

THE VASCULAR SOCIETY OF GREAT BRITAIN AND IRELAND

A Best Practice Clinical Care Pathway for Peripheral Arterial Disease

February 2022



Introduction

The Vascular Society (VS) has developed this quality improvement framework (QIF) to respond to recommendations made in the vascular surgery GIRFT programme report in 2018.¹

Peripheral arterial disease (PAD) is common, affecting 1 in 5 people over the age of 60 in the UK, and carries both the risk of lower limb loss and the increased risk of death from heart attack and stroke.

Prevalence data suggests that a population of 800,000 people should see approximately one presentation with chronic limb-threatening ischaemia (CLTI) every day.²

Over 28,000 lower limb revascularisation procedures are performed each year in England. These are the most frequent arterial interventions performed by vascular surgeons and interventional radiologists.³

Over 4,000 major lower limb amputations are performed each year in England for complications of PAD and/or diabetes.³

The vascular GIRFT visits found that the delivery of revascularisation in CLTI is inconsistent across the UK, in terms of service provision, length of hospital stays and patient outcomes.¹

GIRFT reported universally unacceptable pathway delays to revascularisation. Furthermore, supervised exercise for intermittent claudication cannot be accessed in many parts of the UK. The VS PAD-QIF was developed in collaboration with key stakeholders. It describes the care pathways, workforce and facilities required to improve outcomes for patients with PAD.

All patients: reduced morbidity and mortality from cardiovascular disease.

Intermittent claudication: sustained improvement in walking distance.

Chronic limb threatening ischaemia: restoration of a pain-free and functional lower limb.

Implementation of this QIF aims to reduce unwanted variation in services for people with PAD. Key to achieving this aim is the development of evidence-based, multidisciplinary care pathways that include timelines to access urgent care for CLTI.

In some regions, reorganisation, based upon the network model described in the VS's Provision of Vascular Services documents will be needed.²

In all regions, vascular network leads will need to work with hospital trusts, clinical commissioning groups (CCGs), integrated care systems (ICSs) and other medical and healthcare specialties, especially the multidisciplinary diabetic foot care teams (MDFTs), across their network areas to implement this QIF.

This QIF is aligned with the Vascular GIRFT recommendation that vascular networks develop processes to deliver urgent care.

- 2. POVS 2021 https://www.vascularsociety.org.uk/_userfiles/pages/files/Resources/FINAL%20POVS.pdf
- 3. Hospital Episode Statistics 2019

^{1.} GIRFT 2018 https://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/02/GIRFT_Vascular_Surgery_Report-March_2018.pdf

Peripheral arterial disease

- First line management for people with PAD is cardiovascular risk factor modification (see page 11).
- Arterial networks should provide education for patients, GPs, doctors from other specialties, community nurses and podiatrists in the diagnosis and treatment of PAD.
- Training and education with access to equipment in order to carry out ankle brachial pressure index (ABPI) or toe pressure measurement facilitates earlier PAD diagnosis.

Intermittent claudication

- Evidence-based management for most people is cardiovascular risk factor modification and enrolment in structured supervised exercise therapy:
 - Smoking cessation is effective in improving claudication distance
 - Supervised exercise therapy increases claudication distance.
- Exercise therapies may also be beneficial in the management of other cardiovascular risk factors, such as obesity, hypertension and hypercholesterolaemia.
- Failure to respond to medical therapy and exercise may lead the clinician and patient to consider referral to a vascular specialist for consideration of open surgical or endovascular revascularisation by the lower limb multi-disciplinary team (MDT).
- Naftidrofuryl oxalate is an option when there is no appropriate revascularisation option, and treatment with a vasodilator is appropriate.¹

Acute limb ischaemia

- Patients with acute limb ischaemia, of less than two weeks duration, require immediate referral to vascular surgery.
- Emergency intervention may be required to prevent amputation.

Chronic limb-threatening ischaemia (CLTI)

CLTI is the advanced stage of PAD, where blood supply to the foot is insufficient for the needs of the tissues. The Global Vascular Guidelines definition is "objectively documented atherosclerotic PAD and ischaemic rest pain with abnormal haemodynamic parameters, lower limb ulceration for more than 2 weeks, or gangrene in the lower limb or foot."³

- Evidence-based management is early revascularisation, to prevent limb loss.
- Delay is best avoided by well organised networks with clear referral pathways.²
- Assessment of patients requires members of a multi-professional team, the lower limb MDT (page 5), to be available 24/7.
- Open arterial surgery must be delivered in vascular network arterial centres.
- Endovascular therapy may be best delivered through day care, either at the arterial centre or at a networked hospital depending on network arrangements and geography. Appropriate governance arrangements must be in place.

Best practice care involves active participation in audit and research.

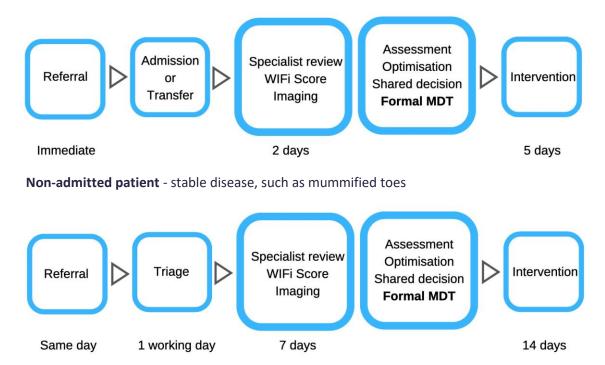
- 1. Efficacy should be assessed after 3-6 months https://cks.nice.org.uk/peripheral-arterial-disease#!scenario:2
- 2. The Manchester amputation reduction strategy (MARS) proposes managing all foot and leg ulcers through a pathway of care from community nurses and podiatrists to secondary care.
- Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischaemia <u>https://doi.org/10.1016/j.ejvs.2019.05.006</u>

QIF aims

- 1. Evidence based, well organised, care for people with peripheral arterial disease, focused on CV risk factor modification.
- 2. Equitable access for people with PAD to
 - supervised exercise therapy
 - timely revascularisation

- 3. Every vascular network has a **lower limb multi-disciplinary team** that collaborates closely with local MDFTs.
- Every patient receives a multi-specialty assessment, including shared decision making over treatment options.

Admitted patient - severe chronic limb threatening ischaemia and/or foot sepsis



These pathways apply to all referrals, including from network emergency departments, networked non-arterial hospitals, and for acute diabetic foot problems with ischaemia.



The PAD-QIF timescales are deliberately challenging. Vascular networks that cannot meet these targets should engage actively with managers and commissioners to implement the changes required to develop safe and effective services that meet the local needs of people with peripheral arterial disease.

Multi-disciplinary lower limb team

- This model of care borrows from the one successfully implemented by multidisciplinary diabetic foot care teams.
- Any appropriately trained member of the team may be involved in the provision of any stage of the pathway.

Core members

Formal lower limb MDT meeting Vascular surgeon - *at least two* Interventional radiologist - *at least two* Vascular specialist nurse Vascular anaesthetist Consultant in care of elderly and frailty Clinical Vascular Scientist MDT administrator

Regular professional working Podiatrist

Vascular ward & IR day care unit nurses Vascular ward and amputee therapists Nutrition team Diabetes specialist nurse Waiting list coordinator - *or equivalent* Discharge coordinator - *or equivalent*

Input available from

Acute pain team Acute medicine Cardiology Respiratory medicine Renal medicine, including access to dialysis Endocrinology Plastic surgery – for skin cover Orthotics and prosthetists Microbiology Tissue viability nurse Amputation counsellor Rehabilitation consultant Palliative care team Network manager

MDT working involves both formal meetings and 24/7 professional working between MDT members.

Formal lower limb MDT meeting

- Should be weekly, led by a chairperson, and have a designated administrator.
- Must have adequate facilities such as room size, with high quality information technology and audio-visual support for remote access.
- Core members should be job planned to attend at least 50% of meetings.¹
- Equal access for clinicians working at the arterial centre and those working at nonarterial networked hospitals.
- The clinician who reviewed the patient / patient's responsible clinician should provide adequate information for the discussion.
- Limb assessment using a standardised classification system, such as WIFI, helps the MDT assess the risk of limb loss and benefit of revascularisation.
- MDT discussions should be minuted and be communicated to the patient and their family/friends so that they may be involved with informed decisions about their care.
- MDT outcomes must be recorded in the patient's medical record.
- MDT data should be utilised to improve completeness and quality of NVR data submission.

The formal MDT meeting must not delay intervention, and in these cases informal discussion between MDT members should be carried out and documented.

Vascular specialist nurses are key to delivering many elements of the PAD-QIF, both in patient-facing and coordination roles.

1. POVS 2018 recommends this is a 1 PA fixed commitment (DCC) allocation in consultant vascular surgeon job plans.

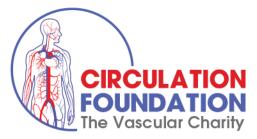
Pre-intervention assessment

- A multi-specialty multi-professional approach to care is required:
 - Patients with CLTI are often elderly, nutritionally deficient and may be frail
 - Patients often have cardiac, renal and respiratory disease and diabetes.
- A patient prepared for an intervention mentally and physically is likely to have a better outcome:
 - Fewer complications
 - Fewer days of hospital stay
 - Lower risk of early readmission.
- A patient for open, including 'hybrid', revascularisation should be reviewed in a specialist clinic, or on the ward, by
 - Pre-operative care nurse
 - Consultant anaesthetist
 - Consultant in care of elderly and frailty, if elderly or frail¹
 - Pharmacist
 - **Dietician**, if nutritionally deficient.
- A patient for endovascular therapy can be either assessed as for open surgery or be assessed via telephone according to agreed written network protocols.
- The aims of these assessments are
 - Risk assessment, including frailty
 - Optimisation of coexisting medical conditions and medications, including referral if required
 - Consideration and institution of prevention measures
 - Access to appropriate support services (i.e. pharmacy, diabetes).

 Anaesthetic work-up for patients undergoing surgery should be based on Guidance on the Provision of Vascular Anaesthesia Services.²

Shared decision making

- Patients should have adequate opportunities to discuss treatment with members of the lower limb MDT.
- A shared decision means reviewing the risks and benefits of each intervention and establishing the best option with the patient as an individual.
- When a patient is very frail and/or has no revascularisation options, then amputation or end of life care should be discussed as options to consider, with appropriate advance care planning.
- Nurses, podiatrists, physiotherapists and amputee counsellors have an important role in exploring patient understanding and concerns; this will also ease anxiety.
- Written patient information on options, benefits, risks and recovery should be provided.
- The Circulation Foundation website contains patient information leaflets for various procedures which may be signposted.



When a patient has not been seen in a specialist clinic the aim should be for equivalent evaluation and optimisation on the vascular ward.

- 1. There is evidence that this assessment improves shared decision-making, clinical outcomes, length of stay and hospital readmissions in frail patients undergoing surgery: https://academic.oup.com/bjs/article/104/6/679/6122956
- 2. RCOA GPAS 2021 <u>https://www.rcoa.ac.uk/gpas/chapter-15</u>

Revascularisation

Hospital admission

- Arterial centres must have sufficient bed capacity for new admissions and transfer from networked hospitals.
- Antibiotics should be prescribed according to microbiology protocols and in the case of diabetic foot disease, in collaboration with the MDFT.
- Screening for infections (i.e. MRSA) must be carried out.
- Venous thrombo-embolism assessment should be carried out and appropriate prophylaxis prescribed.
- Adequate pain control must be provided.
- A pressure area assessment should be carried out, and pressure off-loading optimised.

Open surgical revascularisation

- Timely revascularisation requires sufficient vascular operating theatre time, including at weekends.
- Surgery should ideally be listed on a properly staffed vascular operating list during normal working hours
 - This necessitates flexible scheduling based on a clinical risk assessment.
- If the procedure is performed on an urgent (unplanned) theatre list, the theatre team must be familiar with vascular surgery, including with endovascular procedures.
- An appropriate level critical care bed should be available, according to preoperative assessment, with emergency access to Level 3 care.
- A consultant vascular surgeon and a consultant anaesthetist, or post-FRCA anaesthetic trainee with vascular experience, should be present (except for local anaesthetic procedures).
- For a complex lower limb bypass consider dual consultant operating and cell salvage; some delay in order for the best team to perform the surgery will be necessary on occasion.
- Be cognisant of endovascular alternatives and adjuvants; use hybrid theatre if these may be required.

Endovascular procedures

- Sufficient interventional radiology room and staff time must be available, including at weekends.
- Sufficient access to a 'hybrid' theatre must be in place.
- Lower limb MDT input and governance should be available for every patient.
- Suitable devices must be available for each procedure, including for endovascular management of complications.
- The use of closure devices must be evidence based and follow locally agreed protocols.
- The whole team must be trained in radiation protection.

Endovascular procedures should be performed as day case procedures where possible.

The three frequent exceptions to this are hospital admission for foot sepsis and/or tissue loss, optimisation of poorly controlled diabetes or living alone.



Recovery

Post-procedure

- Patients should be nursed in areas with the expertise to assess limb perfusion and identify complications early.
- A clear plan must be documented for:
 - Antiplatelet and anticoagulant medication (medication prescribed and duration)
 - GP and community nurses (medication and wound care)
 - MDFT and foot protection teams. (wound care and/or foot protection)
- Secure sharing of wound images with other teams should be undertaken as appropriate.
- Patients should be provided with written information that includes:
- What they have had done
- Any medication changes
- Follow up arranged
- 24/7 telephone number to call for advice in case of concern.
- Admitted patients: daily consultant review until medically fit to discharge.
- The following multi-professional input must be available:
 - Specialist vascular ward nursing
 - 24/7 surgical cover, with access to a staffed emergency (hybrid) theatre
- 24/7 IR cover, with access to an IR theatre with fixed high-quality angiographic X-ray system and hybrid theatre
- Physiotherapy and allied support therapies (i.e. occupational)
- Early provision of mobility aids
- Physician and pharmacist medication review (twice weekly)
- Discharge coordinator to address social and rehabilitation needs.
- Non-admitted patients: an appropriately qualified clinician should review before discharge.



Following discharge

- Access to early specialist vascular review, including for patients repatriated to networked hospitals, should be available.
- If open wound is present, follow up in a multi-disciplinary wound care clinic or by specialist community nursing teams should be arranged prior to discharge.
- Evidence based Duplex ultrasound scan (DUS) graft surveillance should be carried out.
- Prescription of anti-thrombotic therapy should be optimised and communicated to the patient's GP.
- Longer term follow-up including enrolment in a formal DUS surveillance programme carried out by trained vascular scientists is recommended.
 - Consider after complex infra-inguinal endovascular procedures as well as lower limb bypass grafts.

Audit

- Vascular networks should have a nominated clinical governance lead.
- Job plans should include contracted time for outcome reporting and audit.
- Local MDTs must ensure data is submitted to the National Vascular Registry (NVR) on all lower limb procedures, including:
 - Open surgical and hybrid procedures
 - Amputations
 - Endovascular procedures, including those performed as day cases.
- Vascular networks should have administration support to optimise NVR data quality, available to both IR and vascular teams.

Network NVR data should be reviewed locally each year to determine where improvements can be made.



Patients presenting with acute diabetic foot disease

- Initial assessment should be by the MDFT, a community nurse or podiatrist.
- Diabetic foot ulcers must be managed in effective collaboration with MDFT.¹
- When ischaemia is a contributory factor urgent revascularisation must be considered (as for patient with CLTI).
- MDFT can help when management involves transfers to and from arterial centres and recovery from surgery.
- Ongoing preventive care should be agreed with the MDFT and foot protection team.
- Local MDFTs should ensure that episodes are registered with the National Diabetes Foot Care Audit of England and Wales (NDFA).

Deep foot sepsis

 Patients presenting with deep limb sepsis should have debridement and/or drainage within 24 hours.

Non-salvageable foot

- The VSGBI Major Amputation StAMP² sets out the best practice clinical care pathway for lower limb amputation.
- Amputation should be performed within 48 hours of decision.

- 1. NICE clinical guidance NG19 underpins this model of combined care
- 2. https://www.vascularsociety.org.uk/ userfiles/pages/files/Resources/Vasc Soc Amputation Paper V2.pdf

QIF standards

Management of patients with peripheral arterial disease	Minimum Standard
*Network wide, and agreed, written pathway of care for PAD	100%
*People who smoke can access a smoking cessation service close to where they live	> 85%
*People with IC can access a supervised exercise programme close to where they live	> 75%
*Peripheral MDT core team (see page 5) quorate at formal MDT meetings (over 12 months)	≥ 95%
*Severity of limb threat in CLTI staged using the SVS WIfI score	> 80%
*Shared decision making demonstrated with evidence in the patient medical record	> 80%
*Written patient information widely available	100%
*Medical specialists trained in comprehensive geriatric assessment (CGA) available to review patients pre- and post-operatively	> 80%
*NVR case ascertainment for bypass, angioplasty and major amputation procedure achieved (compared to Trust HES data)	> 85%
Peripheral MDT discussion documented in patient medical record	100%
Consultant anaesthetist pre-assessment before open surgical procedures	≥ 90%
Open bypass surgery performed at arterial centre	100%
Major (above ankle) amputation performed at arterial centre	> 95%
Revascularisation on planned surgical or interventional radiology list	> 75%
Consultant vascular specialist, surgeon or interventional radiologist, present at procedure	100%
Consultant anaesthetist, or post FRCA trainee, present for general anaesthetic procedure	100%
Documented post revascularisation assessment of procedural success	100%

Referral to secondary care for chronic limb threatening ischaemia	Timescale Compliance > 80%	Source
Referral to vascular specialist	≤ 1 working day	POVS
Triage of referral by vascular specialist	1 working day	NHSE

'Admitted' patient pathway

CLTI with rapid progression, deep tissue infection, and/or uncontrolled pain.

From receipt of referral

Admission or transfer to network arterial centre	≤ 2 days ²	StAMP POVS
From hospital admission		
Cross-sectional imaging (CTA or MRA) +/- DUS by vascular scientist Vascular surgeon 'face to face' review	≤ 12 hours ≤ 14 hours	NHSE NCEPOD
Revascularisation	≤ 5 days ³	POVS

'Non-admitted' patient pathway

CLTI with ulcer, minor necrosis, mummified toes, superficial infection or controlled pain.

From receipt of referral

Vascular surgeon 'face to face' review	≤ 2 working days ¹	POVS
From review by specialist		
Cross-sectional imaging (CTA or MRA) +/- DUS by vascular scientist	≤ 7 days	POVS
Revascularisation	≤ 14 days ¹	POVS

* Corresponds to a Key Performance Indicator in POVS 2021

- 1. Achieving this target requires the provision of urgent ('hot') outpatient appointments with clearly defined pathways for urgent imaging, admission and revascularisation if indicated
- 2. Achieving this target necessitates 48 hourly specialist vascular presence, consultant or specialist nurse, at networked hospitals **or** a written pathway of care for transfer patients to arterial centre for review
- 3. Intervention should not be deferred more than once for non-medical reasons

Cardiovascular risk factor modification

Guidelines for risk factor modification in peripheral arterial disease fall in line with standard secondary prevention strategies for other cardiovascular disorders.

Smoking cessation reduces the risk of cardiovascular events. Behavioural support in combination with medications such as a combination of short- and long-acting nicotine replacement therapy or nicotine-containing e-cigarettes are the most effective smoking cessation strategies.

https://www.nice.org.uk/guidance/ng209

Antiplatelet agents: patients should receive secondary prevention with clopidogrel 75mg OD, unless contraindicated or intolerant. Second line is aspirin 75mg OD. Patients on anticoagulation do not benefit from an additional antiplatelet agent. <u>https://cks.nice.org.uk/antiplatelet-treatment</u> The COMPASS trial has more recently shown benefit from rivaroxaban 2.5mg BD plus aspirin in PAD.

Lipid modification: patients should be offered secondary prevention with high intensity statin treatment e.g. atorvastatin 80mg OD, if tolerated. Prior to statin initiation, causes of secondary hyperlipidaemia should be identified and treated, including excessive alcohol intake, uncontrolled diabetes, hypothyroidism, liver disease and nephrotic syndrome. Patients should be counselled about the small risk of side effects, including muscle pains. *The most serious adverse effects of statins are myopathy and rhabdomyolysis. The estimated incidence are 5 and* 2 cases per 100,000-person years respectively.

NICE recommend baseline blood tests including a non-fasting lipid profile (total cholesterol, HDL-C, non-HDL-C, TG and CK, LFTS, renal function, HbA1c and TSH if dyslipidaemia is present). LFTs should be checked at 3 and 12 months, and HbA1c at 3 months if at risk of diabetes, with annual check of lipids and review for side effects of statins thereafter.

https://cks.nice.org.uk/lipid-modification-cvdprevention Weight management: if Body Mass Index is >25, consider referral for dietary advice and provide a goal for weight loss. https://cks.nice.org.uk/topics/obesity/diagnosis/id

entification-classification/

Diabetes: care should be coordinated with the diabetes team. Aim for HbA1c of <48mmol (higher target if elderly). Manage type 1 and type 2 diabetes according to national guidelines. <u>https://cks.nice.org.uk/diabetes-type-1</u> <u>https://cks.nice.org.uk/diabetes-type-2</u>

Hypertension: blood pressure >140/90 mmHg in the outpatient clinic, or an average ambulatory blood pressure recording of >135/85 mmHg should prompt further assessment and treatment. In patients aged >80 years, target blood pressure should be <150/90 mmHg. If blood pressure is elevated, recommend smoking cessation and reduction of alcohol and caffeine intake. Exercise programmes, relaxation therapy and reduced salt intake are effective lifestyle approaches to lowering blood pressure. Consider causes of secondary hypertension and treat as appropriate. Severe or resistant hypertension should prompt referral to specialist hypertension services. https://cks.nice.org.uk/hypertension-not-diabetic

First choice medication in patients aged <55 years who are not black African or African-Caribbean is an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB) if tolerated. First line for patients >55 years, or black African or African-Caribbean patients is a calcium channel blocker (dihydropyridine type - e.g. amlodipine). If intolerant or in need of second or third line agents, it would be appropriate to consider a thiazide diuretic such as indapamide.

Nutrition: diet should broadly be in line with healthy eating recommendations, i.e. five portions of fruit and vegetables each day, meals based on starchy foods such as pasta, bread, rice or potatoes, moderate amounts of dairy products and protein-rich foods. Intake of foods high in fat, sugar and salt should be reduced. https://www.nhs.uk/live-well/eat-well/

Regular activity and exercise: patients should be advised to break up long periods of sitting with light activity, to aim for at least 150 minutes of moderate aerobic activity every week and to perform strength exercises on 2 or more days a week that work all the major muscles (legs, hips, back, abdomen, chest, shoulders and arms).

Abbreviations / Glossary

ABPI	Ankle brachial pressure index, a measure of lower limb arterial perfusion. If the arteries are incompressible then a toe pressure (TP) or transcutaneous oxygen pressure (TcPO ₂) are used to calculate the ischaemia component of the WIfI score.
CCG	Clinical Commissioning Group, responsible for commissioning community peripheral arterial disease management, including supervised exercise therapy for intermittent claudication, community podiatry and multi-disciplinary diabetic foot clinics.
CLTI	Chronic limb-threatening ischaemia. This replaces critical limb ischaemia (CLI). The European Society of Vascular Surgery uses LEAD (Lower extremity arterial disease).
СТА	Computed tomography angiography
CV	Cardiovascular, refers to the organ systems most frequently affected by atherosclerotic disease, namely the arteries in the brain, the heart, the aorta, the kidneys and the legs.
DUS	Duplex ultrasound scan
ED	Emergency department
RCA / FRCA	Royal College of Anaesthetists / Fellow of the Royal College of Anaesthetists
GIRFT	Royal National Orthopaedic Hospital NHS Trust and NHS Improvement ' <i>Getting it Right First Time</i> ' programme. The vascular surgery programme was led by Professor Mike Horrocks.
Hybrid	Operating theatre equipped with fixed imaging equipment for endovascular procedures. The term 'hybrid' is also used to describe combined open and endovascular procedures.
IC	Intermittent claudication
IR	Interventional radiology
MDT	Multi-disciplinary team
MDFT	Multi-disciplinary foot care team
MRA	Magnetic resonance angiography
MRSA	Methicillin resistant staphylococcus aureus
NCEPOD	National Confidential Enquiry into Patient Outcomes and Deaths
NDFA	National Diabetes Foot Care Audit of England and Wales
NHS, NHSE	National Health Service. NHS England, commissioner for English specialist vascular services.
NVR	National Vascular Registry commissioned by the Healthcare Quality Improvement Partnership in collaboration with the Vascular Society.
PAD	Peripheral arterial disease, occlusive atheromatous disease of the lower limb arteries leading to intermittent claudication, delayed wound healing, ulceration and amputation.
POVS	Provision of Vascular Services, Vascular Society (VS) guidance on service delivery.
QIF	Quality improvement framework
StAMP	A Best Practice Clinical Care Pathway for Major Amputation Surgery. VSGBI Publication 2016.
SVS	Society of Vascular Surgery (United States of America)
VS	Vascular Society
WIfI	Society of Vascular Surgery 'Threatened Lower Limb Extremity Classification of chronic limb threatening ischaemia'. This classification incorporates the severity of wounds (0-3), degree of ischaemia (0-3) and degree of foot infection (0-3).

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