An Exploration of Factors Affecting Timely Referral of Patients with Chronic Limb-Threatening Ischaemia

by

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Abstract

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Chronic limb-threatening ischaemia (CLTI) is the end-stage of peripheral arterial disease. It is associated with significant risks of limb loss and mortality, which increase with delays to revascularisation. There is currently little understanding of how pathways from the community to vascular surgery assessment work in practice, but there is clear evidence that delays are present throughout the patient journey. This thesis aims to identify, define and prioritise facilitators and barriers to the timely and appropriate referral of patients with CLTI from primary care into vascular surgery services. It explores potential solutions to delay and how they can be effectively applied. Multiple methodologies were used to meet these aims and answer four research questions.

The results of this work demonstrated that publicly available guidance regarding referral of patients with suspected CLTI was unclear, used vague wording and rarely involved primary care clinicians or representative groups in the writing or endorsement of guidance documents. Referral pathways in place from the community to vascular surgical assessment varied widely according to local context and resource availability. Qualitative work with hospital and primary care clinicians identified that whilst hospital clinicians were aware of the need for speed in the process, multiple barriers existed, while primary care clinicians struggled with the challenge of delivering care in the current environment and a lack of confidence with regards to CLTI. Rich interview data from patients diagnosed with CLTI generated themes relating to individual behaviours, primary care experiences and vascular surgery processes. Finally, the effectiveness of quality improvement collaboratives in UK surgery was assessed, finding limited data to support their use given weak study design and poor reporting quality.

This thesis has identified several overarching factors affecting timely referral and vascular surgery assessment of CLTI. Evidence-based solutions on national and local levels have been suggested.

“Never let a vein get in the way of a good arterial operation”

Mr Robert Brightwell

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Declaration

I confirm that this work is original and that if any passage(s) or diagram(s) have been copied from academic papers, books, the internet or any other sources these are clearly identified by the use of quotation marks and the reference(s) is fully cited. I certify that, other than where indicated, this is my own work and does not breach the regulations of HYMS, the University of Hull or the University of York regarding plagiarism or academic conduct in examinations. I have read the HYMS Code of Practice on Academic Misconduct, and state that this piece of work is my own and does not contain any unacknowledged work from any other sources. I confirm that any patient information obtained to produce this piece of work has been appropriately anonymised.

Contributors to the studies in this thesis

Chapter 2: A documentary analysis of national and international guidance for primary care clinicians referring patients with suspected chronic limb-threatening ischaemia

This study was conceived jointly with my initial supervisory team: Professor David Cromwell (DAC), Professor Ian Chetter (ICC), Dr Liz Glidewell (LG) and Mr Jon Boyle (JRB), with Professor Ian Kellar (IK) providing supervision during the study process. I performed the literature and online searches. IK validated the document selection and aided with the behavioural change technique analysis. Ms Panagiota Birmpili (PB) acted as an independent scorer for the two clinical practice guideline assessment tools. All listed provided critical review of the final write up. This chapter has been published in BMJ Open Quality following peer review.

Chapter 3: The symptom to assessment pathway for suspected chronic limb-threatening ischaemia (CLTI) affects quality of care: a process mapping exercise

The idea for this study was conceived jointly with my initial supervisory team: (DAC, ICC, LG and JRB). I wrote the protocol which was reviewed by ICC and LG prior to submission to the Hull York Medical School ethics committee. I recruited participating Trusts, facilitated the process mapping exercise with relevant staff members and extracted and analysed the data with assistance from IK. The analysis and write up was completed with the assistance of PB and the National Vascular Registry team: Sam Waton (SW), Amundeep Johal (ASJ), Qiuju Li (QL) and Arun Pherwani (ADP). All listed provided critical review of the final write up. This chapter has been published in BMJ Open Quality following peer review.

Chapter 4: Hospital clinicians' perceptions and experiences of care pathways for chronic limb-threatening ischaemia: a qualitative study

The idea for this study was conceived jointly with my initial supervisory team (DAC, ICC, LG, JRB) as well as PB. IK provided supervision during the study process. I wrote the protocol which was reviewed by ICC and LG prior to submission to the Hull York Medical School ethics committee. I recruited participants, performed and transcribed the qualitative interviews and developed a reflexive thematic analysis of the data. In addition to those named above, themes were discussed and approved by ADP. All listed provided critical review of the final write up. This chapter has been published in the Journal of Foot and Ankle Research following peer review.

Chapter 5: Understanding delays in chronic limb-threatening ischaemia care: application of the Theoretical Domains Framework to identify factors affecting primary care clinicians’ referral behaviours

The idea for this study was conceived jointly with my initial supervisory team (DAC, ICC, LG, JRB). IK provided supervision during the study process. I wrote the protocol which was reviewed by ICC and LG prior to submission to the Hull York Medical School ethics committee. I recruited participants, performed and transcribed the qualitative interviews and coded and analysed the data. PB independently coded 15% of transcripts to ensure reliability of the coding strategy. In addition to those listed above, the analysis was discussed and validated by ASJ, QL, SW and ADP. All listed provided critical review of the final write up. This chapter has been published in the Journal of Foot and Ankle Research following peer review.

Chapter 6: Patient experience of the process to diagnosis of chronic limb-threatening ischaemia: a qualitative study

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Chapter 7: The effectiveness of quality improvement collaboratives in UK surgical settings and barriers and facilitators influencing their implementation: a systematic review and evidence synthesis

The idea for this study was conceived jointly with my initial supervisory team (DAC, ICC, LG, JRB) as well as PB and the rest of the National Vascular Registry team (SW, ASJ, QL, ADP). PB acted as a second reviewer in the systematic review, and assisted with data extraction and coding. All listed provided critical review of the final write up. This chapter has been published in BMJ Open Quality following peer review.

Publications

Peer-reviewed publications relating to this research

- **Atkins E**, Kellar I, Birmpili P, Boyle JR, Pherwani AD, Chetter I, Cromwell DA. Patient experience of the process to diagnosis of chronic limb-threatening ischaemia: A qualitative study. J Foot Ankle Res, 17: e12042 (2024). doi: 10.1002/jfa2.12042
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Presentations

- **Atkins E.** The PAD QIF, the CQUIN and the role of Qualitative Research Initiatives in vascular surgery. Invited oral presentations at the Vascular Society Annual Scientific Meeting, Brighton, UK, November 2024, and the International Consortium of Vascular Registries meeting at the Veith Symposium, New York, November 2024
- **Atkins E**, Young L, Booth M, Wheeler A, Lowis S, Williams N, Pherwani AD, Boyle JR. Using the National Consultant Information Programme (NCIP) to assess national variation in longer-term outcome measures for patients undergoing a lower limb bypass in England. Oral presentation at the Vascular Society Annual Scientific Meeting, Dublin, Ireland, November 2023. Selected for British Journal of Surgery prize session
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- **Atkins E**, Birmpili P, Glidewell L, Li Q, Johal AS, Waton S, Boyle JR, Pherwani AD, Chetter I, Cromwell DA. Variation in pathways for patients with CLTI leads to inequalities in care: process mapping exercise. Oral presentation at the European Society for Vascular Surgery Annual Meeting, Belfast, Ireland, September 2023
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- **Atkins E**, Birmpili P, MacSween S, Tomlinson R, Boyle JR, Cromwell DA. Learning from Quality Improvement Collaboratives in Surgery. Poster presentation at the BMJ / IHI International Forum on Quality and Safety in Healthcare, Copenhagen, May 2023
- **Atkins E**, Birmpili P, Glidewell L, Li Q, Johal AS, Waton S, Boyle JR, Pherwani AD, Chetter I, Cromwell DA. Understanding facilitators and barriers to the effectiveness of quality improvement collaboratives in UK surgical settings: a systematic review and evidence synthesis. Oral presentation at the 21st QI and Audit Symposium, Royal College of Surgeons of Edinburgh, Scotland, April 2023
- **Atkins, E**. Identifying prehospital delays in the management of CLTI patients. Invited oral presentation at the Vascular Society Annual Scientific Meeting, Brighton, UK, November 2022

Chapter 1. Introduction

1.1. Background of the condition

1.1.1. What is vascular surgery, peripheral arterial disease (PAD) and chronic limb-threatening ischaemia (CLTI)?

Vascular surgery is a specialty within medicine covering the diagnosis and management of diseases affecting the blood vessels of the human body, outwith the heart and the brain. One of the conditions vascular surgeons manage is arterial occlusive disease, or peripheral arterial disease (PAD). Risk factors for PAD include hypertension, smoking, high cholesterol, diabetes, male sex and ageing[1]. People with PAD are at significantly increased risk of death and co-morbidity from other cardiovascular diseases with similar risk factors such as stroke and heart disease[2]. The prevalence of PAD is increasing globally, and it is the third leading cause of cardiovascular morbidity, behind heart disease and stroke[3]. Over 200 million people are living with PAD worldwide[3]. In 2015, it was estimated that 3.2 million people in the United Kingdom (UK) had PAD, representing 6.9% of the population[4]. It is a significant problem and can lead to major morbidity, including limb loss, and mortality.

The development of PAD is a chronic process. It tends to occur most significantly in the arteries which supply the legs. Most PAD is asymptomatic[5]. Around 35% of people with PAD experience exercise-induced ischaemic muscular pain or intermittent claudication[6]. The pain is often described as severe cramping, a response to reduced blood flow to the large lower limb muscle groups. It characteristically resolves within a few minutes of rest, and the person is then able to walk a similar distance until they are stopped again by the pain. The majority of people with intermittent claudication remain stable, and usually do not progress to more severe forms of the disease. A systematic review found 21% of patients with intermittent claudication progressed to chronic limb-threatening ischaemia (CLTI) over 5 years[2], an increase from previous studies which found a 10-15% risk of progression[7, 8]. Symptoms of intermittent claudication can be improved by exercise therapy, with supervised exercise programmes being found superior to home-based exercise therapy, walking advice and no exercise in terms of improving walking distance[9, 10]. Supervised exercise therapy has no benefit on quality of life measures compared to home based exercise therapy for intermittent claudication[9], but is beneficial for quality of life measures compared to walking advice alone, and no exercise[9, 10]. Invasive procedures to treat intermittent claudication, such as endovascular revascularisation, have a similar effect on walking distance and disease specific quality of life to supervised exercise therapy[11]. However, revascularisation procedures carry risks of limb loss and mortality not present in patients undergoing different forms of exercise therapy[9, 10, 12].

For patients in whom PAD is progressive, symptoms can deteriorate until patients develop CLTI. This is defined as the presence of PAD with symptoms of rest pain, gangrene or non-healing ulceration over a period of >2 weeks duration[13]. It is estimated that the incidence of CLTI in the UK is 500 to 1000 patients per million per year[14]. This is similar to the incidence of lung cancer in the UK[15]. A UK vascular unit serving a population of 800,000 expects to see one presentation of CLTI each day[16]. CLTI is important because it carries a high risk of mortality and limb loss, with over 45% of patients with tissue loss losing a limb or dying without treatment at 2 years follow up in a German administrative database[17]. In the UK, patients admitted non-electively with CLTI who underwent infra-inguinal revascularisation from 2017-2019 had a mortality of 19.9% at one year where tissue loss was absent, and a mortality of 30% where tissue loss was present[18]. The Rutherford classification is used to define PAD severity (Table 1). The risk of above ankle amputation increases with disease severity at presentation, with 4 year amputation rates being 12.1% for Rutherford 4 disease, 35.3% for Rutherford 5, and 67.3% for Rutherford 6[19].

Table 1: Rutherford Classification for PAD

Category	Clinical description
0	Asymptomatic
1	Mild claudication
2	Moderate claudication
3	Severe claudication
4	Ischaemic rest pain
5	Minor tissue loss – non-healing ulcer or focal gangrene
6	Major tissue loss – foot no longer salvageable

A procedure or operation to improve the blood supply to the affected leg is called revascularisation. Revascularisation decreases the risk of losing a limb or dying following a diagnosis of CLTI[20]. Stella et al identified 15,314 inpatients with CLTI and tissue loss from a German administrative database between 2009 and 2011, 50% of whom were managed conservatively. At two years, amputation-free survival was 39.1% in the treatment group, and 31.0% in the conservative management group, with revascularisation having significant survival and limb salvage benefits ($p<0.001$)[17]. It is desirable to avoid limb loss due to its associated impact on patient reported quality of life, mortality and healthcare costs[21]. Performing primary major amputation for CLTI has higher associated healthcare costs than either endovascular or surgical revascularisation and shorter survival, independent of clinical presentation or patient characteristics[22].

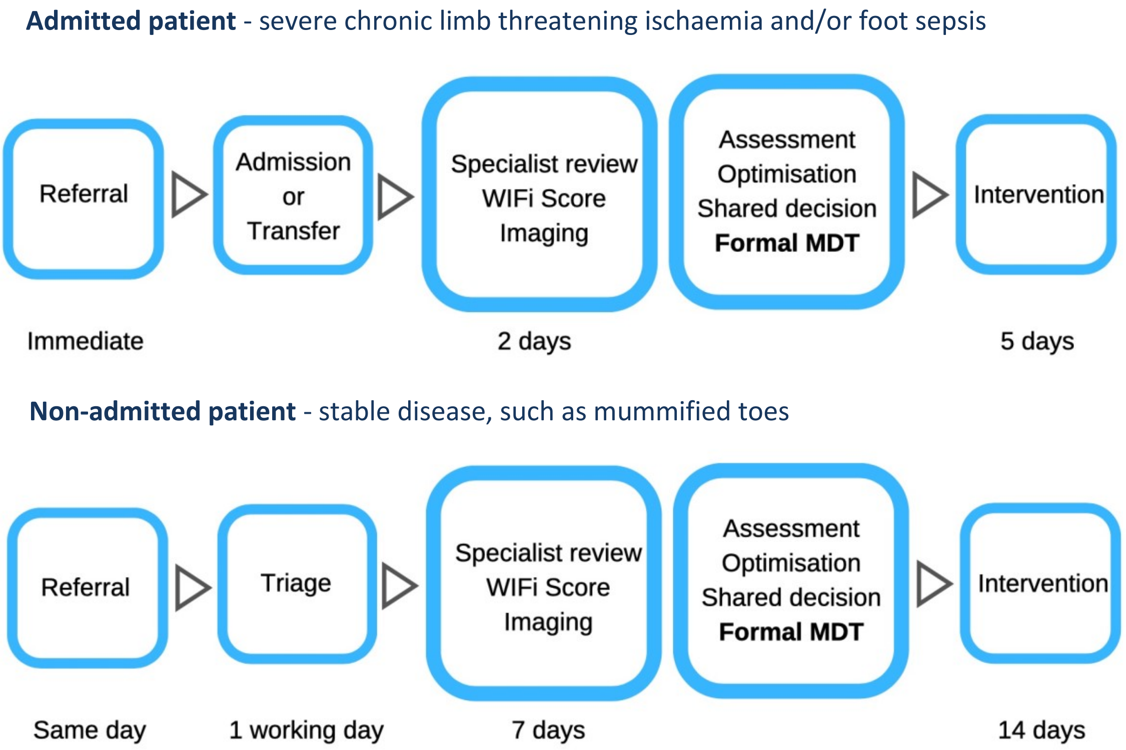
There is variation in care for CLTI across countries, and this leads to differences in amputation rates[23]. PAD is underdiagnosed and undertreated internationally[24], and a current focus of the global vascular surgery community is to reduce CLTI associated amputation rates by increasing quality of care with aggressive risk factor modification, timely revascularisation and prescription of best medical therapy[13].

1.1.2. What has the UK done to improve care for CLTI so far?

In 2018, a report published by the Getting It Right First Time (GIRFT) programme team for vascular surgery identified nationwide variation in care for patients diagnosed with CLTI, specifically in the time to revascularisation[25]. The Vascular Society of Great Britain and Ireland (VSGBI) published the Best Practice Clinical Care Pathway for Peripheral Arterial Disease in response to these findings[26, 27]. Initially published in 2019 and updated in 2022, it describes the multidisciplinary workforce, facilities and care pathways required in vascular units to improve care for PAD.

The Best Practice Clinical Care Pathway also set challenging targets for the assessment and management of patients referred with CLTI in the form of a Peripheral Arterial Disease Quality Improvement Framework (PAD-QIF)[26, 27]. The target time to revascularisation is 5 days for inpatients (with severe CLTI or foot sepsis) and 14 days for outpatients (with stable disease such as mummified toes). The timelines are demonstrated in Figure 1.

Figure 1: PAD-QIF timeline for investigation of CLTI[26]



As part of the implementation of this guideline, the Peripheral Arterial Disease Quality Improvement Programme (PAD-QIP) was formed. This was a collaborative of 13 vascular surgery units who volunteered to participate. The collaborative was based on the Institute for Healthcare Improvement Breakthrough Series model[28], with leadership from an expert team based at the Royal College of Surgeons. The PAD-QIP began in March 2020, and lasted for two years. Quarterly meetings were held, either online or face to face, where members were presented with their data on time-to-revascularisation, benchmarked against their peers. Presentations from collaborative members focussed on one aspect of the pathway, and challenges and strategies to overcome them were shared.

Participants in PAD-QIP increased the proportion of patients treated in 5 days from 57% to 64% (Table 2). An improvement was also observed in the rest of the UK, but at 4%, less than that seen in the PAD-QIP participants. There was also a decrease in patients' length of stay from 13 to 11 days, while the length of stay remained stable for the other UK centres at

15 days. This would have an impact on inpatient bed availability and costs. Formal publication of these results is awaited.

Table 2: PAD-QIP results

	PAD QIP		**Rest of UK**	
	Baseline	**Intervention**	**Baseline**	**Intervention**
% revascularised in 5-days (95% CI)	56.9	64.4	48.7	53.1
Time-to-procedure	5 (2 - 8)	4 (2 - 7)	6 (3 - 9)	5 (2 - 8)
Length of stay (LOS)	13 (7 - 24)	11 (6 - 20)	15 (9 - 27)	15 (8 - 25)
Postoperative LOS	7 (3 - 15)	6 (2 - 13)	8 (4 - 17)	8 (4 - 16)

1.2. Quality improvement

1.2.1. What is quality improvement (QI) in healthcare?

The PAD-QIP formed part of the VSGBI's commitment to improving quality in vascular care in Great Britain and Ireland.

One of the six values in the National Health Service (NHS) Constitution is a "commitment to quality of care"[29]. Quality improvement is a name for the systematic approach to solving complex problems, in order to see a measurable improvement in the quality of care delivered. It has the potential to enhance patient experience and staff productivity, reduce healthcare associated costs, and improve overall outcomes.

The National Quality Board has defined quality in relation to NHS services[30]. Care should be safe, effective, and provide a positive experience by being responsive and caring. Care needs to be well-led, sustainably resourced and equitable. These principles should be considered within every plan for improvement.

There are many approaches to quality improvement, but all involve identification of an issue, understanding the factors that lead to it, developing a theory of change and applying a solution, which can be altered after feedback is received. Understanding the wider context of the environment, organisation or system in which the change is required, and how that may affect implementation, is vital. Here, we will discuss quality improvement strategies that have been used in vascular surgery.

1.2.2. QI strategies: registries

Outcome measurement in surgery was pioneered in the United States of America (USA) in the 1980s, led by cardiac surgeons[31]. Vascular surgery soon followed with a focus on carotid endarterectomy results, and the National Vascular Database was formed in the UK in 2001, the precursor to today's National Vascular Registry (NVR). Elsewhere in Europe, Vascunet was formed in 1997 by a collaboration of European and Antipodean registries, and published its first report in 2007[32]. In the USA, the Vascular Study Group of Northern New England started in 2002[33], which is the precursor of today's Vascular Quality Initiative. On a global scale, the International Consortium of Vascular Registries comprising 13 worldwide vascular surgery registries was set up in 2014[34], including Vascunet (now working with over 40 members from 27 countries[35]) and the Vascular Quality Initiative, demonstrating inter-country variation and with an overarching aim to provide international standards of care. Surgeon-collected vascular surgery registry data is accurate, as we know from validation against national datasets in Sweden[36], Hungary[37] and Finland[38].

Improvement in patient outcomes following identification of variations in care and publishing of said outcomes is well established. The Hawthorne effect refers to a phenomenon where individuals modify their behaviour as a function of being observed, and this has been identified following publication of registry data. The first reporting of surgeon-level outcomes in UK vascular surgery showed a decrease in the absolute number of abdominal aortic aneurysm (AAA) repairs performed[39] and in cardiothoracic surgery there has been a reduction in both volume and variety of trainee-led procedures since the first surgeon-level data were published in 2002[40]. However, institution participation in a registry is associated with better outcomes for vascular surgery patients[41], suggesting the Hawthorne effect is positive in this context.

The large volume of data collected by registries have enabled lessons to be learnt from global collaboration, identifying clinical areas and key parameters where quality improvement efforts could drive significant patient benefit, such as the relatively poorer outcomes for women compared to men in both elective and ruptured aortic aneurysms[42, 43]. Looking to the future, the next step for vascular surgery registries is to capture data on devices implanted into patients, enabling early detection of any issues with the devices following market approval[44].

Capturing frequently performed procedures allows comparison, benchmarking and quality improvement across the world. For rarer diseases, benchmarking is difficult due to the paucity of data. For these conditions, the Vascular Low Frequency Disease Consortium[45] exists to collate data on conditions that appear infrequently, and this has resulted in new learning on rare vascular conditions such as cystic adventitial disease[46].

Registry participation allows measurement of both patient outcomes and process measures, such as time-to-revascularisation. Both can be used as a proxy for quality. The PAD-QIP relied on data from the NVR to monitor process measures and outcomes of the programme, and participation demanded accurate and swift data entry.

1.2.3. QI strategies: collaboratives

Quality improvement collaboratives, such as the PAD-QIP, are a method for delivering change over multiple healthcare organisations. Members of each organisation come together with a shared goal to improve one aspect of care they deliver, learn techniques for QI and share data, ideas and methods that have worked for them. A faculty of experts, who provide resources and facilitate learning, leads the collaborative.

The formation of QI collaboratives began in the late 1980s, with the Northern New England Cardiovascular Disease Study Group improving regional outcomes for coronary artery bypass grafting with an intervention programme including training in QI methods and feedback of outcome data[47].

In the USA, regional collaboratives aligned with the Vascular Quality Initiative have improved prescribing of beta blockers, antiplatelets and statins for vascular surgery patients[41, 48] and increased proportions of patch usage in carotid endarterectomy, reducing clinically significant restenosis at one year[49]. Feedback to vascular surgeons on key performance indicators from a QI registry has similarly shortened time from symptom to carotid intervention and improved best medical therapy of patients with peripheral arterial disease in Sweden[50]. The functions of these regional collaboratives are to improve communication between diverse constituent institutions and facilitate regional data collection[51], rather than address complex organisational problems.

The Institute for Healthcare Improvement's (IHI) Breakthrough Series, developed in the mid-1990s, formalised the growing movement toward large-scale complex intervention. It provides one commonly used framework built for collaborative QI programmes, involving repeated Plan-Do-Study-Act cycles to implement practice changes[28], shared learning and comparative data, facilitated by an expert team over a specified time period. The Breakthrough Series has been applied to many aspects of patient care, from hospital acquired infections[52] to emergency medicine[53]. A QI collaborative aims to use such a framework to motivate and facilitate its members to learn and share improvement techniques, and thus improve healthcare. There is no evidence that the collaborative QI format works universally, as positive, negative and equivocal results have been observed following implementation[54]. Factors which increase the likelihood that a planned intervention will be successful include engaged team members and cross-pollination of ideas at networking events. Barriers to success include lack of organisational support and insufficient time and resources[55]. There is evidence that these QI collaboratives are strongly influenced by context, which refers to the system, organisational or structural makeup of the units involved[56]. Collaborative QI programmes in the surgical specialties are relatively scarce, however.

Collaborative QI programmes have been used to solve complex multifaceted issues in general surgery and orthopaedics, including reducing delays to acute cholecystectomy for cholecystitis[57], improving mortality for emergency laparotomy[58] and reducing length of stay following hip fracture[59]. These surgical QI programmes have all followed the IHI's Breakthrough Series, and have been associated with big data – either in the form of national registries such as the National Emergency Laparotomy Audit (NELA) or the National Hip Fracture Database, or by using national datasets such as Hospital Episode Statistics (HES). The protocols for several upcoming UK surgical collaborative QI programmes have been published[60-62]. Across Europe, QI collaboratives have been seen in medicine[63] but the progress into other specialties including surgery appears to be slower[64].

1.2.4. Collaborative QI in vascular surgery

Despite pioneering collection of registry data in vascular surgery, the specialty has been slow to implement collaborative QI programmes, which may be a reflection of their complexity. However, the Abdominal Aortic Aneurysm Quality Improvement Programme (AAA-QIP) led by the Vascular Society in the UK was highly successful[65]. The AAA-QIP was prompted by publication of Vascunet data in 2008[66] which highlighted that the UK's mortality rates for elective AAA surgery were well above their European colleagues', at 7.5% compared to 3.5%. The AAA-QIP lasted two years and over its course the UK's elective AAA mortality dropped to 2.4%[65].

The AAA-QIP was an uncontrolled before-after study, modelled on the IHI Breakthrough Series. It implemented a package of interventions relating to the management of elective AAA patients. There was a high degree of patient involvement, leading to improved provision of information to patients. Ninety units in 12 regions were involved. The collaborative was regionally led after an initial attempt at national leadership recognised the need for sensitivity to local context and difficulties with engagement.

The AAA-QIP began with an initial national meeting to feedback baseline data, teach QI and plan for the initial interventional steps. Data collected on the National Vascular Database was linked with HES data, fed back to units quarterly and shared in the public domain. Further national meetings were held which shared ongoing knowledge and learning, created a sense of shared purpose and embedded local developments.

Unintended consequences included specialty reconfiguration, with some units recognising that they could not provide a service alone, prompting local unit amalgamation. This, in some instances had a negative effect, with clinicians viewing the AAA-QIP as a threat and therefore being unwilling to engage with the programme. Other barriers included a resistance to change and a lack QI time in the clinicians' job plans.

Facilitators of success in the AAA-QIP included support from hospital executives, commissioners and cardiac and stroke networks, which promoted sustainability of the interventions. Patient stories, credible QI teams, support with data entry and management and the stimulus of data being in the public domain were also cited as factors encouraging success.

A further programme for QI in UK vascular surgery was intended to be based around the Best Practice Clinical Care Pathway for Amputation, published in 2016[67] after a 2014 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report[68] identified a disappointing standard of care in over half of the 519 cases reviewed. Unfortunately, a lack of funding for the project stymied its progression. PAD-QIP, a recent QI collaborative formed to improve care for patients with CLTI, has been discussed elsewhere in this chapter.

1.3. Delays in CLTI care

1.3.1. Delays in the pathway for patients with CLTI

Delays have been identified at all stages of the pathway for patients with CLTI; from first symptom to intervention[69]. There are anecdotal delays in the identification and referral of patients with CLTI[70], and once the patient has been seen and assessed by vascular surgery services there are delays to providing both open and endovascular treatment compared to the PAD-QIF target timeline[71]. Adverse outcomes, including major limb amputation, have been identified in patients with CLTI following delays in referral and treatment[72, 73]. National and international guidelines recommend early referral to vascular surgeons for suspected CLTI[13, 74], but opportunities for identification of CLTI have been missed at the primary care stage for patients who go on to have major limb amputations[75].

The Vascular James Lind Alliance Priority Setting Partnership has gone through an extensive process of setting future priorities for research in PAD with patients and clinicians. Three of the top 10 priorities relate to earlier diagnosis, clinician education and patient experience, indicating little work has been done in this space so far[76].

1.3.2. Referrals for diabetic foot disease and CLTI

Whilst delays have been found in the symptom to treatment pathway for patients with and without diabetes[69], there is a far more established pathway available for the diabetic foot with the existence of multidisciplinary diabetic foot clinics.

Following the discovery of insulin in the 1920s, there was an increase in lower extremity gangrene. In order to treat this burgeoning group of patients, both podiatry and vascular surgery grew as specialties[77]. A UK specialised diabetic foot clinic was established at King's College Hospital in 1981, and a report of its outcomes showed a reduction in major limb amputations with multidisciplinary care[78]. Further multidisciplinary clinics followed throughout Europe, and the St Vincent Declaration in 1989 was agreed between government representatives and experts in diabetic medicine to reduce major limb amputations for gangrene in diabetes by a target of 50%[79].

A number of guidelines have been published since, by international bodies such as the International Working Group on the Diabetic Foot (IWGDF) and nationally by the National Institute of Health and Care Excellence (NICE), which recommend multidisciplinary care at all stages for people with a diabetic foot at risk[80,81]. NICE recommend "robust protocols and clear local pathways for the continued and integrated care of people across all settings including emergency care and general practice", as well as giving target timelines for referral and assessment of patients with varying severity of diabetic foot disease[81]. They recommend foot care structures are in place, which are audited by the National Diabetes Foot Care Audit (NDFA)[82]. These include: a Foot Protection Service (FPS); a multidisciplinary (or interdisciplinary) foot care service; and robust protocols and clear local pathways for care of people across all settings. Early multidisciplinary assessment is especially important in people with diabetes and PAD, who are at higher risk of poor healing and consequent major amputation, especially in the context of infection[83].

The institution of multidisciplinary diabetic foot care has reduced the number of major amputations in the diabetic cohort, with multiple individual descriptions and systematic reviews in the literature[84-86].

Vascular surgery led limb salvage teams were first described in 2009[87], with a focus on diabetic foot complications. The “toe-and-flow” three-tier model was defined for amputation prevention in the diabetic foot by Rogers et al[88], including basic, intermediate and Centre of Excellence elements. Criteria for the latter are set out in the Global Vascular Guidelines to act as standards for current and future services for all patients with CLTI, with or without diabetes[13]. They are displayed in Table 3.

Table 3: Global Vascular Guidelines criteria for CLTI Centre of Excellence designation[13]

Centre of Excellence essential criteria	**Description**
Multidisciplinary team of specialists	Specialists who can surgically and medically manage PAD and infections and provide the general or intensive medical care needed for the complex CLTI patient
Protocol-driven care	A team that follows written, evidence-based clinical practice pathways, policies, and procedures
Outcomes monitoring and reporting	Establishes a process for data collection and reports that data to the community or in the literature
Methods of improvement	Establishes a process for continual improvement based on outcomes and new techniques or therapies
Educational resource	Serves as an educational resource for the medical community through mentoring, publishing, and symposia

Nickinson et al performed a systematic review of vascular limb salvage services according to the criteria in Table 3[89]. Twelve single centre examples were found in the literature to 2019, mostly of moderate or low quality. Services for both diabetic foot ulcer and CLTI were included. They conclude that a vascular limb salvage service can reduce the rate of major amputations, but acknowledge limitations of the published data and provide recommendations for improved reporting in future research in this space[89].

Whilst the "toe-and-flow" model is recommended in the Global Vascular Guidelines[13], and has positive evidence behind it[89], it has not become widespread. Surveys of healthcare professionals in the context of diabetic foot disease have found multiple barriers to obtaining a specialist assessment, especially from vascular surgery services[90-92]. UK podiatrists found the process of referral to vascular surgery services complex with unclear criteria or pathways, and they often needed to refer via the patient's general practitioner (GP) rather than directly to the vascular team[90].

Between 2003 and 2013, the major limb amputation rate in England fell by 20%[93]. A person with diabetes was six times more likely to have a major amputation than a person without diabetes, but half the patients who had major amputations over that time period were non-diabetic[93]. The rate of decrease in amputation rate was half as fast in people without diabetes as in people with diabetes. There was a rise in minor amputations and stump procedures, which was driven by patients without diabetes[93]. It is likely that the non-diabetic cohort here represent patients with PAD and CLTI, with a small number of trauma patients. No specific integrated care structures or timelines are recommended by NICE for patients with PAD in the absence of diabetes[74], and we know vascular limb salvage services are not widespread[89]. This could be a factor contributing to inequity in care between patients with and without diabetes, and could lead to the delays in identification, referral and assessment described previously for patients with CLTI[69].

1.3.3. Awareness of CLTI

The first step of the CLTI pathway is the patient recognising they have a problem, and presenting to a clinician. Patients do not recognise PAD symptoms as important, and prioritise other conditions in consultation with primary care clinicians[94]. In one screening study, a third of people with lifestyle-limiting intermittent claudication had not presented to primary care clinician[95]. There is little knowledge of PAD and its consequences in the general population in both Europe and North America[96, 97]. The awareness that hospital-attending patients have of PAD is far less than other cardiovascular-related diseases such as myocardial infarction, stroke and diabetes[98]. This can be correlated with the incomes of the conditions' respective charities; the Circulation Foundation (Vascular Society) has an income of £306,967, whilst the British Heart Foundation has an income of over £351 million, the Stroke Association over £41 million and Diabetes UK of over £37 million[99]. Patients with PAD describe uncertainty around their condition and a desire for information to support self-management[100, 101], and even once they have progressed to a diagnosis of CLTI, patients have limited understanding of their condition[102]. Knowledge and understanding of PAD in the general population is not only desirable to ensure we have an informed cohort of patients, but perceptions of symptoms and beliefs about treatment predict prosthetic use in patients with PAD who go on to undergo major limb amputation, so awareness can improve outcomes[103].

A similar lack of awareness has been found in primary care clinicians. PAD is underdiagnosed and undertreated internationally[24]. Healthcare professionals involved in the care of PAD do not prioritise its identification or management above other conditions, as it is seen as not contributing to inventive programmes such as the Quality and Outcomes Framework (QOF), and interventions such as secondary prevention do not have an immediately visible patient benefit[94]. There is a lack of awareness of guidelines in PAD amongst primary care clinicians[94]. Patients with PAD are less likely than those with cardiac or cerebrovascular disease to have their hypertension or hypercholesterolaemia optimised, or have an antiplatelet prescribed[104], echoing the comparative disparity in awareness seen in patients.

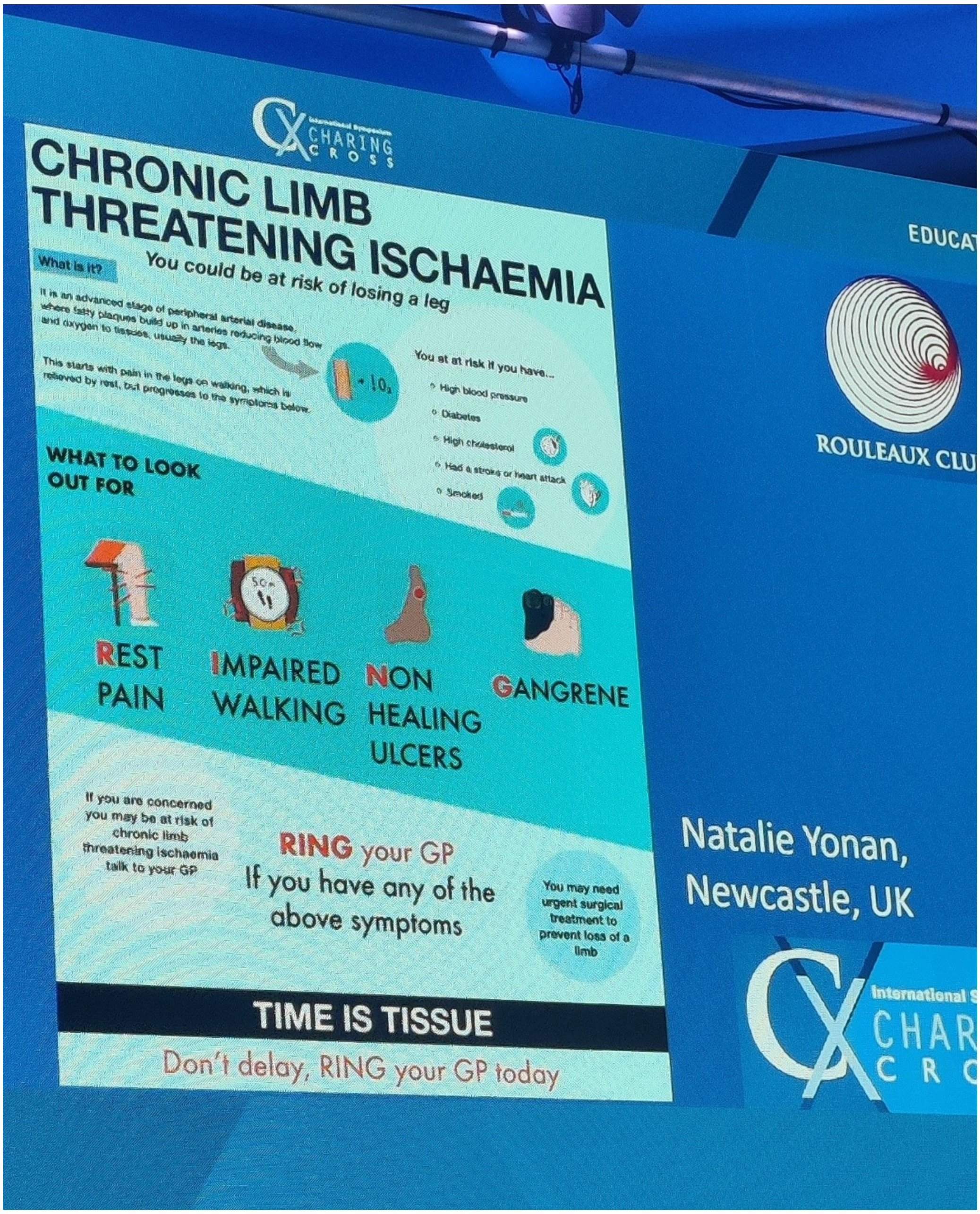
1.3.4. Patient and public awareness of other conditions

Many conditions outside vascular disease have experienced challenges with awareness. In stroke care, NHS England implemented the “Act FAST” national awareness-raising campaign between February 2009 and March 2012[105]. Previous mass media campaigns had been shown to increase awareness, but have limited effect on patient behaviour in relevant age groups[106]. The “Act FAST” campaign has been found to increase awareness of stroke symptoms and perceived response to these in some stroke patients and witnesses as well as the general public[107, 108].

There have been many awareness campaigns for different types of cancer under the “Be Clear on Cancer” umbrella[109]. A lack of awareness of cancer symptoms has been associated with poorer survival[110]. These were run as mass media public awareness campaigns, using television, radio and posters. The campaigns started in 2010 and were run for 11 cancer sites, concentrating on one or two symptoms each. A review paper has synthesised the results for these 11 campaigns between 2012 and 2016, and found attendances to primary care, urgent referrals for further investigation, and diagnoses of cancer following urgent referrals increased in the majority of campaigns, although there was no increase in cancer survival[109].

To date, there have been no national awareness campaigns for PAD or CLTI. Awareness of risk factors for peripheral arterial disease has consequently been found to be low in patients attending clinic for vascular consultations[111]. Success in raising awareness seen in other conditions could perhaps be mirrored in vascular surgery in the future. This has been recognised with “The Hurting Leg” competitions at the 2023 Charing Cross International Symposium offering monetary prizes for infographics and infomercials to educate the public on CLTI[112].

Figure 2: Winning infographic “The Hurting Leg”, Charing Cross International Symposium 2023 – Rouleaux Club X account[113]



CHRONIC LIMB THREATENING ISCHAEMIA

You could be at risk of losing a leg

What is it?

It is an advanced stage of peripheral arterial disease, where fatty plaques build up in arteries reducing blood flow and oxygen to tissues, usually the legs.

This starts with pain in the legs on walking, which is relieved by rest, but progresses to the symptoms below.

You at at risk if you have...

- High blood pressure
- Diabetes
- High cholesterol
- Had a stroke or heart attack
- Smoked

WHAT TO LOOK OUT FOR

REST PAIN

IMPAIRED WALKING

NON HEALING ULCERS

GANGRENE

If you are concerned you may be at risk of chronic limb threatening ischaemia talk to your GP

RING your GP
If you have any of the above symptoms

You may need urgent surgical treatment to prevent loss of a limb

TIME IS TISSUE

Don’t delay, RING your GP today

Natalie Yonan,
Newcastle, UK

1.4. Qualitative research

1.4.1. What is qualitative research?

Qualitative research enables an in-depth understanding of the worlds of participants, by discussing their backgrounds, perspectives and experiences[114]. It allows researchers to understand how people view the world around them[115]. There are multiple qualitative methodologies available to researchers, each of which is a “package of assumptions about what counts as research and how it is conducted”[116]. Methodologies are based on ontological and epistemological perspectives, which in turn influence how the research is carried out.

Qualitative methods are used when authors wish to understand the “why” behind the phenomenon in question. Qualitative research has the ability to make sense of the thoughts and perceptions of participants in the context of their own experiences. This is impossible to do in quantitative research. A qualitative study design captures detailed aspects of participants’ experience in a depth that would not be possible in, for example, a survey study.

1.4.2. Qualitative research in vascular disease

Much of the qualitative work carried out with vascular surgery patients relates to complications of diabetic foot disease or PAD. Several reports have explored the experience of patients with diabetic foot complications in high income countries, including minor and major amputations[117-121]. Littman et al investigated reasons for delays in care prior to minor and major amputation in patients with diabetes receiving care from the USA’s Department of Veterans Affairs, and used thematic analysis to identify patient and system level factors[118]. System level factors related to the process of referral included health care professionals not recognising the seriousness of the presenting symptom, delays in getting an appointment with an appropriate clinician (such as a podiatrist or vascular surgeon), and difficulty for the patient to get to the appropriate care location[118].

A systematic review of 14 qualitative studies in PAD mainly included patients with intermittent claudication, most of which focussed on patients' experience and understanding of their disease whilst awaiting or following intervention[122]. Delays in diagnosis were identified here, similar to the diabetic foot complications, with patients delaying seeking medical attention and health care professionals not recognising their symptoms as PAD[122]. A more recent study of health professionals and patients with PAD identified factors impacting on the diagnosis of PAD including ankle-brachial pressure index (ABPI) availability, health professional attitudes and patient delays including lack of awareness of PAD symptoms[94].

Qualitative literature for patients with a specific diagnosis of CLTI focuses on what patients value in terms of the experience of their inpatient care[123], or the patient's experience of CLTI as it affects their own perception of their body[124]. Whilst Aitken et al identified delays in the treatment pathway of the patients interviewed, this was not expanded upon[123].

1.4.3. Qualitative research on referrals in other specialties

Patient experience of urgent referral pathways for conditions such as cancer has been evaluated previously using qualitative methods[125-127]. Researchers have found variation in patient experience, poor communication and preparation, and minimal patient involvement in decision making throughout different urgent cancer pathways[125, 127]. A 2019 General Medical Council (GMC) commissioned mixed methods study found patients with higher satisfaction with the referral process had been adequately counselled regarding expectations of the timing and purpose of appointments. It also identified that patients felt improvements could be made in communication, clarity and speed of the process[128].

Cancer has some resemblance to CLTI in that symptoms can often be similar to those of more benign conditions, leading to a potential delay in referral[129]. Secondary care cancer physicians in North West London identified delays in referral to oncology services as a factor in delayed diagnosis of cancer, and recommended improved adherence of primary care clinicians to guidelines[130]. Primary care clinicians in turn have previously expressed frustration at policymakers' lack of understanding of risk management in primary care, as well as the complexity and conflict inherent to primary care practice in the context of cancer referrals[131]. It is therefore important for any work on referrals to represent views from both primary care clinicians and hospital services.

There is a paucity of qualitative evidence from patients and clinicians on the process to diagnosis for CLTI and what constitutes a good experience for both groups. The Medical Research Council (MRC) has provided guidance on the development and evaluation of complex interventions, such as a referral pathway, which include recommendations to include meaningful engagement with diverse stakeholders at all stages of the change process[132]. Thus, it is vital to obtain such evidence during the planning phase of any such interventions.

1.5. Aims of this thesis

CLTI is a serious condition, with severe consequences to life and limb. There has been national recognition of the need for improvements in the quality of care for patients with this condition, and strategies including registries and QI collaboratives have been implemented, successfully driving improvement in vascular surgery. There remains room for further improvement, however. There are ongoing delays in the care received by patients with CLTI, with models of multidisciplinary care not being widely available for patients without diabetes, and a lack of patient, public and primary care clinician awareness of PAD.

This thesis aimed to identify, define and prioritise facilitators and barriers of the timely and appropriate referral of patients with CLTI from primary care into vascular surgery services. It explored potential solutions and how they can be effectively applied. Multiple methodologies were used to answer the following research questions:

1. What recommendations are available for primary care clinicians referring patients with suspected CLTI?
2. What pathways are in place for the referral and assessment of patients in the community with suspected CLTI?
3. What are the experiences and perceptions of the process from first symptom of CLTI to diagnosis of patients, primary care clinicians and vascular surgery clinicians?
4. What evidence is there that QI collaboratives are effective to achieve quality improvement objectives in the UK surgical context?

A documentary analysis was performed to assess guidance available to primary care clinicians wishing to refer patients with suspected CLTI to vascular surgery services. A process mapping exercise was carried out to understand processes of referral into vascular surgery services across the country. Qualitative studies of clinicians' and patients' experiences of the referral process were undertaken, and their perceptions of where improvements can be made explored.

A systematic review was performed to ascertain the effectiveness of collaborative QI interventions in UK surgical specialties, and identify relevant facilitators and barriers that could have transferrable elements to a vascular surgery QI collaborative such as PAD-QIP.

The results of the studies above allowed evidence-based intervention strategies to be suggested in the Discussion and Conclusions of this thesis. These may be used by individual vascular surgery units or on a national level to improve the referral process for patients with CLTI.

Chapter 2. A documentary analysis of national and international guidance for primary care clinicians referring patients with suspected chronic limb-threatening ischaemia

2.1. Introduction

Some delays in the CLTI management pathway relate to the timely recognition and referral of patients with suspected CLTI to vascular surgery services from community settings[69]. A reason for this could be a lack of effective recommendations on referral in guidance available to primary care clinicians on the management of CLTI. Poor guidance regarding referrals has been identified in other clinical conditions, with recommendations containing incomplete information or being phrased ambiguously[133, 134].

This study analysed recommendations on the referral of patients with suspected CLTI to vascular surgery services in national and international guidance documents. The aim was to understand what guidance is available for clinicians in the community who wish to refer patients with suspected CLTI for specialist assessment and management, what techniques may be used to attempt to change the behaviour of a referring clinician, and whether existing guidance can be improved.

2.2. Methods

Documentary analysis is a method of qualitative research in which the content of documents on a specified topic is appraised[135]. This study followed the READ approach to documentary analysis: ready materials; extract data; analyse data; and distil findings[136].

2.2.1. Search strategy

A database search of Medline and Embase from inception to 4th November 2022 was carried out, with search terms including Chronic limb threatening isch*mia OR CLTI OR Critical limb isch*mia OR Severe limb isch*mia combined with Refer* and Guid* OR Recommend*. Searches were then carried out using Google and on the websites of guideline developers NICE, Guidelines International Network (GIN), the Trip database, Scottish Intercollegiate Guidelines Network (SIGN) and individual medical Colleges or Societies. Search terms for Google included “CLTI referral guidelines”, “CLTI referral”, “limb ischaemia guidelines” and “limb ischaemia referral”, with broader search terms for guideline databases and individual College or Society websites such as “vascular” and “ischaemia”. A full description of the search strategy is available in Appendix 1. “Document” is used throughout this study as an umbrella term relating to an article, webpage or pdf file containing written data. Once a relevant document was found, the publishing body’s website was searched to ensure the most up-to-date guidance was used. Whilst this is not a formal systematic review, the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) Statement was used as a framework for reporting[137].

2.2.2. Inclusion criteria and study selection

The study included national and international documents providing guidance on referral to a vascular surgery service for patients with suspected CLTI. Local protocols were excluded, in order to capture general principles of referral rather than specific local practice. Documents providing guidance on recognition or operative management of CLTI only, without reference to referrals, were excluded. Guidance could be aimed at any healthcare professional. In this pragmatic study, only publicly accessible documents were included in order to accurately replicate primary care clinician access to the documents. The review was limited to documents written in the English language. Paid-for resources such as UpToDate or journal articles requiring a fee to read were excluded, as they were not considered widely available, especially to community nursing teams or podiatrists who are more likely to be involved in lower limb wound care than general practitioners.

2.2.3. Data extraction and analysis

Data were extracted in a pre-piloted form on a Microsoft Excel spreadsheet and included: date and location published; (medical) discipline of contributors; any guidance endorsements; and on whose behalf the guidance was being issued. Data were also extracted on any referral recommendation, including timing, prompts for referral, to whom the patient should be referred, and consequences of not being referred.

A document providing guidance may be seen as a behaviour change intervention because it aims to influence the behaviour of its audience[138]. Behaviour change techniques can be classified according to the Behaviour Change Technique Taxonomy, a collection of behaviour change techniques which can be used to extract information about intervention content[139]. This was developed in 2013 via a Delphi-style exercise that summarised previously published classifications of behaviour change techniques into a list of 93 techniques within 16 groups[139]. The text in the documents pertaining to referral recommendations for CLTI was coded according to the Behaviour Change Technique Taxonomy.

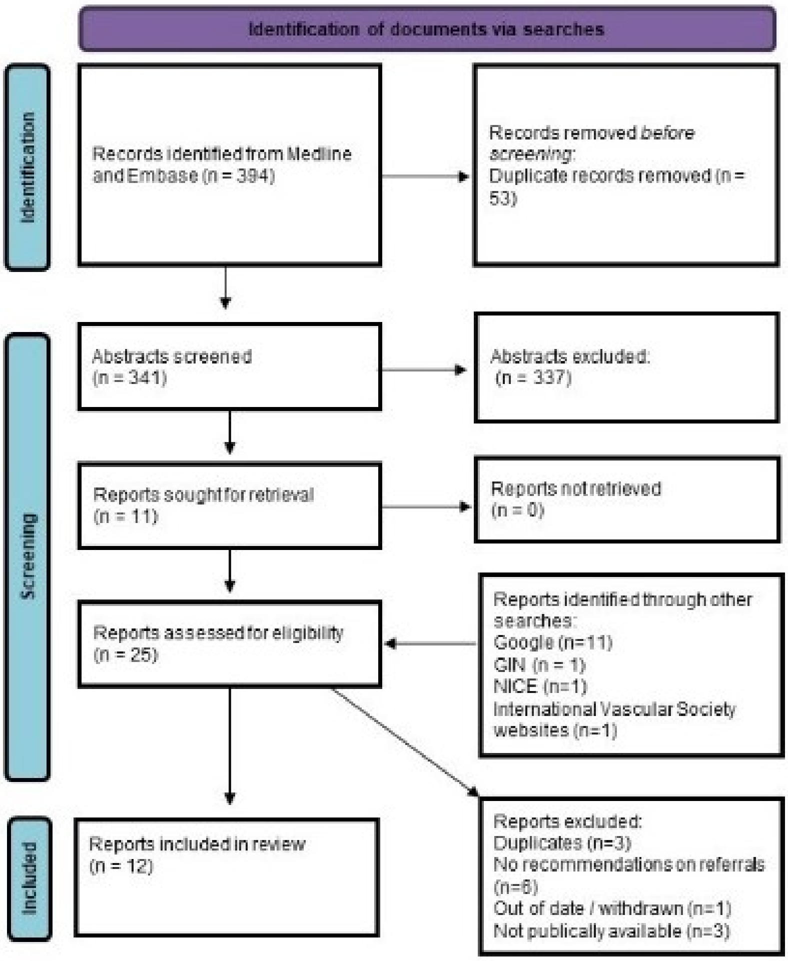
Retrieved documents that met the definition of a clinical practice guideline, that is, recommendations to optimise patient care informed by a systematic review of evidence[140], were scored using selected domains of the Appraisal of Guidelines Research and Evaluation (AGREE) II and Guideline Implementability Appraisal (GLIA) tools, which assess quality and ease of implementation respectively[141, 142]. For the AGREE II tool, each relevant item is ranked on a Likert scale of 1 (strongly disagree) to 7 (strongly agree), based solely on the recommendation for referral of CLTI. Individual scores for each domain were totalled and represented as percentages of the maximum available scores, which were used to rank the guideline quality for each domain. For the GLIA tool, a Y (Yes) or N (No) is used to indicate whether the recommendation meets criteria based on executability, decidability, validity, flexibility, effect on process of care, measurability, and novelty.

I conducted the searches, and the document selection was validated by one supervisor (IK). I extracted the data from the selected documents and performed initial analysis, with IK carrying out the behavioural change technique analysis, which I reviewed and validated. I and PB independently scored the clinical practice guidelines. Any discrepancies of more than 2 points in scoring on the AGREE II tool were discussed amongst the group until a consensus was reached[143]. Discrepancies in the GLIA tool were similarly discussed until a consensus was reached[142]. DAC provided a casting vote in any case of disagreement.

2.3. Results

After automated removal of duplicates, 341 unique results were retrieved from Medline and Embase. Following screening of title and abstract, 11 articles were retrieved for full text analysis. Further searches, carried out on the same day, identified 11 additional unique results for full text analysis. Figure 3 demonstrates a flow diagram for this process.

Figure 3: Flow diagram demonstrating search strategy



One of the 22 retrieved documents was out of date and had been withdrawn from the publishing body's website, and three journal articles were not publicly accessible. They were therefore not included in our analysis. Six of the documents contained no recommendations on referrals for CLTI and were therefore not eligible for inclusion. A list of non-included documents can be found in Appendix 2.

The 12 remaining documents were from across the globe, and mainly from high-income countries. One document was global, three were from the USA, seven from Europe (including four from the UK), and one from the West Indies. Five documents were clinical practice guidelines[140]. Table 4 contains a summary of the 12 documents.

Table 4: Summary of reviewed documents

Document title	Body represented	Country from	Location published	Date published	Publication form	Community clinician involved?
Peripheral Arterial Disease – Diagnosis and Treatment: A Systematic Review[144]	The Swedish Council on Technology Assessment in Health Care	Sweden	Swedish Council on Health Technology Assessment (SBU)	2008	Systematic review	No
2016 American Heart Association (AHA)/American College of Cardiology (ACC) Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease[145]	American College of Cardiology, American Heart Association	USA	Journal of the American College of Cardiology, Circulation, Vascular Medicine	2016	Clinical practice guideline	No
2017 European Society of Cardiology (ESC) Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)[146]	European Society of Cardiology	Europe	European Heart Journal	2017	Clinical practice guideline	No
Guidelines on Management of the Patient with Diabetic Foot Infection[147]	University of the West Indies / University Hospital of the West Indies, Association of Surgeons of Jamaica	West Indies (Jamaica)	West Indian Medical Journal	2019	Clinical practice guideline	No
Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia[13]	Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies	Worldwide	Journal of Vascular Surgery, European Journal of Vascular and Endovascular Surgery	2019	Clinical practice guideline	No
Lower extremity peripheral arterial disease: diagnosis and treatment[148]	American Academy of Family Physicians	USA	American Family Physician	2019	Journal article	Yes

Lower Limb Ischaemia[149]	Finnish Medical Society	Finland	Duodecim Medical Publications	2020	Website	No
Peripheral arterial disease: diagnosis and management[74]	National Institute of Health and Care Excellence	England and Wales	National Institute of Health and Care Excellence	2020	Clinical practice guideline	Nil documented
Recommendations for lower limb ulcers[150]	National Wound Care Strategy Programme	UK	National Wound Care Strategy Programme	2020	Document	Nil documented
Provision of Services for People with Vascular Disease 2021[16]	The Vascular Society for Great Britain and Ireland	UK	Journal of Vascular Societies Great Britain and Ireland	2021	Document	No
Patients with Chronic Limb-Threatening Ischaemia (CLTI)[151]	Society of Vascular Surgery	USA	Society for Vascular Surgery website	2022	Website	Nil documented
A Best Practice Clinical Care Pathway for Peripheral Arterial Disease[27]	The Vascular Society for Great Britain and Ireland	UK	Journal of Vascular Societies Great Britain and Ireland	2022	Clinical care pathway	No

Eight documents were published in peer-reviewed medical journals. Others were only available on websites aligned to various professional bodies, such as the Finnish Medical Society, NICE, the UK National Wound Care Strategy Programme, and the USA Society for Vascular Surgery.

Documents typically stated the range of audiences at which they were aimed (one did not[146]). Two were aimed at community clinicians[148, 149]. Three were aimed at other specific audiences – general surgeons in Jamaica[147], referring physicians[151] and vascular network leads[27]. The remaining six documents stated they aimed to reach an extremely broad audience, including phrases such as "those working in medical or social services"[144], "commissioners, providers and clinicians"[16], and "healthcare professionals, commissioners and providers, adults, and their families and carers"[74] and "intended for use in all clinical care settings"[150].

Nine documents described who was in their author group; three documents did not list any contributors[74, 150, 151]. An average of 16 authors was documented (range 2-58), and in some cases, the specialties of the author group were stated. In four documents, inclusion of more than two specialties was described, such as vascular surgery, interventional radiology, cardiology, diabetology, anaesthetics, medicine, nursing and podiatry[16, 27, 145, 147]. One author group included a patient representative[145]. Just one of the documents, a journal article, mentioned the inclusion of a clinician with a primary affiliation from a community healthcare organisation in the writing process, the article being a collaboration between a vascular surgeon and a family physician[148]. None of the five clinical practice guidelines described inclusion of primary care clinicians in the author group. It seems despite most documents defining an audience including primary care clinicians, guidance authors are not considering community representation in author groups.

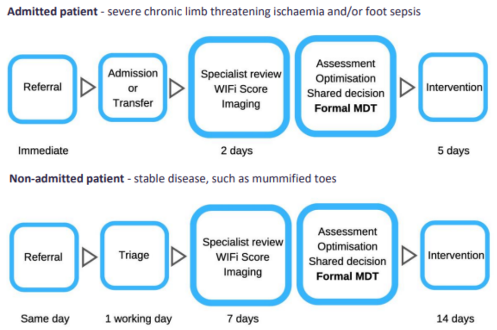
Eleven of the documents were written on behalf of national and international bodies, including medical and surgical societies, government and vascular surgery societies. Those with documented endorsements[13, 16, 27, 145, 146] were endorsed by national and international bodies representing vascular surgical societies and medical, radiological and associated healthcare professional societies. Two documents were endorsed by national podiatric societies, which represent podiatrists providing care both in community and hospital settings[13, 16]. None had official endorsements from a professional body related to medical care in the community.

It is of note that the NICE guideline CG147 did in fact have community representation on the guideline development group in the form of one general practitioner. There were also two patient and carer members of the author group. This information was available on a separate downloadable pdf distant from the CG147 webpage, which was the document analysed in this study[74]. Similarly, there is a long list of stakeholders available in a further downloadable pdf including multiple clinical commissioning groups (CCGs) and the Royal College of General Practice. According to the pragmatism described in the Methods, this information was not immediately accessible to a community clinician seeking guidance so was not included in my analysis.

2.3.1. Behaviour Change Technique Taxonomy coding

The guidance contained within the 12 documents was coded according to the Behaviour Change Technique Taxonomy[139]. Four of the 93 possible techniques were found within the recommendations: action planning (prompt, detailed planning of performance of the behaviour including duration); instruction on how to perform behaviour; information about health consequences; and prompts / cues (introduce or define environmental or social stimulus). Their distribution can be seen in Table 5 along with the content of the guidance.

Table 5: Content of guidance and behaviour change techniques

Document title	BCT	Recommendation
Guidelines on Management of the Patient with Diabetic Foot Infection	4.1 5.1 7.1	"Diabetic patients presenting with an infected foot should have the arterial perfusion of the affected limb assessed clinically for symptoms and signs of severe/critical limb ischaemia. Ankle-brachial index (ABI) should be measured; a Doppler machine is preferable but an automated blood pressure machine may also be used. If clinical critical limb ischaemia is diagnosed and/or ABI is ≤ 0.5, AND the foot is clinically viable, duplex ultrasonography or computed tomography (CT) angiogram should be requested and the results discussed with a vascular surgeon." "The Committee is of the view that if the arterial anatomy is amenable to reconstruction, the patient should be afforded the opportunity for limb salvage if a vascular surgeon is available to accept referral." "If critical limb ischaemia is diagnosed and either the angiogram reveals arterial anatomy unfavourable for revascularization or referral to a vascular surgeon is not feasible or the foot is not viable (and therefore not salvageable even if successful revascularization were feasible), amputation no lower than below knee level should be contemplated."
Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia	4.1 5.1 7.1	"Refer all patients with suspected CLTI to a vascular specialist for consideration of limb salvage, unless major amputation is considered medically urgent."
2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease	4.1 5.1 7.1	"In patients with PAD and signs of foot infection, prompt referral to an interdisciplinary care team can be beneficial" "Patients with CLI should be evaluated by an interdisciplinary care team" "An interdisciplinary care team should evaluate and provide comprehensive care for patients with CLI and tissue loss to achieve complete wound healing and a functional foot"
Peripheral Arterial Disease – Diagnosis and Treatment: A Systematic Review	1.4 5.1 7.1	"Patients who have symptoms of critical limb ischaemia must receive prompt treatment to relieve the pain and minimise or eliminate the risk of deterioration leading to ulcers and tissue death (gangrene)."
Patients with Chronic Limb-Threatening Ischaemia (CLTI)	1.4 4.1 5.1 7.1	"All patients with suspected CLTI should be referred urgently to a vascular surgeon for limb salvage efforts. All patients with rest pain, non-healing foot ulcers/wounds, or gangrene should have vascular testing to assess blood supply and potential for healing." "Early referral to a vascular surgeon for limb salvage efforts is recommended" "Refer all patients with suspected CLTI to a vascular specialist for consideration of limb salvage" (reproduction of Global Vascular Guidelines)
A Best Practice Clinical Care Pathway for Peripheral Arterial Disease	1.4 7.1	

Provision of Services for People with Vascular Disease 2021	1.4 4.1 7.1	“The majority of vascular referrals are time-critical, requiring either inpatient admission or a well organised pathway for outpatient assessment and imaging (i.e., for CLTI with managed rest pain)" "Referral pathways should be in place to ensure that people with non-diabetic lower limb (i.e., venous) and foot ulcers are appropriately referred to vascular services" "Time-critical CLTI pathways should be a key focus for vascular networks: • General practitioners, podiatrists, community nurses and ED doctors should have the necessary clinical skills to diagnose and assess a person presenting with CLTI • People with suspected CLTI should be referred the same day for assessment • Patients with severe ischaemia and/or with foot infection (including sepsis) should be discussed immediately with the on call vascular team for same day admission to the arterial centre"
2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases	1.4 4.1 5.1 7.1	"Early recognition of tissue loss and/or infection and referral to a vascular specialist is mandatory for limb salvage by a multidisciplinary approach." "Early recognition of tissue loss and/or infection and referral to the vascular team is mandatory to improve limb salvage"
Lower Limb Ischaemia	1.4 4,1 7.1	"Patients with critical ischaemia require urgent referral to a vascular surgeon" "If critical ischaemia is suspected, the patient should be referred without delay, even as an emergency case, to a vascular surgery unit"
Peripheral arterial disease: diagnosis and management	4.1 7.1	"Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made"
Lower extremity peripheral arterial disease: diagnosis and treatment	1.4 4.1	"Patients with acute or limb-threatening limb ischemia should be referred immediately to a vascular surgeon" "Patients with any of these findings require urgent referral to a vascular surgeon"
Recommendations for lower limb ulcers	1.4 4.1 5.1 7.1	"Immediately escalate to relevant clinical specialist" [red flag of "acute or chronic limb-threatening ischaemia"] "A person with a non-diabetic foot wound, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service" "People with foot ulcers, whether associated with diabetes or not, are at high risk of leg, foot or toe amputation and increased risk of death. All people with non-healing wounds on the foot should be able to swiftly access services for assessment, diagnosis and treatment planning" "If there is evidence of ischaemia, refer for vascular surgical interventions"

1.4: Action planning – prompt, detailed planning of performance of the behaviour (including duration). 4.1: Instruction on how to perform behaviour. 5.1: Information about health consequences. 7.1: Prompts / cues – introduce or define environmental or social stimulus.

All guidance contained a reference to a suspicion of CLTI to prompt referral, but only five documents referred to specific symptoms such as rest pain, tissue loss or gangrene within their recommendation[13, 27, 145, 146]. Nine documents contained advice on the timing of a referral, with five quantifying the time to referral (as “same day”, “immediate” and “as an emergency case”) [16, 27, 148-150]. The other four referred to “early”, “urgent” and “prompt” referral[144-146, 151]. Ten documents gave information on who to refer to. In nine cases this mentioned vascular surgery[13, 16, 74, 146-151] and one an “interdisciplinary care team”[145].

Seven documents referred to potential consequences of not referring the patient[13, 144-147, 150, 151]. Four of these used the phrase “limb salvage”[13, 146, 147, 151], which, while well recognised by vascular surgeons, may not be a language shared with clinicians outside the specialty. No documents referred to mortality or amputation as a specific consequence of delayed referral.

2.3.2. AGREE II analysis of clinical practice guideline quality

A higher domain score indicates higher guideline quality. The following AGREE II domains were scored:

- *Stakeholder involvement*, which assesses the relevance of the professional groups involved in guideline development according to the audience of the guideline.
- *Clarity of presentation*, which assesses language, readability and ease of use of the referral recommendation only.
- *Applicability*, which assesses facilitators and barriers to implementation of the referral recommendation.

The AGREE II scores for each domain are demonstrated in Table 6. The highest ranked clinical practice guideline in all domains was the Global Vascular Guidelines[13].

Table 6: Summary of AGREE II domain and overall scores

	Scores (%)		
	Domains		
Guideline	**Stakeholder involvement**	**Clarity of presentation**	**Applicability**
Guidelines on Management of the Patient with Diabetic Foot Infection[21]	50.0	71.4	35.7
Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia[29]	52.4	92.9	57.1
2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease[28]	47.6	88.1	30.4
2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)[18]	21.4	90.5	35.7
Peripheral arterial disease: diagnosis and management[26]	42.9	71.4	25.0
Mean domain score	**42.9**	**82.9**	**36.8**

2.3.3. GLIA analysis of clinical practice guideline ease of implementation

The results of the GLIA analysis are demonstrated in Table 7.

- *Global considerations:* Clinical practice guidelines which did not specify their audience or had a non-diverse author group failed criteria in this domain. Only one guideline satisfied all criteria.
- *Executability:* All clinical practice guidelines failed each criterion in this domain, by not giving specific unambiguous recommendations, with enough detail on how to perform the recommended action.
- *Decidability:* The lack of a specified audience and a definition of CLTI led guidelines to fail criteria in this domain, with one study satisfying both applicable criteria.
- *Validity:* Two guidelines failed to make an assessment of the strength of evidence supporting their recommendation on referrals for CLTI, so failed a criterion in this domain.

- *Flexibility:* Some clinical practice guidelines did not cover modifications to the recommendation that may be required due to patient or practice characteristics. They also used ambiguous language to refer to the strength of recommendations such as “should” and “can be”. None of the guidelines satisfied all criteria in this domain.
- *Effect on process of care:* All clinical practice guidelines provided recommendations which would not impact on the usual workflow of the care setting in which they would be applied.
- *Measurability:* Whilst adherence to the recommendation could be measured (if appropriate data were collected), the outcomes of the recommendation were not clear enough in the clinical practice guidelines to enable measuring.
- *Novelty / Innovation:* Recommendations in all guidelines would not be considered unconventional by clinicians or patients.

Table 7: Summary of Clinical Practice Guideline analysis according to the GLIA tool

	Guidelines				
	Guidelines on Management of the Patient with Diabetic Foot Infection	Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia	2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease	2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)	Peripheral arterial disease: diagnosis and management
Global considerations					
Does the guideline clearly define the target patient population?	Y	Y	Y	Y	Y
Does the guideline clearly define its intended audience (i.e., types of providers)?	Y	Y	N (not defined)	N (not defined)	Y
Are the settings in which the guideline is to be used clearly described?	Y	Y	Y	N (not defined)	N (not defined)
Do the organization(s) and author(s) who developed the guideline have credibility with the intended audience of the guideline?	Y	N (no community clinicians in author group)	N (no audience specified)	N (no audience specified)	Y
Does the guideline suggest strategies for implementation or tools for application e.g., a summary document, a quick reference guide, educational tools, patients' leaflets, online resources or computer software?	Y	Y	Y	Y	Y
Is it clear in what sequence the recommendations should be applied?	Y	Y	Y	Y	Y
Is the guideline internally consistent, i.e., without contradictions between recommendations or between text recommendations and flowcharts,	N/A	Y	Y	Y	Y

summaries, patient education materials, etc.?					
Are all recommendations easily identifiable, e.g., summarized in a box, bold text, underlined, etc.?	Y	Y	Y	Y	Y
Are all recommendations (and their discussions) concise?	Y	Y	Y	Y	Y
Executability					
Is the recommended action (what to do) stated specifically and unambiguously?	N (no timing of recommendation)	N (no timing of recommendation)	N ("prompt" is ambiguous)	N ("early" is ambiguous)	N (no timing of recommendation)
Is sufficient detail provided or referenced (about how to do it) to allow the intended audience to perform the recommended action.	N (no definition of CLTI, no information on how to refer)	N (no information on how to refer)	N (no information on how to refer)	N (no information on how to refer)	N (no definition, no information on how to refer)
Decidability					
Would the guideline's intended audience consistently determine whether each condition in the recommendation has been satisfied? That is, is each and every condition described clearly enough so that reasonable practitioners would agree when the recommendation should be applied?	N (no definitions)	Y	N/A (no audience)	N/A (no audience)	N (no definition)
Are all reasonable combinations of conditions addressed?	N/A	N/A	N/A	N/A	N/A
If this recommendation contains more than one condition, is the logical relationship (ANDs and ORs) between conditions clear?	Y	N/A	Y	Y	N/A
Validity					
Is the justification for the recommendation stated explicitly?	Y	Y	Y	Y	Y
Is the quality of evidence that supports each recommendation stated explicitly?	N (no comment on strength of evidence)	Y	Y	Y	N (no comment on strength of evidence)

Flexibility					
Is the strength of each recommendation stated explicitly?	N (“should” used for all)	Y	N (“can be”, “should”)	Y	Y
Does the recommendation specify patient characteristics (such as coincident drug therapy and common co-morbid conditions) that require or permit individualization?	Y	N (no mention)	N (no mention)	Y	N (no mention)
Does the recommendation specify practice characteristics (such as location and availability of support services) that require or permit modification?	Y	N (none specified)	N (none specified)	N (none specified)	N (none specified)
Effect on process of care					
Can the recommendation be carried out without substantial disruption in current workflow?	Y	Y	Y	Y	Y
Can the recommendation be pilot tested without substantial resource commitment?	Y	Y	Y	Y	Y
Measurability					
Can adherence to this recommendation be measured?	Y	Y	Y	Y	Y
Can outcomes of this recommendation be measured?	N (not clear enough)	N (not clear enough)	N (not clear enough)	N (not clear enough)	N (not clear enough)
Novelty / Innovation					
Can the recommendation be performed by the guideline’s intended users without acquisition of new knowledge or skills?	Y	Y	Y	Y	Y
Is the recommendation consistent with existing attitudes and beliefs of the guideline’s intended audience?	Y	Y	Y	Y	Y
Is the recommendation consistent with patient expectations?	Y	Y	Y	Y	Y

2.4. Discussion

This documentary analysis has identified aspects of existing guidance for referral of CLTI that can be improved including the representation of community clinicians and groups, inclusion of behavioural change techniques and how language is used in providing guidance. CLTI is a life and limb-threatening disease, and patients suspected of having the condition must be referred expeditiously to vascular surgery services in order to minimise adverse outcomes associated with delays to treatment. In CLTI, a delay in referral and therefore treatment can lead to increased mortality and limb loss[152].

This documentary analysis analysed 12 current English language documents from national bodies that contained CLTI referral guidance applicable to clinicians in the community. Nine documents appeared to be aimed at primary care clinicians, but the lack of specificity in the documents' audiences indicate that referring clinicians may not have been considered as the principal audience. The AGREE II tool, which assesses the quality and reporting of guidelines[141], adopts the widely held view that, for a good quality guideline, the stakeholder group must include professionals from all relevant groups. Just one of the documents analysed had documented primary care clinician contributions to authorship, and none of the clinical practice guidelines documented community representation in the author groups. All documents analysed were produced by credible sources, written and endorsed by national and international bodies representing vascular surgical societies, medical and surgical societies and government. However, whilst two were endorsed by podiatric societies representing both hospital and community clinicians, none were officially endorsed by a primary care organisation or society, and no guidance was found on family medicine society or College websites. The lack of community representation on author groups and endorsing bodies may act as a barrier to primary care clinicians viewing the guideline as applicable to them[153].

All documents contained a prompt or cue for the clinician in the community to recognise the need for referral. A number of them referred to “chronic limb-threatening ischaemia”, “CLTI” or “critical limb ischaemia” rather than specific symptoms, although definitions of the condition were generally made elsewhere in the document. Where specific symptoms were mentioned, these were not exhaustive and generally referred to the presence of tissue loss. A lack of specificity has been shown to reduce referrals from community medicine[154]. A need for new knowledge has also been shown to act as barrier to adherence to guidance[155, 156].

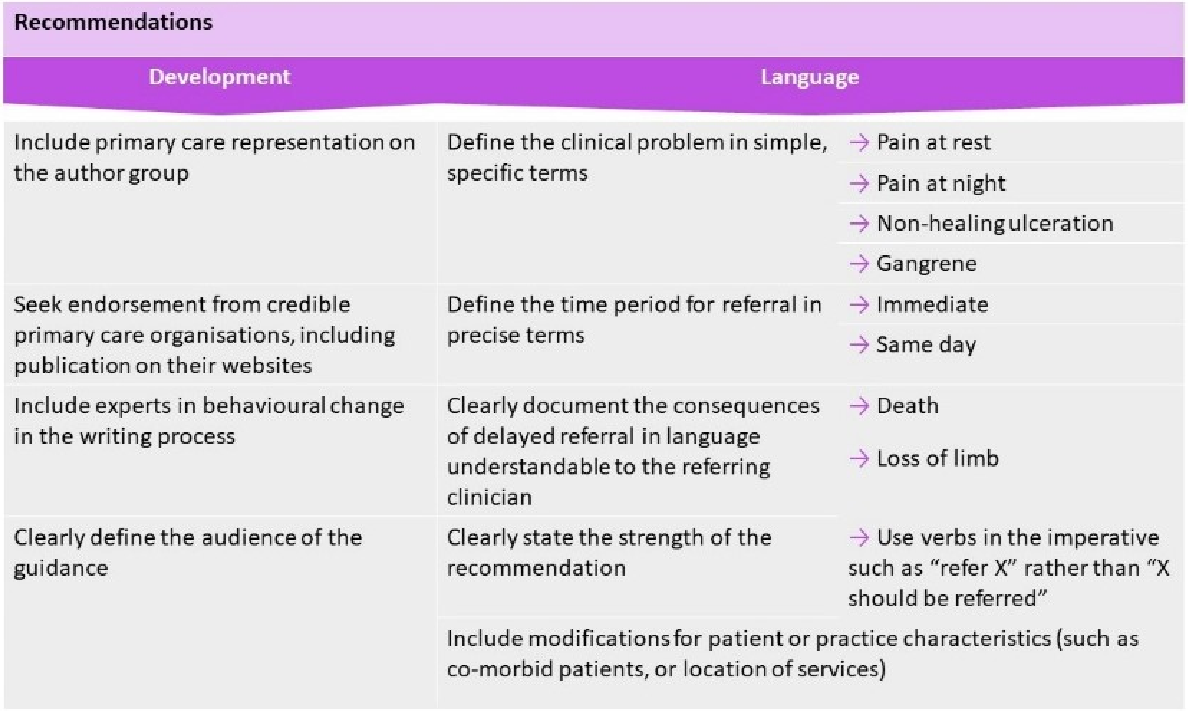
Three of the six documents containing guidance on timing of referrals used words such as “early”, “prompt” and “urgent”. In the primary care context, the time period they refer to is non-specific. “Urgent” is often seen in the United Kingdom with reference to cancer referrals, where it indicates a two week wait for hospital assessment[157]. This is not appropriate in the context of CLTI and may lead community clinicians to delay referral unnecessarily. A lack of precision in behavioural instructions may result in fewer community clinicians following guidance[154]. The use of specific concrete statements increases the understanding and remembering of information[158], and this could help where a lack of knowledge or skill is a barrier to referral[159]. It also allows the clinical audit of whether recommendations have been followed[160]. Guidance written in simple, concise terms allows identification and manipulation of antecedents and consequences of said behaviour[161].

The lack of information on the consequences of delays in management of CLTI (namely major limb amputation and mortality) may also contribute to delayed referral[162]. Beliefs about consequences have been seen to affect referrals both positively and negatively in other conditions[163], and knowledge of such serious consequences may motivate community clinicians to refer in a timely fashion. The use of phrases such as “limb salvage” instead of directly referring to the risk of amputation or mortality may lead to confusion or misunderstanding in the community. Where there is a clear description of the supporting evidence, recommendations are more likely to be adhered to[154].

Just four of the 93 available behavioural change techniques were utilised in the guidance documents analysed. This shows that opportunity exists to consider the application of other behavioural change techniques in future guidance[161]. Specific behavioural change techniques have been identified as leading to higher success rates in behaviour change interventions such as smoking cessation services[164], and further research is required to evaluate their effectiveness in wider contexts[165]. Clinical practice guidelines need to change behaviour to be effective, and according to our analysis a limited number of available techniques are used in this context. The inclusion of behaviour change specialists in the creation of future guidance documents may increase their ability to effect behaviour change, and further work to understand the role of behavioural change techniques in guidance documents is recommended.

The AGREE II tool has been previously used to assess guidelines for pharmacological management, screening and diagnosis of PAD[143, 166, 167]. Similarly to our findings, the guidelines assessed scored poorly in stakeholder involvement and applicability domains compared to clarity of presentation. The Global Vascular Guidelines[13] were only included in Uyagu et al's review of screening and diagnosis of PAD[166], but in agreement with our results, scored higher than the NICE guidelines[74], the AHA/ACC guidelines[145] and the ESC guidelines[146] in two of the three relevant domains. The only domain where our results did not agree was applicability, where the AHA/ACC guidelines scored higher than the Global Vascular Guidelines. Differences in the specific recommendation assessed may explain the variation. These results, as well as the remainder of our analyses, inform our recommendations for new and updated guidance (described in Figure 4).

Figure 4: Recommendations for future guidance documents



Recommendations		
Development	**Language**	
Include primary care representation on the author group	Define the clinical problem in simple, specific terms	→ Pain at rest → Pain at night → Non-healing ulceration → Gangrene
Seek endorsement from credible primary care organisations, including publication on their websites	Define the time period for referral in precise terms	→ Immediate → Same day
Include experts in behavioural change in the writing process	Clearly document the consequences of delayed referral in language understandable to the referring clinician	→ Death → Loss of limb
Clearly define the audience of the guidance	Clearly state the strength of the recommendation	→ Use verbs in the imperative such as "refer X" rather than "X should be referred"
	Include modifications for patient or practice characteristics (such as co-morbid patients, or location of services)	

A thorough search strategy was used to retrieve relevant guidance for this documentary analysis, but some relevant guidance may not have been included. This, however, was a deliberate and pragmatic decision made by the authors, as time spent searching for guidance by primary care clinicians acts as a barrier to referral[168-170]. Only guidance written in English was included, and this may also have limited our retrieved documents. The involvement of primary care clinicians was determined by looking at the author group of the document and reviewing the primary affiliation if present. Any secondary affiliations to community organisations or other acknowledgement of contributions may not have been recognised in the data extraction process, thus the use of authorship as a proxy for involvement of primary care clinicians in the guidance documents may be an oversimplification. Two researchers trained in implementation science and the clinical problem independently scored the clinical practice guidelines, which was within the parameters suggested in the tool guidance. The process of referral and assessment of vascular surgical patients is also complex, with multiple stakeholders including the patient themselves. Effective guidance on referrals for CLTI does not compensate for delayed patient presentation, lack of community clinician knowledge or slow pathways to assessment. In order to reduce delay in the management of CLTI, patient, process, clinician and system factors must be considered in addition to improving guidance available.

In conclusion, there are many publicly available national and international documents which contain information on referrals for CLTI. A number of them are aimed at referring clinicians within their audience, but their credibility and relevance is reduced by not having endorsement or representation on the author group from primary care organisations or clinicians. The content of the guidance itself lacks clarity on symptoms, timing and consequences, without use of a shared language. The wording of the guidance is vague and non-specific. Vascular surgery clinicians must consider these aspects when updating these guidance documents, and work with professional bodies in the community and behavioural change experts to create effective, concise, clearly defined guidance specifically for primary care clinicians.

Chapter 3. The symptom to assessment pathway for suspected chronic limb-threatening ischaemia affects quality of care: a process mapping exercise

3.1. Introduction

When examining the care pathway from first symptom of CLTI to intervention, delays can occur at each stage of the process[69]. This starts with the identification and referral of patients with CLTI[70] and includes the time from referral to assessment by vascular services[71]. To avoid such delays, organisations have introduced various initiatives, such as regular “hot clinics” (which are for emergency referrals only) and streaming patients to specific services such as podiatry. However, this increases the complexity of the care pathway and there is limited evidence to support organisation of vascular services so that they meet the needs of the local population and ensure patients with CLTI have rapid access to vascular services and potential limb salvaging revascularisation.

The majority of patients with CLTI in the UK need to be managed at a specialist vascular unit. While patients with severe CLTI symptoms may present via the Emergency Department (ED), general practitioners or community services will also refer a significant number. The evolving hub-and-spoke organisation of English NHS vascular services into regional networks[171] comprising arterial and non-arterial centres provides an opportunity for vascular units to implement different approaches and for others to learn from their experiences.

This aim of this study was to examine the care pathways implemented by vascular services in a sample of locations within England. This was carried out in order to understand the current situation with respect to CLTI pathways, so future interventions can be targeted at appropriate areas of the pathway. The study focused on the various structures and processes adopted by the units to offer rapid access for patients with CLTI, as per the

Donabedian model[172], and used process mapping to compile representations of a patient's journey through the care pathway[173]. Process mapping is recommended for use in the planning and design of healthcare services and has been used to identify potential causes of delay along care pathways in gynaecological malignancies[174], peripheral neuropathy[175] and rheumatoid arthritis[176].

3.2. Methods

Fourteen NHS English vascular surgery units were invited to participate in the process mapping exercise. These units were selected from 56 English vascular surgery units based on three principal criteria: (i) whether they participated in PAD-QIP (Yes or No), (ii) geographical location, and (iii) size of the vascular unit catchment population. The size of the vascular unit catchment population was calculated from Public Health England NHS Acute (Hospital) Trust Catchment Populations Dashboard[177]. The minimum recommended population for a UK vascular network is 800,000, and network reconfiguration is still underway in various areas to achieve this aim[16].

The selection process resulted in a sample that contained a similar number of units who did or did not participate in the PAD-QIP (Table 8). Among the fourteen, four units were included with a catchment population of <800,000, used as a proxy to reflect practice prior to any network reconfiguration. At least one unit was located within each of the nine Government Office Administrative regions to ensure even national coverage, with even numbers in the North and the South according to the definition from Sheffield University's Social and Spatial Inequalities group[178]. This was judged important given the North-South divide on various social and economic measures[178].

Table 8: Characteristics of units invited to participate in process mapping

Vascular surgery unit	Catchment population	Involved in PAD-QIP?	North / South
Unit A	2.2m	Yes	North
Unit B	0.7m	Yes	North
Unit C	0.7m	No	South
Unit D	1.2m	No	North
Unit E	1.0m	No	South
Unit F	1.4m	No	North
Unit G	0.4m	No	North
Unit H	0.4m	No	South
Unit I	1.2m	No	North
Unit J	1.3m	Yes	South
Unit K	1.8m	No	South
Unit L	1.6m	Yes	North
Unit M	1.7m	Yes	South
Unit N	2.8m	No	South

3.2.1. Process mapping

The approach to process mapping followed recommended practice of: using simple diagrammatic representation; seeking input from groups of multiple stakeholders; having a facilitator for appropriate communication; and providing straightforward training on the process mapping method[179]. Full ethical approval for the project was obtained from the Hull York Medical School Ethics Committee on the 21st April 2022.

An email invitation was sent to the clinical leads of all selected units, describing the project aims and the time commitment required. Subsequently, preliminary meetings were held with the unit clinical lead or deputy during which the project was explained in detail and any questions answered. Once a unit had agreed to participate, a process mapping meeting was arranged, either face to face or over Microsoft Teams. The research team suggested the initial process mapping session included a vascular surgery consultant, a vascular specialist nurse (VSN) and a member of podiatry staff, but as the relevant personnel would depend on the unit's own process, the units could have whoever they felt to be useful attend the meeting. Throughout this study, "VSN" is used as an umbrella term to refer to nurse consultants, vascular specialist nurses and advanced clinical practitioners working in vascular surgery. All meetings were audio recorded, transcribed and anonymised. Each participant read an information sheet, which explained plans for data storage and usage, and signed a consent form. If further detail was required after the initial meeting and process mapping, either secondary meetings were arranged with the appropriate individual or an email was sent with the same process followed. Figure 5 provides an example of questions asked in the process mapping sessions.

Figure 5: Topic guide for process mapping sessions, illustrating initial and follow-up questions

Q: How are referrals for suspected CLTI received from:
    - primary care (different staff groups)
    - Emergency Departments
    - in-hospital podiatry services
    - self-referral
Q: Are there variations in the referral process across the network?
Q: How are the referrals triaged?
- How is this different for a patient in a spoke catchment as opposed to the hub?
- How is this different if the patient has diabetes?
Q: How is the patient assessed (eg. hot clinic, urgent slots, podiatry clinic)
- How is this different for a patient in a spoke catchment as opposed to the hub?
- How is this different if the patient has diabetes?
Q: What are the timings between referral receipt and triage, and triage and assessment?
Q: Which staff are involved in referral receipt, triage, patient liaison and assessment?

A graphical representation of the processes described by the participants was drawn using Mural online software (Tactivos, Inc)[180], a digital whiteboard collaboration space. Once the map for a network was complete, it was shared with the clinical lead and all participants in the process mapping exercise. An iterative process of feedback on the maps and editing was then followed until all parties were satisfied with the completed map.

The completed process maps were analysed to capture variation in the different care pathways, including: methods of referral, triage processes, procedures for assessment of patients with suspected CLTI, differences in management of patients with or without diabetes, and patients local to arterial or non-arterial centres. These data were summarised in a Microsoft Excel spreadsheet and a final summary map was created to visualise all potential processes in all arterial centres.

3.3. Results

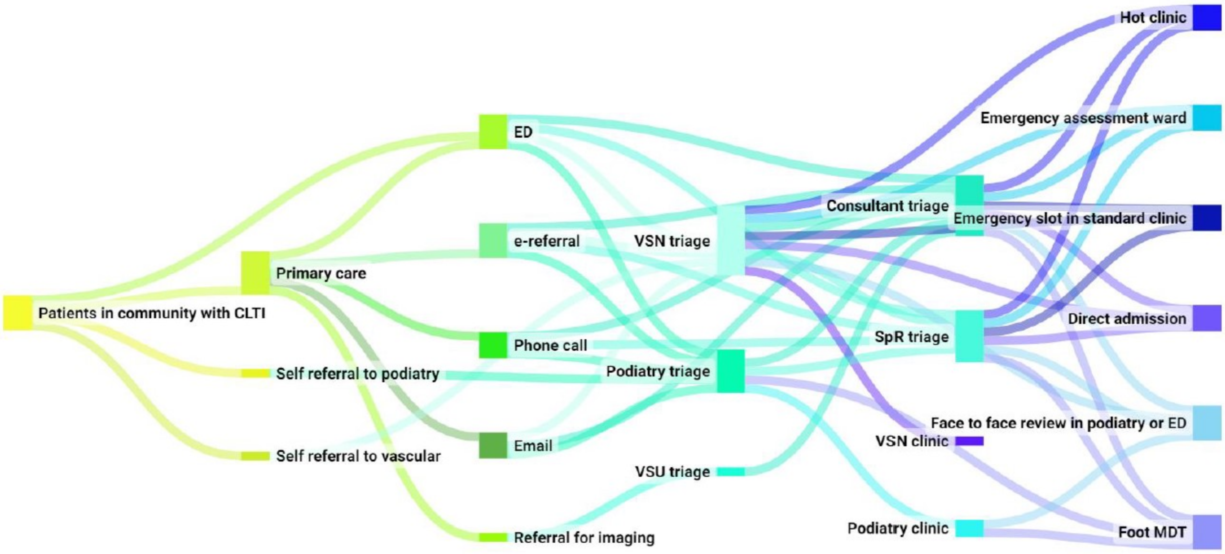
Twelve of the fourteen invited vascular units agreed to participate; M and N did not (Table 8). Reasons for this included insufficient time for the process mapping exercise within the project timeframe, and lack of engagement following the preliminary meeting.

3.3.1. Process mapping

Process mapping interviews took place between 1st June 2022 and 2nd September 2022, and these results represent practice at that time. In total, 45 participants from the 12 units were interviewed. This included: 12 consultant surgeons, two vascular surgery registrars, one surgical care practitioner, 14 VSNs or advanced clinical practitioners, 13 podiatrists, one diabetologist, one member of administration staff and one vascular scientist. Further information was received via email from three podiatrists, one surgeon and one member of administration staff. The median number of staff contributing to a process map per unit was three (range 2 to 7); this included a vascular surgeon in 11 centres, a podiatrist in ten centres, and a vascular specialist nurse in nine of the 12 centres.

The process maps of each arterial centre were summarised into a final summary map (Figure 6). This demonstrates the complexity of pathways for referral of patients with CLTI. Each constituent part of this diagram was present in at least one of the arterial centres.

Figure 6: Final summary process map for all arterial centres



CLTI: Chronic limb-threatening ischaemia, ED: Emergency department, VSN: Vascular specialist nurse, VSU: Vascular studies unit, SpR: Specialty registrar

3.3.2. Participating centre characteristics

The care pathways at all arterial centres involved similar types of staff, namely consultant and trainee vascular surgeons, VSNs and podiatrists, with differing degrees of involvement and in different configurations. Surgeons were involved in receipt and triage of referrals and assessment of patients in all units. VSNs were also often involved in triage and assessment processes, as well as being an initial contact point for certain types of referrals. In some centres, referrals deemed suitable by the triaging clinician were diverted at the point of triage to podiatry services, who assessed the patient. The vascular surgery team was then involved once the diagnosis of CLTI had been confirmed by objective measures of perfusion. Often, the use of non-surgical staff in patient triage and assessment was in addition to existing surgeon pathways, with the intention of reducing pressure on the surgeon role, or to capture patients who had been referred using a non-standard route.

Table 9 demonstrates characteristics of the included centres, and how incoming referrals were received and triaged. It also includes the PAD-QIF target achievement from 2021, demonstrating the proportion of patients admitted with CLTI whose time-to-revascularisation was within 5 days of admission[181]. Whilst this process measure is only determined from the time of admission of the patient, it provides context in terms of how efficient the unit is in treating inpatients with CLTI.

All units indicated that they would accept referrals from all staff groups, although some referral modalities are only available to selected clinicians (eg. e-Referral Service (eRS) systems are only available to staff working in a GP practice).

Three units were in vascular networks that had adopted the same procedure for the referral of patients with suspected CLTI for all centres within their network – ie. all referrals for suspected CLTI were directed to the arterial centre. Of the nine remaining units, two were not networked with any non-arterial centres, and one unit's interview was a partial map focussing on one non-arterial centre in particular, as they had a novel lower limb assessment service led by podiatrists. Of the remaining six, there was a range of one to three non-arterial centres within the networks.

Table 9: Characteristics of networks, referral and triage processes

Characteristics			Referral options					Process measure
Arterial centre	**North / South**	**In Network**	**e-RS triage**	**Self-referral accepted**	**ED referral goes to**	**Direct email referrals received by~**	**Referrals to podiatry**	**PAD-QIF target achievement 2021**
Unit A	North	Yes**	Consultant		Hub SpR	Vascular secretaries	e-RS / email / phone	44%
Spoke 1A			Podiatry		Hub SpR		e-RS / email / phone	
Unit B	North	Yes*	Consultant		Hub SpR		e-RS / phone	76%
Unit C	South	Yes	SpR		SpR		e-RS	53%
Spoke 1C			SpR		Hub SpR		e-RS / email	
Unit D	North	Yes	Consultant	Y	SpR / VSN	VSN	Email	38%
Spoke 1D			Consultant		Hub SpR / VSN		Email	
Unit E	South	Yes	Consultant	Y	SpR	VSN	Email / phone	51%
Spoke 1E			Consultant		Hub SpR		e-RS	
Spoke 1E			Consultant		Hub SpR		Email / phone / letter	
Unit F	North	Yes	Consultant	Y	SpR	VSN	Email / phone	33%
Spoke 1F			VSN		Hub SpR		e-RS	
Unit G	North	No	Consultant	Y	SpR / consultant		Email	<10 cases
Unit H	South	No	Consultant		SpR / consultant	VSN / consultant	Email / phone	88%
Unit I	North	Yes*	Consultant		Hub SpR / podiatry	MDT coordinator	Phone / email	42%
Unit J	South	Yes	Consultant	Y	SpR		Email / phone	59%
Spoke 1J			VSN	Y	Hub SpR	VSN	Email / phone	
Spoke 2J			Consultant		Hub SpR		Email / phone / letter	
Spoke 3J			Consultant		Hub SpR	Vascular secretaries	Email / phone (if urgent)	
Unit K	South	Yes	Consultant		SpR	SCP	Email	31%
Spoke 1K			Consultant		Hub SpR	VSN	Email	
Spoke 2K			Consultant		Hub SpR	Consultant	Email / phone	
Unit L	North	Yes*	VSN	Y	Hub SpR	VSN / consultant	Email / phone	66%

**Unit I, Unit B and Unit L have the same process for triage of referrals from non-arterial centre catchment as those from arterial centre catchment area; **Unit A non-arterial centres have not been fully mapped; SpR = registrar working in vascular surgery; SCP = surgical care practitioner; VSN = vascular specialist nurse; ^All units accepting self-referral did so only from patients already known to the department. All were via VSNs*

3.3.3. Methods of referral from primary care

All units accepted urgent referrals from all primary care clinicians. All units used e-RS, a national electronic referral system provided by NHS Digital, enabling clinicians based in general practice to refer patients for specialist care. Two units' e-RS systems included an embedded referral pro-forma, allowing them to collect information deemed necessary for triage. e-RS referrals can be marked as urgent or routine at the referring clinician's discretion. To complement this, individual centres had adopted additional options for urgent referrals, although these might be available only for specific primary care clinicians. For example, eight arterial centres had a direct email to the vascular team which tended to be used by community podiatrists, tissue viability nurses or district nurses who did not have access to e-RS. These emails were received by VSNs, members of the surgical team or administration staff.

All units had an on call member of staff available via telephone to primary care clinicians in their catchment area. This was a registrar in all arterial centres, with vascular specialist nurses available in addition in six arterial centres. A consultant was always available in addition to the registrar in all arterial centres, and they were described as receiving direct phone referrals for CLTI in four arterial centres. Six vascular units accepted self-referral from patients previously known to the team, although they could present with a new problem.

All arterial centres were aligned with podiatry services for high-risk patients, which independently received, triaged and assessed referrals from primary and secondary care. Most podiatry services were located in the same hospital as the arterial centre, but community-based "high-risk" services were also available in three networks. In five of the 12 arterial centres, podiatry clinics were exclusively for patients with diabetes. Commissioning of podiatry services was given as the reason for seeing or not seeing patients without diabetes.

Across all networks, podiatrists received and triaged referrals daily during the week and saw urgent referrals in an assessment clinic within 48 hours of their receipt. Podiatrists escalated to vascular surgery once CLTI was diagnosed, usually by direct phone call or face to face discussion with an on call vascular clinician, or by booking the patient in to a multi-disciplinary clinic including vascular surgery.

The speed and process of triage was dependent upon route of referral. Podiatry teams carried out at least daily triage of phone, email, letter and e-RS referrals. Email and phone call referrals received by on call registrars, consultants or vascular specialist nurses would also be triaged within at most 24 hours. The speed of triage of e-RS referrals by consultants, registrars and VSNs was more variable between centres, and could be anywhere from daily to weekly (Tables 10a and 10b). The triage performed by one staff group could trigger a further triage process, with (for example) a vascular specialist nurse or podiatrist escalating a referral to a consultant or registrar if they felt the patient was unwell enough to require emergency admission that same day. In the five arterial centres where podiatry exclusively saw patients with diabetes, these patients often benefited from faster triage than a patient without diabetes referred to the vascular surgeons via e-RS.

Table 10a: Timing of emergency outpatient assessment for suspected CLTI – arterial centres

Name of arterial centre	Timing of e-RS triage	Frequency of hot clinic	Hot clinic led by	Frequency of emergency slots (consultant clinic)	Maximal timing for outpatient review via e-RS (days)
Unit A**	48 hourly (if urgent)	Weekly	Consultant	None	9
Unit B*	48 hourly	None	Consultant and VSN	2 per clinic (daily)	3
Unit C	Weekly	3x weekly	VSN	None	9
Unit D	4x weekly	None	-	None	-
Unit E	Daily	3x weekly	Consultant	None	3
Unit F	Weekly	3x weekly	Consultant and VSN	None	9
Unit G	Daily	None	-	None	-
Unit H	48 hourly	Weekly	Consultant	None	9
Unit I*	Weekly	4x weekly	Consultant	None	9
Unit J	Daily	Up to 4x weekly	Consultant and VSN	None	3
Unit K	Daily (if urgent)	Daily	SpR	None	2
Unit L*	Daily	Weekly	Consultant	1 per clinic (daily)	2

Table 10b: Timing of emergency outpatient assessment for suspected CLTI – non-arterial centres

Name of arterial centre	Name of non-arterial centre	Timing of e-RS triage	Frequency of hot clinic	Hot clinic led by	Frequency of emergency slots (consultant clinic)
Unit J	Spoke 1J	Sporadic	Weekly	VSN	Overbook
	Spoke 2J	Daily	None		Move out less urgent
	Spoke 3J	Weekly	None		Overbook
Unit C	Spoke 1C	Weekly	None		Overbook
Unit E	Spoke 1E	Weekly	None		Move out less urgent
	Spoke 2E	Weekly	None		Overbook
Unit F	Unit 1F	3x weekly	Weekly	VSN	6-8 per week
Unit K	Spoke 1K	Daily (if urgent)	None		Overbook
	Spoke 2K	Sporadic	Daily		Overbook
Unit D	Spoke 1D	4x weekly	None		None

**Unit I, Unit B and Unit L have the same process for triage of referrals from non-arterial centre catchment as those from arterial centre catchment area; **Unit A non-arterial centres have not been fully mapped*

3.3.4. Patient assessment facilities and process

Arterial centres had adopted different combinations of hot clinics and standard outpatient clinics, both in terms of capacity and timing. Two arterial centres had no dedicated urgent clinic slots for reviewing referrals with suspected CLTI, meaning the majority of patients were reviewed on emergency assessment wards. Two arterial centres had emergency slots in standard clinics available to review emergency patients. Nine arterial centres held hot clinics; in two of these, the clinics were held once per week. In the other seven, hot clinics were held at least three times per week, aligning with PAD-QIF recommendations[27] (Table 10a). One of these centres augmented their hot clinic capacity with emergency slots in standard clinics.

All but two arterial centres had an assessment unit available in hours for a vascular registrar, VSN or consultant to review patients with suspected CLTI who were perceived as unable to wait for an emergency clinic appointment, or where emergency clinic appointments were not available. Other available methods of assessment included face to face assessment in ED or podiatry clinics, including multidisciplinary foot clinics, VSN-led clinics and via direct admission to the vascular ward.

Patients referred to podiatry had access to faster assessment, with referrals triaged as urgent being assessed within 48 hours. In the five centres where podiatrists exclusively saw patients with diabetes, patients without diabetes referred to vascular surgery via e-RS would often need to wait longer for a review. Three arterial centres made use of the faster times to assessment provided by podiatrists, diverting suitable referrals to be seen initially by podiatry, with escalation to vascular surgery only once CLTI was confirmed with objective measures of perfusion. For one of the three arterial centres, this service was only available for patients with diabetes, creating a two-tier service to the detriment of patients without diabetes.

3.3.5. Arterial vs. non-arterial centres

Networked non-arterial centres in the hub-and-spoke model had their processes mapped alongside the arterial centres. Three arterial centres had the same processes as their non-arterial centres for dealing with e-RS referrals – all were diverted to the arterial centre and managed centrally. There was overlap within the network pathways, and much of this depended on the perceived urgency of the patient’s condition to the referring clinician, with the arterial centre direct phone call always being an option for referral of all patients local to non-arterial centres. Timing of review in a non-arterial centre was slower, with triage taking place less frequently, and fewer formal emergency clinic slots being available, with reviews relying on overbooking or moving less urgent patients from standard consultant clinics. This can be seen in Table 10b. All but one non-arterial centre had on-site podiatry services, offering similar time to triage and assessment as the arterial centre podiatry services. Of the 11 non-arterial centre podiatry services, eight saw patients with diabetes exclusively.

3.4. Discussion

This study highlights national variation in referral, triage and assessment processes for patients with suspected CLTI, aligning with GIRFT findings of variation in the timeliness of care delivered to vascular surgery patients with CLTI across the country[25]. Diversity and complexity in the ways vascular surgery networks have tackled the challenge of providing urgent care to these patients has been demonstrated, both in terms of structure and process. Each vascular unit covers a unique population, employs different staff and has its own structural and organisational challenges, and the pathways described reflect all of these factors[182]. The adoption of the CLTI Commissioning for Quality and Innovation (CQUIN) scheme in May 2022, giving Trusts a financial incentive to reduce time-to-revascularisation for inpatients with CLTI[183], may have encouraged units to make changes to pathways, which will have been captured in our work.

Primary care clinicians who refer these patients have many options for how to involve vascular surgery in their care. The multitude of ways patients can enter the pathway reflects the complexity of CLTI and the range of symptoms with which it can present. Vascular services have thus developed the processes described in order to capture as many of these patients and assess them as quickly as possible. Attending ED is always an option, and will be necessary for some patients presenting with CLTI. However, patients who may not require immediate admission are often better served by an emergency clinic model[13, 184-186]. Such models are in place in ten of the 12 participating units, and were described as the preferred way of assessing emergency referrals, as often imaging is available alongside the clinic and they allow a faster review than a routine clinic appointment.

Even within an emergency clinic model, wide variation was seen across arterial centres in the potential time period between receipt of referral and patient assessment (Table 10a). Figure 1 is a reproduction of the PAD-QIF targets for time-to-revascularisation, indicating all patients should be seen within seven days, and those that require admission within two days. It is not always possible to tell from a referral whether a patient will require admission, but only five of the ten arterial centres who use an emergency clinic model are able to meet the seven day target consistently following a referral received through e-RS, and only two of the ten would meet the two day target consistently. This indicates that simply having access to emergency clinic slots is not enough – there needs to be appropriate capacity within the model and supporting triage processes of adequate urgency.

Structural factors affecting the process of triage and assessment include the vascular network configuration. Patients referred to non-arterial centres in the six networks where referrals are not diverted to the arterial centre are likely to have longer times from referral to revascularisation, and correspondingly are more likely to have inferior outcomes[152]. My work confirms that pathways where the patient with suspected CLTI is referred to a non-arterial centre have greater potential times to referral triage and patient assessment. This inequity of care across vascular networks must be a priority for future service improvement.

Another element of structure affecting quality of care is the difference in pathways for patients with and without diabetes, related to commissioning of podiatry services. In five of the 12 arterial centres and eight of the 11 non-arterial centres, podiatrists were not seeing patients who did not have diabetes, meaning that the swift times from referral to podiatry and assessment are only benefiting patients with diabetes with suspected CLTI. This could add a further element of delay to patients with suspected CLTI without diabetes, and contribute to the similar outcomes seen by patients with and without diabetes following revascularisation for CLTI, despite patients with diabetes presenting with a greater frequency of tissue loss and having less favourable anatomy for revascularisation[187].

This exploration of available processes in multiple vascular units helps clinicians, managers and commissioners understand how this variation and complexity in structure and process can lead to delays from referral to assessment of patients with CLTI. Benefits are likely to be gained from simplification, and three primary foci for quality improvement have been identified; the triage process, the way networked vascular services approach referrals for suspected CLTI, particularly to non-arterial centres, and the provision of care for patients without diabetes compared to patients with diabetes.

Further work to do has been identified, not least in reducing inequalities in the care offered to English patients with suspected CLTI. Patient-level data can identify the pathways from the community to vascular surgery assessment associated with the best outcomes. Initial work has been carried out by individual vascular units, showing swift access to a limb salvage clinic can improve long term outcomes compared to alternative pathways[186], but this may not be effective in all contexts.

This unique national project demonstrates the variation in referral, triage and assessment processes that currently exists and highlights areas which could be simplified. Previous process mapping studies have focussed only on individual patients and not pathway differences between different local contexts, with the majority considering only one centre[174-176]. The 12 participating centres represent over 20% of English vascular surgery units and the national coverage is a strength of this work.

This study was limited by the lack of available patient-level data to identify which pathways are utilised most frequently, and which are the most efficient processes in relation to patient timelines. The individual context of vascular units is likely to be a cause of variation in pathways, and therefore any exemplar pathways identified in this exercise may not function in an alternative context. Whilst a significant proportion of vascular units in England were included in the process mapping exercise, it was impossible to include all vascular units and the study is unlikely to have captured all national pathways. Many factors exist outside these pathways that affect timely care and patient outcomes; from patient and primary care clinician recognition of symptoms, to availability of imaging, to surgical or endovascular treatment following assessment. The process mapped, however, is part of the patient journey that vascular surgery units have control over and thus an ability to carry out improvement work.

In conclusion, there is a wide variation in processes demonstrated for the referral, triage and assessment of patients who experience symptoms of CLTI in the community, and associated variation in timing along pathways. Structural factors such as commissioning of services and network configuration contribute to processes available in each centre. The diversity of these pathways reflects the ingenuity of vascular surgery units in recognising and reacting to the urgency of providing care to patients with suspected CLTI, but there are opportunities to improve quality of care for this patient group.

Chapter 4. Hospital clinicians' perceptions and experiences of care pathways for patients with chronic limb-threatening ischaemia: a qualitative study

4.1. Introduction

Missed opportunities in primary care to refer patients with CLTI to vascular surgery services and barriers to patients accessing appropriate care have been documented[75, 188]. A database study suggested patient factors, including age and deprivation, can affect the timely recognition and referral of CLTI by primary care clinicians[75]. Qualitative methods in primary care settings have identified factors affecting diagnosis and referral of PAD including a lack of awareness of guidelines, dependence on ABPI and patient delay in presentation[189]. There has been little further research on factors affecting the processes occurring prior to expert assessment for suspected CLTI.

Further work has been called for to investigate factors affecting timely referral to secondary care for patients with suspected CLTI[75]. This study aims to explore the experiences, perceptions and opinions of clinicians involved in the triage and assessment of patients with suspected CLTI regarding current processes, in order to inform future improvement projects.

4.2. Methods

A qualitative interview study with relevant clinicians was designed and conducted. Design was pragmatic, according to resource available, whilst ensuring conceptual coherence with the research question. We sought to investigate participants' individual experiences, perceptions and opinions regarding current referral, triage and assessment processes for patients with CLTI and define any common themes, whilst understanding potential contextual confounding factors. The analysis was approached from a critical realist position, where multiple experiences and perceptions of a single reality exist, combining ontological realism with epistemological relativism. Critical realism understands knowledge and experience to be articulated through language[190] and consequently mostly semantic data were coded. The main criteria for coding and theme development was meaning, as opposed to recurrence, in keeping with a "big Q" qualitative paradigm, with a fully qualitative approach[191]. This avoided a lean towards positivism, or searching for a single truth in our data. Reflexive thematic analysis was used, a method that entails identification, analysis and reporting of patterns within the data[116]. It was initially described by Braun and Clarke in 2006[192], and acknowledges that the researcher is part of the world they wish to understand. Its flexibility allowed me to inductively develop an analysis according to my critical realist position. Reflexive thematic analysis is a method considered useful in under-researched areas such as this one, and it can produce analyses suited to informing policy change[192]. The consolidated criteria for reporting qualitative research (COREQ) has guided the reporting of this study[193]. Full ethical approval was granted by the Hull York Medical School Ethics Committee (ref. 21/22 32).

4.2.1. Identification and recruitment of participants

This study followed the process mapping study (Chapter 3), which involved detailed interviews regarding referral pathways for patients with suspected CLTI in 12 English vascular surgery units[194]. Three pathways were identified according to staff group involvement in an "ideal" patient pathway. Purposive sampling was based on this to identify clinicians for interview, with four clinicians recruited from each pathway, ensuring all staff groups were captured (Table 11). This allowed maximum variation of experiences with different pathways.

Table 11: Sampling grid for vascular clinicians

	Vascular surgeon	Podiatrist	Vascular specialist nurse
Surgeon-led pathway	2	1	1
Podiatry-led pathway	1	2	1
Nurse-led pathway	1	1	2

The chosen number of participants was informed by recommendations for qualitative interview studies in relatively homogenous groups, following an experiment in data saturation where 12 interviews were found sufficient to understand common perceptions and experiences[195].

Selection of potential participants was based on their previous engagement with the process mapping project, and their stated willingness to be involved with ongoing work. Recruitment from a broad range of vascular units was also prioritised. The sole inclusion criterion was that the clinician had participated in the process mapping study as an interviewee. There were no exclusion criteria.

4.2.2. Information and consent

Potential participants were invited to be part of the study over email, with a brief explanation of the planned project and a Participant Information Sheet (PIS) attached. Opportunity was given for further explanation and any questions were answered. Once the participant was ready, a mutually suitable time for an online interview was agreed. Consent was confirmed verbally both before and after the recorded online interview, and a signed consent form was received from the participant.

4.2.3. Interviews

I carried out semi-structured interviews with participants, as a female vascular surgeon working towards a postgraduate qualification. Whilst I had no formal interviewing training, much of my clinical work as a surgeon involves similar techniques[196]. My eight years of experience in vascular surgery meant I was able to share a language with the participants, and understand clinical scenarios they described with ease.

Interviews were carried out online, using Microsoft Teams. Non-participants were not present. A pre-piloted topic guide was used as a framework for the interviews, which was iteratively altered as the study progressed (Appendix 2). This posed open questions about different stages of the patient's pathway where delays were possible. Prompts were used, such as, "can you tell me more about that?" when further details were required. One pilot interview was carried out with a medical clinician at one of the vascular units.

As a vascular surgeon, I had pre-existing assumptions and situated knowledge around the research question. Care was taken during the interviews to remain neutral and not express opinions throughout, or to lead the participant. Reflexive thematic analysis acknowledges the researcher's subjectivity, and uses it to inform analysis[116]. A reflexive diary was kept throughout the process and individual reflections written after each interview, including information on how pre-existing assumptions were challenged. Data coding and theme generation were informed by regular reflection, seeking to understand my subjectivity and ensure all meaningful data was coded. This led to a complex, nuanced analysis of the data.

4.2.4. Analysis

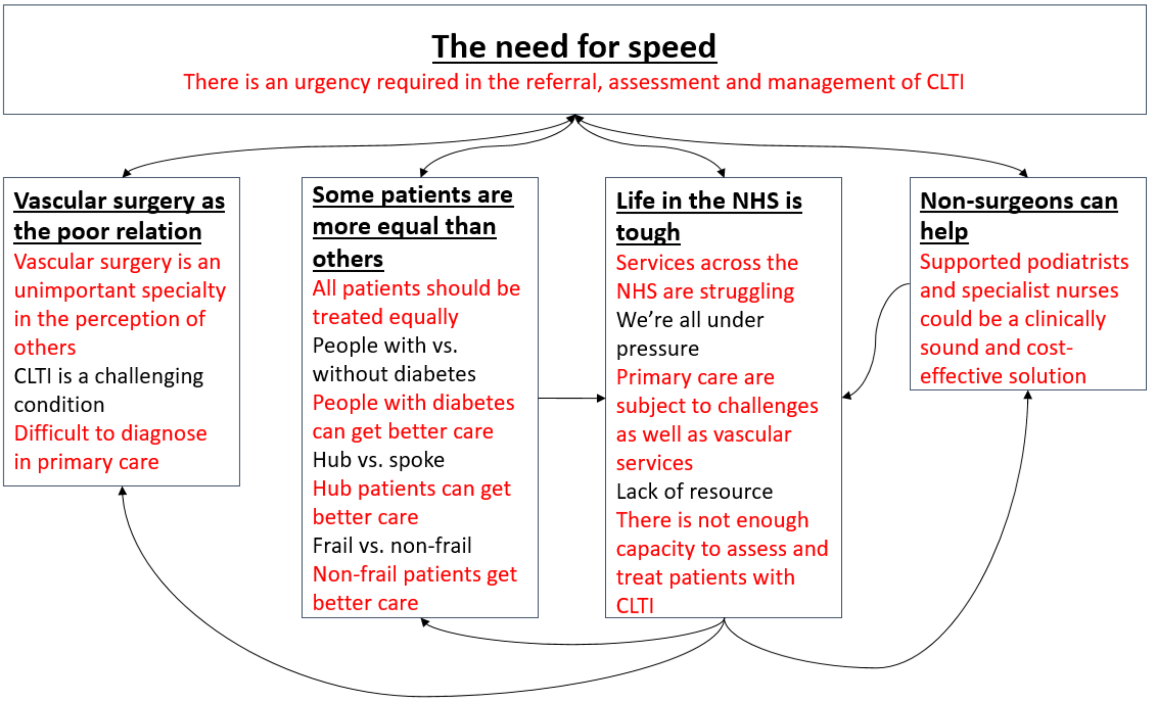
Each interview was audio and video recorded and Microsoft Teams software used to carry out an initial transcription. This transcription was edited according to the audio recording until it was verbatim, then anonymised. According to Braun and Clarke's six phases of thematic analysis, immersion in the data took place both with the audio recordings and the transcripts, with initial notewriting of questions, observations and interpretations. Familiarisation began after completion of all the interviews. I carried out formal inductive coding using Nvivo software, followed by two cycles of re-coding. Both semantic and latent coding took place. Candidate themes were generated initially, then developed and revised following discussion with the supervision team (IK, DAC) and re-engagement with the original data. Themes were then refined, defined and named. The connections between themes were discussed and mapped visually.

4.3. Results

Twelve participants were approached for inclusion in the study, and all accepted the invitation. None dropped out or rescinded consent at a later stage. Four vascular specialist nurses, four podiatrists and four vascular surgeons from 10 of the 12 hospitals previously involved in the process mapping were interviewed (Table 11). One further interview was included, from a medical clinician involved in the assessment process of one of the surgeon-led pathways, with whom the topic guide had been piloted. As such, this interview was carried out first, and the interviewee was initially selected due to their role as a stakeholder clinician outwith the participant groups previously defined in Table 11. I felt this interview added useful contributions and perspective to the dataset, so it was included in my analysis. The interviews lasted between 30 and 64 minutes. All participants were known to me prior to the study commencement. Participants knew my background as a vascular surgeon, and understood the purpose of the research. Reflection on the content of the dataset during the familiarisation process found the 13 interviews to contain adequate richness to fulfil our research aims, as per the concept of information power[197].

Four key themes were developed: vascular surgery as the poor relation; some patients are more equal than others; life in the NHS is tough; and non-surgeons can help. These will each be discussed in turn, with reference to sub-themes. They are linked by one overarching theme, the need for speed (Figure 7).

Figure 7: Themes and sub-themes



4.3.1. Theme 1: Vascular surgery as the poor relation

The theme "vascular surgery as the poor relation" reflects the core idea expressed across the dataset that vascular surgery, the specialty which deals with CLTI, is perceived as an unimportant specialty by others. This was reflected in a perceived lack of awareness of CLTI, across patients, primary care clinicians and hospital management.

"I think peripheral vascular disease has always been one of those things that hasn't really been studied, particularly through medical training. It's one of the things that's touched briefly on, but not really in depth. And it's, I think it's just lack of awareness really." Vascular specialist nurse, podiatry-led pathway

"*Patients describe things like, a bit of a scab, or, I banged my toe, or, it's a bit weepy round my nail. Me and you would describe that as gangrene. And I think that the normal, generalised population haven't got the words to be able to articulate what's going on with their foot, so that it equals critical limb ischaemia in the clinician's mind." Vascular specialist nurse, nurse-led pathway*

This unimportance was demonstrated by participants in comparison to other conditions, including cancer, stroke and heart attack.

"But I do think that, you know, you get all this education for strokes and things like that, but is it as well thought out of, like publicized in the wider public about recognizing the symptoms of CLTI, than it is, you know, these like things like stroke and heart attack and things like that." Podiatrist, podiatry-led pathway

CLTI was described as a challenging condition – more challenging than others, which is a sub-theme within this idea.

"I think that it's very difficult to identify critical limb ischaemia. I think that our patients are very complex. They are presenting with neuropathic pain and vascular pain, and sometimes that can be difficult to differentiate." Podiatrist, surgeon-led pathway

The perceived lack of awareness of CLTI was deemed responsible for delays. Participants described this in the context of poor referral quality, lack of a shared language between patients, primary care clinicians and secondary care clinicians, and in engagement of management to facilitate urgent treatment pathways. Vascular surgery's status as the poor relation was expressed as something that could be changed, with national campaigns, education and improved relationships between primary care and clinicians who assess CLTI recommended.

Sub-theme: CLTI is a challenging condition

Participants presented the difficulty of making a diagnosis of suspected CLTI in primary care as three-fold: a challenging group of patients who suffer from this condition; characteristics of the condition itself; and the wide range of primary care clinicians who it may present to.

"I think because the symptoms of rest pain, or perceived pain in in the extremity can overlap with lots of fairly benign conditions, and therefore they probably feel a little bit nervous about

referring something urgent that could be something very benign." Surgeon, podiatry-led pathway

"I think with CLTI, though, and the variety of symptoms you've got, you're not necessarily gonna end up with a nurse. You could end up in a GP, in the podiatrist, in the diabetic centre, within the nursing service because - is it pain on your foot? Is it? Is it a scab? Is it a toenail? Is it an infection? And there's so many ways that it can be badged initially, that many, many people could see it in terms of that first recognition." Vascular specialist nurse, nurse-led pathway

4.3.2. Theme 2: Some patients are more equal than others

Inequalities in the pathway from first symptom to assessment were described within three sub-themes. They were presented throughout as undesirable – it was clear that participants thought that all patients with suspected CLTI should ideally be treated equally, with no discrimination against or in favour of a specific group of patients.

"…get rid of the diabetic foot clinic and just have a lower extremity wound clinic or something. You know, the limb salvage approach where, because it's the same, it's the same pathology. It's just some arbitrary cut-off which has been put there… It probably made sense 20 years ago and it doesn't anymore. And I think that is probably the direction we should be heading." Medical clinician, surgeon-led pathway

Each of the three sub-themes represents a different source of inequality.

Sub-theme 1: People with diabetes vs. people without diabetes

People with diabetes were viewed by participants as receiving better care than people without diabetes, with increased awareness of symptoms in patients and primary care clinicians, the availability of alternative (better) pathways into assessment by an appropriate clinician and services for people with diabetes being prioritised with funding.

“And I don't think that's the case with diabetes, because diabetic patients, patients with diabetes have a bit more general education, because it's more of a progressive illness over time, so they get regular checks and regular education. So I think they're probably a bit more switched on about attending when they develop…” Surgeon, nurse-led pathway

“I think because the diabetic foot service is so good, they're very keen to flag patients that we need to see. And in some ways they probably get a better service, because they've been managed, you know, from early and I think those patients have rapid access to the podiatrists anyway. So a lot of those patients will know if they get a foot wound, they fall and they come and see podiatry, and podiatry will then flag it. So I think those patients probably do quite well actually out of their service.” Surgeon, surgeon-led pathway

There was a sense of disappointment and unfairness, that people should be treated differently due to the presence of a comorbidity.

“if I could change anything, if resources were no option, I would take out this whole stupid, you have diabetes or don't. I think that is an absolute – I, you know, I'm sure you have this as well, you have two people in the same, you know, in the same bay, they have exactly the same disease, but one has diabetes and one doesn't have diabetes and they get treated completely differently. And it's such an unfair system.” Surgeon, surgeon-led pathway

Sub-theme 2: Hub vs. spoke

Participants considered that reconfiguration of vascular services into a network of arterial and non-arterial centres, or a hub and spoke model, resulted in the non-arterial centre population having difficulty accessing services, leading to substandard care.

“Sadly, I think the, one of the downsides personally in my view would be with the, sort of, centralisation of services, is that we've taken away the expertise out of the spoke hospitals, and so, many people with foot problems are managed by clinicians who have no experience.” Surgeon, surgeon-led pathway

"*I think the spoke patients have more delay to being seen. And that is because in [Unit] we have, you know, four times a week CLI [critical limb ischaemia] clinic, whereas we don't have that in any of the other spokes." Surgeon, surgeon-led pathway*

Sub theme 3: Frail vs. non-frail

Patient frailty and the presence of comorbidities were considered by participants to negatively affect assessment options, particularly for patients requiring hospital transport, or those unable or unwilling to travel long distances. More complex assessment processes were required in these cases, which took time and led to frustration.

"*Now we know that not every ambulatory patient, or not every patient with CLTI is ambulatory and equally just because the patient is bedbound with CLTI, does not mean that they shouldn't be reviewed. But we do have a massive issue with being able to get these patients into hospital because we – ED [emergency department] is not an appropriate route for them, they can't come to the surgical triage unit because they come bedbound, they're hoisted and there isn't space or staff to care for them." Vascular specialist nurse, nurse-led pathway*

4.3.3. Theme 3: Life in the NHS is tough

This theme comprises two sub-themes. Overall, the theme notes that services in the NHS are struggling. Clinicians felt they could not offer optimum care to patients, or perceived that other clinicians were prevented from offering optimum care by constraints external to their individual clinical practice.

"I think one of the major barriers, especially for the community nursing team is just staffing turnover. So they get, they just seem to have a massive turnover of band five and six staff that just constantly move on. Recruitment battles is a big thing, so everything becomes so much more fraught." Podiatrist, nurse-led pathway

The first sub-theme considers the pressure across all services. In the second sub-theme, participants noted the lack of resource present for improvement, or indeed to provide an adequate service for patients with CLTI.

Sub-theme 1: We're all under pressure

Participants reported working in a pressurised hospital environment, describing an increased demand for vascular surgery services, with challenges arising from inadequate staffing, the Covid-19 pandemic and competing priorities.

"So there's an issue from a staffing point of view as well is that we've had a significant increase in the number of patients that we receive into the service, and yet our staffing and our infrastructure remains exactly the same as it was five years ago." Vascular specialist nurse, nurse-led pathway

Participants appreciated that these pressures extend into primary care, affecting primary care clinicians, as well as patient access to primary care.

"And again, like, I appreciate what it's like for clinicians in the community, and the time constraints, busy clinics, patient after patient coming in." Podiatrist, podiatry-led pathway

Sub-theme 2: Lack of resource

The idea that there was a lack of resource was strongly expressed throughout the interviews. This was detailed both in terms of the capacity to assess patients and treat them following the diagnosis of CLTI.

"So we're capturing the patients in the much earlier stages, but actually getting them that angioplasty, or that surgical intervention has – it's sort of highlighted that there's a bit of a delay. And certainly our consultant diabetologist, on Friday, I said, you know, we've seen this patient, he's gonna have - he's had his duplex scan, he's gonna have an angioplasty and there was no like, great we've done that in 24 hours. It was like yes, but how long is he

gonna wait for an angioplasty, you know what I mean?" Vascular specialist nurse, nurse-led pathway

Improvement in the current service was perceived to require additional resource, or lead to the worsening of care for other patients. The lack of resource for timely intervention for CLTI once assessed and diagnosed was seen as a barrier to encouraging improvements in timely referral from primary care clinicians.

4.3.4. Theme 4: Non-surgeons can help

The final theme communicates a potential solution to the timely assessment of patients with suspected CLTI. Participants perceived non-surgeons involved in care pathways, such as podiatrists and vascular specialist nurses, to be key facilitators of the processes in place for assessment of patients referred with suspected CLTI.

"However, podiatry are very good at triage and stuff, so if they're not sure about presentations or what exactly is going on, I know that they will see their patients regardless and pass on quickly if needed. So they are very good at picking up stuff." Vascular specialist nurse, podiatry-led pathway

Participants said the involvement of non-surgeons, with support from vascular surgeons, was clinically and cost-effective and may improve holistic patient care.

"It's probably a better use of [vascular specialist nurse's] time rather than our time, I suspect, if you're looking at the, you know, cost benefit." Surgeon, nurse-led pathway

"Maybe it's that patients feel more comfortable with nurses. I think it's something about the caring role that nurses do that, I think, patients feel more comfortable telling nurses things they wouldn't necessarily tell doctors." Vascular specialist nurse, nurse-led pathway

Participants described the use of non-surgeons within CLTI pathways as enabling clinicians to work at the top of their game. This included both the non-surgeons assessing patients and the surgeons who were protected from this work.

"I also think as well, we have to ration consultants to be where they need to be. So to me, a consultant needs to be on call. They need to be responding to the trauma bleep. Or they need to be operating because they are all the things that only a surgeon can do." Vascular specialist nurse, nurse-led pathway

Pro-formas were proposed as a mechanism to improve non-surgeon utility in the pathway, but it was noted that they may affect referral quality.

"*Well if it was a specific sort of pro-forma, it could be triaged by the nurse specialist, with a consultant, with a hot clinic consultant, a CLTI consultant available for any uncertainties." Surgeon, nurse-led pathway*

"You know, I think that as I've seen referrals go from personal telephone conversations for people who think they might have an urgent problem towards a pro-forma, I've seen the quality of the referral drop off, and you end up not knowing how to triage the patients so yeah." Surgeon, podiatry-led pathway

The importance of good administrative support in enabling timely assessment was also a clear idea within this theme.

4.3.5. Overarching theme: The need for speed

The urgency required in the management of CLTI was an overarching theme, emphasised throughout the interviews and linking the other four themes. The perceived unimportance of CLTI represents a cause of delay according to the participants, whether because patients don't present with symptoms they put down to other causes, primary care clinicians don't recognise the symptoms as being due to CLTI, or vascular disease not being prioritised relative to other conditions.

"*So I think GPs are very aware of all the 2 week cancer pathways. I don't think they're aware of the CLTI world. And I think that's very difficult as to how to tap into that." Surgeon, surgeon-led pathway*

"Again, we see evidence of this all the time where GPs haven't picked up on this. They don't realize the repercussions and people have come in with late presentations, and obviously ultimately lost limbs." Vascular specialist nurse, podiatry-led pathway

Participants felt that inequalities can limit the speed at which some patients are assessed, and the pressure on services and lack of resource can explain delays in recognition, assessment and management of CLTI.

"If I have a diabetic patient in the same situation, I could get them to see vascular on Thursday. So there is quite a difference between, say, diabetes and non-diabetes. And having a diabetes label, certainly, you know, things move along a lot quicker, or have more access to services quicker." Podiatrist, nurse-led pathway

Delays in the pathway were thought to lead to adverse outcomes, and the importance of a timely process from first symptom to assessment by an appropriate clinician was evident throughout the dataset.

"One of the things I think that should happen is that the sooner we see someone and get a diagnosis about why they have a foot problem and what we're going to do about it the better." Medical clinician, surgeon-led pathway

"And what I do get a bit concerned about is quite a bit of the move nationally for people, to my mind, to muck about in the community, to do toe pressures and ankle brachial pressure indexes on things that just need to be in front of a decision maker sooner. If you've got a

black toe and you can't feel someone's pulses, I don't care what your ABPI [ankle brachial pressure index] is. I just want you on [vascular ward] right there with somebody who knows what they're doing" Surgeon, surgeon-led pathway

"And I think there are often delays in seeking confirmatory ABPIs and things like this, which I have to say we don't find very useful." Surgeon, surgeon-led pathway

"The big delays for us, as soon as the patient gets to us, is now cross-sectional imaging. And we've got huge delays, and that's a post-Covid thing. So an urgent scan now with us will take at least 6 to 8 weeks." Surgeon, podiatry-led pathway

4.3.6. Reflexive diary

Through the course of the data gathering and analysis for this study, a reflexive diary was kept. It allowed me to record my personal perceptions such as how I felt my background affected participants' reactions to me, and record and challenge my own assumptions on the research questions. Recognising these factors allowed me to develop awareness of my interviewing style and ensure I avoided being too enthusiastic when I personally agreed with what a participant was saying, for example. During the analysis, writing down my thoughts helped with refining codes and ensuring my thematic analysis was appropriately concentrated on shared meaning rather than taking the form of a topic summary.

4.4. Discussion

This qualitative study explored the perceptions, experiences and opinions of hospital clinicians involved in the referral and assessment processes for patients with suspected CLTI. The finding of the overarching need for speed in this process is supported by national and international guidance documents where urgent, prompt or early referral in the case of suspected CLTI is recommended[27, 145, 146, 198]. There is, however a perception amongst clinicians that this importance is not shared by referring primary care clinicians, and vascular disease is considered “lesser than” other conditions. This is supported by a previous survey study, which found discrepancy in mortality perceptions between PAD and cancer[199]. Education and increasing of awareness has been suggested as a solution, for both clinicians and patients, and a survey of registered podiatrists has indicated a need for education regarding assessment and referral of patients with PAD[200]. Other qualitative studies have investigated stakeholders’ experiences with referrals in different specialties, and found similar issues with referrer awareness and patient understanding affecting these processes[201, 202].

There was recognition that the whole of the NHS is under significant pressure, and is struggling with lack of resource. The King’s Fund has described a worsening workforce crisis in the NHS[203] and the Health Foundation report that people are living more years in poor health, life expectancy has stopped rising and inequalities are widening[204]. Funding of the NHS has failed to align with demand for services in the context of growing staff shortages[205], and it is clear that the hospital clinicians not only feel that pressure, but are aware that it extends to primary care as well.

Inequalities have been considered as a factor affecting referrals previously in terms of patient age and deprivation, both of which contribute to frailty[75]. Whilst major amputation rates have fallen in England, the rate of decrease was faster in people with diabetes than people without diabetes[93]. The emergence of multi-disciplinary diabetic foot teams, which are recommended by NICE alongside clear timelines and foot care structures, will likely have contributed to this decrease[81]. The provision of similar foot services for people without diabetes is much less widespread[89]. Vascular services have been reconfigured over the past decade into a hub-and-spoke model, leading to geographical changes in vascular presence across networks. Mortality and limb salvage outcomes for patients with CLTI who are referred to spoke hospitals, or non-arterial centres, are worse compared to those who present to hub hospitals (arterial centres)[152]. Additionally, people with diabetes from more deprived areas are more likely to be discharged from secondary care with a diagnosis of PAD and / or CLTI compared to those from less deprived areas, highlighting the importance of acknowledging geography and deprivation when creating or altering CLTI care pathways[206].

The use of non-surgeons in the process of referral and assessment of CLTI has been widely documented. The inter-disciplinary team approach has been recommended for many years for foot care in patients with diabetes[207], and has had marked success in reducing major limb amputation rates[84-86]. More recently the “toe-and-flow” model has recommended this be extended to all wounds and CLTI care[13, 88, 208]. Podiatrists in Greater Manchester have developed a community-based gatekeeper service for patients with CLTI, improving patient access to vascular assessment and protecting vascular surgeon time[209]. In Leicester, the Vascular Limb Salvage (VaLS) clinic, a specialist nurse-led model of care, provides timely CLTI assessment and reduces amputations[210]. Vascular surgeons value the benefits of involving these staff groups in the patient pathway. Formalising these roles in a recommended model of care may be a potential solution to some of the barriers to timely assessment.

In this qualitative study, rich interview data has been collected and analysed to explore hospital clinicians’ experiences, perceptions and opinions of the CLTI care pathway. This was an appropriate study design, given little pre-existing evidence on this topic. The participants were diverse with regards to role, geography and process, which maximises potential for transferability of the results. However, the study included only hospital clinicians, and thus these results alone should not be used to implement changes to CLTI care pathways. The study included participants from ten vascular networks, representing less than 20% of the total number in England, and whilst the overall sample size was satisfactory according to data saturation and information power, there were small numbers of participants in each type of pathway from each staff group. This may mean that some hospital clinicians’ perceptions have not been captured. Participants were also selected on the basis of good engagement with an earlier study, and this engaged cohort may have skewed attitudes towards CLTI pathways, therefore not representing hospital clinicians as a whole.

In conclusion, this study indicates that clinicians involved in the assessment of suspected CLTI recognise the need for speed throughout the process to diagnosis. Further key themes were generated representing barriers to patients receiving timely care including; inadequate resource and system pressures, lack of awareness in other clinicians and the public, and inequality across patient characteristics. A final theme, where non-surgeons can deliver appropriate care, has also been discussed as a potential solution.

Chapter 5. Understanding delays in chronic limb-threatening ischaemia care: application of the Theoretical Domains Framework to identify factors affecting primary care clinicians' referral behaviours

5.1. Introduction

Early referral of suspected CLTI is important, as delays in revascularisation are associated with increased mortality and limb loss[152]. The VSGBI have published guidance recommending patients diagnosed with suspected CLTI by a clinician in the community should be referred to vascular surgery services on the same day[27].

Previous studies, including Chapter 4 of this thesis, have suggested both patient factors, such as age, deprivation and delay in presentation, and primary care clinician factors, such as lack of awareness of guidelines and reliance on ABPI, can affect timely referral[75, 94]. Clinician education has been promoted as a potential mechanism to improve quality and timeliness of PAD referrals[199, 211, 212]. None of these studies, however, used theory or a theoretical framework to reach their conclusions.

The Theoretical Domains Framework (TDF) was created in 2005 in order to integrate and simplify behaviour change theories, making theory more accessible to other disciplines[213]. During its development 33 theories of behaviour and behavioural change were synthesised into 14 domains, representing similar theoretical constructs[213, 214]. It provides a theoretical lens allowing identification of influences on health professional behaviour related to implementation[214]. The TDF enables understanding of implementation problems and potential solutions[215]. It has been used in the past to understand blood transfusion behaviour in clinicians[216], to identify barriers and enablers for GP referrals for pulmonary rehabilitation[163, 217] and to understand other complex, multilevel behaviours such as prescribing[218]. If a theoretical approach is not taken to understand implementation difficulties, the opportunities to understand behaviour change and optimise resulting interventions will be limited[219].

An understanding of the factors influencing the recognition and referral of suspected CLTI from primary care is important in order to inform future strategies to reduce delay in the referral process. This qualitative study uses a theoretical approach to establish an evidence base in order to increase understanding of the primary care clinician-reported factors affecting timely referral for suspected CLTI. Difficulty changing behaviour is often the reason for failure of recommendations in guidelines to be translated into practice in healthcare[220], but using theory in the design of complex interventions increases the likelihood that they are successful in changing future behaviour[132, 221].

5.2. Methods

5.2.1. Design

A qualitative study was conducted using a semi-structured topic guide to interview primary care clinicians. The framework method was used for analysis, with a matrix output providing structure and enabling data management using case and code[222]. The framework method is not aligned to any specific epistemology or ontology, allowing it to reflect the critical realist position of the research team, where multiple experiences and perceptions of a single reality are present. COREQ guided the writing of this chapter[193]. Ethical approval was granted by the Hull York Medical School Ethics Committee.

5.2.2. Identification and recruitment of participants

This study followed a process mapping study[194] (Chapter 3), involving interviews with staff at 12 vascular surgery units, to define referral processes for patients with CLTI.

Primary care clinicians who (potentially) refer patients with CLTI into the units that had previously been process mapped were purposively sampled, supplemented with snowball sampling techniques. Vascular clinicians identified primary care clinicians from their personal or professional networks, and community services were emailed directly to identify employees interested in study participation. Primary care clinicians were sampled to include a wide geographical spread, reflecting practice across different referral processes and different staff groups. The inclusion of nurses, podiatrists and GPs reflects the varied potential presentations of CLTI, which is not limited to a single staff group. The chosen number of 20 participants was informed by recommendations for qualitative interviews following an experiment in data saturation[195], but increased from the recommended 12 interviews to reflect a slightly higher degree of heterogeneity within our participant group due to their different roles.

Inclusion criteria were that the clinician had experience of working in primary care in the catchment area of a relevant vascular surgery unit. There were no exclusion criteria. No remuneration was offered for taking part in the interviews.

5.2.3. Information and consent

Potential participants were invited to take part in the qualitative interview study over email, with an explanation of the project and a PIS attached. Consent was confirmed verbally both before and after the online interview, and a signed consent form was received from each participant.

5.2.4. Interviews

I carried out the interviews, as a female vascular surgery trainee leading the research project. By this point, I had experience in qualitative interviewing, and my clinical background involves similar techniques of information gathering and rapport development.

Interviews took place online using Microsoft Teams. Video and audio content was recorded. A topic guide (Appendix 3) was used, containing open questions based on the TDF, designed to elicit general and specific beliefs about the relevance of each domain to timely referral of suspected CLTI. The topic guide was subject to minor iterative alterations as the interviews progressed. Prompts were used, such as “tell me more”, when further explanation was considered useful.

My background as a vascular surgeon meant I had pre-existing assumptions around the behaviour of primary care clinicians. Using the TDF as a basis for the study helped ensure subjectivity was limited when planning and carrying out interviews and analysis[215]. Care was taken to remain neutral during the interviews and not to express opinions. A reflexive diary was used throughout, including reflective debrief after each interview, in order to recognise and challenge assumptions.

5.2.5. Analysis

Recorded interviews were transcribed verbatim and anonymised. Directed content analysis was performed according to the framework method[222, 223]. Following familiarisation with the data, the TDF domains were used to generate a framework in Microsoft Excel, into which I coded content from the transcribed interviews, using a coding strategy based deductively on the TDF (Appendix 4), edited inductively as coding progressed. PB independently carried out coding of a random subset representing 15% of transcripts during this process to ensure reliability of the coding strategy. PB coded utterances, or phrases, that I had previously coded, blinded to previous allocation, and other utterances considered relevant. Responses that were coded in different domains were discussed, and the coding strategy altered accordingly. Atkins et al’s recommendations for use of the TDF guided the analytic process[224].

Following initial coding, I used coded utterances to generate belief statements, sentences summarising the core thought behind the coded utterances of the participant. These belief statements provided detail about the role the TDF domain is perceived to have in influencing the behaviour in the form of a short sentence[216, 225]. Similar responses from different participants were coded as the same belief statement. The belief statements and utterances that gave rise to them were reviewed by PB and IK to ensure the belief statements were an accurate representation of content.

Previously, relevance criteria have been used to determine which domains could be targets for future intervention[216, 218, 225]. Similar criteria were applied in this study: frequency of coding of belief statements within a domain; content of the responses of the participants coded to a particular domain (eg. perceived as relevant, or not); and conflicting belief statements coded to a domain. Relevance of domains was confirmed through discussion with IK, considering these criteria concurrently.

5.3. Results

Thirty primary care clinicians were invited to take part. Two replied to generic email invitations to community podiatry services and one was invited following snowball sampling via a participant who identified a colleague as someone interested in participating. The remainder were identified directly by vascular surgery clinicians involved in the study in Chapter 3. Twenty interviews took place. Reasons for non-participation included a self-perception of unsuitability for the project, inability to find a mutually convenient time for interview within the project timeline, and lack of reply to an initial approach.

Eight podiatrists, seven GPs and five nurses were interviewed between November 2022 and February 2023. They referred into 11 of the 12 vascular units involved in the previous process mapping project. Interviews lasted between 30 and 56 minutes (mean 44 minutes).

A total of 1450 utterances from the 20 interviews were coded into the 14 domains of the TDF. There was substantial agreement between coders, with Cohen's kappa being calculated as 0.678, indicating acceptable inter-rater reliability[224, 226].

5.3.1. Domains reported not relevant

Five TDF domains (optimism, beliefs about consequences, intention, goals or social influences) appeared less relevant in terms of influencing recognition and referral behaviours (Table 12). Individual participants are referred to by a letter indicating their role and an identifying number (P# = podiatrist, N# = nurse, D# = GP). *Optimism* was not reported as an issue for referral, with faith in the local vascular team consistently described. The majority of primary care clinicians understood that not referring CLTI led to poor outcomes including amputation and death, so *beliefs about consequences* were not a barrier to referral. The conscious decision, or *intention*, to refer was driven by a perceived duty of care for most participants. *Goals* of referral were primarily relevant to improving the patient's quality of life, and universal throughout the cohort. Finally, the majority of participants described using both discussion with vascular clinicians and local colleagues to inform recognition and referral decisions, indicating a lack of *social influences* is not a barrier to referral.

Table 12: Belief statements and sample quotes from non-relevant domains

Domain	**Belief statement**	**Quote**	**Frequency (out of 20)**
Optimism (Opt)	I have faith in the vascular team to get the best outcome possible	P9: But when we get the patients into vascular, we're much more confident that, because it's a specialist service that the patients are going to get what they need	19
		N4: I think just knowing that they are a good service and they will get picked up. Yeah, it's good to have that confidence in a in a service to be honest.	
		D6: Actually, they've been brilliant. They've been very good and I guess that faith comes from perhaps, outpatient letters about problems for patients I haven't really been involved in referring in.	
Beliefs about consequences (Bel Con)	Not referring leads to bad outcomes for the foot (amputation)	P6: I, you know, you would looking at all kinds of end stage nasty wounds, looking at minor and major amputations, death, as well, if they didn't present quick enough, or be referred efficiently enough.	18
		N2: Ohh well, they're gonna lose their limbs, aren't they? And I think not enough people understand that. And I'll certainly, you know, if not a whole limb, part of a limb.	
		D7: Equally, they might also progress to acute ischaemia and amputation. So the knock on effects are massive.	
	Not referring leads to systemic deterioration (sepsis, heart attack, death)	P9: The patient might get sepsis if they've got tissue loss, often infection with peripheral arterial disease might present differently. So it, although it's infected and people don't, might not recognise that, it might lead to sepsis, premature death.	12
		N4: Yeah, I mean, I guess there could be like, well, could be death, sepsis and limb loss. Stroke, heart attack it's, yeah, not even worth thinking about	
		D6: And I suppose, thinking it through, that probably if you've got atherosclerosis of those arteries, you're probably gonna have them elsewhere, so renal disease, cardiac disease, cerebrovascular and the rest.	
Intentions (Int)	It is my duty of care to refer if necessary	P1: I feel fine with it because it's the right thing to do	15
		N1: You know, you're kind of at the moment doing everything you can, you should be doing to help them.	
		D2: But if you know it's gonna be for the best of the patient, then you do it. So there's no like incentive other than that, really.	
Goals (Goals)	I want the patient to be revascularised	P2: We're hoping for revascularisation, so hoping that they will undertake an assessment and find out where the blockage is, and then hopefully, yeah, hopefully surgery if possible and revascularise them.	15
		N3: That they'd get the interventions provided by vascular to, you know, increase the arterial supply, to get the blood flow, and save the limb, and prevent the death.	

		D1: And so it's just about definitive surgery, really, to kind of revascularize that limb. And then he can heal and get better, and that sort of stuff.	
	I want the patient's symptoms to improve	P4: Well, for some of them, that they're gonna end up having a revascularisation procedure. So then hopefully, you know, either the wound that they've got will heal or they'll be much more comfortable not having the rest pain or the claudication.	15
		N4: Just so that we can get, I mean nothing's more satisfying than getting an ulcer healed.	
		D4: And secondly it's for symptom control, so someone in such severe pain that, particularly that we're struggling to really manage, then often that's a really good motivating factor to get someone referred in.	
	I want to prevent amputation	P8: Well, it might save that save their foot, save their leg, that's the end goal, really.	12
		N2: Healed patients! And patients who haven't lost their limbs at the end of the day.	
		D3: So if I think the, in particular, if I think the limb is at risk.	
Social influences (Soc)	Discussion with local colleagues informs my / their decisions	P5: I mean, the other thing is that you may get a colleague in and say, what do you think? Take a photograph, take it along and show a colleague, show a consultant. Go, I’m not happy with how this looks, what do you think?	19
		N4: And yeah, like maybe like with tissue viability or even with like colleagues within the team, just like, you know what, I'm not sure about this, what do you reckon? Yeah, just to get - it's always good to get a second opinion.	
		D2: Like nurses are very good with, you know, like I say, they do dressings all the time, and, you know, managing all of that. And so you might ask them and see if they've, you know, what they think. You might ask your fellow GP next door what they think.	
	There is opportunity to discuss with vascular prior to referral	P5: And even sending a photograph over to the vascular team and just say, will you have a look, what do you think? You know, and they will, they're very good like that, you know	18
		N5: And like I say, if I did have a little bit of uncertainty, I've always got the vascular team to give a ring and just say this is what I'm finding, what would you suggest? So there's always that back up, really, there.	
		D5: But, you know, if I'm unsure, I’d just pick up the phone and spoken to the consultant on call or spoken to [vascular consultant], and they tend to say we'll see them outpatients tomorrow or something along that lines.	

5.3.2. Domains reported relevant to referral behaviour

Nine TDF domains were considered relevant to recognition and referral behaviours (Table 13).

Table 13: Belief statements and frequencies from relevant domains

Belief	Podiatrists	Nurses	GPs	Frequency (out of 20)
Knowledge (Know)				
CLTI is an urgent condition	6	4	4	14
I can take an appropriate history	7	3	4	14
I use guidance / tools routinely (local guidance, NICE, NWCSP, WIFI, SINBAD, NEWS)	7	3	3	13
Local guidance / pathways would be helpful	4	3	5	12
I know the appropriate referral pathway(s)	7	1	4	12
I believe I understand what CLTI is	7	3	1	11
I am aware of guidance / tools but I don't use them routinely (local, NICE, NWCSP, SINBAD, WIFI)	5	3	1	9
I know the appropriate referral pathway(s) (incongruous belief)	1	4	3	8
A lack of knowledge can limit (appropriate / timely) referrals	3	2	2	7
GP knowledge is supported by systems			5	5
There is limited vascular teaching in primary care training			5	5
Guidance is more helpful for less experienced members of staff	2	3		5
I am not aware of specific guidance / tools			4	4
I am not confident with what CLTI is		1	3	4
The appearance of the limb can signify CLTI (not referring to ulcers)	1	2		3
I believe I understand what CLTI is (incongruous belief)	1	1	2	4
I am confused between acute and chronic ischaemia			1	1
I picked up my knowledge through experience	1			1
I can take an appropriate history (incongruous belief)		1		1
Environmental context and resources (Env)				
Making a referral / getting advice is time-consuming	8	5	7	20
People with diabetes have different (usually better) pathways	7	4	6	17
Any potential costs are irrelevant	4	2	5	11
Referral forms are helpful where they exist	3	3	5	11
Good tech facilitates referrals	1	3	5	9
There is a lot of pressure on people in the community		1	7	8
Doing a proper assessment takes time which is not always available	2	2	3	7
Telephone consultations are challenging			6	6
Shared notes are helpful where available	3	1		4

Standardised tools are not available for all	3		1	4
There is lack of time / resource for training	1	1	2	4
Poor connectivity (wifi / phone) hinders our capability	3			3
There is lack of resource for equipment	1	1	1	3
There is limited access to objective measures			3	3
Network configuration causes issues			2	2
Printing is difficult	1	1		2
A lack of equipment hinders our capability (ABPI / TP)	1			1
Assessment needs to be incentivised			1	1
Covid has delayed presentations			1	1
Not everyone can use required technology	1			1
Referral forms have downsides			1	1
There are many different channels of communication			1	1
There is pressure on vascular services	1			1
We are encouraged not to refer by the media			1	1
Beliefs about capabilities (Bel Cap)				
I am confident in recognising CLTI	8	2	2	12
I am confident in referring CLTI	7	3	1	11
Experience gives me confidence in recognition	6	2	1	9
Not everyone is confident in referring CLTI	2	3	4	9
No matter how capable I am, there are some things I can't deal with and need referring	2	1	5	8
Not everyone is confident in recognising CLTI	2		5	7
Objective measures of perfusion increase my confidence	3	3	1	7
Experience gives me confidence in referral	3	1		4
I don't want to refer things that I can manage	1		3	4
Not everyone is confident to discuss consequences	2	1	1	4
Some staff groups are perceived to not be allowed to refer to vascular surgery by themselves or others	2	1	1	4
Training gives me confidence in recognition	1	2	1	4
Vascular ought to understand referrers' roles / capabilities	1	1	2	4
I can help people get appropriate treatment	1	2		3
Written pathways increase confidence to refer	1	2		3
I can understand when something isn't normal			2	2
I am less confident referring others' patients			1	1
I refer more because I have less experience			1	1
Lack of experience leads to lack of confidence (ABPI)			1	1
Training gives me confidence in referral		1		1
Professional role and identity (Id)				
It is my role to refer patients to vascular	7	2	5	14
It is not my role to make decisions on palliating / not assessing / not treating	7	4	2	13
GPs are guided by nurses when vascular input is needed		3	5	8

Keeping updated requires personal effort	4	3	1	8
I can decide whether or not to refer someone (end of life)		1	5	6
It is not just my role to refer patients to vascular			6	6
I don't refer directly to vascular but I would like to	2	3		5
GPs / nurses need to refer to podiatry sooner	3			3
I can feel impostor syndrome when referring	1		2	3
Podiatry should be a gatekeeper for CLTI	2	1		3
It is not seen as my role to discuss consequences	1			1
Skills (Skill)				
Obtaining consent for referral can be challenging	8	4	5	17
I can examine a patient appropriately including objective measures	8	5	3	16
There is a need for improvement in our skills	3	3	2	8
We improve our skills with training	5	3		8
Vascular consultations can be challenging	2		5	7
I picked up my skills through experience rather than training	2	1	2	5
I can examine a patient appropriately (not including objective measures)			4	4
Staff assessing feet are irregularly trained			1	1
Memory, attention and decision processes (Mem)				
Wishes / affect of family / patient are taken into account	6	2	6	14
Findings on examination reinforce my decision	5	3	1	9
What the patient tells me reinforces my decision	4	2	2	8
It is difficult to know what the right thing to do is in frail patients	5		2	7
Referral decisions should not be based exclusively on tools / scores / readings	3	2	2	7
Decision making is unaffected by patient / family	2	2		4
Stress can divide attention			4	4
Regular reviews highlight deterioration which triggers referral	3			3
You can miss something in a consultation	2			2
I will err on the side of referral if I am worried			1	1
It needs to be severe in order to refer			1	1
Emotion (Em)				
There can be apprehension when it comes to contacting the vascular team	6	1	2	9
Referral leads to personal satisfaction	3	3	2	8
I can be sad on behalf of the patient who needs a referral	2	2	1	5
I don't have time to feel anything, it's just doing the job	1	1	3	5
There is relief associated with referring	3	2		5

There is significant responsibility on the referrer which can be stressful	3	2		5
Not being able to fix everyone is frustrating	2		1	3
How you are feeling may affect capabilities	1		1	2
Stress makes me more likely to refer			2	2
The consent process can be frustrating			2	2
The referral process can be frustrating (feeling not listened to)			2	2
The referral process can be frustrating (lack of time)			2	2
There can be anxiety associated with decision making	1		1	2
An unclear pathway is demoralising			1	1
I feel guilty if the patient doesn't turn up	1			1
Reinforcement (Reinf)				
Some referrals can get a negative reaction from vascular	5	2	4	11
Previous experience reinforces decisions	5	1	3	9
We are supported by the vascular team	6	2		8
There are no national incentives to diagnose / refer			1	1
We are trusted by the team who make referrals to vascular		1		1
Behavioural regulation (Beh Reg)				
I seek results of past referrals to self-monitor	6	4		10
We do the same thing with every patient	5	2		7
A clear referral pathway / criteria really helps	4		2	6
Referrals are audited			1	1
Regular reviews highlight deterioration which triggers referral	1			1
Structured referral tools like SBAR help	1			1

Knowledge

Most participants believed they knew what CLTI was, understood the urgency and were aware of the appropriate referral pathway, but some contradicted this professed knowledge with their responses, and others stated they weren’t sure what CLTI was. The lack of knowledge was attributed to a paucity of teaching on the subject during clinical training.

P8: So it's peripheral arterial disease, along with rest pain or an ulceration or gangrene or something like that.

P4: Yes. So we can now refer directly to vascular. We don't have to go via the GP, which is really, really brilliant, it speeds things up a bit.

N5: So obviously if it were, if I were really worried, if it were quite critical, I'd just send them to A&E [accident and emergency] and I'd ring the vascular team to say I've sent this patient to A&E. [This is not consistent with referral processes at N5’s local unit]

D7: Yeah, I have to admit that was one I had to Google, because I was... I mean, I think we all know the signs of the acute ischaemia, and that's drilled into you with your Ps and your learning in medical school. And then you've kind of got your, ohh a bit of claudication type of thing. But I think that in between that chronic limb ischemia, I wouldn't have recognised that as a descriptor and had to look it up.

D3: I had no other formal training through my foundation years or through GP training, actually. I don't think we did any specific vascular training in, through those three years of GP training.

Whilst some participants were aware of and used guidance regularly to influence their referral decisions, others were not aware of guidance, or felt it was only relevant to less experienced members of staff. Over half the participants indicated local guidance or pathways would be helpful to their decision-making process.

P9: What we tend to use, we've just implemented very recently, is the WIfI, so the wound, ischaemia, foot infection tool and we use the ESVS [European Society of Vascular Surgery] calculator on their app. So that does help us to guide, you know, with the referrals and things.

EA: Do you know of any guidance relating to CLTI? D6: I don't. To be totally honest, I don't.

P6: I think, because I work in it a lot, I guess it's always there in my mind, I don't... But for junior staff, I think it is helpful because it's actually like a, ohh, right, OK, what am I doing and you're following the arrows.

D4: So I think that would be really helpful, just to make sure there's clear guidance and it's really clear for everybody in… If it's not clear for me, and I still don't think it is, then I think it mustn't be clear for an awful lot of GPs in the region.

Environmental context and resource

All participants found recognising and referring suspected CLTI to vascular surgery time-consuming, describing pressure on people in the community and lack of time available to undertake a comprehensive patient assessment.

P1: But yeah, it is. It's obviously time consuming. That's the thing.

N3: And I think because there's a lot of junior staff and new starters who have recently come into sort of, in this job environment and working in the community, it's a lot to learn. And I think there's just so much pressure everywhere that people struggle sometimes. They panic, and they don't know which way to go.

D1: And it's like I hardly ever feel for pulses or look at feet. And that's partly again time. You know, can you take your socks and shoes off? You just lost 3 minutes.

Technology was an issue, with good technology improving the ease of referral, but poor technology such as the lack of shared notes or unreliable internet access acting as a barrier. Different resources were available for other conditions, which could be used a template for improvements in vascular surgery processes.

P4: Because we have, like, we have smartphones to take photos with. We've got laptops which we could take into patient's houses. And, you know, we could do the referral right there and then.

P7: It varies as well, in terms of if their GPs are on the same System One system as us and if the sharing's available. So sometimes I can see everything, and I can get a lot of information and I'll sort of get a better idea about, you know, might, what might be going on. Sometimes I'm quite blind.

D2: So it's something called DXS. I think practices have to pay for this thing, DXS. It's like a software, but all the forms are on there, and actually it's a place where you can put guidelines as well. […] So that's really helpful.

Most participants noted that patients with diabetes often have access to different pathways than those without diabetes, promoting inequality.

N2: Yes, in that, well, it's easier just to shove referrals through to podiatry, because you can just say, look, they're diabetic and I have concerns.

Conflicting beliefs were observed regarding the value of referral forms. Some participants found them helpful, with others reporting downsides.

D2: Whereas other specialties, they do have proformas for different conditions. So it's like tickbox, tickbox – quite quick and easy for us to fill in, and also quick and easy for the secretaries to just send off.

D1: So I'm a member of the LMC [local medical committee], and so we often talk about these forms because the difficulty with the forms is if they're not perfectly completed, you can get rejections. And I just think that's completely, totally not helpful, you know?

Beliefs about capabilities

More participants described themselves and colleagues as being confident in recognition of CLTI than its referral. One reason for not being confident in referral was being perceived as not being allowed to refer to vascular surgery. The presence of written pathways and having the result of an objective measure of perfusion were highlighted as reasons for confidence.

P5: I would say I'm quite confident because I can recognise the signs.

D7: Actually, I'd probably feel quite insecure about them, because I don't think we tend to see an awful lot. There's not a lot of exposure for us, and so, you know, in terms of our pattern recognition, common things being common, common things you feel much more secure about.

N4: Yeah, I haven't thought of doing that [referring to vascular surgery]. I don't think that's ever kind of been said before. But no, if that was, if that were, if we knew we could do that…

N1: I guess it would feel - you'd feel more confident if you were following the pathway, and going rather than just like ringing someone up and just be like, hiii.

P7: It's been really helpful since we started doing toe pressures, cause I feel like that does give me a little bit more of a potentially objective, you know, idea about what's going on.

Professional role and identity

Most participants stated it was their role to recognise and refer patients with suspected CLTI to vascular surgery. Some participants felt, however, that it was not their role to make decisions *not* to refer patients to vascular surgery, even whilst suspecting the patient may not be a candidate to undergo intervention due to frailty or other co-morbidities. GPs were often asked by nurses to make the referral to vascular surgery services for a patient when a nurse had suspected CLTI following their assessment but felt it wasn’t part of their role to personally make the referral. Participants who felt it wasn’t their role to refer to vascular surgery would want to be able to make referrals in future.

N5: If we're looking after them and we find it, then yeah, definitely. It's anybody's role, really if they're concerned.

EA: Are you happy to make that decision that they're not suitable for referral, or would that be something that you would look for the vascular surgery advice on? P6: Absolutely. And the GP involved, and the family. No, I certainly would not ever make that decision. I don't think it's my role.

N2: So literally I write extensively in the notes all my history taking and my concerns, and then I electronically task one of the GPs who will do the referral for me. And they tend not to ask to see the patient again. They tend to rely on what I've said and they're more than happy.

P8: I do think it would be a good thing for us to be able to do in the future, I think. We don't have that much exposure to sort of, the referrals and everything because I've never done a referral to the vascular team.

Skills

The main difficulty described by participants was obtaining consent from patients for referral. Vascular consultations were considered challenging. Most participants were comfortable examining patients, but described a need for additional skills training e.g. undertaking toe pressures and ABPI assessments.

D5: It wouldn’t prevent me referring, but it would prevent the patient accepting referral which is part of the consent process. So there are undoubtedly patients that will not go to hospital now, that we end up doing end of life stuff with at home.

D4: So, you know, I think they're the ones I think that are really difficult to then identify at what point are they actually into critical. And when actually, and what's arterial and what's actually part and parcel of their other comorbidities, and how do we get that in and communicate that appropriately before they end up being acute admissions.

N1: Yeah, so, well, if we were thinking like, we’re worried about kind of arterial problems, it would be the look of the wound, if it was located sort of foot, ankle, if it was round, defined edges, progressing fast and like raised edges. […] That's the other thing, obviously I’d do Dopplers and things, I forgot to say about that. Yeah, pulses.

P9: There's not been enough training, perhaps definitely with the lack historically of toe pressures and things like that, it's very easy to see the patient, from a podiatry perspective, put dressings on and review the patient a week later without getting to the actual cause of what, you know, how, recognising CLTI.

Memory, attention and decision processes

Most participants saw the patient holistically and used the wishes of the patient in addition to the clinical findings to guide referral decisions. Some participants suggested referral decisions should not only be based on diagnostic tools, scores or readings.

N2: We had a situation at our GP practice where an automated ABPI was done on the patient. It was done perfectly well. The ABPI was normal, but the history that the patient actually gave was not good at all. That patient should have been referred into vascular and wasn't, and ended up losing a limb.

Whether to refer a patient or not was often reported as a difficult decision, especially where patients were frail.

P2: I think what's different in podiatry now is, not necessarily just in podiatry, maybe, we see a lot more patients who perhaps there isn't anything that can be done. And they, you know, they aren't suitable for surgery. And those are the ones where I think we as clinicians probably struggle a little bit more.

Emotion

Despite recognition and referral leading to personal satisfaction or relief for some participants, a feeling of apprehension was described when it came to contacting the vascular team. Frustration with the process was described for many reasons, including delay in recognition, gaining consent, lack of time and feeling not listened to.

N4: Just so that we can get, I mean nothing's more satisfying than getting an ulcer healed. But also knowing that I'm doing my job and giving our patients the best treatment.

P5: Sometimes it's a relief that we've got them in, or they've agreed to go in.

D3: I think I've always had that, I think a lot of people have that nervousness about speaking to a specialist on the phone. I think it goes back to like hospital days as a junior.

P1: Well sometimes it's very frustrating, because the patient’s been like this a long time and it's never been addressed or picked up on or recognised. That's frustrating, because you always think, oh, this could have, this has been going on six months, you know.

Reinforcement

Previous experience with vascular surgery referrals reinforced how participants behaved. Some had had negative experiences with vascular referrals, whilst others felt supported.

D7: And we do tend to find that sometimes we get sarcastic replies back, or what's perceived as a sarcastic reply back for referrals, which then makes you again feel more insecure in what you're assessing.

D1: So you think, well, why would I bother referring to vascular? They're probably not even seen for 9 bloody months. And so you get that nihilistic attitude…

P2: Our vascular surgeon is, she is really approachable. And you don't feel like that at all. And she's really, she respects what you say.

Behavioural regulation

Where feedback from referrals wasn't immediately available, participants sought the results of previous referrals in order to monitor their practice. Sometimes this was a convoluted process, but participants found it helpful. Others found a clear referral pathway helped regulate referral behaviour.

N3: We have to go searching. And so I'd often look through their letters and see who they're under. And I'll just e-mail the consultant's secretary, or ring the secretary, or the specialist nurses. I'll ring whoever I can get hold of!

P4: So we've got our own PAD pathway that we use and that's built into our template that we use in clinics for record keeping. So there's a lot of guidance on there for staff to, you know, refer to, to make sure they're making their appropriate referrals.

5.4. Discussion

This study applied the TDF to explore self-reported influences on recognition and referral behaviour in primary care with regards to suspected CLTI. The most frequently mentioned, relevant or conflicting beliefs acting as barriers to referral behaviour adhering to published guidelines were categorised in the Knowledge, Environmental context and resources, Beliefs about capabilities, Skills, Professional role and identity, Memory, decision and attention processes, Emotions, Reinforcement and Behavioural regulation domains. Interventions designed to reduce delays in referral from primary care to vascular surgery units could include behaviour change techniques targeting these domains (Table 14)[219, 227].

Domains of the TDF identified as irrelevant may describe enablers of recognition and referral of suspected CLTI. Future interventions should take this into account and ensure evaluation of any such intervention considers these domains alongside domains identified as relevant.

Table 14: Behaviour change techniques suggested according to TDF domain[227]

Domain	Example behaviour change technique
Knowledge (Know)	Information regarding behaviour, outcome
Environmental context and resources (Env)	Environmental changes (eg. objects to facilitate behaviour)
Memory, attention and decision processes (Mem)	Self-monitoring
	Planning, implementation
	Prompts, triggers, cues
Beliefs about capabilities (Bel Cap)	Feedback
	Increasing skills: problem-solving, decision-making, goal-setting
	Rehearsal of relevant skills
Professional role and identity (Id)	Social processes of encouragement, pressure, support
Skills (Skill)	Graded task, starting with easy tasks
	Modelling / demonstration of behaviour by others
	Rehearsal of relevant skills
Emotion (Em)	Coping skills
	Stress management

NB: Reinforcement and Behavioural regulation domains were not used as constructs in the referenced study

Participants' responses centred around two key issues. Firstly, participants' confidence, both in themselves and in vascular surgery, was a factor influencing recognition and referral across multiple domains. Whilst all vascular units indicated in the previous process mapping exercise (Chapter 3) reported that referrals would be accepted from any member of primary care staff, this was not the experience reported by participants. Some responses indicated a lack of confidence in knowledge or skills to recognise CLTI, and expressed desire for written pathways and additional training to support their involvement in the referral process. Confidence to make a referral to vascular surgery was also lacking, with some participants describing tension, apprehension, and previous negative experiences.

Secondly, the context in which primary care clinicians are working is extremely challenging. There are multiple demands on clinicians' time and attention, which can affect clinical behaviours, including promoting less thorough patient assessment. Poor technology can affect the ease of making referrals or seeking the results of previous referrals, and further add to pressure on clinicians. Participants also noticed increasing patient complexity, including both frailty and unwillingness to consent to referral, adding challenges to their decision making. These perceptions are not only recognised by vascular surgery clinicians, as described in Chapter 4, but supported by evidence from the King's Fund, who report a substantially increased workload in primary care, without being matched by increased funding or workforce, as well as increasingly complex patient care needs[228].

Our results echo the findings of previous studies in primary care, which have indicated a lack of awareness of guidelines and unclear pathways affect referral behaviour[90, 94]. Beliefs coded to the TDF domains of Knowledge and Memory, attention and decision processes add essential detail to the findings in the literature, including the importance of easy availability of guidelines, such as those accessible within IT systems. The assurance offered to primary care clinicians by the implementation of a local pathway is also clear in our data.

Patient factors have also previously been implicated in recognition and referral of CLTI, including a delay in presentation in PAD[94], perceived poor motivation to undergo pulmonary rehabilitation in chronic obstructive pulmonary disease (COPD)[163, 217] and lack of adherence to guidelines in primary care[229]. The results of our study indicated that clinicians found the consent process challenging, and some patients would refuse referral despite explanations of the possible consequences. This has not previously been described and adds to current understanding of patient factors affecting referral behaviour.

The TDF does not specify relationships between its domains, unlike the theories used in its development. Previous studies have used the TDF to identify other useful theories which could be used to link relevant domains and guide further analysis[216]. In our study the reported importance of the Knowledge and Environmental context and resource domains may be further explored with the knowledge-attitude-behaviour model[230] and the Consolidated Framework for Implementation Research (CFIR)[231] respectively.

Using the TDF allowed systematic identification of barriers and enablers of timely recognition and referral to vascular surgery for suspected CLTI in primary care. Interviews were carried out with a diverse range of primary care clinicians, both in terms of role and geography. Barriers and enablers reported can guide further theory-driven research, including design, implementation and evaluation of interventions, as the TDF allows their mapping to both theory and behaviour change techniques[216, 219, 227]. Finally, the use of the TDF as a basis for the interview topic guide may have prompted the identification of barriers and facilitators of recognition and referral that participants may not have reported in an interview uninformed by a theoretical framework.

This interview study allowed primary care clinicians to explain their own behaviour regarding recognition and referral for suspected CLTI, but the TDF does not provide evidence of actual influences on clinical practice, and clinicians' interview data may be subject to post-hoc rationalisation and concern as to how they may appear to the interviewer. Quantitative work involving behaviour change interventions can provide this evidence. Future work in this area should explore what factors are relevant in changing practice. The results also demonstrate the importance of patient factors in the referral process. Interviewing patients may have identified further barriers and facilitators of referral. Differences between staff groups interviewed in this study have also not been investigated.

In conclusion, this study has used a theoretical framework to identify barriers and enablers reported by primary care clinicians as relevant to the timely recognition and referral of patients in the community with suspected CLTI. Potential explanations are offered for known delays in the symptom to assessment pathway. These findings may help develop, implement and evaluate targeted, theory-driven interventions to optimise the recognition and referral process mapped directly from the TDF domains.

Chapter 6. Patient experience of the process to diagnosis of chronic limb-threatening ischaemia: a qualitative study

6.1. Introduction

Little is known about the patient experience of CLTI, with published studies focussing on complications of diabetic foot disease[117-121]. This patient cohort has some overlap but important differences from patients with CLTI, including in the available care pathways, as described in Chapters 3, 4 and 5. Approximately 50% of patients receiving inpatient treatment for CLTI do not have a diagnosis of diabetes[152]. The scant existing literature on patients with CLTI not specific to diabetes explores their concerns and values around treatment, or perception of their own body, and does not expand on processes of care[123, 124].

Patient understanding of PAD and consequent delay to first presentation has been implicated in previous interviews with clinicians as a cause for delay to treatment, both in the literature[94] and in Chapters 4 and 5. This study aims to explore the experiences and perceptions of patients with CLTI, focussing on their process to diagnosis, in order to understand potential factors associated with process delays as told by patients themselves.

6.2. Methods

A qualitative interview study was performed. Qualitative research enables understanding of how the world is viewed by research subjects[115]. The authors sought to explore individual participants’ experiences and perceptions of achieving their diagnosis of CLTI, and define common meaning across the cohort. A critical realist framework underpinned the analysis, appreciating that multiple experiences and perceptions of a single reality exist. Coding and theme development was based on meaning, as opposed to frequency, in keeping with a “big Q” qualitative paradigm[191]. Reflexive thematic analysis, a qualitative method developed by

Braun and Clarke, was used to explore and interpret the dataset, allowing the authors to develop and tell a story of its patterns of meaning[116]. COREQ guided the reporting of this study[193].

6.2.1. Identification and recruitment of participants

Participants were recruited by vascular surgery clinicians at seven NHS Trusts in England all involved in the process mapping study in Chapter 3. Eligible participants had been diagnosed with CLTI in the past year, had no cognitive impairment and were able to speak English. The purposive sampling strategy aimed for maximum variation in age, gender, diabetes status and patient location in the vascular network (near an arterial or non-arterial centre). The diabetes status and patient location within the network have previously been identified in Chapters 3 and 4 as areas of inequality in care pathways for suspected CLTI.

Potential participants were consented by a vascular clinician involved in their care for the sharing of their contact details with the research team. Participants were then contacted by the research team and if interested given more study information in a PIS. They were provided with the opportunity to ask questions. Written consent was obtained from each participant prior to interview and confirmed verbally immediately before and after the interview. Ethical approval for this study was gained from the NHS Health Research Authority and the South Yorkshire Research Ethics Committee (22/YH/0290).

6.2.2. Interviews

I carried out semi-structured interviews, as a female vascular surgeon with experience in qualitative interviewing following the studies reported in Chapters 4 and 5. All interviews were carried out over the telephone. A topic guide consisting of open questions was used as a framework for the interviews, with prompts used where necessary (Appendix 5). It was iteratively altered as interviews progressed.

I kept a reflexive diary throughout the process, recording individual reflections after each interview. These written reflections enabled reflexive thematic analysis, where the researcher's subjectivity is acknowledged and informs the analysis[116].

6.2.3. Analysis

All telephone interviews were audio recorded, transcribed verbatim, anonymised and imported into a qualitative software package (NVivo) to aid data analysis. As per Braun and Clarke's six phases of thematic analysis, immersion in the data took place both with the audio recordings and the transcripts, with initial noting of observations, questions and interpretations. I carried out formal inductive coding, followed by two cycles of re-coding. Candidate themes were generated initially, then developed and revised following discussion with IK and re-engagement with the original data. Themes were then refined, defined and named.

6.3. Results

Telephone interviews were undertaken with 16 participants diagnosed with CLTI in the preceding year. Participants were aged 59-80 (mean 67.4) years, two were female and four had diabetes. Half were local to an arterial vascular centre (Table 15). No participants dropped out or rescinded consent at a later stage.

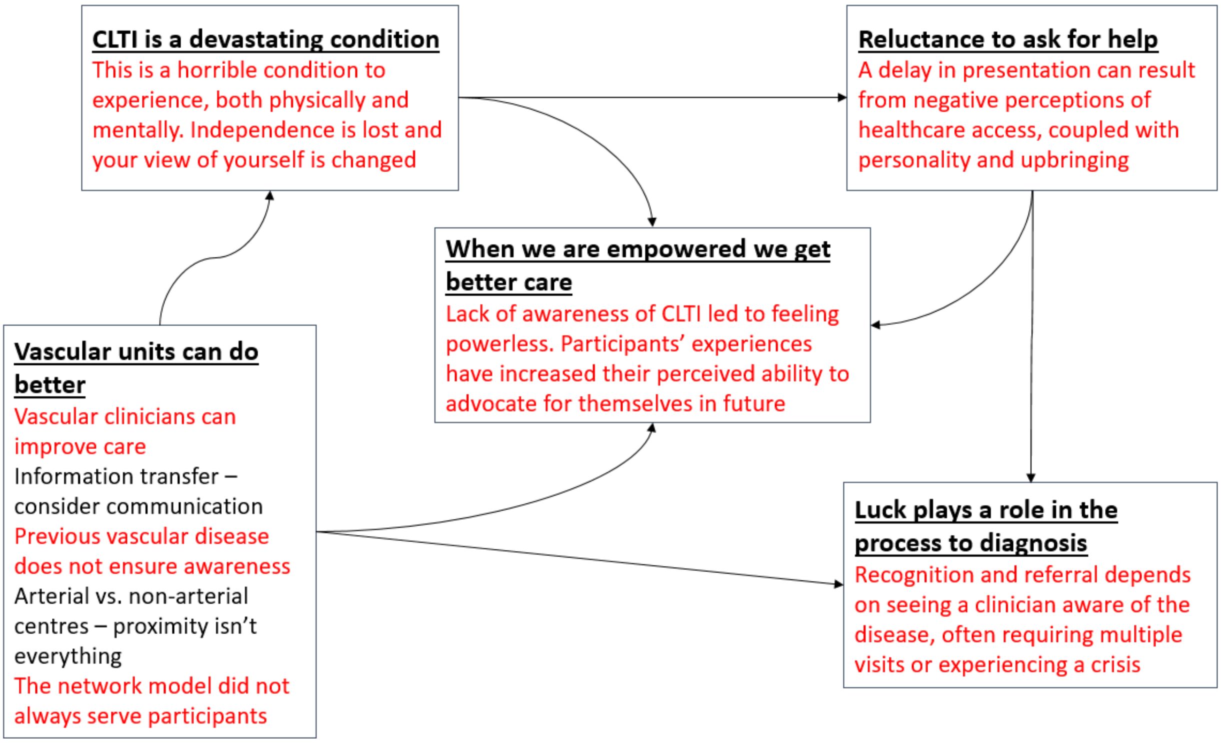
Interviews lasted from 38 to 61 (mean 47) minutes. Reflection on the content of our dataset found the interview data adequately rich to fulfil our research aim, according to the concept of information power[197].

Table 15: Participant characteristics

Patient code	Male / Female	Age	Diabetes	Arterial / non-arterial centre
A	M	59	No	Arterial
B	F	63	Yes	Non-arterial
C	M	63	No	Arterial
D	M	66	Yes	Arterial
E	M	74	No	Arterial
F	M	69	Yes	Non-arterial
G	M	67	No	Arterial
H	M	65	Yes	Arterial
I	M	60	No	Non-arterial
J	F	72	No	Non-arterial
K	M	74	No	Arterial
L	M	80	No	Non-arterial
M	M	59	No	Arterial
N	M	72	No	Non-arterial
O	M	65	Yes	Non-arterial
P	M	71	No	Non-arterial

Reflexive thematic analysis of the interview data led to the development of five key interrelated themes: CLTI is a devastating condition; reluctance to ask for help; when we are empowered we get better care; luck plays a role in the process to diagnosis and vascular units can do better (Figure 8).

Figure 8: Diagram of themes



6.3.1. Theme 1: CLTI is a devastating condition

The theme "CLTI is a devastating condition" reflects the participants' descriptions of CLTI as a condition with multiple effects on every aspect of their lives. Physical symptoms, particularly impaired mobility, pain and sleep deprivation, were severe and profoundly disabling.

"They cramped, and they locked. It's like your legs have been locked, and when you get up, you're sort of hopping around, trying for the pain to go away, like. And that was it virtually every day, every night, like, you know." Participant K

"Whenever I tried to walk anywhere, the pain was like pretty intense, and resting, well, it wouldn't let me rest. It would be painful." Participant C

"I was having to sleep in a chair, a dining chair, with my feet down, which was uncomfortable!" Participant P

“I was having an hour and a half, two hours sleep a night.” Participant G

“To me, it's a lifetime when you're waiting a week for an appointment, when your toe’s black, and it's smelly. A week’s a lifetime.” Participant H

The severity of symptoms led to mental health challenges, including thoughts of self-harm and suicide. The symptoms changed how participants viewed themselves.

“So I just came home. Basically went on to smoke myself to death. Well, I didn’t think there was nothing to live for.” Participant G

“See, I'll go up on a railway line one night and put my leg on there and, you know, hope for a train to go over it.” Participant K

“I’ve come to realise that I'm not a young man anymore. I'm more susceptible to disease and things going wrong. It has changed my outlook as well.” Participant D

Symptoms led to a loss of independence. Participants described being unable to carry out normal activities of daily living, including socialising, and relying on friends or family for help. Participants found this difficult, having previously been independent. Predominantly female family members were involved in helping their relative struggling with CLTI symptoms.

“And it's hard sort of accepting, nope, you’ve now fallen into the net of being in a bit of need.” Participant O

“It meant that, you know, I wasn't going out very much at all, and even to do shopping, I was getting shopping delivered, etcetera, etcetera. And I was getting picked up by a member of the [workplace] staff and brought home again.” Participant P

“I didn't eat properly because I couldn't stand and cook anything, you know?” Participant B

“Well, my daughter was cooking me dinners, and I was like… By the time I came into hospital, she was cooking me dinners. She was doing the hoovering, doing everything.” Participant G

CLTI also impacted on working life, leaving participants with difficulty carrying out their normal duties in their employment, which could lead to financial consequences.

“I was trying to go to work, and if it wasn't for my workmates I wouldn't really have made through it, because they covered for me. While I just had a good rest, sat at a desk, did computer stuff, paperwork.” Participant D

“I'm now still off work. You know, we’re selling stuff, you know, to basically keep the wolf from the door.” Participant I

Another struggle for participants was the lack of an initial diagnosis. They didn’t know what was wrong with them and this was difficult to manage mentally, leading to frustration.

“More than anything, I think, yeah, not knowing what it was, you know, infuriated me a bit.” Participant A

“Well, once we knew what was happening, what was wrong. That was the big thing. It was the not knowing. And it wasn't getting any better.” Participant I

6.3.2. Theme 2: Reluctance to ask for help

The reluctance of participants to ask for help was described in terms of a personality type or upbringing, coupled with a negative perception of the process of accessing healthcare or not wishing to waste anyone’s time. Participants described themselves as stoic generally.

“But I, to be honest, I don't like hospitals because I'm one of them, I’m sturdy.” Participant N

“You know, I'm a fairly strong character, I think.” Participant M

How participants were brought up, and consequently how they saw their role in society, affected their willingness to ask for help.

“We were always contributors, we were never takers, and, you know, we had pride in that. I don't know what work ethic it was Mum and Dad had, that they put into me, but it was a case of, no, we're supporters, we're not vulnerable, we're not needy. You know, we look after ourselves, we'll deal with it.” Participant O

The NHS was seen to be under pressure, with healthcare providers perceived to have plenty to deal with. Participants didn’t want to add to that pressure unnecessarily.

“The NHS [National Health Service] are really busy, so I just left it and left it.” Participant A

“And then over the years, with the way that they, like, the way that they’ve been put under the cosh, you don't want to torment them anymore than what you have to.” Participant G

“You know, I don't want to waste their time. Their time, it is as precious as anybody else's.” Participant C

Participants anticipated difficulty, discomfort or futility in accessing care, based on previous experiences of accessing care in the community, which put them off seeking help.

“Well, the GP surgery’s just - it's a nightmare. So, unfortunately, you know, unless I'm absolutely desperate I tend not to use them.” Participant M

“…but I certainly would be able to speak to my GP - if I can get an appointment with my GP, of course, because that in itself is like gold dust, trying to get a hold of an appointment.” Participant B

“Wasting time all the time. Sitting around, waiting. Trying to get… You can’t take a nap. You can't close your eyes for a minute, because somebody's gonna pop into you. And I was

always watching my foot, you know, where people are pushing trolleys past you. It's hectic. It’s mayhem.” Participant E, referring to the emergency department

“I haven't gone back, because if he [vascular surgeon] said there was nothing they could do, I thought, well, what can the GP do?” Participant K

Other things were also going on in their lives, which participants placed more importance on than their own health.

“Because I couldn't walk far, because I had pain. But I put it all to one side, didn't do anything about it because I was struggling with my husband at that time.” Participant J

6.3.3. Theme 3: When we are empowered we get better care

This theme describes the ability of participants to demand better care if they are aware of the likely cause of their symptoms and are able to articulate this to their clinicians.

“Look. If I hadn’t taken action myself, and spoken to the vascular nurses, who I’d been under at [arterial centre], who knew me, I think I'd have still been stuck at home. They knew all my history, had all my notes, and that sort of prompted things into action, for me.” Participant J

Participants described a lack of personal and public awareness of PAD including its severity, urgency and consequences, leading to a feeling of powerlessness during their process to diagnosis.

“And it was after that that I noticed that I couldn't walk very far. And I just put that down to the lack of exercise and age. I was getting - my legs were starting to really ache badly after, you know, after a couple of hundred metres.” Participant M

“I just didn’t have a clue whatsoever what was going on, really […] I didn't realise it was that serious.” Participant F

“But what could I say to them? You go to the doctors’, and they tell you what they think. I can only say, it's hurting, and they say, don't be a wuss. You know what I mean?” Participant L

The importance of advocacy was expressed by participants, whether that is advocating for oneself, or having friends, family or trusted clinicians that can fulfil that role.

“No, you know, and I virtually insisted that I wanted to go to hospital, like, and have it checked out like, you know.” Participant K

“Because I say, I feel, well, I'm quite articulate, and can fight my corner, but there's a lot that can’t. And that’s a bit of a worry, you know. They just accept, or wait so long, and you know...” Participant J

The experience of CLTI that participants have lived through has enabled them to feel more competent to advocate for themselves in the future.

“Well, I’d recognize the signs sooner, so that would be a bonus. I mean, I would probably demand an earlier referral.” Participant B

Participants reported unwillingness to use the internet to search for information, preferring face-to-face advice from experts. This was variously due to a lack of access to the internet, a lack of trust in the information found online and a perception that information found may increase the perceived severity of their symptom.

“I don't go on computers to investigate this, that and the other. I’d rather a face to face. And be told point blank. And not, it's possible... It could be... Whereas... And you’re reading between the lines and you think you've got everything! So no, I don't go on to websites and things like that.” Participant E

“…because if you're gonna worry, you can make yourself worry a hell of a lot more if you go onto Google, can’t you?” Participant H

6.3.4. Theme 4: Luck plays a role in the process to diagnosis

Luck was required for the participant to come across a clinician able to recognise and refer CLTI appropriately, or for an event to occur to precipitate diagnosis.

“And then the chance observation at my local GP, with their review nurse, who says, go on, let’s have a look at your foot. And what's this on your toe? Right, you’d better go and see them…” Participant O

Little awareness of CLTI symptoms and referral pathways was demonstrated by primary care and ED clinicians in the experiences of our participants. Participants frequently required multiple visits to clinicians, with minimal continuity of care, and it was often by chance that a clinician was seen who was able to recognise and refer appropriately. Diagnoses of gout or arthritis were often made, and if a wound was present there was often a period of dressing it without investigating underlying causes of poor healing.

“So back to the doctor. She decided to take blood tests to establish what the problem was. There was a suspicion of gout, or arthritis.” Participant C

“So when I went to hospital, [non-arterial centre], I got this Asian doctor and he said to me, it’s gout. Take ibuprofen.” Participant N

“Right, [nurse 2] dressed it, [nurse 1] dressed it. [Nurse 1] mostly dressed it. She wasn't happy about it, but she wasn't sure what to do. She spoke to plastic surgery people, and this, that and the other. Then there was two or three at [town 3], when they couldn’t get me in at [town 2] or [town 1].” Participant I

“Because I saw three GPs, all different ones. We lost our original one. I think he would have been better at it. You know, because he… If you look at a person three times, you see a difference. But if you see three different people, it's a – you don't get the same effect. So it was just unlucky I got three different GPs.” Participant L

"And it got to March, I collapsed. I went to [non-arterial centre], they took me to [non-arterial centre], and the doctor who saw me that time spotted it straight away." Participant N

There could be a delay in obtaining objective measures of perfusion, with participants not seeing a clinician who could carry out the test, the test itself being delayed, or delay to interpretation and actioning of results.

"And then after about two weeks, two or three weeks, one of the nurses said, I'll do a Doppler, and did a Doppler on my leg. And that's when she referred me. And that's where she found out that my leg was, you know, 50% below sufficient." Participant P

"So after that I made an appointment with a doctor on the 24th. […] After that, the 27th, I was supposed to have had a blood pressure test, on the two arms and two feet, or ankles. That got cancelled. […] But I had an appointment with the nurse on the Wednesday, and that got cancelled again. That was the 29th. On the Thursday, I had to see a nurse on the Monday, and they should they put the traces on me, the arm bands, blood pressure things. On the two arms and two legs. And that was that, she gave it to the doctor. And I went to the doctor's on the 4th of April, and he, I don't know what he said, but I finished up going to… Ohh, they said it looked bad, but it wasn't bad enough to make a decision." Participant L

A diagnosis could be precipitated by a crisis, seen as lucky by the participant.

"But I was lucky, in a way, to have that ulcer on my heel, otherwise I'd have just carried on as normal." Participant P

6.3.5. Theme 5: Vascular units can do better

This theme comprises two sub-themes, focussing on specific points for improvement. It communicates where vascular units can improve the care they provide to avoid delays. Vascular pathways were often described as slow, certainly much longer than recommended time-to-revascularisation targets[27].

“The communication possibly… it seems to take, yeah, we want you to see the surgeon. Well, they can see you in three weeks. Well, you know, when you've got the black toe, I think you need to be seen quicker sometimes.” Participant H

Sub-theme 1: Information transfer

Some participants reported previous contact with vascular surgery, with long-standing histories of peripheral arterial disease or previous experiences of CLTI. A lack of patient awareness was evident, however, even in these cases, indicating vascular surgery communication with the patient had not been effective.

“EA: And back when they said, ohh there's nothing else we can do. Did they give you any symptoms to watch out for, or any sort of conditions where they might do something?
Participant F: No. None whatsoever.”

Despite recent experiences, participants lacked understanding about the pathology of PAD and the rationale behind treatment decisions made by vascular clinicians.

“Yes, I became aware that I had issues. Which I always found peculiar because at the time I was going in for that, and they were all there wanting to cannulate in my arms, and obviously for the intravenous and all the other bits and pieces, every nurse that I saw said, what fabulous veins you’ve got!” Participant O

“So I almost have that feeling, that it would have been better… Prevention rather than cure would have been a good thing. If they’d acted two years ago, instead of leaving it until it actually gets infected this year.” Participant H

Referral pathways did not seem to have been made clear to primary care clinicians by vascular networks, with a lack of awareness of local processes described.

“And to cut that story short, the GP said, all I can do for you is ring 999. So that's what happened.” Participant J

"And then I went back a week later, and saw him again. And I said, what's happening about this hospital appointment? Because I really can't carry on like this for much longer. And he said - and by this time the toes were really quite purple at this point. And he said that they'd written back to him and they wanted more information, and they weren't sending out an appointment yet." Participant B

Sub-theme 2: Arterial vs. non-arterial centre – proximity isn't everything

Differences between arterial and non-arterial centres were described by participants with experience of both. The arterial centre was often seen as a better hospital than non-arterial centres.

"Basically, just, because I know, I think it's a better hospital than [non-arterial centre]." Participant I

The network model was highlighted as a cause for delay, with issues transferring participants for review and few opportunities to see urgent referrals at the non-arterial centre.

"It was just hard for them to get transport. That was where I got stuck at [non-arterial centre] for longer when [arterial centre] were saying to [non-arterial centre], well, we've got the bed waiting. Where is she?" Participant J

"They looked to see if there was anything before that day, but apparently that clinic was only held one day a week, on Wednesday at [non-arterial centre], and there was nothing." Participant B

Participants were willing to travel to the arterial centre, and it was described as easier to get to than some network non-arterial centres. Accommodations made to increase accessibility helped this.

“It's probably slightly easier bus wise, although it's a longer journey, to get to [arterial centre] than it is to try and get to [non-arterial centre] from here, because I don't think there’s a direct bus anymore.” Participant B

“No, because even the night before the operation, I was given free accommodation at the hospital. So there was no problem at all, because they wanted me there at 7 o'clock in the morning. And to get from [non-arterial centre] to [arterial centre] at that early hour, I don't think I would have made it.” Participant F

6.3.6. Reflexive diary

During the course of the study, a reflexive diary was kept, with entries following each interview and throughout the analysis. This allowed me to reflect on my position of privilege and power relative to the participants in the study, and how that could have affected the interview dynamic. This informed changes in the interview topic guide throughout the data collection process. During analysis, the reflexive diary helped me record my thoughts around coding and theme development, noting ideas and opinions whilst organising the data. It allowed me to consider how my own previous experiences have influenced my perceptions of the participants’ stories, and informed the generation of themes.

6.4. Discussion

This qualitative study has explored the experiences of patients recently diagnosed with CLTI. The participants provided an increased understanding of the CLTI care pathway from a patient perspective, and recognise those factors relevant to delays in the process directly from lived experience of CLTI diagnosis. In agreement with previous suggestions in the literature[94, 118] and Chapters 4 and 5, participants described a lack of personal awareness of PAD and CLTI, as well as its urgency, severity and potential consequences. In addition, the themes of “the role of luck in the process to diagnosis” and “when we are empowered we get better care" describe a lack of awareness of clinicians in primary care and EDs when participants presented, requiring either luck or patient knowledge and advocacy to ensure a diagnosis of CLTI is considered. A lack of awareness of CLTI across healthcare professionals has previously been identified as a barrier to timely referrals in Chapters 4 and 5, as well as in the literature[118], and missed opportunities to identify and refer CLTI have been described in a primary care database study[75], supporting our participants' perceptions. There is little evidence to suggest the most effective way to educate other clinicians, especially when they are dealing with high pressures throughout the healthcare system. There is an opportunity for improvement here, not only just to improve care for patients with suspected CLTI, but to add to the educational literature.

Some participants were reluctant to ask for help, as described in Theme 2, which is reflective of older adults' desire to meet their needs without assistance[232]. Access to healthcare is complex, depending on interplay between individuals and healthcare services[233]. Socio-economically disadvantaged people are both more likely to be diagnosed with CLTI[234] and manage their health in a series of crises[233]. However, previously reported barriers preventing attendance for health promotion or prevention such as financial costs[235] or lack of other resource such as transport[236] were not described by our participants. They indicated instead that in being reticent to attend healthcare services they were reducing pressure on the NHS, which aligns with more recent findings[237]. Improving this is a challenge whilst there remains high pressure on NHS services, but suggestions have included improving information provision and building better connections across the health and care system[237].

Some of the barriers to timely diagnosis reported by participants are in the control of vascular surgeons, as described in the theme "vascular units can do better". This links with the previously discussed lack of awareness, as participants demonstrated that even following diagnosis of CLTI, their understanding of the condition was poor. This is a common problem, with patients leaving hospital often unaware of their diagnosis and treatment plan[238, 239]. Our data indicate participants were unlikely to use the internet to research their symptoms and in addition, the internet cannot be relied upon to provide good quality information[240, 241]. CLTI is associated with poor health literacy[242]. This, in combination with our findings and the fact that CLTI has a significant risk of recurrence[243, 244], suggests vascular clinicians need to optimise the delivery of information to patients with PAD and CLTI. Education of patients can lead to fewer recurrences in diabetic foot ulcers, a similar condition[245]. A change in vocabulary has previously been suggested in CLTI care, with the use of the word “remission” to signpost high rates of recurrence, aligning with language used in cancer management[246].

Participants described well recognised pressures on the NHS, which are unlikely to improve in the current context of increasing patient complexity and funding shortages[204, 205]. Ensuring primary care and ED clinicians are aware of local referral and escalation pathways for CLTI will reduce multiple visits to primary care and EDs, relieving pressure and reducing delay to treatment, which is associated with worse outcomes for mortality and limb loss[152]. Co-production of care pathways with primary care clinicians, especially community nurses and podiatrists who are involved in lower limb wound care, would ensure that these groups are integrated into the care of patients with CLTI following diagnosis to reduce the burden on vascular surgery services. Empowering patients with known PAD to recognise signs and symptoms and refer themselves where such services are available could have the same effect[247].

This qualitative interview study has explored the experience of participants diagnosed with CLTI in the preceding year. This is an appropriate study design, given little existing evidence in the literature. Participants were recruited nationally and selection prioritised variation in terms of comorbidity and location within the vascular network, ensuring different experiences were included. Notwithstanding this, our participants will not reflect all experiences of CLTI, especially as our cohort was relatively young and some patients with CLTI would be excluded from participation due to cognitive impairment and inability to speak English. This is particularly relevant regarding our finding that participants would be willing to travel to arterial centres rather than be seen in local hospitals, which may not be an option for more frail, comorbid patients. I am a vascular surgeon and used my subjectivity in this area to develop themes presented. This unique analysis is a hallmark of reflexive thematic analysis and should be embraced rather than seen as a detriment to the analysis. An alternative researcher, however, with different assumptions, experiences and background, may have generated differently situated knowledge.

The themes generated in this study suggest that whilst CLTI is a profoundly distressing condition, patients are reluctant to ask for help due to perceived pressure on the NHS and their personality or upbringing. Once they do present, their symptoms are often not recognised as CLTI, and they undergo convoluted routes into vascular surgery assessment, often dependent on chance. Participants felt that, had they been empowered by increased awareness of the condition and / or advocated for, they would have accessed care sooner. The contribution of vascular surgery systems and processes to delay in care pathways is recognised in our data. In addition to work with other stakeholders, such as referring clinicians and those receiving referrals and assessing patients with suspected CLTI, these results should be fundamental to the design of interventions to improve care pathways for CLTI. The thread of awareness running through these themes has been highlighted as particularly important in the experiences of participants who have lived experience of CLTI.

Chapter 7. The effectiveness of quality improvement collaboratives in UK surgical settings and barriers and facilitators influencing their implementation: a systematic review and evidence synthesis

7.1. Introduction

Surgical care can always be improved. Time, money and patient lives can be lost by not providing the best quality care. In the NHS, quality is defined as care that is safe, effective and provides a positive experience for the people that need it[30]. The GMC states in Good Medical Practice that doctors have an overriding duty to take part in systems of quality assurance and improvement[248], and the four UK and Ireland Surgical Royal Colleges recommend surgeons are committed to quality improvement as a core part of clinical duties[249]. There are many different approaches used to improve quality in healthcare, and the evidence for these techniques continues to evolve, with none as yet being recognised as superior[250].

QI collaboratives (QICs) are one such approach. Evaluations of their effectiveness have reported mixed results, but this has not prevented them being adopted worldwide[64]. The majority of QICs have been implemented in medical specialties, and few are from the UK[251]. Wells et al suggested in their review that “collaboratives reporting success generally addressed relatively straightforward aspects of care”[251]. Delivery of surgical care is an example of a moderately complex process of care[252] and examining the effectiveness of QICs in a surgical setting could provide insight into whether and how QICs could be effective beyond simple care processes.

Previous systematic reviews have found effectiveness of QICs is highly dependent on context, which is typically defined as “anything external to the intervention that may act as a barrier or facilitator to its implementation, or its effects” [56, 253]. Context can be modified by factors related to the healthcare setting, the project itself and organisational characteristics[254, 255]. The procedural aspect of the surgical specialties leads to a specific context for quality improvement in surgery, with care pathways needing to negotiate the complex tension of managing capacity when having to provide rapid access to theatres alongside planned activity.

There is a burgeoning trend of QICs being carried out in UK surgery, and in the current resource-limited environment, exploration of whether ongoing investment should be made in this quality improvement approach is warranted. The aim of this review was to examine the evidence on whether QICs are effective in improving the delivery of surgical services in the UK and to explore facilitators and barriers to effective implementation of QICs. Focus on a single health care system aimed to limit the degree of heterogeneity in the care process, given the importance of context in influencing the success and failure of QICs. There are too few QICs carried out in vascular surgery to carry out a specialty-specific analysis, and it was thought to be of interest to learn from other surgical specialties, who face similar challenges in delivering acute alongside elective care.

7.2. Methods

7.2.1. Search strategy

This systematic review was registered with PROSPERO (CRD42022324970) and the protocol prepared using the Cochrane Effective Practice and Organisation of Care's (EPOC) Protocol and Review Templates for Intervention Reviews and Qualitative Evidence Synthesis[256, 257]. Relevant reports were identified by searching two databases (MEDLINE and EMBASE) from inception to 7th January 2022. Search strategies were developed with the help of an information specialist and contained Medical Subject Headings and keywords related to "surgery", "UK" and "quality improvement collaborative" (Appendix 6). Grey literature searches were carried out on www.opengrey.eu, www.pdq-evidence.org and www.epistemonikos.org. Reports written for the Health Foundation “Scaling up”, “Closing the Gap” and “Spreading Improvement” programmes were reviewed for inclusion. Reference lists of all included studies were screened for additional studies that would merit inclusion, as were relevant systematic reviews.

7.2.2. Inclusion criteria and study selection

Our definition of a QIC was a prospectively planned quality improvement project with the involvement of a number of sites over a specified time period, which had a defined patient group who received surgical treatment and a defined set of improvement outcomes. Studies involving any surgical specialty, carried out in the NHS, with the same expert team leading the project across multiple sites were eligible for inclusion. Other common features of QICs described in the literature are listed in Table 16[56, 254]. The study used broad inclusion criteria in order to incorporate multicentre quality improvement programmes which deviated from previous descriptions of QIC in the literature[56, 254] but retained the spirit of collaboration, to reflect real life practice. The review excluded studies which evaluated the comparative effectiveness of different devices or surgical interventions, or education / training programmes for surgical staff. The review focused on primary evaluations and excluded conference abstracts, reviews, editorials and guidelines. Two members of the review team independently screened the titles and abstracts to determine suitability for full text review. Full texts of potentially eligible reports were then obtained, and independently assessed against inclusion criteria by the same two reviewers. Any disagreements were resolved by discussion, with a third reviewer involved when required, to determine inclusion.

Table 16: Key features for definition of a quality improvement collaborative

	Feature	**Description of key feature**	**Criteria for key feature**
Essential	Multi-centre	An approach that involves teams from a planned number of different sites	At least 3 sites contribute from start to end of the project
	QI objective / Need for improvement	Evidence that provides the rationale for the QI intervention and which informs the objective	An explanation of the problem, reasons or assumptions that were used to develop the project and reasons why the project was expected to work
	Outcome measures	A defined set of outcome measures. These could focus on structure, process or (patient) outcome quality indicators.	Data on measures are collected at two or more points in time to show a change (from baseline).
	Expert team	QI facilitation by an expert team by providing sites with training in QI theory and methods	Sites have at least two sessions with the expert team during the planning and intervention phases of project
Optional	Networking among sites	Structured activities where teams come together to share learning, methods, ideas and experiences	Sites have at least two networking sessions/activities to share knowledge and experiences.
	Data sharing	A model for improvement where data is fed back and informs small scale change within the individual teams	A description of data sharing methods

7.2.3. Data extraction and quality assessment

Data were recorded in a previously piloted Microsoft Excel spreadsheet template. One reviewer extracted data from reports concerning half of the QICs, and one reviewer extracted data from the other half. Each then reviewed and checked the other's extractions for accuracy. Any discrepancies were resolved by discussion, with a third reviewer (DAC) consulted when required. Data extracted on the study and the attributes of the QIC included: study aim, study design, process and outcome measures, the pre-existing care pathway, details of the structures of the quality improvement intervention, the planned quality improvement processes and those that actually took place, the intervention outcomes and the effectiveness barriers and facilitators. Each quantitative or mixed methods report including quantitative analysis was scored against the Quality Improvement Minimum Quality

Standards (QI-MCS), a tool for critical appraisal of quality improvement publications which scores quality on a scale from 0 (poor quality) to 16 (high quality)[258].

7.2.4. Data synthesis

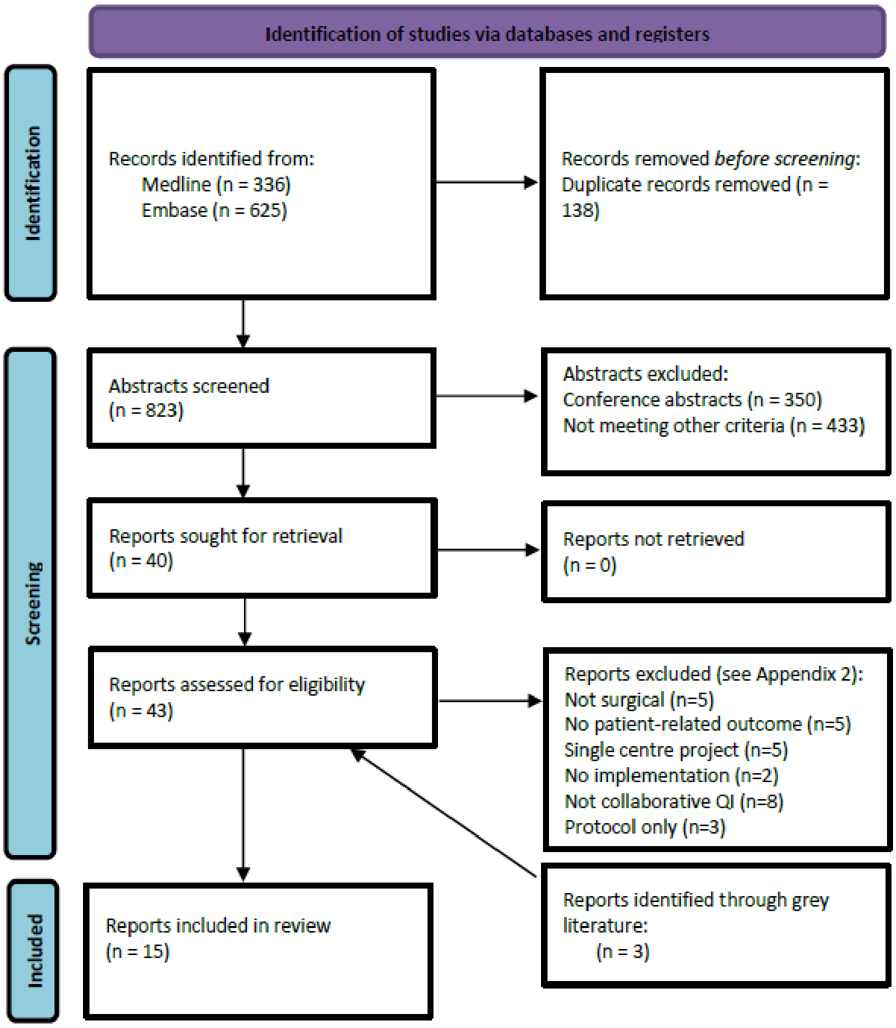
The effectiveness of each included QIC was assessed according to the aim of the study. A QIC was deemed effective if there was an improvement in a process or patient outcome indicator that aligned with specified study objectives. Due to heterogeneity of indicators of effectiveness, meta-analysis was not possible.

In order to explore reasons for the success or failure in achieving the collaborative objectives, the Consolidated Framework for Implementation Research (CFIR) was used[231]. All reports relating to each QIC, including quantitative, qualitative and mixed-methods reports, were coded, and factors could be suggested by study authors or identified by participants as part of a qualitative process. The CFIR is a collection of constructs grouped within five domains (intervention, outer setting, inner setting, individuals and process) that influence implementation of interventions. For every study, each construct of the CFIR was coded as +1 (facilitator), -1 (barrier), 0 (neither facilitator nor barrier) or X (both a facilitator and barrier)[259]. It has been previously noted that the CFIR does not contain constructs relevant to teams, which are an important part of QICs. For this reason, Rogers' constructs related to teams[260] were used alongside the CFIR in our coding strategy. This could be related to either the expert team, or the participating site team. Factors related to the effectiveness of implementation presented in each report were mapped to individual CFIR constructs. As before, one reviewer coded the reports concerning half of the QICs, and one reviewer coded the other half. Each reviewer then reviewed the other's coding for accuracy. Any discrepancies were resolved by consensus, with a third reviewer when required. All reviewers are experienced in quality improvement and the two primary coders have a clinical background.

7.3. Results

The search was conducted on 7th January 2022 and retrieved 823 unique citations, which underwent screening. Forty citations and three reports identified in grey literature searches were retrieved for full-text review. Following full-text assessment, 15 reports were selected for inclusion in the review. Those not included are listed in an additional file (Appendix 7). Figure 9 demonstrates the PRISMA flow chart.

Figure 9: PRISMA flow chart



7.3.1. Study characteristics

The fifteen selected reports described 10 QICs in UK surgical contexts. Table 17 gives a summary of the included studies, presented according to quality of study design, then type of surgery (elective or emergency). The primary aim of five QICs was to improve patient outcome indicators such as mortality or length of stay[58, 65, 261-263]. Four QICs had primary aims to improve process indicators: two related to time to surgery[57, 264], and one related to having a booked “to come in” date for surgery[265] and one looking at implementation of a monitoring device[266]. The one remaining QIC had a broad aim of “providing… care of the highest quality”[59], and looked for changes in a set of patient outcome and process measures. All studies reported process indicators, with eight reporting patient outcome indicators[58, 59, 65, 261-264, 266] (Table 17).

Table 17: Summary of included QICs

Main publication author (year)	**Surgical condition**	**Study design (meets EPOC inclusion criteria Y/N)**	**Study aim**	**Number of intervention sites**	**Outcome indicators**	**Process indicators**	**Other indicator**
Peden (2019)[22, 30, 31, 32, 34]	Emergency laparotomy	Stepped-wedge cluster randomised controlled trial (RCT) (Y)	Reduce post-operative mortality	93, split into 15 clusters	90 day / 180 day mortality, post-op length of stay (LOS), 180 day readmission	Adherence to 10 metrics	-
Bamber (2019)[57, 267]	Emergency laparoscopic cholecystectomy	Controlled cohort evaluation (Y)	Reduce time to emergency cholecystectomy	13, 1 withdrew	-	8 day surgery rate	-
McNaney (2011)[263]	Elective surgery	Controlled interrupted time series (Y)	Reduce post-operative length of stay	15, 1 withdrew	LOS, readmission, patient reported outcome measures (PROMs) for hip and knee replacements	Day of surgery admission	Adoption of full implementation, patient experience
Aggarwal (2019)[58]	Emergency laparotomy	Uncontrolled interrupted time series (Y)	Reduce post-operative mortality	28	Risk-adjusted and crude in-hospital mortality, LOS	Adherence to 6 metrics in care bundle	-
Tadd (2019)[59]	Hip fracture	Controlled interrupted time series (N)	Improve care via guidance implementation	6 recruited, 2 not included in analysis	30 day mortality, LOS, readmission rate	Adherence to 23 metrics	Return to own home
McLeod (2003)[265]	Elective day case surgery	Controlled interrupted time series (N)	Increase proportion of patients with a “to come in date”	24 (varying numbers in different analyses)	-	Proportion of patients with booked admission date, did not attends (DNAs), proportion waiting ≥6 months	-
Potgieter (2012)[65]	Elective AAA repair	Uncontrolled before-after study (N)	Reduce post-operative mortality	90, split into 12 regions	In-hospital mortality, LOS	Turn down rates	Case ascertainment

Kuper (2011)[266]	Emergency and elective surgery	Uncontrolled before-after study (N)	Implement intraoperative oesophageal Doppler monitoring	3	LOS, postop stay, readmission rate, reoperation rate, inpatient mortality, oesophageal trauma, pulmonary oedema	Use of Doppler monitors	Volume/type of iv fluids, peri-op change in stroke volume, use of invasive monitoring
Huddart (2015)[261]	Emergency laparotomy	Uncontrolled before-after study (N)	Reduce post-operative mortality	4	P-POSSUM risk-adjusted and crude 30 day mortality, in-hospital mortality	Adherence to 7 metrics in care bundle	-
Feinberg (2018)[264]	Surgery for right iliac fossa pain	Uncontrolled before-after study (N)	Eliminate delay in operative management	4	Incision to discharge, LOS, 30 day readmission	Compliance with Royal College of Surgeons (RCS) guidelines on time to surgery, admission to booking, booking to incision	-

There was heterogeneity in the design of the studies. Four used uncontrolled before-after designs[65, 261, 264, 266], with a historical cohort acting as a comparison group. Four studies used an interrupted time series design, with three using population level data as a control[59, 263, 265] and one uncontrolled[58]. One study used a controlled cohort evaluation design, again using population level data (excluding participant sites) as a control[57], and one was a stepped-wedge cluster RCT[262]. Four studies met criteria for inclusion in a Cochrane EPOC[268] review[57, 58, 262, 263]. Nine studies documented the duration of the QIC intervention which ranged from five weeks (the shortest duration of the stepped-wedge cluster RCT) to two years. The numbers of centres included in the collaboratives ranged from 3 to 93. The number of expert team-led sessions varied from 2 to 16 across the QICs. QI methods used included Plan-Do-Study-Act cycles[58, 59, 65, 261, 262], lean-based QI methodology[264], driver diagrams[58], Human Factors[264] and systems analysis[58], and the care bundle approach[261]. Data sources for the process and patient outcome indicators included national databases such as KH07 Central Returns[265], national administrative hospital data (HES[57, 65, 262, 263]), national clinical registries (NELA[58, 262], the National Hip Fracture Database[59], and the NVD[65]) as well as locally collected data[57, 59, 261, 264-266].

An expert team leading the collaborative was a defining key feature of a QIC in this review. Eight studies described at least one attribute of at least one member of the expert team, including expertise[59, 264, 269], job role[58, 65, 263] and employing organisation[265, 266]. Multidisciplinary quality improvement teams were described in seven studies[57, 58, 65, 261, 262, 264, 266, 269], and in the remainder the composition of the team was not discussed. Patient involvement was described in four studies[59, 65, 263, 269].

Networking opportunities generated by the QIC for the participating sites were described by all but one study[264]. These opportunities were generally organised by the expert team, and did not occur organically. There was no description of the structure or content of any networking activities undertaken by any of the QICs, but learning from other teams' experiences at meetings between QI teams was described by four studies[261, 262, 265, 266].

Data sharing between collaborative sites was described by three studies[58, 59, 65]. Feedback of data to individual sites was reported in six studies[57-59, 65, 261, 266].

7.3.2. Quality assessment

A quality assessment of the quantitative report of the ten included QICs was carried out using the QI-MCS[258]. The QI-MCS scores typically ranged from 11 to 13 (Table 18). The reports identified from the grey literature[59, 65, 263] were of poorer quality than those published in peer reviewed journals.

Table 18: Quality assessment of included studies using QI-MCS (Met = 1, not met = 0)

	Organisational Motivation	Intervention Rationale	Intervention Description	Organisational Characteristics	Implementation	Study Design	Comparator	Data Source	Timing	Adherence / Fidelity	Health Outcomes	Organisational Readiness	Penetration / Reach	Sustainability	Spread	Limitations	Total (Max possible = 16)
McLeod (2003)	1	0	1	0	1	0	1	1	1	0	0	1	0	1	1	0	9
Kuper (2011)	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1	1	13
McNaney (2011)	1	0	0	0	0	0	1	1	0	1	1	1	0	1	1	0	8
Potgieter (2012)	1	1	1	0	1	0	0	1	0	1	1	1	0	1	1	0	10
Huddart (2015)	1	1	1	0	1	0	1	1	1	1	1	1	0	1	1	1	13
Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines[270] published (2016)																	
Feinberg (2018)	0	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	12
Aggarwal (2019)	1	1	1	0	1	0	1	1	1	1	1	0	0	0	1	1	11
Peden (2019)	1	1	1	0	1	1	0	1	1	1	1	1	0	0	1	1	12
Tadd (2019)	1	1	1	0	1	0	0	1	1	1	1	1	0	1	1	0	11
Bamber (2019)	1	1	1	0	1	1	0	1	1	0	0	1	1	1	1	1	12

Poorly reported domains included organisational characteristics (where reports had to list at least two organisational characteristics), penetration / reach (where reports had to describe the number of eligible units that actually participated) and the type of study design. The best reported domains were spread, data source, organisational readiness (where at least one barrier or facilitator is reported), organisational motivation and intervention description (describing one specific change in detail).

7.3.3. Effectiveness of quality improvement collaboratives in UK surgical settings

Effectiveness of the QICs was assessed according to the primary indicator most relevant to the aim stated by the study. A summary of reported results is presented in Table 19. The primary indicator was not always the pre-specified outcome reported by the study. If there were a number of different indicators related to the aim of the collaborative reported, the one reported first by the study is described (eg. risk-adjusted mortality vs. unadjusted mortality, where both are reported). Where there was no p value reported in the study for that outcome, which was the case in five of the ten studies, we used the conclusion of the study authors to reflect what exists in the literature. The QIC intervention was deemed effective by the authors in eight of the ten studies. The two studies reporting that the QIC was ineffective were among the highest quality studies, with robust design and independent control groups.

Table 19: Self-described effectiveness of QICs (ordered by study quality)

Main publication author (year)	**Study aim**	**Primary indicator (*italics represent process indicators*)**	**Results (intervention vs comparator)**	**Described as**
Peden (2019)	Reduce post-operative mortality	90 day mortality	Mortality 16% vs 16% (p = ns)	Ineffective
Bamber (2019)	Reduce time to emergency cholecystectomy	*8 day surgery rate*	8 day rate 14.6% vs 9.4% (no p value)	Effective
McNaney (2011)	Reduce post-operative length of stay	*Length of stay*	No numbers reported (no p value)	Ineffective
Aggarwal (2019)	Reduce post-operative mortality	Crude in-hospital mortality	Mortality 8.3% vs 9.8% (no p value)	Effective
Tadd (2019)	Improve care via guidance implementation	30 day mortality	Mortality 5.8% vs 9.2% (p <0.001)	Effective
McLeod (2003)	Increase proportion of patients with a “to come in date”	*Proportion of patients with booked admission date*	Dates for 66.2% vs 51.1% (p <0.001)	Effective
Potgieter (2012)	Reduce post-operative mortality	In-hospital mortality	Mortality 2.4% vs 7.5% (no p value)	Effective
Kuper (2011)	Implement intraoperative oesophageal Doppler monitoring	*Use of Doppler monitors*	Doppler used 65% vs 11% (no p value)	Effective
Huddart (2015)	Reduce post-operative mortality	Risk-adjusted 30 day mortality	Mortality 9.6% vs 15.6% (p = 0.003)	Effective
Feinberg (2018)	Eliminate delay in operative management	*Compliance with Royal College of Surgeons (RCS) guidelines on time to surgery*	Breach 3.5% vs 13.7% (p = 0.00)	Effective

7.3.4. Consolidated Framework for Implementation research

Facilitators and barriers to QIC effectiveness are summarised in Table 20. All reports related to each QIC, whether quantitative, qualitative or mixed-methods, were coded if they contained information on factors affecting effectiveness of its implementation. Two of the five reports relating to the Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial contained no description of facilitators or barriers[271, 272].

Table 20: Barriers and facilitators to QIC effectiveness

Domain	Construct	Peden, Stephens[269], Martin[273]	Bamber, Stephens[267]	McNaney	Aggarwal	Tadd	McLeod	Potgieter	Kuper	Huddart	Feinberg
Intervention	Intervention Source		🟩					🟩			
	Evidence Strength & Quality (good / poor)	▲	🔻		▲	▲			🔻		
	Relative Advantage[1]					🟩					
	Adaptability	🟩	🟩			🟩	🟩	🟩			
	Trialability			🟩		🟩		🟩			
	Complexity (high / low)	▼			🔺			▼			
	Design Quality & Packaging (high / low)	▲	▲		🔻	🔻▲		▲			
	Cost (high / low)			▼		🔺					
Outer setting	Patient Needs & Resources							🟩			
	Cosmopolitanism[2]		🟩		🟩	🟩		🟩			
	Peer Pressure (present / absent)				▲	▲🔻		▲			
	External Policy & Incentives	🟥	🟩	🟩	🟩		🟩	🟩			
Inner setting	Structural Characteristics		🟥			🟥	🟥	🟥			🟥
	Networks & Communications	🟩		🟩							
	Culture		🟩	🟩							
	Tension for Change		🟩			🟩		🟩			
	Compatibility[3]	🟥						🟥			
	Relative Priority	🟥	🟥	🟩		🟥					
	Organisational Incentives & Rewards	🟥									
	Goals and Feedback					🟩		🟩			
	Learning Climate					🟩					
	Leadership Engagement (good / poor)	▲		▲			▲	▲	▲		🔻
	Available Resources (good / poor)	🔻	▲🔻	▲		🔻	▲🔻	▲	🔻		▲🔻
	Access to Knowledge & Information							🟩			
Individual	Knowledge & Beliefs	🟩	◩	🟩			◩	🟩	🟥		
	Self-efficacy								🟥		
	Individual Stage of Change						◩		🟥		
	Other Personal Attributes					🟥	◩	🟩			
Process	Planning						🟥				
	Engaging (presence / lack of)		▲🔻	🟩		▲🔻	▲🔻	🟩	🟩		▲🔻
	Executing	🟥	◩	🟩			🟩		🟩		
	Reflecting & Evaluating	◩	◩	🟩	🟩	◩		🟩		🟩	

Team	Team Size							🟩			
	Team Turnover / Stability	🟥					🟥				🟥
	Team Workload					🟥					
	Teamwork	🟩	🟩	🟩		🟩	🟩	🟩			
	Team Culture			🟩		🟩					
	Compatibility										🟥
	Team Efficacy		🟩	🟩		🟩					

1. Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution. 2. The degree to which an organisation is networked with other external organisations. 3. The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
🟩 = facilitator, 🟥 = barrier, ◩ = both facilitator and barrier. Coloured arrows (▲▼) are used to show congruity between barriers and facilitators – eg. high cost as a barrier (▲) is congruent with low cost as a facilitator (▼)

Numbers of facilitators and barriers reported per QIC ranged from 1 to 28. Just one report presented key influences on success according to a framework (Normalisation Process Theory)[267]. More facilitators than barriers were reported throughout (106 of 158, 67.1%). There was no obvious correlation between numbers of facilitators and barriers reported and the measured effectiveness of the QICs. The key facilitators and barriers in each domain for QICs in UK surgery are described below.

Intervention characteristics

Facilitators and barriers related to the intervention were described by eight studies. Interventions which contained a degree of flexibility were described as having a greater chance of being successful[57, 59, 265], and this adaptability of the intervention was useful in meeting the needs of diverse sites[65, 262]. An evidence-based intervention was welcomed by QI teams[58, 262, 269, 273], but where the evidence was not perceived to be strong by clinicians[57, 266], implementation was a challenge. Quality of the design and presentation of the intervention to the implementing teams helped to motivate clinicians and influenced engagement with the programme[65, 262, 267], but where the assembly of the intervention was in conflict with clinician expectation, this acted as a barrier to change[58, 59].

Outer setting

Outer setting constructs were powerful facilitators for quality improvement across six studies that described them as such. The backing of Royal Colleges, specialty associations and national initiatives [65, 263, 267] were effective drivers for change. However, broader external pressures led to service reorganisation and fiscal instability in one study, which did not support change efforts[269]. Other strong facilitators were: (i) the collaboration between clinicians which often led to the exchange of ideas, sharing of good practice and a sense of community beyond one's own organisation[59, 65, 267], and (ii) the competitive pressure of having data shared within the collaborative[58, 59, 65].

Inner setting

The inner setting was the domain factors affecting QIC implementation were mapped to most frequently. Resource availability appeared to be key, specifically with regards to time for staff to participate in QI activities[57, 59, 262, 264, 265, 267, 269], financial resource[59, 65, 263, 265, 266, 269] and human resource[59, 264, 265, 269]. Members of one collaborative used sharing of local data to encourage the provision of extra resource[65].

The presence or absence of organisational leadership engagement was also important for the success of individual sites within the collaborative; support from senior leadership helped to overcome financial issues[266] and embed change[65], but lack of leadership engagement was seen as a barrier to performance by several other studies[264, 265, 269].

Studies found structural characteristics of involved organisations had a significant bearing on the success of the intervention, especially as a barrier with regards to units facing service reorganisation[65, 265]. Other challenges related to the relative priority of the intervention within the organisation, with other improvement targets focussed on, to the detriment of the QIC[59, 267, 273]. Studies did not typically highlight specific aspects of the surgical setting, such as theatres, surgical or anaesthetic departments as barriers or facilitators, but one did describe a locally challenged emergency department as a barrier to improvement in a related process indicator[59].

Individuals

Characteristics of individuals was the only domain to have more barriers than facilitators mapped to it. Positive beliefs about the intervention were important as a facilitator[65, 262, 263, 273], but negative beliefs acted as a barrier to QIC effectiveness, even if positive beliefs were co-existent[57, 265-267]. Reluctance to change usual ways of working, specifically in relation to clinicians, was described as a barrier for two QICs[265, 266].

Process

All ten studies reported factors coded to the process domain. It was clear that engagement was a strong facilitator when present, and a barrier when absent[57, 264]. Engagement was achieved in different ways for different QICs, and for some clinical opinion leaders in anaesthetist, specialist nurse and surgeon roles were important[65, 263, 265]. Some referenced clinical champions as a specific role to increase engagement[263, 264, 266], and others used patients and their stories as external change agents to motivate staff[59, 65, 263, 267]. Data collection and feedback was recognised as an important enabler of QI evaluation [58, 59, 65, 261, 263], and lack of data was a common barrier to improvement, usually because of inadequate resource to support data collection[59, 267, 269].

Teams

Eight studies reported factors relevant to quality improvement teams at participating QIC sites. Instability of the team was a frequently reported barrier to effectiveness, with team members leaving[264], absence of surgical specialty leads[269] or lack of management continuity[265] all implicated. Teamwork and positive culture, however, were universal facilitators when present, whilst their absence was not reported as a barrier. In some cases, QICs led to improved multidisciplinary team working across all members of the surgical team, by providing a common language for discussions between surgeons and anaesthetists[273], increasing perceived value of team members[263] and changing ways of working between ward, surgical, anaesthetic, theatre and therapy teams[59]. Strong teams led to effective quality improvement in several QICs[59, 65, 263, 265, 267]. No factors relating to the expert team were discussed.

Not all of the facilitators and barriers coded in the reports were associated with the collaborative method for quality improvement. Constructs in the outer setting were most likely to be associated with QIC participation, and facilitators and barriers in the inner setting and process domains would have been relevant to many other approaches to quality improvement.

7.4. Discussion

There are an increasing number of published studies on QICs[251] and there have been relevant protocols for QICs introduced into surgical services recently published[60-62]. However we currently have a limited understanding of whether (and how) QICs are effective in improving care for surgical patients, with their less simple care processes. Most studies in this review reported that QICs were effective in improving both process indicators and patient outcome indicators that reflected primary aims of the collaboratives. However, consistent with previous less context-specific reviews[54, 251], there are various reasons why the study results must be treated with caution. The study designs were not uniformly robust, with only five of the ten studies incorporating a contemporaneous control group in order to adjust for secular trends in process or outcome indicators, and only one of these was a randomised controlled trial. Only four of the ten studies met criteria for inclusion in an EPOC review. The other reports used historical data as a baseline, and are therefore more susceptible to bias and confounding. We suspect that it is not a coincidence that the two studies that reported QICs as ineffective in achieving their primary aim used study designs with contemporaneous controls, and met EPOC criteria.

The collaboratives themselves were a heterogeneous set of interventions, and differed in relation to: the numbers of sites included, the duration of the intervention, the measurement of effect, types of indicators reported and their comparators. The statistical significance was not reported for the change in the primary process or outcome indicator in five of ten QICs and one report[263] relied on graphs alone to demonstrate change over time rather than giving a numerical result. Another report[58] described a significant effect in the second year after the implementation of the intervention only.

The description of interventions in the reports was limited and reproduction elsewhere would prove difficult. Similar issues with reporting of the content of the intervention have been seen in reviews of QICs[54], as well as in other non-drug interventions[274]. Resources that offer a framework for intervention descriptions such as the template for intervention description and replication (TIDieR) checklist could be used to improve intervention reporting[275]. The quality of reporting according to scoring on the QI-MCS was variable, and notably poorer in the non-peer reviewed grey literature.

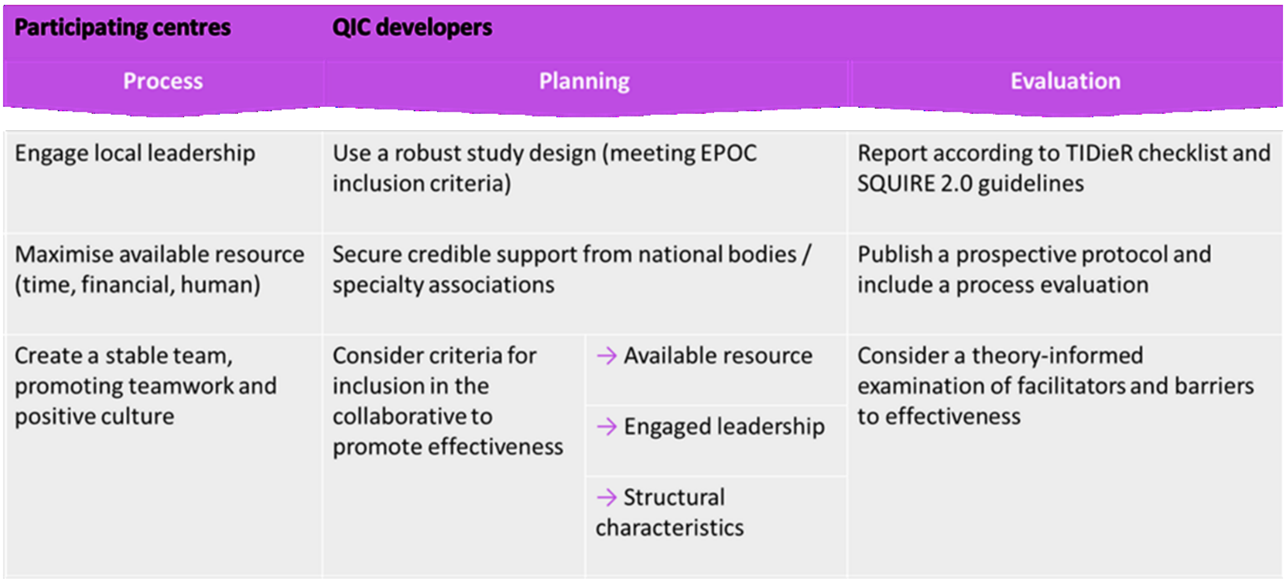
Half of the QICs included in this review were published prior to the publication of the SQUIRE 2.0 guidelines[270] in 2016, which describe 19 items that should be used when reporting formal studies of quality improvement. This may have contributed to the poor quality of reports. In addition, the MRC recommend process evaluation as an essential part of the design and testing of complex interventions, and provide guidance on how to carry them out[253]. Just two QICs in our review had process evaluations published[267, 269]. Only one published a protocol[276] and few reports indicated any differences between the planned and delivered intervention. Limitations in reporting of the QICs meant that specific intervention components could not be linked to structure, process or outcome indicators, and evaluation according to Donabedian's model[172] of care quality could not take place. Paucity of descriptions of current care processes leaves the authors unable to draw conclusions on how effective QICs are at different levels of complexity within surgical care, but we know surgical care is more complex than other specialties[252] and our findings could therefore be generalizable to other less simple care processes. Reporting future QICs according to SQUIRE 2.0 guidelines and the TIDieR checklist, incorporating process evaluation into the design of QICs, and publishing intervention protocols would allow more in depth evaluation of what contributes to the effectiveness of QICs.

Using the CFIR to map facilitators and barriers to effectiveness of implementation of QICs in UK surgery highlights the importance of constructs within the inner stetting as both facilitators and barriers to implementation in moderately complex care processes. A systematic review using the same framework in QIC in stroke care found similar results[55]. Available resources and engagement of leadership were key to success in implementation, which emphasises the importance of context in quality improvement, and has been previously found by Zamboni[254] and Schouten[56] with regards to QIC.

Many of the facilitators and barriers reported by the included QICs were not an intrinsic part of a QIC, as opposed to any other approach to quality improvement. Facilitators that were directly related to QIC participation were mainly coded within the outer setting domain, with support from national bodies and specialty organisations being helpful, as well as networking with other QIC participants and the peer pressure associated with data benchmarking. Only two barriers related to QIC participation were reported, due to inadequate leadership by expert team-nominated regional leads and included site characteristics. The paucity of barriers associated specifically with QIC participation may indicate that participation has a universally positive impact on the quality improvement objective, and any barriers to improvement are specific to the participating sites.

Our recommendations for future quality improvement interventions fall into two halves (Figure 10), for researchers planning and evaluating QICs, and those in the participating centres implementing the intervention.

Figure 10: Recommendations for future QICs



Participating centres	QIC developers		
Process	Planning		Evaluation
Engage local leadership	Use a robust study design (meeting EPOC inclusion criteria)		Report according to TIDieR checklist and SQUIRE 2.0 guidelines
Maximise available resource (time, financial, human)	Secure credible support from national bodies / specialty associations		Publish a prospective protocol and include a process evaluation
Create a stable team, promoting teamwork and positive culture	Consider criteria for inclusion in the collaborative to promote effectiveness	→ Available resource	Consider a theory-informed examination of facilitators and barriers to effectiveness
		→ Engaged leadership	
		→ Structural characteristics	

This systematic review and evidence synthesis combined a thorough database review and a grey literature search, but it is possible that relevant studies may not have been included. This risk was minimised by reviewing reference lists of previous systematic reviews and included articles, as well as a comprehensive grey literature search focussing on quality improvement funding reports. Studies were included that did not meet all the criteria in the literature for QIC, in order to maximise inclusion despite poor reporting of these criteria and gain learning where possible. Most included reports showed a positive effect from the QIC, and may therefore be subject to a publication bias. Studies dating back to 2003 were included, and the relevance of the earliest studies to the current NHS context could be debated. However, the methodology of QICs has not changed over this time, and frameworks used have not evolved[28]. Facilitators and barriers to effectiveness in the current context are likely to have been captured in the more recent reports.

In conclusion, the evidence base regarding the effectiveness of QICs in UK surgery, a moderately complex care process, is limited. This review highlights that, whilst eight of the ten UK surgical QICs reported the QIC method was effective, the quality of many of the studies was poor and these positive results must be treated with caution. QICs do carry benefits for participants in terms of credibility associated with being part of a project endorsed by a national body or specialty organisation. Future QICs in complex care processes should ensure that the limitations are not repeated, with publication of protocols, robust study design including a contemporaneous control group and reporting and evaluation of both process and content of the intervention. In order to overcome barriers to effective implementation, inner setting constructs of the CFIR should be considered when selecting collaborators. Specifically, it is crucial to secure organisational leadership engagement and adequate dedicated resources.

Chapter 8. Discussion and conclusions

8.1. Key findings

This thesis investigates how patients suspected of having CLTI arrive at vascular surgery services, and explores factors affecting delays in this process. Recent national efforts have been made to speed up the treatment of CLTI, with the GIRFT report emphasising variation in practice[25] and the VSGBI's Best Practice Framework for Peripheral Arterial Disease providing targets for time-to-revascularisation[27]. Work has taken place to improve the services vascular surgery networks are providing, with the Peripheral Arterial Disease Quality Improvement Programme and the CQUIN encouraging participating centres to ensure treatment of inpatients with CLTI is carried out within a 5-day target[183]. These national efforts have focussed attention on CLTI, and ensured it is no longer deprioritised relative to other vascular surgical conditions. Much of this work, however, has been concentrated on expediting time-to-treatment along pathways where a diagnosis has already been made. There remains little evidence to support our understanding of how patients enter vascular surgery services.

This thesis sought to identify, define and prioritise facilitators and barriers to the timely and appropriate referral of patients with CLTI from primary care into vascular surgery services, by answering four research questions. It aimed to consider overall how pathways from the community into vascular surgery services can be improved. Here, the findings of each chapter are summarised.

Chapter 2 comprised a documentary review of guidance available to community clinicians containing information on referral of patients suspected to have CLTI. The pragmatically designed study demonstrated that whilst there is guidance on this topic available that is aimed at referring clinicians, it is rarely created in collaboration with these clinicians, or endorsed by groups or organisations relevant to primary care clinicians. Content of the guidance was found to be unclear with regards to specific symptoms of concern, the timing necessary for such referrals, and the consequences of not referring. The wording of the guidance was vague and did not use a shared language, with phrases such as “limb salvage” used without explanation. These findings suggest further work is urgently required to create concise, effective and credible guidance aimed at referring clinicians.

In Chapter 3, a process mapping exercise was carried out with 12 English vascular surgery centres in order to understand current processes in place from the receipt of referral to assessment of patients suspected of having CLTI. Wide variation in processes was demonstrated with respect to referral, triage and assessment, with associated differences between centres in timing of such pathways. Pathways were affected by local context such as service commissioning and network configuration. The diversity seen reflects the ingenuity of vascular centres in devising pathways to capture and assess these patients with appropriate urgency, but the exercise identified opportunities to improve quality of care for this patient group. Suggested interventions to improve time from referral to assessment included ensuring all referrals throughout the network were triaged within 24 hours of receipt, slots to review referrals where CLTI was suspected were available at least 4x weekly, and expansion of podiatry services to cover patients without diabetes.

In Chapter 4, 13 clinicians involved in the triage and assessment of patients referred to hospital with suspected CLTI were interviewed. All had previously been involved in the process mapping exercise described in Chapter 2, so the context in which they were working was known. A reflexive thematic analysis of their transcribed interview data was performed, which generated one overarching theme that there was a need for speed throughout the process to diagnosis. Further key themes representing barriers to timely, appropriate care included inadequate resource and system pressures, a lack of awareness in other clinicians and the public, and inequality present across different patient characteristics. A final theme, where non-surgeons such as podiatrists and vascular specialist nurses can carry out elements of the pathway, was offered as a facilitator of delivery of appropriate care.

In Chapter 5, the TDF was used as the basis for a further qualitative study involving 20 primary care clinicians referring into the English vascular surgery centres which participated in the process mapping exercise. Community podiatrists, community nurses and general practitioners were interviewed according to a semi-structured topic guide, drafted according to domains in the TDF. Directed content analysis of transcribed data was then carried out, with utterances coded deductively to the relevant domain in the framework. Belief statements were generated by grouping similar utterances. The TDF allowed identification of influences on primary care clinician recognition and referral of suspected CLTI. Nine of the 14 TDF domains were found to be relevant according to frequency, presence of conflicting beliefs and content. These domains comprised Knowledge, Environmental context and resources, Beliefs about capabilities, Skills, Professional role and identity, Memory, decision and attention processes, Emotions, Reinforcement and Behavioural regulation. Two key issues were derived from the coded data: primary care clinician confidence, both personally and with regards to the vascular surgery team they were referring to, and the challenging context in which primary care is delivered.

Chapter 6 describes the final piece of qualitative work in this thesis. Sixteen patients diagnosed with CLTI in the preceding year at a vascular surgery centre previously involved in the process mapping exercise were interviewed on their experience from first symptom to diagnosis of CLTI. Reflexive thematic analysis was performed on the transcribed data to generate five interrelated themes leading to potential delay in diagnosis and management of their condition. These are situated along the patient pathway, starting with a personal reluctance of the patient to ask for help, due to perceived pressure on the NHS and their personality or upbringing. Once they do present to a primary care clinician, they describe their symptoms often not being recognised as CLTI, and they undergo convoluted routes into vascular surgery assessment, often dependent on chance. Participants felt that had they been empowered by increased awareness of the condition and / or advocated for, they would have accessed appropriate care sooner. The final theme recognises the contribution of vascular surgery systems and processes, such as network design, to delay in care pathways.

In Chapter 7, a systematic review and narrative synthesis was carried out in order to investigate the effectiveness of QICs, a multi-organisational approach to improving quality. The VSGBI have used this approach to attempt to improve inpatient outcomes in both aortic aneurysm and CLTI care. There is evidence that QIC effectiveness is highly dependent on context, but there is little evidence that it is an effective model in the UK surgical context specifically. If the VSGBI were to consider further use of the approach to improve the timeliness of referrals in CLTI, it should be based on evidence that it is effective in this context. The review used a theory-based analytic framework, the CFIR, to identify barriers and facilitators to QIC effectiveness in UK surgery. The review identified that QICs may be effective in the UK surgical context, but weak study designs including a lack of contemporaneous control groups and poor reporting quality hampered the ability to draw unequivocal conclusions. The review identified benefits of QIC participation, such as the credibility added to the intervention by being part of a national body or specialty organisation endorsed project. Based on this review’s findings, recommendations for the participants and developers of future QICs have been developed in order to improve the quality of evidence regarding this model in the UK surgical context.

8.2. Implications

The evidence presented herein describes barriers and facilitators of timely referral and assessment of patients experiencing symptoms of CLTI. A documentary review has confirmed inadequacy of current guidance available to referring clinicians, and a process mapping exercise has demonstrated the complexity of current pathways in place, as well as where and why potential delays may occur in the assessment of patients with suspected CLTI. Qualitative interviewing and analysis techniques have allowed an in-depth exploration of rich data in order to generate themes relating to the research questions from primary care clinicians, vascular surgery clinicians and patients themselves. Finally, a systematic review has provided mixed evidence on the effectiveness of QICs in the UK surgical context. The work from these studies can be linked together to draw overarching conclusions on barriers and facilitators of a timely diagnosis of CLTI.

8.2.1. Guidance

Chapter 2 investigated the national or international referral guidance available to primary care clinicians, finding barriers to effective communication of what to refer, when to refer it and the consequences of not referring. In Chapter 5, primary care clinicians told of a lack of knowledge of available guidance, or felt it was not relevant to them. Most participants indicated that the availability of guidance or pathways would be helpful in making decisions regarding referral of patients. This lack of knowledge of the national and international guidance analysed in Chapter 2 indicates that despite primary care clinicians being often named as an audience of the guidance, it is not useful in practice. Poor adherence to guidance has been found to lead to delayed diagnosis in cancer, indicating this is not just a vascular surgery problem[129].

Improvements can be made in this area. Future iterations of national and international guidance should consider their proposed audience when creating guidance, and ensure it is appropriate to them. Endorsement should be sought from primary care organisations, and primary care clinicians should be involved in the writing process of guidance which concerns them. Local pathways were also seen as important. They increased confidence of primary care clinicians to refer patients to vascular surgery, especially those who were not in general practitioner roles and would not traditionally refer to secondary care. Where guidance was available this was used as part of the referral process and could be built into record-keeping templates, providing a framework for the consultation.

8.2.2. Triage processes

In Chapter 3, a process mapping exercise demonstrated the complexity of pathways leading from first symptom of CLTI to vascular surgery assessment. Much of this complexity is due to CLTI as a condition (recognised in Chapter 4), with a varied constellation of potential symptoms. These symptoms may lead to presentation to many different clinicians in primary and / or secondary care. It is important to retain a wide variety of ways patients may reach vascular surgery assessment, but it should not be at the cost of a timely assessment. This reinforces the importance of triage processes for all methods of referral across the whole network. Chapter 3 presents a wide range of potential time-to-triage depending on patient location within a network. Geographical issues have been previously noted in the USA[118]. Within Chapters 4 and 6 there is recognition that not all patients with symptoms of CLTI will be referred as “urgent”, so timely triage must extend to all referrals.

8.2.3. Referral processes

Chapter 5 demonstrated conflicting beliefs between some clinicians in the community with regards to the referral process they would prefer to follow. Some clinicians would prefer a referral pro-forma, to help structure their consultation and ensure that all information the triaging clinician needed was on the referral. Others found pro-formas to be unhelpful in that they could provide an extra barrier to the patient accessing the care the clinician thought necessary. In Chapter 4, vascular clinicians described a lack of shared language between secondary and primary care and poor quality of referrals being a barrier to appropriate triage, but noted that whilst pro-formas could enable non-surgeon triage, they could also be associated with reduced referral quality compared to a conversation. In Chapter 6, participants described their primary care clinicians not being able to access vascular surgery support, and thus not being aware of pathways and processes to obtain urgent vascular surgery assessment described in Chapter 3. In cancer services, patients felt similarly that improvements needed to be made in communication, clarity and speed of the process[128]. It is important that whatever referral processes are in place for a particular network are communicated to referring clinicians, and ideally these processes would be co-produced. In Chapter 5, primary care clinicians described IT being key to easy access to referral processes in other conditions, and this should be the case for vascular surgery as well.

8.2.4. The use of objective measures of perfusion

The use of objective measures of perfusion, including toe pressures and ABPIs, in the community was viewed differently across the clinicians interviewed. Some primary care clinicians in Chapter 5 welcomed the use of objective measures, as they were perceived to legitimise their concerns regarding perfusion, increasing their confidence to make a referral. Others, however, found them difficult to obtain, potentially adding delay to patient pathways, and acknowledged a risk of a “normal” result influencing the clinician to not refer someone who otherwise was demonstrating CLTI symptoms. Vascular clinicians and patients in Chapters 4 and 6 recognised their potential to cause delays from first symptom to referral, and vascular clinicians found they were unlikely to influence clinical decision making in a secondary care scenario. The usefulness of objective measures of perfusion in a referral can be debated, and may be a valuable area for future research, but they should not lead to delay in patient access to vascular care.

8.2.5. Availability of urgent vascular surgery assessment

The need for speed in the process from first symptom to diagnosis was recognised as an overarching theme by vascular surgery clinicians in Chapter 4 and is supported by data showing worse mortality and limb salvage outcomes in delayed revascularisation of CLTI[152]. Chapter 3 describes how vascular services were designed to expedite vascular assessment following referral, including the institution of emergency clinics and emergency slots in regular clinics, incorporating elements from the “toe-and-flow” model[88]. This urgent need for assessment was recognised by the patient participants in Chapter 6, describing the symptoms detrimental to their quality of life they experienced prior to diagnosis. This thesis supports the institution of urgent assessment processes such as emergency clinics, but there must be adequate awareness of these as an option for primary care clinicians, similar to previous findings in diabetic foot disease[118]. In order to provide these services amidst a vascular surgery workforce crisis, some centres are using trained non-medical clinicians, such as vascular specialist nurses and podiatrists. Chapter 3 indicated podiatry services are often much faster to assess patients referred urgently, and this could be utilised where available to speed up pathways. Chapter 3 also demonstrates few centres are meeting 48h targets for assessment following receipt of referral, and the availability of urgent assessment slots in combination with triage processes is a reason for this.

8.2.6. Addressing inequalities

Inequalities present in the care for patients with CLTI were demonstrated throughout this thesis. Chapter 3 describes how patients with diabetes can benefit from faster times-to-assessment, which may be a reflection of prevalent multidisciplinary foot care teams for patients with diabetes[86]. The chapter also describes faster potential time-to-assessment for those in the arterial centre catchment population. Chapter 4 recognises the same two inequalities and adds a third; patients who are frail, for example those who are bedbound or who require hospital transport, and are therefore not suitable to attend emergency clinics or surgical assessment units. Vascular clinicians found these inequalities unfair. Primary care clinicians interviewed for Chapter 5 recognised that patients with diabetes had specialist services available for them, excluding those without diabetes. This may contribute to the faster fall in major limb amputation rates seen in patients with diabetes compared to those without diabetes[93]. Patients interviewed in Chapter 6 described the greater availability of services and expertise at the network arterial centre rather than their local hospital, and indicated that travel to the arterial centre in the network was not a problem. This may however be a reflection of the cohort of patients interviewed in the study, who were likely to be less frail than the CLTI cohort as a whole. Current services have been set up in order to deliver care for CLTI as close to home as possible but this means personnel are spread thinly, which contributes to the slower time-to-assessment in the non-arterial centres seen in Chapter 3. Patient participants in Chapter 6 reporting that travel to the arterial centre in the network is tolerated may indicate services should be redesigned with resources should be concentrated centrally.

The inequalities described in this thesis could lead to direct patient harm due to delay in revascularisation, and provision of care for CLTI should not be affected by someone's location, diabetes status or frailty.

8.2.7. Raising awareness

A strong theme in Chapter 4 was a perceived lack of importance ascribed to vascular surgery as a specialty throughout primary and secondary care, and a lack of awareness in the public. All of this is supported in previous studies, with poor clinician and public knowledge of CLTI and PAD reported[94, 102]. This was echoed in Chapter 5, where Knowledge was the most relevant domain of the TDF according to belief frequency, with generalist clinicians such as GPs admitting a lack of personal knowledge and training on CLTI. Lived experience reported in Chapter 6 reflected this, with patients describing having lower limb wounds dressed for weeks before recognition as potential CLTI, and misdiagnosis of their symptoms as gout or arthritis. The diversity of pathways described in Chapter 3 indicates the wide net vascular surgery services have to cast in order to identify these patients.

Greater awareness of CLTI in primary care clinicians could eliminate the role of luck in diagnosis, as described in Chapter 6, as more clinicians would consider it when faced with a non-healing lower limb wound, for example. Guidance for primary care clinicians was confirmed inadequate in Chapter 2, and improving available guidance may work towards this goal. Greater awareness in the public could increase the number of patients empowered to advocate for themselves, and knowing potential consequences of CLTI may overcome any intrinsic reluctance to ask for help, which were both described as important to receive appropriate care in Chapter 6. Caution is advised in the planning of awareness campaigns aimed at patients, however, as in Chapter 6 participants described not accessing the internet with regards to their condition.

Many of the participants in Chapter 6 reporting a delay to diagnosis had a prior diagnosis of PAD or CLTI. Most did not have direct access to a vascular clinician following the prior diagnosis, and described lack of awareness of the potential symptoms that would require urgent input, or the consequences of their previous diagnosis such as risks of amputation or mortality.

8.3. Local interventions

Based on this thesis, a menu of recommendations follows for vascular surgery centres who wish to improve the process between first symptom and assessment of patients with suspected CLTI. All are context dependent, and appropriate planning for implementation and evaluation would be necessary.

- Create local referral pathways with primary care clinicians so the context in which they are working is understood and appreciated, and ease of referral prioritised. Such co-production can deliver better healthcare services[277].
- Ensure local pathways are clearly documented and publicised to relevant staff groups in the community, including the availability of emergency clinics. This will increase awareness and promote appropriate referral[94].
- Engage primary care clinician groups who are at high likelihood of seeing patients with CLTI, such as community podiatrists or district nurses, and ensure they are

supported to refer anyone with relevant symptoms, and develop a system to give constructive feedback.

- Ensure a timely triage process is in place for all referrals received to all parts of the network.
- Perform outreach work with primary care clinicians, aimed to raise awareness of vascular surgery conditions and services available to them for the review of patients with suspected CLTI. This will help to avoid missed opportunities to refer patients[75].
- Liaise with community and hospital IT services in the network area to incorporate local guidance or pathways into software used by primary care clinicians.
- Develop a unit policy on the use of objective measures of perfusion in referrals, and ensure this is disseminated to primary care clinicians. If objective measures of perfusion are deemed essential for referral, appropriate training, equipment and personnel must be available in the community to carry this out in a timely manner.
- Ensure the adequate availability of urgent assessment slots such as an emergency clinic or emergency slots in regular clinics at least 4x a week to meet PAD-QIF targets[27]. Appropriately trained and supported non-surgeons can help provide these services. The Centre of Excellence essential criteria from the Global Vascular Guidelines should be used as a model[13].
- Consider the network configuration and ensure equality across all areas of the network in terms of timing of vascular surgery assessment. This may require patients to travel, utilisation of specialist nursing or podiatry services at non-arterial centres and flexibility from vascular surgeons across the network.
- Understand where services are available solely for patients with diabetes (such as high-risk podiatry) and work together with them, managers and commissioners to expand to cover patients without diabetes.
- Ensure assessment for suspected CLTI is available at the same urgency for frail patients by working with assessment areas in your unit.

- Educate patients who have been seen by vascular surgery services and diagnosed with PAD and CLTI on symptoms with which we would want to see them urgently in the future. We know patients with CLTI have poor awareness of their condition[102], and that reduced health literacy is a risk factor for mortality in older cohorts in the UK[278], as well as better health literacy leading to improved quality of life in people with peripheral arterial disease[279].. Improving health literacy could therefore potentially improve outcomes in the CLTI cohort.
- Consider making direct vascular surgery access available to patients known to the unit to limit delay to assessment.

8.4. National interventions

As well as the local interventions documented above, the VSGBI are ideally situated to lead national improvement. The research in this thesis has identified three areas where improvement could be led on a national scale:

- A need has been demonstrated in Chapter 2 for accessible national guidance on referrals for CLTI, written collaboratively with primary care clinicians and behavioural change experts, with endorsement and publicity sought from primary care clinician organisations in order to overcome barriers to their use[153, 154, 161, 162].
- A general raising of awareness of PAD and CLTI is necessary, amongst both clinicians and the general public. The Circulation Foundation, the vascular charity, is well placed to deliver information campaigns, and improve knowledge of the condition throughout the population. This could be modelled on the “Act FAST” campaign from NHS England related to stroke which improved public awareness[107, 108]. There is an opportunity for future research on behaviour change techniques and health literacy interventions in the context of PAD.
- The struggle for resource for services throughout the NHS is acknowledged in Chapters 4, 5 and 6, however vascular surgery was still described as the “poor

relation” compared to other specialties by one of the vascular clinicians in Chapter 4. Pressure on government from the VSGBI via the All-Party Parliamentary Group on Vascular and Venous Disease, or through other routes, could increase funding for our specialty. One way this can be directed is to ensure the VSGBI-recommended provision of one vascular surgeon per 100,000 population is achieved, by increasing vascular surgery training numbers and prioritising retention of current trainees.

If the VSGBI were to consider a further QI collaborative as an approach to improve quality in the time from first symptom to vascular surgery assessment, the recommendations developed in Chapter 7 should be considered in the development of such an improvement programme.

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Appendix 1. Document search strategy

Database search

Your Journals@Ovid
Ovid MEDLINE(R) ALL <1946 to November 4, 2022>
Embase <1974 to 2022 November 4>

1 (Chronic limb threatening isch*mia or CLTI or critical limb isch*mia or severe limb isch*mia).mp. [mp=ti, ab, tx, ct, ot, nm, hw, fx, kf, ox, px, rx, ui, sy, tn, dm, mf, dv, dq] 15799
2 Refer*.mp. [mp=ti, ab, tx, ct, ot, nm, hw, fx, kf, ox, px, rx, ui, sy, tn, dm, mf, dv, dq] 2859430
3 (Guid* or recommend*).mp. [mp=ti, ab, tx, ct, ot, nm, hw, fx, kf, ox, px, rx, ui, sy, tn, dm, mf, dv, dq] 4290508
4 1 and 2 and 3 394

Websites searched

Guideline developer organisations	National Institute of Health and Care Excellence	https://www.nice.org.uk/
	Guidelines International Network	https://g-i-n.net/
	Trip medical database	https://www.tripdatabase.com/
	Scottish Intercollegiate Guidelines Network	https://www.sign.ac.uk/
National / international vascular surgery organisations	European Society of Vascular Surgery	https://esvs.org/
	Vascular Society of Great Britain and Ireland	https://www.vascularsociety.org.uk/
	Society of Vascular Surgery (USA)	https://vascular.org/
	Canadian Society for Vascular Surgery	https://canadianvascular.ca/
	Australia and New Zealand Society for Vascular Surgery	https://anzsvs.org.au/
	The Vascular Society of Southern Africa	http://www.vascularsociety.co.za/
	Asian Society for Vascular Surgery	https://asianvascular.com/
National / international community care organisations	American Board of Family Medicine	https://www.theabfm.org/
	Royal College of General Practitioners	https://www.rcgp.org.uk/
	American Academy of Family Physicians	https://www.aafp.org/home.html
	Royal Australian College of General Practitioners	https://www.racgp.org.au/
	World Association of Family Doctors	https://www.globalfamilydoctor.com/
	South African Academy of Family Physicians	https://saafp.org/

Search strategy

For Google:

- “chronic limb-threatening ischaemia referral guidelines”
- “chronic limb-threatening ischaemia referral”
- “limb ischaemia guidelines”
- “limb ischaemia referral”

First ten pages of results reviewed for each search term.

For guideline development websites listed above:

- “chronic limb-threatening ischaemia”
- “critical limb ischaemia”
- “vascular”
- “ischaemia”

All search results reviewed.

For vascular surgical societies listed above:

- “chronic limb-threatening ischaemia”
- “critical limb ischaemia”

All search results reviewed.

For community care websites listed above:

- “vascular”
- “limb ischaemia”
- “ischaemia”

All search results reviewed.

Appendix 2. List of non-included documents

Publically available documents with no information on (timing of) referrals for CLTI

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Naidoo, N. G., Veller, M. G., Mulaudzi, T. V., Pillay, B., Mistry, P. H., Le Roux, D. A. (2022). Vascular Society of southern Africa (VASSA) 2020 clinical practice guidelines on the management of peripheral arterial disease. SAMJ: South African Medical Journal, 112(2b), 128-182.

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Kolossváry, E., Farkas, K., Colgan, M. P., Edmonds, M,. Fitzgerald, H. P., Fox, M., Pécsvárady, Z., Wautrecht, J. C., Catalano, M.; VAS-Vascular-Independent Research and Education-European Organization. "No more amputations": a complex scientific problem and a challenge for effective preventive strategy implementation on vascular field. Int Angiol. 2017 Apr;36(2):107-115.

Non publically available documents

Bandyk, D. F. The diabetic foot: Pathophysiology, evaluation, and treatment. Seminars in Vascular Surgery 31 (2018) 43-48.

Savill, P. Early diagnosis of peripheral arterial disease can save limbs. The Practitioner. October 2012-256 (1755): 19-21.

Minar, E. Critical limb iscahemia. Hämostaseologie 2009; 29: 102-109.

Withdrawn documents

SIGN 89: Diagnosis and management of peripheral arterial disease. A national clinical guideline. October 2006

Appendix 3. Indicative interview topic guide: vascular surgery clinicians

Introduction:

- My name
- My role
- Aims of interview
- Safety information

Consent

- Are you happy to proceed?

Start recording

Data on centre

- So first of all, I'll ask you to confirm for me which centre you work in, and what your role is within the referral process

Primary care questions

- Before we go onto the specific process map for your area, I'll ask some questions about primary care.
  - Do you feel primary care clinicians have the ability to pick up on the symptoms / cues that should lead them to suspect CLTI?
    - If not, what are they lacking?
    - What is the cause of the discrepancy?
    - Specific staff group?
  - CLTI should be referred urgently. Do you think primary care clinicians are aware of the urgency of these symptoms, and have the ability to act in a timely manner?
    - If not, what are they lacking?
    - What is the reason behind your answer?
  - Do you think primary care clinicians have sufficient knowledge of the referral pathway for patients with suspected CLTI?
    - If not, what are they lacking?
    - Why is there such a discrepancy?
  - Thinking about the [unit] pathway, do primary care clinicians have the skills to negotiate an urgent referral within the context of the pathway?
    - Do you think the [unit] pathway is easy to negotiate from primary care clinicians
    - If not, what are they lacking?
  - Do primary care clinicians have an appreciation of the harms of failure to urgently refer?
    - If not, what are they lacking?
    - What prevents them from recognising the harms?
  - We've spoken about clinicians, how about patients from the first symptom?
    - Do patients recognise symptoms?
    - Can they access the care they need?

Further questions

- Now, we'll look at the process map that we created together with you and other members of the team

- This is the process map put together by the vascular unit you work at. Is it accurate? You will maybe only be able to tell me about your bit of the pathway – that's fine
    - What is good about your current referral pathway?
        - Why? Can you give me an example?
    - What specific areas of this referral pathway could be better and how?
        - Any others?
        - How would you ideally like to receive a referral?
            - Why?
            - Would a proforma help / Does your proforma help?
        - How would you ideally like a referral to be triaged?
            - Why?
        - How would you ideally like to see a patient with CLTI?
            - Why?
    - Your process map is heavy on the use of ___ (VSN / podiatry / vascular surgeon). What is good about this?
        - What sort of feedback is given by patients?
        - Are there any downsides?

- We'll now talk about some of the delays in the system demonstrated on the map, and how they could be improved
    - Delays
        - We've discussed some of the issues with primary care clinicians. What do you think are the most important contributors to delays in the process from patients developing a symptom and being assessed by your team?
            - Where in this referral process?
                - Why?
            - Is it different if they live near the hub or the spoke?
            - Referral set up across network into hub or spokes?
            - Is it different if they have any specific comorbidities? Like diabetes?
    - Potential resources
        - How do you think we can improve delays in the system within current resource available?
        - What do you think would help reduce delays in care of patients with CLTI if resources weren't an issue?
            - Why will this work?
        - Is there anything already in place in other specialties / locations that you think might help?
            - Why are they good?
            - Are there any downsides?
        - Have you heard of any suggestions at conferences or in newspapers that do you think wouldn't help?
            - Why?
        - Does your unit engage with primary care clinicians?
            - Why / why not?
            - If yes, what has it been like?

- Now, we’re in fantasy land thinking about what would be ideal. This can be wider than just your specific area, so thinking about the entire process map and all patients that may need vascular surgery assessment
  - Pathways
    - What would your ideal pathway for a patient from first symptom to assessment by vascular surgery look like?
    - We’ve said your unit uses ___ (VSN / vascular surgeon / podiatrist). Would expanding the roles of any other specialties help reduce delays to assessment?
      - Expanding podiatry role for non-diabetics?
    - This is a generic version of the process map showing all pathways used across the country. Are there any pathways you see on the map that might improve the process in your unit?

Thank you

- Thank you so much for your time
- Is there anything you’d like to add on the topics we’ve discussed?
- Do you have any questions?

Next steps

Appendix 4. Indicative interview topic guide: primary care clinicians

Questions are likely to include the following:

- Introduction, aims of interview, safety information, consent
- Gathering data on participant
  - Professional role
  - Number of vascular referrals over past 6 months? Year?

Using Theoretical Domains Framework to assess knowledge, capability and motivation

- Knowledge
  - What do you understand by the term “chronic limb threatening ischaemia (CLTI)”?
  - Do you use, or know of any guidance relating to CLTI?
  - PROMPTS: Local or national guidance on when and how to refer?
  - Tell me about any training or teaching you’ve had on vascular disease
    - PROMPTS: Any training during your qualification, since your qualification, any e-learning?

- Skills
  - Can you describe how you would take a history from a patient with foot pain or an ulcer who you suspect might have vascular problems?
  - How would you examine a patient who you suspected of having CLTI?
  - Do you carry out ABPIs or toe pressures? If not, why not?
  - If you decided the patient needed further assessment, can you tell me about how you’d refer in your practice?
    - Are there features of the patient / presentation that might change your approach?
    - PROMPTS: Does it matter if they are diabetic or not?
- Professional role and identity
  - Is it your role to refer patients with CLTI to vascular surgery?
    - If not, who should do it?
- Beliefs about capabilities
  - How confident do you feel in recognising CLTI?
    - What makes you confident / not confident?
  - How confident do you feel in referring CLTI?
    - Why?
    - Does the person you are referring to make a difference?
  - Have you had any issues with referrals for CLTI in the past?
    - Have you met who you’re referring to?
- Optimism
  - How confident are you that referral will have the best possible outcome for the patient?
  - How much faith do you have in the vascular team that you’re referring to?
- Beliefs about consequences
  - What would happen to the patient if the referral wasn’t made? If they declined, for example, or if they presented late?
  - What would happen if the referral process worked for patients with CLTI?
    - What would happen to the patient?
    - Would there be any other consequences?

    - Do you tell the patients about consequences?
- Reinforcement
    - What might reinforce, or strengthen your decision to make a referral?
        - PROMPT: Would you discuss with a local colleague? Would you discuss with a hospital colleague?
    - What factors might hinder this decision process, or make you less likely to refer?
    - Have you ever had feedback on a referral?
        - How did that make you feel? Why?
        - Do you think feedback would be helpful?
- Intentions
    - What do you hope to achieve with a referral for a patient with CLTI?
    - Do you anticipate any problems?
    - PROMPTS: Any patient factors that might cause a problem?
- Memory, attention and decision processes
    - What is the alternative to referral?
        - When would you choose to do the alternative? Why?
        - Are there patient factors that affect your decision?
        - PROMPTS: What would you do with a palliative, or end of life patient?
    - What do you think might help you make the decision to refer, or not?
    - PROMPTS: We talked about guidance earlier, is there anything like that? A decision aid?
    - Would you refer to anyone but the vascular surgeons? Podiatry?
- Goals
    - What motivates you to refer a patient? Why would you do this?
    - Are there any incentives for referrals? Any benefit to you or the practice you work in?
    - Are there any costs for referrals?
- Environmental context and resources
    - Are there any factors in the environment you work in that affect the referral process?
        - PROMPTS: Like how busy the clinic is, time available to call / email?
        - PROMPTS: Form of consultation (?telephone), pressure on GP in terms of decision making / capacity for risk?
    - Are there any environmental factors from the hospital end that affect the referral process?
        - PROMPTS: Do you have to fill in an online form, waiting for switch to bleep the reg etc.
- Social influences
    - Do you know what your colleagues do with patients with suspected CLTI?
    - Do you discuss referrals as a group?
    - Are you encouraged or discouraged to make referrals?
- Emotion
    - How does referring / having to refer a patient make you feel?
        - Why?
    - Do patients' and families' emotions affect your decision making?
    - Does how you feel at the time affect what you might do?
- Behavioural regulation
    - How do you ensure that your referral behaviour is appropriate to the situation?

    - Do you have personal strategies to standardise your practice?

Questions not immediately related to TDF

- Pathways
    - What would your ideal pathway for referring a patient to vascular surgery look like?
    - PROMPT: Who would you like to refer to, and how?
    - How could your current pathway be better?
- Potential resources
    - What do you think would help support you referring patients with suspected CLTI?
        - Why will this work?
    - Is there anything you think wouldn't help? Anything that's already been tried?
        - Why?
    - Do you know of any resources already in place in other specialties?
        - Why are they good / bad?

Close

- Anything you'd like to add, or anything that we haven't covered?

Questioning here will be adapted in response to ongoing iterative analysis of the interview data.

Appendix 5. TDF coding manual

Domain Definition	Constructs	Notes
Knowledge (know) An awareness of the existence of something	Knowledge (including knowledge of condition / scientific rationale) Procedural knowledge Knowledge of task environment	• Knowledge of CLTI (definition, urgency) • Knowledge of referral pathways • Knowledge of what to ask in a history • Knowledge and use of guidelines / pathways (including desire for criteria / pathway) • How knowledge is gained (teaching) • Support for knowledge • Consequences of a lack of knowledge (Knowledge may be both correct and incorrect knowledge – eg. incorrect definition of CLTI, or admitting a lack of understanding)
Skills (skills) An ability or proficiency acquired through practice	Skills Skill development Competence Ability Interpersonal skills Practice Skill assessment	• Ability to examine a patient • Consultation skills (consent for referral) • Challenges needing to be overcome during consultations • How skills have been gained (training / experience) • Need for improvement in skills
Social / professional role & identity (id) A coherent set of behaviours & displayed personal qualities of an individual in a social or work setting	Professional identity Professional role Social identity Identity Professional boundaries Professional confidence Group identity Leadership Organisational commitment	• Clinicians' expressions about their own professional identity / job / role / professional boundaries • Comparisons of their role with that of other professionals • How different professions work together • The role of personal effort (seeking out training) • (Not) others' role / responsibility • Impostor syndrome

Beliefs about capabilities (bel cap) Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use	Self-confidence Perceived competence Self-efficacy Perceived behavioural control Beliefs Self-esteem Empowerment Professional confidence	• Perceptions about their own competence / confidence in assessing / managing CLTI • What gives them the competence / confidence to assess / manage CLTI • Thoughts on others' competence / confidence with regards to CLTI • Opinions on what they can manage vs need for referral • Perceived competence / confidence compared to others
Optimism (opt) The confidence that things will happen for the best or that desired goals will be attained	Optimism Pessimism Unrealistic optimism	• Degree of faith in the vascular team that the best possible outcome will be achieved • Perceptions of waiting times • Things that change optimism (eg. network configuration, meeting people)
Beliefs about consequences (bel con) Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	Beliefs Outcome expectancies Anticipated regret Consequences	• Perceptions of what happens if CLTI is / isn't recognised / referred (negative or positive, related to patient, self or work environment) • Perceptions of the vascular surgery assessment process (negative or positive) • Beliefs relating to the treatment of CLTI and its outcomes • Beliefs relating to the referral process for CLTI
Reinforcement (reinf) Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response & a given stimulus	Rewards Incentives Punishment Consequents	• Previous experience of referrals affecting how the participant thinks of the referral process (positive or negative) • Degree of trust from vascular team
Intentions (int) A conscious decision to perform a behaviour or a resolve to act in a certain way	Stability of intentions Stages of change	• What the decision to refer a patient comes down to (duty of care) • Decisions being made case by case – not letting external factors affect each consultation • Ensuring good quality of referral

Memory, attention & decision processes (mem) The ability to retain information, focus selectively on aspects of the environment & choose between two or more alternatives	Memory Attention Decision making Cognitive overload / tiredness	• How decisions are made on whether to refer or not (findings on examination, tools / scores, patient history) • Effect of family or patient wishes on decisions • Effect of stress • Situations in which decision making is difficult (frailty)
Goals (goals) Mental representations of outcomes or end states that an individual wants to achieve	Goals Implementation intention	• What participants are hoping to achieve by referring a patient (affecting self / patient)

Environmental context & resources (env)
Any circumstance of a person's situation or environment that discourages or encourages the development of skills & abilities, independence, social competence & adaptive behaviour
	Environmental stressors
	Resources / material resources
	Organisational culture
	Person x environment interaction
	Barriers and facilitators
		• Describing the presence or absence of resources / equipment / services / clinicians / organisational structures which facilitate / impede performing the behaviour – eg:
		  • Equipment
		  • Technology
		  • Referral forms / tools
		  • Time
		  • Clinical demands / pressure
		  • Shared notes
		  • Network configuration
		  • Means of communication between primary and secondary care
		• Presence of alternative pathways for some patients (diabetics)
		• Views on the costs associated with the referral
		• Effect of form of consultation on the assessment of CLTI
		• Effect of Covid

Social influences (soc) Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours	Social pressure / norms / comparisons Group conformity / norms Social support Power Intergroup conflict Alienation Group identity Modelling	• Effects of contact with the vascular team (including different staff groups) • Feedback given (or not) following referrals • What local colleagues do (same or different to participant) • Formal or informal learning taking place • Communication between primary and secondary care (the act of communication as opposed to means of) • Communication within primary care • Perceptions of discussing with different types of vascular clinician (nurse v. surgeon)
Emotion (em) A complex reaction pattern, involving experiential, behavioural, & physiological elements, by which the individual attempts to deal with a personally significant matter or event)	Fear Anxiety Positive / negative affect Stress Depression Burnout	Reference to any emotions experienced by the participant with reference to the assessment / referral process for CLTI: • Anxiety • Apprehension • Frustration • Relief • Satisfaction • No feelings
Behavioural regulation (beh reg) Anything aimed at managing or changing objectively observed or measured actions	Self-monitoring Breaking habits Action planning	• Statements on how the participants self-monitor • Statements about processes / prompts in place which help standardise behaviour (pathways / criteria / tools) • Statements about personal strategies to standardise behaviour (doing the same thing with each patient) • Processes in place to audit behaviour

Coding manual based on definitions provided in Cane, O’Connor & Michie (2012). TDF, Theoretical Domains Framework

Appendix 6. Indicative interview topic guide: patients

Questions are likely to include the following:

- Introduction, aims of interview, safety information, reminder that the interview is being recorded, the participants can stop at any time, reminders of any possible escalation in the event of risk disclosure
- Confirm consent
- Patient characteristics:
  - Age, gender
  - Comorbidity (diabetes)
  - Local hospital (hub or spoke)
- I understand you've had a diagnosis of chronic limb-threatening ischaemia in the last year. Can you tell me a bit more of your story?

  Allow participant to tell their story uninterrupted in their own words. Then go through, slowly, picking out relevant points to discuss further. Allow the participant to lead the conversation.

- When did you first notice something wasn't right? What symptoms were you having?
  - What did you do? Did you tell anyone?
  - What support did you need?
  - Did your symptoms affect your relationships with friends or family?
  - Did your symptoms affect your working life?
  - How did that all make you feel?
- Did you see a primary care doctor (GP), nurse or podiatrist? Did you go to A&E?
  - What did you tell them?
  - What did they tell you?
  - How did you feel?
  - Was there any delay?
- When did you first see the vascular surgery specialists at the hospital – this might have been a nurse, a podiatrist or a doctor?
  - What was that experience like?
  - Was there a delay?
  - How did you feel?
  - Did having diabetes make a difference to who you saw?
- Were you a smoker?
  - Did you feel judged for smoking?
- If spoke patient, did you travel to the hub?
  - Was this an issue?
  - What do you think of the hub compared to the spoke?
- When did you first see a vascular surgeon?
  - What did they tell you?
  - How did you feel?
- At what point did you understand what your diagnosis was? – A lack of blood supply putting your foot / your leg at risk.
    - Have you heard the term "chronic limb-threatening ischaemia" or CLTI before?
    - Did you Google your symptoms?
- If your next door neighbour had the same thing, what would you tell them?

- What was good about your experience from first symptom to assessment?
- What was bad about your experience from first symptom to assessment?
    - Was there any effect of delays on your trust in medical services?

- What would matter to you the most if you were to have the same problem on the other leg?
    - Would you change anything you did the first time?
    - PROMPTS: Would keeping your independence matter to you? Would being pain free matter to you? Would keeping your leg matter to you?

- Any questions for me?
- What would you like to hear from us in the future?
    - PROMPTS: Would you like to hear the results of all the interviews? How you have helped us?
- We would love to have more people like you involved in making our services better. Would you consider being involved in future projects?

Questioning here will be adapted in response to ongoing iterative analysis of the interview data and feedback from participants.

Appendix 7. Search strategies

Table 1a: MEDLINE search strategy

Database	Medline
Date	7/1/22
1	Quality Improvement/
2	Program Evaluation/
3	implementation science/
4	(surgery or surgic* or surgeon or operat*).ti,ab.
5	(UK or GB or brit* or NHS or national health service or engl* or scot* or wales or welsh).ti,ab.
6	(multi?centre or collab* or breakthrough series or IHI or institute for healthcare improvement or model for improvement or bundle or PDSA or hospitals or units or national or regional or cluster).ti,ab.
7	(Quality adj3 (improv* or enhanc* or intervention* or initiative* or strateg* or program* or project*)).ti.
8	1 or 2 or 3
9	4 and 5 and 6
10	7 or 8
11	9 and 10
12	limit 11 to english language

Table 1b: EMBASE search strategy

Database	Embase
Date	7/1/22
1	total quality management/
2	Program Evaluation/
3	implementation science/
4	(surgery or surgic* or surgeon or operat*).ti,ab.
5	(UK or GB or brit* or NHS or national health service or engl* or scot* or wales or welsh).ti,ab.
6	(multi?centre or collab* or breakthrough series or IHI or institute for healthcare improvement or model for improvement or bundle or PDSA or hospitals or units or national or regional or cluster).ti,ab.
7	(Quality adj3 (improv* or enhanc* or intervention* or initiative* or strateg* or program* or project*)).ti.
8	1 or 2 or 3 or 7
9	4 and 5 and 6
10	8 and 9
11	limit 10 to english language

Appendix 8. Papers not included after full text review

Not surgical

Dowsett C, Taylor C. Reducing variation in leg ulcer assessment and management using quality improvement methods. Wounds UK. 2018;14(4):46-51.

Edmiston R, Anmolsingh R, Khwaja S, Kumar BN. ENT Quality Improvement Program as a tool to improve the collection of morbidity and mortality data: a multisite audit carried out over 6 months. BMJ open quality. 2019;8(3):e000501.

Malcolm W, Nathwani D, Davey P, Cromwell T, Patton A, Reilly J et al. From intermittent antibiotic point prevalence surveys to quality improvement: experience in Scottish hospitals. Antimicrobial Resistance and Infection Control. 2013.

Russell GK, Jimenez S, Martin L, Stanley R, Peake MD, Woolhouse I. A multicentre randomised controlled trial of reciprocal lung cancer peer review and supported quality improvement: results from the improving lung cancer outcomes project. British Journal of Cancer. 2014.

McGrath BA, Lynch J, Bonvento B, Wallace S, Poole V, Farrell A, et al. Evaluating the quality improvement impact of the Global Tracheostomy Collaborative in four diverse NHS hospitals. BMJ quality improvement reports. 2017;6(1).

No patient-related outcome

McCulloch P, Morgan L, Roberston E, New S, Catchpole K, Hadi M, et al. Combining systems and teamwork approaches to enhance the effectiveness of safety improvement interventions in surgery: The safer delivery of surgical services (S3) program. Annals of Surgery. 2017;265(1):90-96.

Moore J, Merchant Z, Rowlinson K, McEwan K, Evison M, Faulkner G, et al. Implementing a system-wide cancer prehabilitation programme: The journey of Greater Manchester's 'Prehab4cancer'. European Journal of Surgical Oncology. 2021;47(3):524-532.

Pinto A, Benn J, Burnett S, Parand A, Vincent C. Predictors of the perceived impact of a patient safety collaborative: an exploratory study. International journal for quality in health care : journal of the International Society for Quality in Health Care. 2011;23(2):173-181.

Burnett S, Benn J, Pinto A, Parand A, Iskander S, Vincent C. Organisational readiness: exploring the preconditions for success in organisation-wide patient safety improvement programmes. Quality & safety in health care. 2010;19(4):313-317.

St John ER, Scott AJ, Leff DR, Irvine TE, Pakzad F, Layer GT. Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland. 2017;15(4):190-195.

Single centre

Ahmed K, Khan N, Anderson D, Watkiss J, Challacombe B, Khan MS, Dasgupta P, Cahill D. Introducing the productive operating theatre programme in urology theatre suites. Urologia Internationalis. 2013.

Chiwera L, Wigglesworth N, Newsholme W, McCoskery C, Lucchese G. Reducing adult cardiac surgical site infections and the economic impact of using multidisciplinary collaboration. Journal of Hospital Infection. 2018;100(4):428-436.

Leary A, Corrigan P. Redesign of thoracic surgical services within a cancer network-using an oncology focus to inform change. European journal of oncology nursing : the official journal of European Oncology Nursing Society. 2005;9(1):74-78.

Lechner M, Chandrasekharan D, Vithlani R, Sutton L, Grandidge C, Elmiyeh B. Evaluation of a newly introduced tonsillectomy operation record for the analysis of regional post-tonsillectomy bleed data: a quality improvement project at the London North West Healthcare NHS Trust. BMJ open quality. 2017;6(2):e000055.

Twose P, Jones G, Lowes J, Morgan P. Enhancing care of patients requiring a tracheostomy: A sustained quality improvement project. Journal of Critical Care. 2019;54:191-196.

No implementation

Kocman D, Regen E, Phelps K, Martin G, Parker S, Gilbert T, et al. Can comprehensive geriatric assessment be delivered without the need for geriatricians? A formative evaluation in two perioperative surgical settings. Age and ageing. 2019;48(5):644-649.

Esain AE, Williams SJ, Gakhal S, Caley L, Cooke MW. Healthcare quality improvement - policy implications and practicalities. International Journal of Health Care Quality Assurance. 2012;25(7):565-581.

Not collaborative QI (service evaluation, guideline, national audit)

Garriga C, Murphy J, Leal J, Price A, Priet-Alhambra D, Carr A, et al. Impact of a national enhanced recovery after surgery programme on patient outcomes of primary total knee replacement: an interrupted time series analysis from "The National Joint Registry of England, Wales, Northern Ireland and the Isle of Man". Osteoarthritis and cartilage. 2019

McLellan AR, Gallacher SJ, Fraser M, McQuillian C. The fracture liaison service: success of a program for the evaluation and management of patients with osteoporotic fracture. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA. 2003;14(12):1028-1034.

Mariappan P, Johnston A, Padovani L, Clark E, Trail M, Hamid S, et al. Enhanced Quality and Effectiveness of Transurethral Resection of Bladder Tumour in Non-muscle-invasive Bladder Cancer: A Multicentre Real-world Experience from Scotland's Quality Performance Indicators Programme[Formula presented]. European Urology. 2020;78(4):520-530.

Neuburger J, Tsang C, Cromwell DA, Van Der Meulen J, Currie C, Wakeman R et al. The Impact of a National Clinician-led Audit Initiative on Care and Mortality after Hip Fracture in England. Medical Care. 2015.

Simpson JC, Moonesinghe SR, Grocott MPW, Kuper M, McMeeking A, Oliver CM, et al. Enhanced recovery from surgery in the UK: an audit of the enhanced recovery partnership programme 2009-2012. British journal of anaesthesia. 2015;115(4):560-568.

Winstanley JH, Leinster SJ, Wake PN, Copeland GP. The value of guidelines in a breast screening service. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology. 1995;21(2):140-142.

Powell AE, Davies HTO, Bannister J, MacRae WA. Challenge of improving postoperative pain management: Case studies of three acute pain services in the UK National Health Service. British Journal of Anaesthesia. 2009;102(6):824-831.

Drew S, Judge A, Gooberman-Hill R, Cohen R, Fitzpatrick R, Barker K. Enhanced Recovery after Surgery implementation in practice: An ethnographic study of services for hip and knee replacement. BMJ Open. 2019;9(3):e024431.

Protocol only

Scrimshire A, Booth A, Fairhurst CM, Tadd W, Laverty A, Corbacho B et al. Scaling up Quality Improvement for Surgical Teams (QIST) - Avoiding surgical site infection and anaemia at the time of surgery: Protocol for a cluster randomised controlled trial. Trials. 2020;21(1):234.

Taylor J, Wright P, Rossington H, Mara J, Glover A, West N, et al. Regional multidisciplinary team intervention programme to improve colorectal cancer outcomes: study protocol for the Yorkshire Cancer Research Bowel Cancer Improvement Programme (YCR BCIP). BMJ open. 2019;9(11):e030618.

Wagstaff D, Moonesinghe SR, Fulop NJ, Vindrola-Padros C. Qualitative process evaluation of the Perioperative Quality Improvement Programme (PQIP): study protocol. BMJ open. 2019;9(7):e030214.

Glossary

A&E	Accident and emergency
AAA	Abdominal aortic aneurysm
AAA-QIP	Abdominal Aortic Aneurysm Quality Improvement Programme
ABPI	Ankle-brachial pressure index
ACC	American College of Cardiology
AGREE	Appraisal of Guidelines Research and Evaluation
AHA	American Heart Association
CCG	Clinical Commissioning Group
CFIR	Consolidated Framework for Implementation Research
CLTI	Chronic limb threatening ischaemia
COPD	Chronic obstructive pulmonary disease
COREQ	Consolidated criteria for reporting qualitative research
CQUIN	Commissioning for Quality and Innovation
DNA	Did not attend
ED	Emergency Department
EPOC	Effective Practice and Organisation of Care
EPOCH	Enhanced Peri-Operative Care for High-risk patients
eRS	e-Referral Service
ESC	European Society of Cardiology
ESVS	European Society of Vascular Surgery
FPS	Foot Protection Service
GIN	Guidelines International Network
GIRFT	Getting It Right First Time
GLIA	Guideline Implementability Appraisal
GMC	General Medical Council
GP	General Practitioner
HES	Hospital Episode Statistics
IHI	Institute for Healthcare Improvement
IT	Information technology
IWGDF	International Working Group on the Diabetic Foot
LMC	Local medical committee
LOS	Length of stay
MDFTs	Multi-disciplinary diabetic foot teams
MRC	Medical Research Council
NCEPOD	National Confidential Enquiry into Patient Outcome and Death

NDFA	National Diabetes Foot Care Audit
NELA	National Emergency Laparotomy Audit
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NVD	National Vascular Database
NVR	National Vascular Registry
PAD	Peripheral arterial disease
PAD-QIF	Peripheral Arterial Disease Quality Improvement Framework
PAD-QIP	Peripheral Arterial Disease Quality Improvement Programme
PIS	Participant Information Sheet
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PROMs	Patient reported outcome measures
QI	Quality improvement
QI-MCS	Quality Improvement Minimum Criteria Set
QIC	Quality improvement collaborative
QOF	Quality and Outcomes Framework
RCT	Randomised controlled trial
READ	Ready materials; Extract data; Analyse data; Distil findings
SBU	Swedish Council on Health Technology Assessment
SIGN	Scottish Intercollegiate Guidelines Network
SQUIRE	Standards for QUality Improvement Reporting Excellence
TDF	Theoretical Domains Framework
TIDieR	Template for intervention description and replication
UK	United Kingdom
USA	United States of America
VaLS	Vascular Limb Salvage
VSGBI	Vascular Society of Great Britain and Ireland
VSN	Vascular specialist nurse
WIfI	Wound, infection, foot ischaemia