

A Best Practice Clinical Care Pathway for Peripheral Arterial Disease

March 2019

**“Urgent vascular care delivered by
integrated vascular networks.”**

Introduction

The Vascular Society of Great Britain and Ireland (VSGBI) has developed this quality improvement framework (QIF) to respond to recommendations made in the vascular surgery GIRFT programme report (2018).

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 an 800,000 population should see approximately one presentation with critical limb ischaemia (CLI) and five presentations with diabetic foot problems every day. (POVS 2018)

23,000 lower limb revascularisation procedures are performed each year in the UK. These are the most frequent arterial interventions performed by vascular surgeons and interventional radiologists. (NVR 2018)

5-6,000 major lower limb amputations are performed in the NHS each year for complications of peripheral arterial disease and/or diabetes. (POVS 2018)

The vascular GIRFT visits found that the delivery of revascularisation in CLI is inconsistent across the UK, in terms of service provision, length of hospital stays and patient outcomes. (VASCULAR GIRFT 2018)

GIRFT reported universally unacceptable pathway delays to revascularisation. Furthermore, supervised exercise for intermittent claudication cannot be accessed in many parts of the UK.

This VSGBI QIF has been 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.

Critical limb 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, multi-disciplinary care pathways that include timelines to access urgent care for CLI.

In some regions, reorganisation, based upon the network model described in the VSGBI's Provision of Vascular Services documents will be needed.¹

In all regions, vascular network leads will need to work with hospital trusts, clinical commissioning groups (CCGs) 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.

¹ https://www.vascularsociety.org.uk/_userfiles/pages/files/Document%20Library/VS%202018%20Final.pdf

Best practice

Peripheral Arterial Disease

- First line management for people with PAD is cardiovascular risk factor modification (page 10).
- Arterial networks should provide education for patients, GPs, community nurses and podiatrists in the diagnosis and treatment of PAD.
- Community access to ankle brachial pressure index (ABPI) 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 improves claudication symptoms.
- Exercise therapies may also be beneficial in the management of other cardiovascular risk factors, such as obesity, hypertension and cholesterol.
- Failure to respond to medical therapy and exercise may lead the clinician and patient to consider referral to a vascular specialist for consideration of **Angioplasty or bypass surgery** - options available through the lower limb multi-disciplinary team (MDT).
- **Naftidrofuryl oxalate** is an option when there is no easy revascularization 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.

Critical limb ischaemia

CLI is the advanced stage of PAD

Blood supply to the foot is insufficient for the needs of the tissues. European consensus definition is 'persistently recurring rest pain requiring analgesia for more than 2 weeks OR ulceration OR gangrene of the foot or toes; AND ankle pressure < 50mmHg and/or toe pressure <30mmHg.'

- 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 a multi-professional team, the lower limb MDT (page 5) available 24/7.
- Open bypass surgery must be delivered in vascular network arterial centres.
- Endovascular therapy maybe best delivered through day care, either at the arterial centre or at a networked hospital depending on network arrangements and geography.

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.

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.
4. Every patient receives a **multi-specialty assessment**, including **shared decision making** over treatment options.

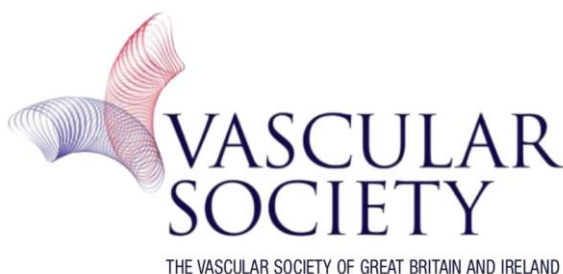
Admitted patient - severe critical limb ischaemia and/or foot sepsis



Non-admitted patient - stable disease, such as mummified toes



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



The 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 their patients with peripheral arterial disease.

Multi-disciplinary lower limb team

- This model of care borrows from the one successfully implemented by multi-disciplinary diabetic foot care teams

Core members
<p>Formal lower limb MDT meeting</p> <p>Vascular surgeon - <i>at least two</i></p> <p>Interventional radiologist - <i>at least two</i></p> <p>Vascular nurse specialist</p> <p>Vascular anaesthetist</p> <p>Consultant in care of elderly and frailty</p> <p>Vascular scientist</p> <p>MDT administrator</p>
<p>Regular professional working</p> <p>Podiatrist</p> <p>Vascular ward & IR day care unit nurses</p> <p>Vascular ward and amputee therapists</p> <p>Nutrition team</p> <p>Diabetes specialist nurse</p> <p>Waiting list coordinator - <i>or equivalent</i></p> <p>Discharge coordinator - <i>or equivalent</i></p>

Input available from
<p>Acute pain team</p> <p>Acute medicine</p> <p>Cardiology</p> <p>Respiratory medicine</p> <p>Renal, including access to dialysis</p> <p>Endocrinology</p> <p>Plastic surgery – <i>for skin cover</i></p> <p>Orthotics</p> <p>Microbiology</p> <p>Tissue viability nurse</p> <p>Amputation councillor</p> <p>Rehabilitation consultant</p> <p>Palliative care team</p> <p>Network manager</p>

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, IM&T and AV support.
- 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 non-arterial networked hospitals.
- Specialist submitting patient is responsible for providing minimum data set for patient to be discussed.
- Limb assessment using a standardised classification system, such as Wifl, 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 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 on occasion discussion of a patient will occur after treatment.

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

Pre-intervention assessment

- A multi-specialty multi-professional approach to care is required
 - patients with CLI are often elderly, nutritionally deficient and may be frail.
 - patients often have cardiac, renal and respiratory disease, and diabetes.
- A well-prepared patient is likely to have a better outcome
 - fewer complications;
 - fewer days of hospital stay;
 - less chance of early readmission.
- A patient for open, including 'hybrid', revascularisation should be reviewed in a specialist clinic, or on the ward, by
 - **Consultant anaesthetist;**
 - **Consultant in care of elderly and frailty**, if elderly or frail;¹
 - **Dietician**, if nutritionally deficient.
- A patient for endovascular therapy can be either assessed as for open surgery or be telephone assessed according to agreed written network protocols.
- The aims of these assessments are
 - risk assessment, including frailty;
 - referral and optimisation of coexisting medical conditions;
 - 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. (RCA 2019) ²

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.

² <https://www.rcoa.ac.uk/document-store/guidance-the-provision-of-vascular-anaesthesia-services-2019>

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.
- Nurses, physiotherapists and amputee councillors have an important role in exploring patient understanding and concerns; this will also ease anxiety.
- Provide written patient information on options, benefits, risks and recovery.

Hospital admission

- Arterial centre must have sufficient bed capacity for new admissions and transfer from networked hospitals.
- Antibiotics should be prescribed according to microbiology protocols. -
 - in the case of diabetic foot disease, in collaboration with the MDFT.
- Screen for infections (i.e. MRSA).
- Provide venous thrombo-embolism assessment and prophylaxis.
- Provide adequate pain control.
- Provide a pressure area assessment, including pressure off-loading.

Revascularisation

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 procedure 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 occasions.
- Be cognisant of endovascular alternatives and adjuvants; use hybrid theatre if these may be required.

Endovascular procedures

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

Endovascular procedures may be performed via a day care unit.

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

Post-procedure

- Patient nursed in areas with the expertise to assess limb perfusion and identify complications early.
- Clear plan documented for
 - Anti-thrombotic medication; (*medication prescribed and duration*)
 - GP and community nurses; (*medication and wound care*)
 - MDFT and foot protection teams. (*wound care and/or foot protection*)
- Patient 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
 - Specialist vascular ward nursing;
 - 24/7 surgical cover, with access to a staffed emergency (hybrid) theatre;
 - 24/7 IR cover, with access to a staffed IR room 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**, consultant should review pre-discharge.

Recovery

- Access to early specialist vascular review, including for patients repatriated to networked hospitals.
- If open wound, follow up in a multi-disciplinary wound care clinic or by specialist community nursing teams.
- Evidence based graft surveillance and prescribe anti-thrombotic therapy.
- Longer term follow-up, including formal surveillance for lower limb bypass grafts, is recommended.
 - Consider also after complex infra-inguinal endovascular procedure.

Audit

- Vascular networks should have a nominated clinical governance lead.
- Vascular networks should have admin support to improve NVR data quality.
- Job plans should include contracted time for outcome reporting and audit.
- National vascular registry (NVR)
 - report all lower limb procedures; surgery, endovascular and 'hybrid' procedures and amputation;
 - include all day case procedures.
- Reporting ipsilateral amputations following revascularisation allows the NVR to report amputation free survival.

Annual network NVR data should be reviewed locally to determine where improvements can be made.

Acute diabetic foot

- Initial assessment will 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 CLI).
- 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 StAMP** 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

QIF standards

Management of people with peripheral arterial disease	Target
Commissioned stop smoking services for people diagnosed with PAD	100%
Commissioned supervised exercise therapy for people diagnosed with IC ¹	> 90%
Peripheral MDT core team (see page 5) quorate at formal MDT meetings (<i>over 12 months</i>)	> 95%
WIFI, or equivalent, classification system documented in patient medical record for CLI	> 80%
Peripheral MDT discussion documented in patient medical record	100%
Evidence of shared decision making in patient medical record	> 80%
Written patient information provided	100%
Consultant anaesthetist pre-assessment before open surgical procedures	100%
Consultant in care of elderly and frailty assessment of frail or elderly patients	> 80%
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%
Post revascularisation assessment of procedural success	100%
NVR submission for bypass, angioplasty and major amputation procedure	100%

¹ Within 1 hours travel time, except in remote rural areas of the UK and Ireland.

Referral to secondary care for critical limb ischaemia	Timescale Compliance > 80%	Source
Referral to vascular specialist Triage of referral by vascular specialist	Same day One working day	POVS NHSE

'Admitted' patient pathway

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

From receipt of referral

Admission or transfer to network arterial centre	≤ 2 days ¹	StAMP POVS
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From hospital admission

Cross-sectional imaging with CTA or MRA	≤ 12 hours	NHSE NCEPOD
Vascular surgeon 'face to face' review	≤ 14 hours	

Revascularisation	≤ 5 days ³	POVS
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'Non-admitted' patient pathway

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

From receipt of referral

Vascular surgeon 'face to face' review	≤ 7 days ²	POVS
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From review by specialist

Cross-sectional imaging (CTA or MRA)	≤ 7 days	POVS
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Revascularisation	≤ 14 days ³	POVS
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¹ 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.

² Achieving this target requires the provision of urgent ('hot') outpatient appointments with clearly defined pathways for urgent imaging, admission and revascularisation if indicated.

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. Forms of behavioural counselling in combination with medications such as varenicline are the most effective smoking cessation strategies.

<https://cks.nice.org.uk/smoking-cessation>

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. <https://cks.nice.org.uk/antiplatelet-treatment>
The Compass trial has more recently shown benefit from rivaroxaban 2.5mg BD plus Aspirin.

Lipid modification, patients should be offered secondary prevention with high intensity statin treatment e.g. atorvastatin 80mg OD, if tolerated. Prior to statin initiation, identify and treat causes of secondary hyperlipidaemia, 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 full lipid profile (cholesterol, HDL, Non-HDL, TG and CK, LFTs, renal function, liver function and HbA1c). Check cholesterol after 3 months, aiming for a reduction in non-HDL-cholesterol of >40%. Check LFTs at 3 and 12 months. Thereafter, yearly check lipids and review for side effects of statins. <https://cks.nice.org.uk/lipid-modification-cvd-prevention>

Weight management, if Body Mass Index is > 25, consider referral for dietary advice and provide a goal for weight loss.

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.

<https://cks.nice.org.uk/diabetes-type-1>

<https://cks.nice.org.uk/diabetes-type-2>

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, aim for blood pressure of <150/90 mmHg. If blood pressure is elevated, recommend smoking cessation and reduce 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 is an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB) if tolerated. First line for older adults, or Afro-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. Reduce foods high in fat, sugar and salt.

<https://cks.nice.org.uk/obesity#scenario>

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

Abbreviations

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.
CLI	Critical limb ischaemia. The new global vascular guidelines use the term CLTI (Chronic limb-threatening ischaemia) and the European Society of Vascular Surgery use LEAD (Lower extremity arterial disease).
CTA	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.
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 'Get it Right First Time' programme. The vascular surgery programme is 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 of Great Britain and Ireland.
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 (VSGBI) guidance on service delivery.
QIF	Quality improvement framework
StAMP	A Best Practice Clinical Care Pathway for Major Amputation Surgery. VSGBI Publication 2016.
VSGBI	Vascular Society of Great Britain and Ireland
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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