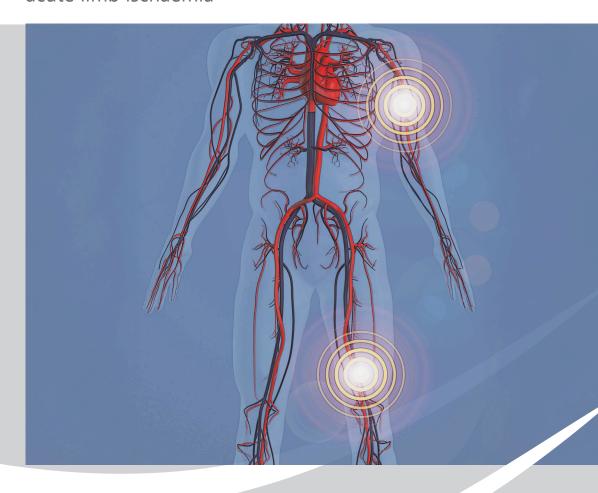
Risking Life and Limb A review of the quality of the care provided to adults with

acute limb ischaemia





RISKING LIFE AND LIMB

A review of the quality of care provided to adults with acute limb ischaemia (ALI)

A report published by the National Confidential Enquiry into Patient Outcome and Death (2025)

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Cohort: Adults over the age of 18 years who were admitted to a vascular hub as an emergency between 1st January 2023 and 31st March 2023 for the treatment of ALI.

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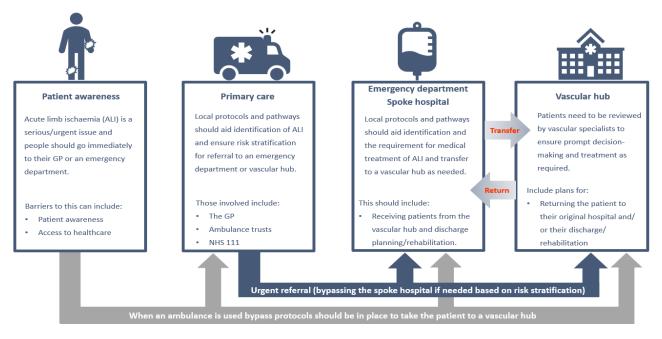
PATHWAYS OF CARE – TO SET THE SCENE



Vascular networks are organised on a hub and spoke model with 58 vascular hubs and 134 spoke hospitals across England, Wales, Northern Ireland and Jersey. Vascular hubs and spoke hospitals will be used as the terminology throughout the report, but vascular hubs may also be called vascular centres or arterial centres and spoke hospitals may be called network hospitals or non-arterial centres. Spoke hospitals are those where a patient might present as there is an emergency department, but there are no 24/7 inpatient specialist vascular services.

Click here or on the map for more details about vascular networks.

The treatment of ALI first relies on the patient recognising the severity of their symptoms and then seeking medical assistance. Patients may present to primary care services, call NHS 111, call an ambulance or self-present to the emergency department at their closest hospital (which may be a vascular hub or a spoke hospital). Some may present directly to the vascular hub, knowing that it provides vascular surgical services. If an ambulance is called, it may take patients directly to a vascular hub because it is the closest hospital or by activating bypass protocols. These complex referral and transfer processes increase the risk of delays in triage, diagnosis and imaging and missed opportunities for timely initial treatment as well as transfer to the vascular hub.



The pathway of care for patients with acute limb ischaemia

NOTES FOR READERS

Signs of acute limb ischaemia - the '6Ps'

The possible signs of acute limb ischaemia are grouped into a phrase known as <u>the '6Ps'</u> and can be used to help diagnose the condition. Although it should be noted that younger people and those without all the defined six signs can still have ALI.

Pain - constant, usually unrelieved by over-the-counter analgesics

Pallor (or cyanosis or mottling)

Paraesthesia or reduced sensation or insensate limb

Paralysis or reduced power

Perishingly cold (poikilothermia)

Pulselessness - ankle pulses are always absent

The Rutherford classification

This is a system used to categorise the severity of acute limb ischaemia once it has been diagnosed.

Grade	Category	Sensory loss	Motor deficit	Prognosis
1	Viable	None	None	No immediate threat
lla	Marginally threatened	None or minimal (toes)	None	Salvageable if promptly treated
IIb	Immediately threatened	More than toes	Mild/moderate	Salvageable if promptly revascularised
III	Irreversible	Profound, anaesthetic	Profound, paralysis	Major tissue loss amputation. Permanent nerve damage inevitable

LINKS TO ADDITIONAL REPORT SECTIONS

GLOSSARY

REFERENCES

ACKNOWLEDGEMENTS

USEFUL RESOURCES ON THIS TOPIC

IMPLEMENTATION SUGGESTIONS FOR THE RECOMMENDATIONS

ALL THE FIGURES AND TABLES IN THIS REPORT

ADDITIONAL INFORMATION IN CHAPTERS 2 to 11 AS ONE DOCUMENT

QI TOOLS FOR THIS STUDY

INTRODUCTION FROM OUR CHAIR

(BACK TO CONTENTS)

Acute limb ischaemia (ALI) is a sudden decrease in limb perfusion that threatens the viability of the limb and is a vascular emergency. It is highly treatable if diagnosed and treated promptly; delay can result in permanent disability, amputation or death. The scale of the problem is unknown as there is no consistent coding of ALI. There is a misconception that ALI is most common in older people, but this study found that the mean age was 70, with a quarter being 60 years or younger.

The most used scoring system for the severity of ALI, the Rutherford classification, has four categories (I, IIa, IIb and III). The most critical is IIb, where there is an immediate but potentially reversible threat to the viability of the limb if the target of revascularisation within six hours is not met. This requires patients to recognise the potential severity of their symptoms and seek medical attention, and healthcare professionals to make the diagnosis and treat the condition rapidly, with prompt admission or transfer to a vascular centre. Assessing patients for the '6Ps' (pain, pallor, paraesthesia, paralysis, perishingly cold and pulselessness) is essential, although not all must be present to diagnose ALI. This report found inconsistent recording of the '6Ps', with peripheral pulses being recorded in primary care in only a third of patients.

Over 90% of patients in this study had associated comorbidities (coexisting medical conditions) such as hypertension, atrial fibrillation, peripheral vascular disease and diabetes, with over 70% having multiple conditions. Almost 80% of people with ALI were current or ex-smokers. Treating these comorbidities, giving lifestyle advice and warning high-risk patients of the symptoms of ALI can help reduce the risk of ALI and ensure that people seek medical attention early.

Delays in seeking or accessing medical advice can have serious consequences for patients with ALI. It is vital that healthcare professionals triaging patients are aware of the symptoms and signs of ALI and the need for prompt treatment, ideally in a vascular centre. Vascular services are provided on a hub and spoke model, with patients presenting to spoke hospitals being transferred to vascular hubs for specialist treatment. This can add delay, making it even more important that these patients are identified quickly and prompt transfer is arranged. It is vital that supportive treatment, including anticoagulation, intravenous fluids and oxygen are started as soon as possible, and that patient records and imaging can be transferred easily.

National guidance, reporting standards, comprehensive data collection and a quality improvement framework for the treatment for ALI are recommended to improve outcomes.

I am grateful to everyone involved in developing and carrying out this study and those involved in writing the report and its recommendations.



Dr Suzy Lishman CBE, NCEPOD Chair

ACUTE LIMB ISCHAEMIA IS A SUDDEN LOSS OF BLOOD FLOW TO AN ARM OR LEG. IT IS TREATABLE IF DIAGNOSED VERY QUICKLY; DELAY CAN CAUSE PERMANENT DISABILITY, AMPUTATION OR DEATH.

TO IMPROVE THE CARE PROVIDED TO PATIENTS WITH ACUTE LIMB ISCHAEMIA...

We reviewed the care of patients who were admitted to a vascular hub as an emergency, between 1st January 2023 and 31st March 2023 for treatment of ALI was reviewed using 330 sets of secondary care case notes, 111 primary care case notes, 293 clinician questionnaires and 105 spoke/51 vascular hub organisational questionnaires.



Recognise acute limb ischaemia and what prompt actions to take to reduce any delay in treatment and potentially save the limb.

Delays occurred throughout the patient pathway due to a lack of recognition of the symptoms of acute limb ischaemia by both healthcare professionals and patients with the condition.

Delays to presentation were common with 144/283 (50.9%) patients presenting more than 24 hours after the onset of their symptoms.

There were missed opportunities to recognise ALI prior to admission, most commonly due to a lack of patient awareness (82/115; 71.3%) and/or recognition in primary care (24/115; 20.8%).



Refer or transfer patients with new or worsening symptoms of acute limb ischaemia who are at high risk of losing their limb directly to a vascular hub.

Patients most likely to benefit from an intervention (Rutherford category IIb) were not always directed to a vascular hub, delaying their treatment beyond the accepted target of six hours.

The median time from arrival at the spoke hospital to arrival at the vascular hub was 8.16 hours, exceeding the time from development of symptoms to treatment target for immediately threatened limbs.

Using an ALI pathway in the vascular hub appeared to have a positive impact on care by reducing review delays.



Organise vascular networks to provide timely access to vascular specialists skilled in treating people with acute limb ischaemia.

Networks were underused and nonvascular specialists reported not being confident to treat patients in the spoke hospitals but had no formal transfer option to the vascular hub. There were 34/91 spoke hospitals in which medical records could be shared electronically and 56/91 in which images could be shared immediately. All other systems that were described, such as email and paper copies, risk delays or other harm.

In total, 138/330 (41.8%) patients attended a spoke hospital and were then transferred to a vascular hub.



Develop a national guideline for the management of acute limb ischaemia.

There is no national guideline covering the care pathways between primary care, spoke hospitals and vascular hubs for patients with acute limb ischaemia. Written guidance specific to the management of suspected ALI was available in only 56/91 spoke hospitals, and when it did exist key components were often missing. Using an ALI pathway in the vascular hub appeared to have a positive impact on care: 3/46 (6.5%) patients experienced a delay on an ALI pathway compared to 18/165 (10.9%) not on a pathway.

Capture focused data on acute limb ischaemia, to report on procedures and outcomes for patients with ALI.



There is no clinical code for acute limb ischaemia and no registry to record data locally, therefore the true number of patients with ALI is unknown, leading to an absence of data to promote improvement in patient outcomes.

Only 22/47 vascular hubs stated they recorded data on surgical procedures and 19/42 on interventional radiological procedures.

The use of prospectively collected data for shared learning was uncommon with most learning occurring in morbidity and mortality meetings or due to reported adverse events.

RECOMMENDATIONS

These recommendations have been formed by a consensus exercise involving all those listed in the acknowledgements. The recommendations have been independently edited by medical editors experienced in developing recommendations for healthcare audiences to act on.

	Raise awareness of acute limb ischaemia, how to recognise it and what actions to take to reduce delays in the treatment pathway.	
1	 Raise awareness with patients and the public about the symptoms and who to contact. Raise awareness with healthcare professionals in primary care, community care and all emergency departments (vascular hubs and spoke hospitals). Note: younger people and those without all of the defined six symptoms of ALI (Pain, Pallor, Paraesthesia, Paralysis, Perishingly cold, Pulselessness - the '6Ps') can still have ALI. 	
RATIONALE FOR THE RECOMMENDATION	Delays occurred throughout the patient pathway due to a lack of recognition of symptoms of acute limb ischaemia by the patients and delays in recognition and diagnosis of acute limb ischaemia on behalf of the healthcare professionals. Delays can lead to amputations and should be avoided wherever possible.	
	PATIENT AND PUBLIC AWARENESS	
FOR ACTION BY	The Office for Health Improvement and Disparities (previously Public Health England), Public Health Wales, Public Health Agency Northern Ireland, Public Health Jersey.	
	CLINICAL AWARENESS Commissioners (including NHSE Vascular Services clinical reference group) and integrated care boards in discussion with their trusts/health boards.	
ADDITIONAL STAKEHOLDERS	Vascular Society, British Society of Interventional Radiology, NHS 111, Royal College of Surgeons of England, Royal College of Anaesthetists, Association of Surgeons of Great Britain and Ireland, Association of Anaesthetists, Royal College of General Practitioners, Royal College of Emergency Medicine, Royal College of Physicians, Royal College of Radiologists, British Society of Endovascular Therapy, Association of Ambulance Chief Executives, Joint Royal Colleges Ambulance Liaison Committee, Royal College of Nursing, Diabetes UK, Legs Matter, The Patients Association.	
	NHSE: PERIPHERAL ARTERIAL DISEASE, AN OVERVIEW	
ASSOCIATED GUIDANCE	NHSE: COMPLICATIONS OF TYPE 2 DIABETES PATIENT INFO: LIMB EMBOLISM AND ISCHAEMIA ROYAL COLLEGE OF EMERGENCY MEDICINE: ACUTE LIMB ISCHAEMIA LEGS MATTER: ACT NOW TO SAVE LIMBS AND LIVES	
IMPLEMENTATION SUGGESTIONS: CLICK HERE		

2	Risk stratify and refer/transfer patients with symptoms of acute limb ischaemia and new sensory or motor impairment* directly to a vascular hub. *These would be patients with a Rutherford IIb category, affecting more than the toes See also recommendation 3
RATIONALE FOR THE RECOMMENDATION	Patients likely to benefit most from an intervention (Rutherford category IIb) were not always directed to a vascular hub, causing a delay in their treatment beyond the accepted target of six hours. Furthermore, the Rutherford classification was rarely used outside of vascular hubs. This also links with recognition in recommendation 1.
FOR ACTION BY	Commissioners and integrated care boards in discussion with their trusts/health boards.
ADDITIONAL STAKEHOLDERS	Vascular Society, British Society of Interventional Radiology, Royal College of Surgeons of England, Royal College of Anaesthetists, Association of Surgeons of Great Britain and Ireland, Association of Anaesthetists, Royal College of General Practitioners, Royal College of Emergency Medicine, Royal College of Physicians, Royal College of Radiologists, Royal College of Nursing, Association of Ambulance Chief Executives, Joint Royal Colleges Ambulance Liaison Committee.
ASSOCIATED GUIDANCE IMPLEMENTATION SUG	 NICE CLINICAL KNOWLEDGE SUMMARY: ACUTE LIMB ISCHAEMIA VASCULAR SOCIETY: PROVISION OF SERVICES FOR PEOPLE WITH VASCULAR DISEASE 2024 BRITISH SOCIETY OF INTERVENTIONAL RADIOLOGY: PROVISION OF INTERVENTIONAL RADIOLOGY SERVICES 2023 ROYAL COLLEGE OF EMERGENCY MEDICINE: ACUTE LIMB ISCHAEMIA GESTIONS: CLICK HERE

3	Organise vascular networks to provide timely access to vascular specialists skilled in treating people with acute limb ischaemia.
RATIONALE FOR THE	Networks were under used and non-vascular specialists reported not being
RECOMMENDATION	confident to treat patients in the spoke hospitals but had no formal transfer
	option to the vascular hub.
FOR ACTION BY	Commissioners and integrated care boards in discussion with their trusts/health
TOR ACTION DI	boards.
	Royal College of Surgeons of England, Vascular Society, British Society of
	Interventional Radiology, Royal College of Anaesthetists, Association of Surgeons
ADDITIONAL	of Great Britain and Ireland, Association of Anaesthetists, Royal College of
STAKEHOLDERS	General Practitioners, Royal College of Emergency Medicine, Royal College of
	Physicians, Royal College of Radiologists, Association of Ambulance Chief
	Executives, Joint Royal Colleges Ambulance Liaison Committee.
ASSOCIATED	VASCULAR SOCIETY: PROVISION OF SERVICES FOR PEOPLE WITH VASCULAR
GUIDANCE	<u>DISEASE 2021</u>

•	BRITISH SOCIETY OF INTERVENTIONAL RADIOLOGY: PROVISION OF
	INTERVENTIONAL RADIOLOGY SERVICES 2023

IMPLEMENTATION SUGGESTIONS: CLICK HERE

4	Develop a national guideline for the management of acute limb ischaemia.
RATIONALE FOR THE RECOMMENDATION	There is no national guideline covering the care pathway for patients with, or at risk of ALI from primary care to spoke hospital to vascular hubs. In addition, there is no national data collection system and no quality improvement framework. In severe cases (Rutherford IIb), patients need to be treated by specialist staff within six hours of their symptoms appearing.
FOR ACTION BY	The Vascular Society with the British Society of Interventional Radiology.
ADDITIONAL STAKEHOLDERS	Royal College of Surgeons of England, Royal College of Anaesthetists, Association of Surgeons of Great Britain and Ireland, Association of Anaesthetists, British Society for Haematology, Royal College of General Practitioners, Royal College of Emergency Medicine, Royal College of Physicians, Royal College of Radiologists, British Society of Endovascular Therapy, Association of Ambulance Chief Executives, Joint Royal Colleges Ambulance Liaison Committee.
ASSOCIATED GUIDANCE	 NICE CLINICAL KNOWLEDGE SUMMARY: ACUTE LIMB ISCHAEMIA VASCULAR SOCIETY: PROVISION OF SERVICES FOR PEOPLE WITH VASCULAR DISEASE 2024 BRITISH SOCIETY OF INTERVENTIONAL RADIOLOGY: PROVISION OF INTERVENTIONAL RADIOLOGY SERVICES 2023
IMPLEMENTATION SUG	GESTIONS: <u>CLICK HERE</u>

	Support the national vascular registry to capture focused	
	data on acute limb ischaemia, and to report on procedures	
5	and outcomes for patients with ALI*	
	*ICD-11 will be mandated in the UK in the next five years and has codes for upper and lower ALI that will allow data comparisons with the national vascular registry data and national patient episode data, unlike ICD-10 where ALI is coded with chronic limb-threatening ischaemia.	
RATIONALE FOR THE	There is no UK data collection (registry) on acute limb ischaemia. This needs to	
RECOMMENDATION	be in place to monitor and improve outcomes and allow benchmarking for quality	
RECOMMENDATION	improvement.	
	Funders and commissioners of the national vascular registry, working with the	
FOR ACTION BY	Royal College of Surgeons of England and partners as the current contract holder	
	for the registry.	
ADDITIONAL	Vascular Society, British Society of Interventional Radiology, NHSE Vascular	
STAKEHOLDERS	Services Clinical Reference Group, Vascular Anaesthetic Society of Great Britain	
STAKEHOLDERS	and Ireland	
ASSOCIATED	■ EUROPEAN SOCIETY FOR VASCULAR SURGERY (ESVS) 2020 CLINICAL PRACTICE	
GUIDANCE	GUIDELINES ON THE MANAGEMENT OF ACUTE LIMB ISCHAEMIA	
IMPLEMENTATION SUGGESTIONS: CLICK HERE		

SUGGESTIONS FOR FUTURE RESEARCH

- Anticoagulation options for patients not requiring immediate/early revascularisation
- Assessment of the impact of ethnicity, body mass index (BMI), alcohol consumption, and cognitive baseline on outcomes (not collected in the National Vascular Registry)
- Variation in outcomes by socioeconomic status/postcode
- > The impact of vaping and electronic tobacco products on cardiovascular disease in general
- The role of endovascular embolectomy/thrombectomy systems to establish their role and cost effectiveness
- Improved risk stratification system for patients with acute limb ischaemia
- Collection of acute limb ischaemia patient reported outcomes.

ONGOING RESEARCH TO NOTE

- The <u>ESTAbLIsh Trial</u>, a randomised controlled trial comparing open surgical to endovascular treatment for people with ALI, will run from 4/5/26 for two years
- Medical management after acute limb ischaemia using <u>Cardiovascular Outcomes for People Using Anticoagulation Strategies (the COMPASS Trial)</u> vs subgroup focused.

1 METHODS

DETAILED FINDINGS ABOUT THE METHODS ARE AVAILABLE HERE

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Study advisory group

A multidisciplinary group of clinicians was convened to steer the study from design to completion, define the objectives of the study and advise on the key questions. The group comprised lay and patient representatives and healthcare professionals in vascular surgery, interventional radiology, vascular nursing, general nursing, anaesthesia, diabetes care, emergency medicine, haematology and general practice.

Study aims and objectives

The objectives of the study were to explore the current care pathways for patients with acute limb ischaemia (ALI) to identify the remediable clinical and organisational factors that could improve ALI care.

Study population and case ascertainment

Inclusion criteria

Adults over the age of 18 years who were admitted to a vascular hub as an emergency, between 1^{st} January 2023 and 31^{st} March 2023 for treatment of ALI.

Exclusion criteria

Patients who received only anticoagulation or palliative care at a spoke hospital.

Identification of a sample population

The incidence of ALI is unknown as there is no ICD-10 code for ALI. The identification of ALI was made more challenging by its many modes of presentation and breadth of treatment options, which are often used to treat chronic limb-threatening ischaemia. A local study contact (vascular surgeon or vascular radiologist) had to screen patient notes to identify those with acute limb ischaemia from those with chronic limb-threatening ischaemia. Patients were randomly selected from this sample.

Data collection

- A clinician questionnaire was sent to the named vascular surgeon.
- > A primary care questionnaire was sent to the listed GP surgery for each included patient.
- A vascular hub or spoke hospital organisational questionnaire was used to collect data on the organisational structures in place to deliver the service to patients who have ALI.
- ➤ Copies of the case notes were requested for the included admission for peer review by a multidisciplinary group of case reviewers.
- > Surveys were completed anonymously by patients and healthcare professionals.

Data analysis rules

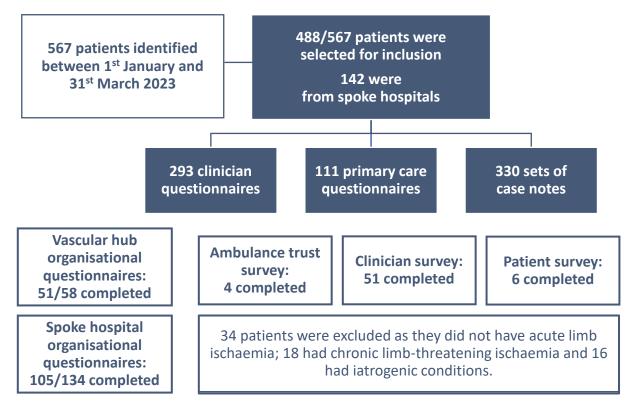
- > Small numbers have been suppressed if they risk identifying an individual (usually <3-5)
- Any percentage under 1% has been presented in the report as <1%</p>
- Percentages were not calculated if the denominator was less than 100 so as not to inflate the findings, unless to compare groups within the same analysis
- There will be variation in the denominator for different data sources and for each individual question as it is based on the number of answers given.

2 DATA RETURNED AND THE STUDY POPULATION

DETAILED FINDINGS ARE AVAILABLE HERE

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Data returned



- ➤ It is widely believed that acute limb ischaemia (ALI) predominantly occurs in older people. However, in this study, 70/290 (24.1%) patients were 60 years or younger and 92/290 (31.7%) were of working age (65 or younger) (F2.1). These data highlight that age should not be a factor to exclude ALI in any adult with an acutely painful limb and highlights the need for a national registry for ALI to better understand the population and their needs.
- There were 260/268 (81.7%) patients in the study sample who were White. It is not believed that this dataset has under recorded the incidence of ALI in Black and ethnic minority patients (T2.1) but longer-term population data would confirm this. Ethnicity is not currently recorded in registries such as the National Vascular Registry nor in hospital episode statistics recorded in secondary care but is available from primary care datasets.
- Comorbidities (coexisting medical conditions) associated with an increased risk of ALI, or which might contribute to delayed presentation, were present in 257/290 (88.6%) patients, with 212/290 (73.1%) patients having more than one (F2.2).
- Almost a quarter of patients presenting with ALI had type 2 diabetes mellitus, while type 1 was much less associated. Excessive alcohol use, illicit drug use, mental health issues or dementia are likely to affect compliance with medication or delay presentation to healthcare providers (F2.2). One or more of these factors was identified in 46/293 (15.7%) patients.

- In total, 211/293 (72.0%) patients were taking one or more than one medication, including 24.9% (73/293) who were taking anticoagulants (T2.2).
- In this study 117/266 (44.0%) patients were current smokers and 94/265 (35.5%) were ex-smokers, underscoring the importance of smoking as a risk factor for ALI (T2.3).
- Prior to the hospital admission with ALI, 261/282 (92.6%) patients were living in their own home (T2.4). Where the data were available, the majority of patients were managing without additional social support or care (189/261; 72.4%).
- There were 162/330 (49.1%) patients were fit, well or managing well prior to their admission (F2.3).
- In total, 34/305 (11.1%) patients had communication difficulties comprising language (10), hearing (8), learning disability/difficulties (5) and post-stroke impairments (4), which may make it harder to communicate symptoms of ALI quickly (T2.5).
- The majority of patients in the study had a lower limb affected with ALI (303/330; 91.8%) (T2.6). Most patients had only one limb affected, but a small number had more than one limb affected (F2.4).
- This admission was the first episode of ALI for 241/293 (82.3%) patients, but 25/293 (8.5%) had experienced an episode of ALI in the previous ten years (history of ALI was unknown for 27 patients). There were 60/293 (20.5%) patients who had undergone previous surgical or endovascular revascularisation procedures for ALI or peripheral artery disease (PAD) and 11/293 (3.75%) patients who had undergone a previous amputation. Monitoring ALI procedures and outcomes at a national level would provide a benchmark for assessing readmissions/recurrence of disease.
- The majority of patients had no ischaemic symptoms in the presenting limb before this presentation (178/293; 60.8%), but these are often mild and the clinicians in the vascular hub identified 109/293 (37.2%) patients with symptoms of chronic PAD in the presenting limb (T2.7).
- In this study, only 11 patients in total and six patients with symptomatic PAD were taking a direct oral anticoagulant (DOAC) and antiplatelet agent. Irrespective of whether intervention is a consideration, patients with chronic PAD should be offered appropriate medical management, in addition to promoting healthy behaviours, to reduce life and limb-threatening events. This study suggests that such simple preventative strategies are not well embedded in the current management of PAD.
- Seeing a patient with chronic PAD in clinic offers valuable educational opportunities. These include provision of information on the symptoms of ALI and who to contact, and empowering patients to present rapidly to the vascular hub if they develop loss of sensation and or movement in association with acute limb pain.

3 THE SEVERITY OF ACUTE LIMB ISCHAEMIA

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The first-line treatment for acute limb ischaemia, unless the patient needs palliative care only, <u>is</u> <u>anticoagulation</u>, <u>intravenous</u> (IV) <u>fluids and supplemental oxygen</u>. <u>Analgesia is also essential</u>, <u>with involvement of the acute pain team as needed</u>.

Once a diagnosis has been made, the urgency of treatment is determined by whether there is newly altered sensation and/or movement in an acutely painful limb. This simple assessment can be carried out by all healthcare professionals, including nurses and allied health professionals.

To understand the urgency and quantify the severity of a patient's condition to facilitate communication between healthcare professionals the Rutherford classification is used (T3.1).

The ESVS 2020 ALI guideline made some minor modifications to the original Rutherford classification. The full classification includes the use of handheld arterial and venous Doppler, an assessment tool generally only used by vascular specialists.

Distinguishing between the classifications of Rutherford IIa and IIb, and between IIb and III, can sometimes be challenging. Not all patients with ALI require revascularisation or amputation. Some will be appropriately treated with anticoagulation alone (primarily those with ALI, Rutherford I).

The Rutherford category may deteriorate, particularly with delays to treatment, as the lack of blood supply causes tissue and nerve damage. Without treatment Rutherford IIa ALI will usually progress to IIb and then III. Patients with ALI categorised as Rutherford IIb the accepted plan is that patients require revascularisation as soon as possible and ideally within six hours for fully functional limb salvage.

Compartment syndrome where swollen muscles compress the arterial supply and venous drainage is related to the severity and duration of ALI. It may be aggravated by revascularisation and increases the risks of amputation, muscle necrosis and nerve damage. Performing a fasciotomy can relieve the compartment pressure but should be performed within two hours; waiting longer than six hours is not acceptable practice as fasciotomies are not without risk and compilations can include infection, and the need for skin grafts.

4 TIME FROM SIGNS AND SYMPTOMS TO PRESENTATION

DETAILED FINDINGS ABOUT THIS AREA OF CARE ARE AVAILABLE HERE

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CASE STUDY – GOOD CARE

A patient who developed acute calf and foot pain overnight called 999 the following morning. The ambulance paramedics who attended, suspected ALI with decreased ankle movement and sensory impairment. The patient was transferred directly to a vascular hub where they were seen within two hours of the initial presentation and underwent revascularisation within four hours of the initial presentation.

The reviewers considered that this was good care with an effective bypass protocol in place to direct ambulances straight to the vascular hub when needed.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with a history of chronic limb-threatening ischaemia, smoking and excessive alcohol use presented to their local emergency department (ED) after five days of sudden onset severe pain in their left leg. The assessment in the ED took over three hours. They were initially misdiagnosed, and it took a further 12 hours before a referral was made to the nearest vascular hub, and a further delay of four hours waiting for an ambulance to transfer them.

The reviewers considered that there were too many delays in all stages of this pathway.

- For the 283 patients where the reviewers were able to make an assessment, the median time from symptoms to presentation was 1.1 days (F4.1).
- There were only 65/283 (22.9%) patients who presented within six hours of their symptoms starting. A further 38/283 (13.4%) patients presented between six and 12 hours and 36/283 (12.7%) between 12 and 24 hours (F4.2). Delays to presentation were common, with 144/283 (50.9%) patients presenting more than 24 hours after the onset of their symptoms. National data on delay to presentation would help target education and patient awareness campaigns.
- When time to presentation was assessed against the Rutherford classification (in the vascular hub), 20/62 (32.2%) patients with a Rutherford IIb category first presented to healthcare within six hours and 43/62 (69.3%) presented within 24 hours (F4.3).
- NHS 111, whose advice algorithm directs patients to attend their local emergency department, was rarely used (or rarely recorded in the notes) (12/325; 3.7%) (T4.1) but when it was, the median time from onset of symptoms to contact with NHS 111 was 4.8 hours (F4.4).
- Patients with ALI who self-presented to a spoke emergency department also had shorter median times to presentation (23.5 hours) than those who presented to a vascular hub emergency department (1.3 days) or primary care (6.14 days) (F4.4).
- There were missed opportunities to recognise ALI prior to admission, most commonly due to a lack of patient awareness (82/115; 71.3%) and/or recognition in primary care (24/115; 20.8%). The reviewers noted that there was also a missed opportunity to recognise ALI by NHS 111. These findings support a public and pre-hospital services awareness campaign, like that for stroke.
- ➤ When patient factors delayed presentation the reviewers considered the outcome was more than likely affected for 11/60 patients.

5 PRESENTATION TO PRIMARY CARE

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CASE STUDY – GOOD CARE

A patient presented to their GP with a cold, pale, numb painful, pulseless foot that had developed overnight. The GP took a complete history, performed an examination and diagnosed suspected acute limb ischaemia, noting the '6Ps', which included sensory-motor deficit, then organised an emergency transfer by ambulance to the nearest vascular hub where the patient underwent an embolectomy and was discharged home one week later.

The reviewers stated that the GP's recognition of the symptoms of acute limb ischaemia and immediate referral the patient to the vascular hub hospital was exemplary care and likely contributed to the good outcome for this patient.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with type 2 diabetes presented to their GP with a two-day history of severe leg pain. The leg was pale and painful, yet foot pulses and a pain score were not recorded. The patient went home with a prescription for low-dose aspirin. The next day they called NHS 111 and attended their local emergency department with worsening leg pain, numbness and weakness. They were transferred to a vascular hub, where they were diagnosed with ALI (Rutherford IIb) and required an amputation.

The reviewers stated that there was a missed opportunity to intervene earlier and save the limb. If the patient had been aware that their symptoms were serious and presented earlier, or if the GP had referred them directly to a vascular hub.

- ➤ Of the 249 patients who had a procedure (revascularisation and/or amputation), the majority presented to a hospital, contacted their GP or called 999 (188/249; 75.5%). Those who presented directly to a hospital had a median time to procedure of 1.2 days compared with those patients who went to primary care first. Their median time to procedure was longer at 2.3 days (F5.1).
- Detailed local written guidance to assist in the recognition and initial management of ALI was available in 36/111 (32.4%) primary care organisations. It was noteworthy that in 41/111 (36.9%) this was unknown.
- ➤ There were 79/111 (71.2%) primary care organisations where it was expected that the '6Ps' would be recorded, yet they were recorded in only 21/48 (43.8%) patients.
- A Rutherford category was not recorded for any patients in primary care.
- Most GPs predicted that the patient would be referred to the nearest emergency department or vascular hub, but this occurred in 27/48 patients and 12/48 patients respectively, demonstrating some disconnection between expected standards and the reality of clinical practice (F5.2).
- Pain was the most frequently recorded of the '6Ps' (42/48) (T5.1). It is important to record the absence as well as the presence of the '6Ps' as not all will be present in every patient. Review of the case notes did not allow differentiation between information not collected and symptoms that were not present.
- Acute limb ischaemia was diagnosed or suspected in 21/48 patients attending primary care. In 27/48 ALI was not diagnosed, but other vasculitis, cellulitis, or deep vein thrombosis were.
- Making a correct diagnosis of ALI in primary care is not essential, provided it is recognised that the patient requires urgent assessment. The need to expedite care was not identified in 4/45, who were advised to return home and go to the emergency department if their symptoms deteriorated.

6 PRESENTATION TO A SPOKE HOSPITAL

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CASE STUDY – GOOD CARE

A patient with acute limb ischaemia (Rutherford category IIa) presented to a spoke hospital following NHS 111 advice. The patient was reviewed rapidly in the emergency department and ALI was diagnosed. There was good communication with the vascular hub, and the patient was transferred within two hours and had an operation two hours later.

The reviewers thought this was an example of good pathway organisation.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient was taken to their local hospital by ambulance with a non-viable leg (Rutherford III), pneumonia, chronic renal failure and severe frailty. They were transferred to the vascular hub where they received palliative care and died three days later.

The reviewers considered this to be an unnecessary transfer to the vascular hub with the patient dying away from their family.

- ➤ In total, 138/330 (41.8%) patients had attended a spoke hospital before being transferred to a vascular hub. There were 72/138 (52.2%) patients taken by ambulance and ALI was mentioned on the patient report form (PRF), where it was available, for 29 patients. For 22 patients ALI was not mentioned on the PRF. This suggests that ambulance bypass protocols for ALI are not universal or that existing protocols are not being followed. National data monitoring could aim to reduce the number of avoidable transfers.
- In the view of the reviewers there was a delay in the triage/streaming process for 18/138 (13.0%) patients and a delay in the initial assessment in 21/138 (15.2%). Misdiagnosis (6/19) was the most common reason for delay. This highlights the need for further information for patients and for the healthcare professionals involved in assessment/triage.
- The clinicians at the hospital also identified delays in the patient presenting to their local hospital in 31 instances, with patients delaying seeking help being the most common reason (T6.1).
- Delays were reported in the examination/investigations in 17/138 (12.3%) patients. Imaging should not delay a transfer but if it can be performed quickly without causing a delay, it can be beneficial for planning treatment in advance. Although, this applies only if imaging can be shared electronically; otherwise, it may pose an unnecessary risk of repeated imaging at the vascular hub.
- The Rutherford category for the patients attending the spoke hospital indicated that 30/106 (28.3%) required revascularisation within six hours of their development of sensory-motor symptoms, while 8/106 (7.5%) probably required a primary amputation (T6.2). At least 38/106 (35.8%) patients were in a hospital where the treatment they required could not be provided, suggesting that many vascular networks are not grasping the organisational opportunities to improve the care of ALI.
- A record of the discussion with the vascular hub was evident in 118/138 (85.5%) cases reviewed, while 9/23 (39.1%) respondents in the clinician survey identified difficulties contacting the vascular surgical team as a barrier to care.

7 TRANSFER FROM A SPOKE HOSPITAL TO A VASCULAR HUB

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CASE STUDY – GOOD CARE

A patient attended a spoke hospital with a threatened but viable acutely ischaemic arm. Documentation of the examination and decision-making was excellent. Anticoagulation therapy was started and the patient transferred to a vascular hub without delay. Surgical embolectomy took place within four hours of arrival, and the patient was discharged home two days later.

The reviewers considered that this was good use of an ALI proforma in the spoke hospital.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient presented to a spoke hospital and was initially seen quickly but misdiagnosed as having had a stroke. Once they had been correctly diagnosed, following a senior review, and a referral made to the vascular hub, it took a further four hours for an ambulance transfer.

The reviewers stated this to be an unnecessary delay.

- In total, 7/78 spoke hospitals described a network where they referred to two or more vascular hubs. A more complicated picture emerged with the number of spoke hospitals from which the vascular hub received referrals. This ranged from 0-22, with a mean of 3.54 and mode of two. The total number of spoke hospitals this was based on was 170, suggesting that there are 36 spoke hospitals referring to more than one vascular hub.
- All the patients in this study were admitted to a vascular hub. In 16/50 vascular hubs, at least one spoke hospital within the network was more than an hour away by blue light ambulance in working hours. The median time from arrival at the spoke hospital to arrival at the vascular hub was 8.16 hours, exceeding the recommended target for treatment of immediately threatened limbs (Rutherford IIb) from relevant sensory-motor symptom onset.
- For 34/138 (24.6%) patients the reviewers reported that the time spent at the spoke hospital was too long. Waiting for an ambulance was the most common reason for the delay (11/34) (T7.1).
- There were 13/81 (16.0%) patients who had a delay of greater than 24 hours (F7.1). The nine patients who had a deterioration in their Rutherford category in the spoke hospital had a mean transfer time of ten hours (range 3.9 to 19.4 hours). Reviewers stated that eight patients would have benefited from being admitted directly to the vascular hub.
- A well-organised vascular network should be able to reduce the issues that have been identified with presentations to spoke hospitals. Written guidance specific to the management of suspected ALI was available in only 56/91 spoke hospitals (T7.2), and where it existed key components were often missing.
- The Rutherford category was included in only 8/56 spoke hospital guidelines which may explain why it was so infrequently used.
- There were 34/91 spoke hospitals in which medical records could be shared electronically and 56/91 in which images could be shared immediately (T7.3). All other systems that were described, such as email and paper copies, risk delays or other harm.

8 CARE AT THE VASCULAR HUB

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CASE STUDY – GOOD CARE

A patient with suspected acute limb ischaemia (Rutherford IIb) was transferred from a nearby spoke hospital by ambulance. The patient was admitted and assessed and underwent a femoral endarterectomy within one hour of arrival. They stayed in the vascular hub for four days then were repatriated back to their local hospital allowing their family to visit and support them in their recovery.

The reviewers felt that this was a good example of a vascular network working well with good communication between hub and spoke hospitals, good decision making at each stage of the pathway, and excellent patient-centred care.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient with a history of alcohol excess, smoking and type 2 diabetes presented to the emergency department (ED) of a vascular hub, with a painful leg. They initially refused any examination or treatment and left the ED on one occasion. They were eventually examined by the resident emergency doctor, misdiagnosed as having a deep vein thrombosis and admitted to a medical ward. After review by a consultant physician later that evening they were transferred to the vascular surgery department and diagnosed with acute limb ischaemia, with an embolectomy undertaken within 12 hours.

The reviewers felt that the lack of protocolised care, the lack of awareness of the emergency medicine resident doctors, the delays in senior review and the lack of input from the alcohol or psychiatric liaison teams all contributed to the delays in the care for this patient.

- ➤ There were 192/330 (58.2%) patients who presented directly to a vascular hub. The most common route was via presentation to an emergency department (82/192; 42.7%), followed by primary care referrals (30/192; 15.6%) and blue light ambulance (34/192; 17.7%) (T8.1).
- Patients diagnosed and transferred from a spoke hospital were referred directly to vascular surgery. This was supported by their median time from arrival at the vascular hub to procedure of 15.4 hours (F8.1). The median time from presentation at the vascular hub to procedure was 28.4 hours.
- The '6Ps' were inconsistently recorded at the first assessment in the vascular hub (T8.2).
- A Rutherford category was documented in the vascular hub for 69/330 (20.9%) patients (T8.3).
- ➤ In 15 patients there was a deterioration in their limb with 8/15 deteriorating to a Rutherford category IIb, an immediately threatened limb that required urgent revascularisation for salvage, and 3/15 to an unsalvageable limb requiring amputation (T8.4 and T8.5).
- There was a delay in making the diagnosis of ALI in the vascular hub in 25/297 (8.4%) patients, including 18/25 emergency department attendances (T8.6). This reinforces the need for effective emergency department initial assessment of acutely painful limbs to correctly diagnose and accelerate the care of those with ALI. The most common reasons for the delay were misdiagnosis in 12 patients, deep vein thrombosis in six and chronic limb-threatening ischaemia in six (T8.7).
- ➤ Using an ALI pathway in the vascular hub appeared to have a positive impact on care: 3/46 (6.5%) patients experienced a delay on an ALI pathway compared to 18/165 (10.9%) not on a pathway.
- A delay in treatment planning occurred in 34/330 (10.3%) patients (T8.8).

9 PROCEDURES UNDERTAKEN

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CASE STUDY – GOOD CARE

Two years after an endovascular aneurysm repair a patient developed a painful calf and foot. After 24 hours they attended the emergency department in a spoke hospital. Evaluation was quick and the suspected acute limb ischaemia confirmed, which revealed that all three calf arteries were badly damaged. Within an hour of arrival in the hub a successful hybrid operation was followed by a calf embolectomy and thrombolysis, and stent insertion.

Reviewers believed the delayed presentation did not affect the outcome and the care was good.

CASE STUDY – ROOM FOR IMPROVEMENT

A patient presented to hospital with a numb foot. The severity of the condition was not recognised and acute limb ischaemia was only confirmed several hours later, following a senior vascular review. The patient was referred for emergency surgery. Further delay to the procedure occurred due to lack of theatre access out-of-hours. A below-the-knee amputation was eventually performed.

Reviewers stated that there were avoidable delays in the pathway. Earlier recognition and faster theatre access may have improved the outcome.

- There were 249/330 (75.5%) patients in this study who underwent one or more procedure with 78/330 (23.6%) treated with an anticoagulant alone or with palliative care.
- Overall, in the 249 patients who had a procedure, the median time to treatment was four days (F9.1). These included 35/249 (14.1%) patients who had a primary amputation, where delaying surgery to optimise the patient or define the required level of amputation can reflect good care.
- ➤ Of the 52 patients classified as having Rutherford category IIb ALI, only 5/52 (9.6%) achieved the six-hour target, with a median time of 3.1 days (F9.1).
- Popen surgical revascularisation was more commonly performed (159/249; 63.9%) than endovascular (28/249; 11.2%) as the primary revascularisation procedure (T9.1).
- ➤ Delays to revascularisation or amputation were observed in 50/249 (20.1%) patients, including 11 with Rutherford category IIb ALI. The delay was considered to have altered the outcome in three patients. The reason for the delay was not recorded in 17/50 patients and not all the delays were within the control of the clinicians or the hospital (F9.2). National data would provide greater oversight of the delays impacting on patient outcome.
- Complications occurred in 69/243 (28.4%) patients, of which three were considered avoidable and affected the patient's outcome.
- The reviewers highlighted several areas of good quality care postoperatively including appropriate analgesia in 215/220 (97.7%) patients and appropriate anticoagulation in 228/233 (97.8%).
- There was room for improvement in the postoperative monitoring/escalation plans with a complete plan documented in the notes for only 82/249 (32.9%) patients (T9.2).
- In 57/233 (24.5%) patients, one or more subsequent procedure(s) were performed (11 patients had more than two). Surgery was the most common approach for second procedures (29/57) (T9.3).
- Three or more procedures were uncommon (14) and when they did occur, they most commonly included an amputation (10/14) (F9.3).

10 DISCHARGE AND OUTCOME

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CASE STUDY – GOOD CARE

A patient with type 2 diabetes and a history of smoking had acute-on-chronic limb ischaemia and was discharged two days after the hybrid iliac thrombectomy and iliac stent operation. At discharge, they were given information about how to recognise worsening symptoms of acute limb ischaemia and what to do. In addition to the follow-up with the vascular team, they were referred for follow-up at the diabetic clinic and the smoking cessation team.

The reviewers believed this represented good discharge planning and follow-up.

CASE STUDY – ROOM FOR IMPROVEMENT

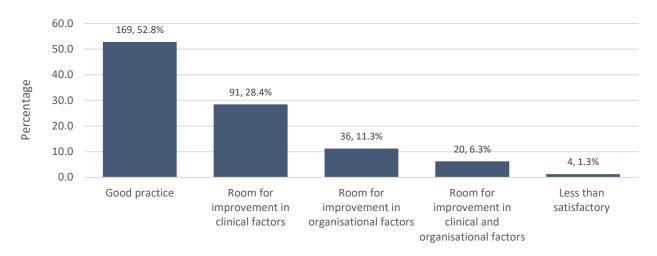
A patient with a cold painful foot was treated with heparin for three days in a vascular hub. The condition improved and they went home. The pain recurred 12 hours later. NHS 111 advised attendance at the local (spoke) emergency department which led to a transfer to the vascular hub 12 hours later. The patient's foot improved again with heparin treatment, and six weeks of anticoagulation therapy was prescribed.

The reviewers highlighted the lack of safety-netting, the inappropriate advice from NHS 111, poor use of resources and the omission of any anti-thrombotic treatment at the first discharge.

- The median length of stay was 19 days for the whole study population and 28 days for patients who had an amputation (F10.1).
- Only 10/291 (3.4%) patients who survived were discharged back to a spoke hospital and 13/291 (4.5%) were transferred to a step-down or rehabilitation unit.
- Only 18/58 vascular hubs returning an organisational questionnaire stated that they had a policy or standard operating procedure for repatriating patients to their referring hospital.
- The reviewers identified a discharge summary for 262/291 (90.0%) patients who survived to discharge. Information was missing in 44/262 (16.8%), and the discharge planning was considered inadequate in 19/257 (7.4%) (T10.1). The most common omission was details of the vascular follow-up (27/44; 61.4%).
- Anticoagulants were prescribed in 148/291 (50.9%) patients and antiplatelet medication in 114/291 (39.2%) (F10.2).
- No risk management was documented for 44/291 (15.1%) patients and where documentation existed, it was considered inadequate in 20/291 (6.9%) cases, including 15 patients who should have had smoking/vaping cessation advice. Smoking cessation advice was offered to 58/92 (63.0%) current smokers.
- ALI is a life-changing event for many patients. For those who survived, 210/330 (63.6%) patients were discharged home without the need for additional support, whereas at admission this figure was 162/330 (49.1%) (F10.3).
- While the Rockwood frailty score for 141/255 (55.3%) patients was unchanged at discharge, a small number showed an improvement (18/255; 7.1%), and the reviewers identified a deterioration in functional status in 68/255 (26.7%) patients (T10.2).

11 OVERALL QUALITY OF CARE

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Overall quality of care rating

Figure 11.1 Overall quality of care; *n*=320 Case review data

The reviewers were asked to assign a grade to the overall quality of care received by each patient in the study (F11.1). Overall quality of care was rated as good for 169/320 (52.8%) patients. The reviewers reported there was room for improvement in the clinical and/or organisation of care for 151/320 (47.2%). A less than satisfactory rating was assigned to four patients (1.3%). These ratings do not consider the patient factors that have been shown to impact the care in this study.

Measuring performance is crucial for quality improvement. Only 22/47 vascular hubs stated that they recorded data on surgical procedures, while 19/42 collected data on interventional radiological revascularisation procedures for ALI. When asked about shared learning across the ALI network, the use of prospectively collected data was uncommon with most learning occurring in morbidity and mortality meetings or in response to reported adverse events.

Delays were identified as a key area of concern in improving ALI care. Considering the data relating to delays in the pathway, 123/249 (49.4%) individual patients who had a procedure experienced a delay at some stage between their initial presentation and first procedure. Excluding the patient-related delays in presenting, there were 115/249 (46.2%) individual patients delayed at some point in the pathway. National data collection for ALI would aid benchmarking and monitoring of the delays occurring thought the entire ALI pathway. This could focus resources as well as educational opportunities.

The vascular hubs identified delays in patient presentation, initial assessment, recognition of and imaging for ALI as areas requiring improvement, along with transfer delays between vascular hubs and spoke hospitals. Additional challenges included a limited number of vascular surgical beds, the lack of a hybrid theatre, and too few interventional radiologists, limiting the treatment options. Embedding this into a registry would ensure that these factors can be considered beyond this report alone.