.1213/ane.0b013e3181adc208. Review. PubMed PMID: 19690276.
019	Association of British Healthcare Industries	Access to PAD services and improved public education	Current outcomes are relative to which region the patient is domiciled.	Equity of access	NHS Atlas of Variation in Healthcare for People with Diabetes – June 2012
020	Association of British Healthcare Industries	Improvements in Primary Care diagnosis of PAD	Linked to earlier diagnosis and recognising the signs of PAD earlier in the pathway. This could be addressed with ankle brachial pressure index screening.	Amputation reduction	The Kerr Report: Foot Care for People with Diabetes: The Economic Case for Change NHS Diabetes March 2012
021	Association of British Healthcare Industries	Earlier endovascular interventions	Increasing vascularisation using and endo vascular approach can lead to reduced risk of amputation and less morbidity compared to bypass surgery	Less morbidity and reduced risk of amputation.	The Kerr Report: Foot Care for People with Diabetes: The Economic Case for Change NHS Diabetes March 2012 Faglia et al; Eur J Vasc Endovasc Surg 29, 620–627

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					(2005)
022	NHS England	Please ensure the Vascular Society have been registered as a stakeholder organisation (and if not they should be) The QS should take account of the CVD Outcomes Strategy (published by DH on 5th March 2013), which contains priority areas for improvement in peripheral arterial disease services.			
023	Foot in Diabetes UK		All GP Practices ensure they create and monitor PAD Registers from their patient populations, as per the QOF standard for PAD. A particular focus should be all people with diabetes who are found at their annual diabetes foot screening have non-palpable foot pulses, smoking history and presenting with leg symptoms that limit walking. General Practice PAD registers are reviewed annually by NHS Commissioners in primary care, along with other key cardiovascular registers and significant variance in practice populations registered with PAD is shared, analysed and acted upon.	PAD registers have only recently emerged as a QOF indicator for GPs. Diabetes foot screening outcomes on foot pulse palpation are not always translated into clinical action e.g. further assessment to confirm or exclude PAD If PAD registers are discussed and compared locally along with other long term condition registers, it will raise the profile and local GP Practice incentive to perform quality measurable PAD activity	NICE QOF Indicators NICE CG10 Diabetes and Feet
024	Foot in Diabetes UK		All people with diabetes who are suspected to have PAD following foot screening must have a comprehensive lower limb arterial assessment involving symptom history and clinical examination involving foot, popliteal and femoral pulses, handheld Doppler ultrasound and ankle brachial pressure index.	Although most people with diabetes receive annual foot screening, it is not always made clear locally what must happen next for people with suspected PAD. Clinical provision needs to be enhanced for locally available lower limb PAD diagnosis and proactive cardiovascular and limb management where PAD is subsequently diagnosed.	NICE 2012 PAD

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			All people with diabetes and peripheral arterial disease must be regularly and routinely reviewed for modifiable cardiovascular risks and if found must be targeted for individual education and support to recognise and minimise all risks.		
025	Foot in Diabetes UK		NHS commissioners must make available local, accessible supervised exercise programmes for all people with diabetes and intermittent claudication, with a focus on both cardiovascular and limb exercise. This may involve creating exercise access for PAD within existing cardiac rehabilitation programmes.	In most NHS organisations Supervised Exercise Programmes for people with PAD / IC do not exist currently. There are however many Cardiac Rehabilitation programmes, which could be opened up to receive diagnosed PAD claudicants.	*No additional information provided by stakeholder*
026	Foot in Diabetes UK		All people with diabetes who present with a new foot problem need to have their foot pulses assessed and if non palpable, with associated pain, redness, ulceration or necrosis, they must be referred within 24 hours for a full vascular assessment by an experienced diabetes or vascular clinician. All people with diabetes foot disease who attend multidisciplinary diabetes foot clinics must be considered for referral to the nearest Vascular Team if they have peripheral arterial disease. They must be promptly referred to see a Vascular Surgeon if	People are commonly perceived to be referred late either to the Diabetic Foot Protection Team, multidisciplinary Diabetic Foot MDT or Vascular MDT. This can be often due to geographical, organisational or cultural barriers or a lack of working local integrated care pathways	NICE 2012 PAD NICE CG 10 Diabetes and Feet

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			the foot disease is severe, static or deteriorating.		
027	Foot in Diabetes UK		All clinical teams treating people with severe or critical limb ischaemia must regularly review pain management and ensure it is optimised. Where people are found to have significant chronic ischaemic pain, particularly if it is unremitting and disturbing sleep, such teams must act quickly to facilitate a pain management review by the Vascular Team, GP or Specialist Pain Management Team.	It is not always clear who is taking the lead on the pain diagnosis, management or onward referral with severe ischaemic pain. GP, diabetes physician or Vascular Team?	NICE 2012 PAD
028	Boston Scientific	Access to PAD services and improved public education	Current outcomes are relative to which region the patient is domiciled.	Equity of access	NHS Atlas of Variation in Healthcare for People with Diabetes – June 2012
029	Boston Scientific	Improvements in Primary Care diagnosis of PAD	Linked to earlier diagnosis and recognising the signs of PAD earlier in the pathway. This could be addressed with ankle brachial pressure index screening.	Amputation reduction	The Kerr Report: Foot Care for People with Diabetes: The Economic Case for Change NHS Diabetes March 2012
030	Boston Scientific	Earlier endovascular interventions	Increasing vascularisation using endovascular approach can lead to reduced risk of amputation and less morbidity compared to bypass surgery	Less morbidity and reduced risk of amputation	The Kerr Report: Foot Care for People with Diabetes: The Economic Case for Change NHS Diabetes March 2012 Faglia et al; Eur J Vasc Endovasc Surg 29, 620–627 (2005)
031	Boston Scientific	Reducing amputation rates across the country and reducing variation	Limb salvage needs to be the overarching goal of lower limb PAD	There are too many instances where amputation is part as the treatment options rather than the last resort	NHS Atlas of Variation in Healthcare for People with Diabetes – June 2012

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032	Boston Scientific	Multidisciplinary team approach	There needs to be better coordination and education between specialties in order to improve outcomes of patients with lower limb PAD	Fragmented care leads to reduced outcomes for patients and to an increase in unnecessary amputations. The MDT needs to include diabetic foot experts: podiatrists and diabetologists, as well as vascular experts: vascular surgeons and interventional radiologists. Podiatrists need to be better educated in vascular complications of diabetic foot.	*No additional information provided by stakeholder*
033	Boston Scientific	Quicker access to vascular services	As the CG on lower limb PAD highlighted, vascular complications can be prevented with surgical or endovascular interventions to revascularise the arteries. There needs to be faster access to: diagnostic such as Doppler scanning and to revascularisation	Not provided	There are some hospitals around the UK offering access to duplex scanning within 24/48 hours of admission and endovascular treatment within a week
034	Boston Scientific	Boston Scientific fully supports the comments and response from ABHI which we have included verbatim in our response and added to it. Please note this as part of our response			
035	Medtronic Ltd	Early intervention in patients presenting with peripheral arterial disease	Amputation too often is seen as treatment rather than a failure of treatment. Early revascularisation crucial to avoid amputation and associated morbidity and mortality. Endovascular procedures have been shown to lead to a reduced risk of amputation when compared to open by-pass surgery. Best practice tariffs have been established for interventional radiology procedures for peripheral arterial disease – widespread adoption has the potential to improve	In some centres the mortality rate for major amputations could be as high as 16.8%. Evidence from Kings College Hospital London shows that 80% of amputations (complicated by diabetes) could be avoided. The adoption of best practice tariffs need to be monitored and incentivised to ensure adoption.	The Kerr Report: Foot Care for People with Diabetes. The All Party Parliamentary Group on Vascular Disease – *"Putting Vascular Disease at the Centre of Government Thinking";*

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			outcomes and provide value for the NHS.		
036	Medtronic Ltd	Use of multi-disciplinary Teams is deciding on a treatment plan	PAD is often associated with diabetes. Diabetics are twice as likely to develop PAD and the condition is one of the most common causes of amputation. The use of multi-disciplinary foot teams – which include a vascular specialist and or a interventional radiologist – have been shown to improve patient outcomes.	There are between 10,000 and 11,000 lower limb amputations annually and 60% are complicated by diabetes. More than 80 hospitals in England and Wales do not provide this service.	The All Party Parliamentary Group on Vascular Disease – *"Putting Vascular Disease at the Centre of Government Thinking";* R Greenhalgh. (2009) Unacceptable major amputation rates widespread. Vasc News. [online]. Available from: http://www.cxvascular.com/vn-features/vascular-news---feature/unacceptable-major-amputation-rates-widespread
037	Medtronic Ltd	PAD care services need to be accessible, and disseminating information to high risk groups is important	The prospects of those suffering with vascular disease is dependent on which Health Authority they are treated.	Equity of access throughout the NHS	The NHS Atlas of Variation – Strategic Health Authority Vascular related amputation rates
038	Johnson & Johnson Medical	MDT Access	Johnson & Johnson Medical (J&J) wholeheartedly agree with the clinical guideline published to support best practice in the treatment of Peripheral Arterial Disease (PAD). We are especially pleased that the guideline recognises the importance of a multi-disciplinary approach to managing episodes and as such identifies the benefits of Angioplasty prior to surgery. We believe such an approach is vital in ensuring that	Ensuring patients receive the least invasive intervention appropriate to their condition is globally recognised as best practice and is a key part of the NICE Guideline on PAD. Previous experience of NICE implementation within the NHS suggests that maximum benefit is created when best practice is measured. In this instance a simple, yet transparent, record which ensures patients are afforded access to an MDT is likely to drive compliance towards the clinical guidelines recommendations. An extension of such a scheme would be to	Variations in local practice can be observed through HES data, although nuances in coding make objective assessment difficult. It is, however, well established anecdotally that such variation exists and expert opinion is likely to support our recommendation

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			patients do not receive potentially unnecessary and invasive surgical procedures. Given regional variation in access to interventional techniques can be high we believe that a standard set of nationally agreed and visible metrics, which record the fact the patients entering secondary care are seen by a MDT, would create an incentive for providers to ensure all patients are assessed by the appropriate care givers prior to treatment plans being confirmed. Such a measurement could be simply implemented and published via a basic audit tool which NICE have significant and credible experience of administering.	record and publish the relative levels of Angioplasty, Bypass Surgery and Amputation at provider level. While it is accepted both Bypass Surgery and Amputation are important surgical procedures, it is recognised that procedural volumes relative to interventional techniques, such as Angioplasty, can vary greatly without significant evidence of epidemiological diversity.	
039	SCM1	I do consider that like a lot of chronic conditions, the patient very often needs to be persuaded into accepting that they have the disease (not the health professional) and have a responsibility to seek advice and treatment to reduce the effects of the condition and its deterioration. (Comment for internal team removed).	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
040	SCM2	4.2 Supervised exercise programmes	Recently published data demonstrates the importance of exercise programmes in the	Randomized clinical trial of percutaneous transluminal angioplasty, supervised exercise and combined treatment for intermittent	However, it is recognised that no more than 30% patients are being offered access to

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			management of patients with intermittent claudication Mazari FA, Khan JA, Carradice D, Samuel N, Abdul Rahman MN, Gulati S, Lee HL, Mehta TA, McCollum PT, Chetter IC. Br J Surg. 2012 Jan;99(1):39-48. doi: 10.1002/bjs.7710. Epub 2011 Oct 21.	claudication due to femoropopliteal arterial disease	such programmes. This was recognised during development of the NICE PAD guideline: NICE costing report Lower limb PAD August 2012
041	SCM2	Imaging for patients with suspected PAD:	The NICE PAD guideline recommends the use of MRI in assessment of patients who are being considered for intervention (1.4.2 page 11). This is referred to in the 2010 report into inequalities within healthcare in England: http://www.rightcare.nhs.uk/atlas/qipp_nhsAtlas-LOW_261110c.pdf	There is under-provision of vascular MRI meaning that patients are investigated using potentially harmful ionising radiation.	*No additional information provided by stakeholder*
042	SCM2	Amputation rates in England	Wide regional variation in rates of lower limb amputation are recognised within England and there are particular concerns regarding the diabetic population. This is recognised by HES data and not only by heath care professionals but has also been the subject of media attention. This reflects not only delays and difficulties in diagnosis and referral, but under-provision of services such as interventional radiology. Four references are cited below:	*No additional information provided by stakeholder*	Delay influences outcome after lower limb major amputation Moxey et al Eur J VascEndovasc Surg 2012 44(5) 485-90 Quality improvement framework for major amputation surgery Vascular Society of Great Britain and Ireland 2010 Securing the future workforce supply: Clinical Radiology

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					Stocktake 2012 http://www.bbc.co.uk/news/health-17270379
043	SCM3	Early diagnosis of PAD (intermittent claudication [IC] and critical limb ischaemia [CLI]) in primary care	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
044	SCM3	Prompt appropriate referral for to a vascular service for further specialist management where appropriate	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
045	SCM3	Any patients with a break in the skin below the knee that has not healed within 2 weeks should be referred urgently to a vascular service for specialist investigation and management.	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
046	SCM3	access to a supervised exercise programme	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
047	SCM3	access to lifestyle modification support (smoking, obesity, alcohol etc.)	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*	*No additional information provided by stakeholder*
048	SCM4	Provision of exercise programmes	*No additional information provided by stakeholder*	The evidence for their effectiveness and cost effectiveness was pretty good but programmes of this kind were not widely available. There was discussion as to the possibility of combining a PAD programme with that of cardiac rehab.	*No additional information provided by stakeholder*

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
049	Patient safety function of NHS England	Assessing people for the presence of PAD if they have non-healing wounds including ulcers	*No additional information provided by stakeholder*	Patient safety issue	*No additional information provided by stakeholder*