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Documentary analysis of national and international guidance for community clinicians referring patients with suspected chronic limb-threatening ischaemia

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ABSTRACT

Background Delayed referral of patients with chronic limb-threatening ischaemia (CLTI) from the community to vascular services may increase risk of amputation due to delayed revascularisation. Lack of appropriate guidance for clinicians in the community may contribute to this problem. This documentary analysis investigated referral guidance available to primary care clinicians.

Methods National and international documents providing guidance on CLTI management were identified by searching sources including Medline, Embase, Guidelines International Network and College/Society websites. Data were extracted on referral recommendations, target audience and author groups. Recommendations were coded according to the Behaviour Change Technique Taxonomy. Clinical practice guideline quality and ease of implementation were assessed independently by two reviewers using the Appraisal of Guidelines Research and Evaluation (AGREE) II and Guideline Implementability Appraisal (GLIA) tools, respectively.

Results 12 documents containing guidance on CLTI referrals were included. Five were clinical practice guidelines. Nine targeted clinicians in the community among their audience, yet only one included a primary care clinician in their author group. Recommendations on identification and referral of CLTI were often in non-specific language and frequently assumed specialist knowledge of vascular disease. Just 4 of the 93 behaviour change techniques were identified in the guidance documents. Three relevant domains of the AGREE II tool were scored for five clinical practice guidelines: stakeholder involvement (range 21.4%-52.4%, mean 42.9%), clarity of presentation (range 71.4%–92.9%, mean 82.9%) and applicability (25.0%-57.1%, mean 36.8%). The GLIA tool identified barriers to ease of implementation for all five clinical practice quidelines.

Conclusions Most guidance for clinicians in the community on the management of CLTI has been written without their input and assumes knowledge of vascular disease, which may be lacking. Future guidance development should involve community clinicians, consider using additional behaviour change techniques, and improve the applicability and ease of implementation of recommendations.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There are delays in the referral and management of chronic limb-threatening ischaemia (CLTI), one reason for which could be guidance available to clinicians in primary care.

WHAT THIS STUDY ADDS

⇒ This documentary analysis evaluated recommendations in 12 national and international documents containing guidance for clinicians in the community who refer patients with suspected CLTI to vascular surgery services. Documents were assessed on clarity of recommendations, stated audience and author group. The study found most available guidance documents do not adequately support clinicians in the community in the referral process.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

Guidance regarding CLTI referrals needs to be improved to ensure clinicians in the community are supported to refer appropriately. We have provided recommendations for future guidance documents.

BACKGROUND

Chronic limb-threatening ischaemia (CLTI) is the end stage of peripheral arterial disease. It leads to high costs for health systems around the world. 1-3 Delays are evident at every stage of the patient pathway and are associated with poorer outcomes for patients including limb loss and mortality. 4 In CLTI, a lack of blood supply to the leg or foot causes severe pain at rest, gangrene or non-healing ulceration. Management includes risk factor optimisation, best medical therapy including secondary cardiovascular prevention and early revascularisation.

Patients with CLTI have a high risk of mortality and limb loss, with an amputation-free survival of less than 60% at 2 years in the presence of tissue loss.⁵ The risk of limb loss and death is significantly lower in those revascularised.⁵ Some delays in the management



pathway relate to the timely recognition and referral of patients with suspected CLTI to vascular surgery services from community settings. A reason for this could be a lack of effective recommendations on referral in guidance available 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. The patients of the patients

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 primary care clinicians 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 the guidance may be improved.

METHODS

Documentary analysis is a method of qualitative research in which the content of documents on a specified topic is appraised. This study followed the READ approach to documentary analysis: ready materials, extract data, analyse data and distill findings. 10

Search strategy

A database search of Medline and Embase from inception to 4 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 National Institute for Health and Care Excellence (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 online supplemental additional file 1. Once a relevant document was found, the publishing body's website was searched to ensure the most up-to-date guidance was used. While this is not a formal systematic review, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement was used as a framework for reporting.11

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. The 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 UpTo-Date 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. Additionally, qualitative work carried out by the author group with community clinicians indicated little use of paid-for resources to guide practice.

Data extraction and analysis

Data were extracted in a prepiloted form on a Microsoft Excel spreadsheet and included the 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. 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. This was developed in 2013 by Michie *et al* via a Delphi-style exercise that summarised previously published classifications of behaviour change techniques into a list of 93 techniques within 16 groups. The text in the document 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, 14 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. 15 16 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.

One author (EA) conducted the searches, and the document selection validated by a second author (IK). Two authors (EA and PB) conducted the data collection and

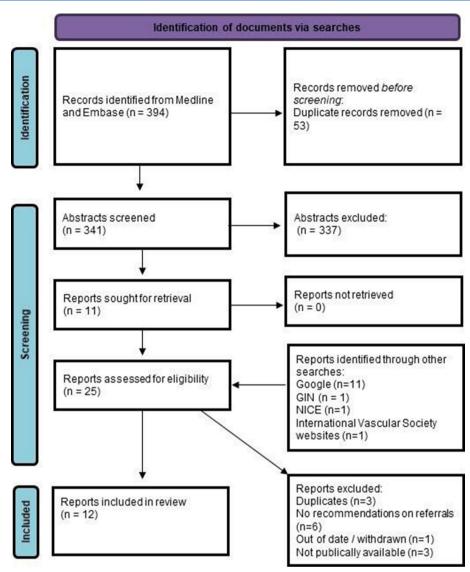


Figure 1 Flow diagram demonstrating search strategy.

analysis. A third author carried out the initial behavioural change technique analysis (IK), which was reviewed by another author (EA). Two authors (EA and PB) independently scored the clinical practice guidelines. Any discrepancies of more than 2 points in scoring on the AGREE II tool were discussed among the group until a consensus was reached.¹⁷ Discrepancies in the GLIA tool were similarly discussed until a consensus was reached.¹⁶ DAC provided a casting vote in any case of disagreement.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

RESULTS

After the automated removal of duplicates, 341 unique results were retrieved from Medline and Embase. Following screening of the 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 1 demonstrates a flow diagram for this process.

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 not eligible for inclusion.

The 12 remaining documents were from across the globe, mainly from high-income countries. Five documents were clinical practice guidelines. ¹⁴ Table 1 contains a summary of the 12 documents.

Eight documents were published in peer-reviewed medical journals. Others were only available on websites aligned with 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 not¹⁸). Two were aimed

Document title	Body represented	Country from	Location published	Date published	Publication form	Community clinician involved?
Peripheral Arterial Disease – Diagnosis and Treatment: A Systematic Review ²⁴	The Swedish Council on Technology Assessment in Health Care	Sweden	Swedish Council on Health Technology Assessment (SBU)	2008	Systematic review	No
2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease ²⁸	American College of Cardiology, American Heart Association	USA	Journal of the American College of Cardiology, Circulation, Vascular Medicine	2016	Clinical practice guideline	No
2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS) ¹⁸	European Society of Cardiology	Europe	European Heart Journal	2017	Clinical practice guideline	No
Guidelines on Management of the Patient with Diabetic Foot Infection ²¹	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 ²⁹	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 ¹⁹	American Academy of Family Physicians	USA	American Family Physician	2019	Journal article	Yes
Lower Limb Ischaemia ²⁰	Finnish Medical Society	Finland	Duodecim Medical Publications	2020	Website	No
Peripheral arterial disease: diagnosis and management ²⁶	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 ²⁷	National Wound Care Strategy Programme	UK	National Wound Care Strategy Programme	2020	Document	Nil documented
Provision of Services for People with Vascular Disease 2021 ²⁵	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) ²²	Society of Vascular Surgery	USA	Society for Vascular Surgery website	2022	Website	Nil documented
A Best Practice Clinical	The Vascular Society for Great	UK	Journal of Vascular	2022	Clinical care	No

Societies Great

Britain and Ireland

solely at community clinicians. ^{19 20} Three were aimed at other specific audiences—general surgeons in Jamaica, ²¹ referring physicians ²² and vascular network leads. ²³ The remaining six documents stated they aimed to reach an extremely broad audience, including community clinicians, using phrases such as 'those working in medical or social services', ²⁴ 'commissioners, providers and clinicians', ²⁵ and 'healthcare professionals, commissioners and providers, adults and their families and carers' ²⁶ and 'intended for use in all clinical care settings'. ²⁷

Care Pathway for Peripheral Britain and Ireland

Arterial Disease²³

Nine documents described who was in their author group; three documents did not list any contributors. ²² ²⁶ ²⁷ 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, the inclusion of more than two specialties was described, such as vascular surgery, interventional radiology, cardiology, diabetology, anaesthetics, medicine, nursing and podiatry. One author group included a patient representative. Ust 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. 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

pathway

not considering community representation in author groups.

11 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 18 23 25 28 29 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.²⁵ 29 None had official endorsements from a professional body related to medical care in the community.

Behaviour Change Technique Taxonomy coding

The guidance contained within the 12 documents was coded according to the Behaviour Change Technique Taxonomy.³⁰ 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; prompts/cues (introduce or define environmental or social stimulus). Their distribution can be seen in online supplemental table 1 along with the content of the guidance.

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. 18 23 28 29 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'). ^{19 20} 2³ 2⁵ 2⁷ The other four referred to 'early', 'urgent' and 'prompt' referral. 18 22 24 28 10 documents gave information on whom to refer to. In nine cases, this mentioned vascular surgery^{18–22} ^{25–27} ²⁹ and one an 'interdisciplinary care team'. 28

Seven documents referred to potential consequences of not referring the patient. 18 21 22 24 27-29 Four of these used the

phrase 'limb salvage', ^{18 21 22 29} 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.

AGREE II analysis of clinical practice guideline guality

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 2. The highest-ranked clinical practice guideline in all domains was the Global Vascular Guidelines.²⁰

GLIA analysis of clinical practice guideline ease of implementation

The results of the GLIA analysis are demonstrated in online supplemental table 2.

- Global considerations: Clinical practice guidelines which did not specify their audience or had a nondiverse 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.

	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 ²³	52.4	92.9	57.1	
2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease ²²	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) ²⁴	21.4	90.5	35.7	
Peripheral arterial disease: diagnosis and management ²⁷	42.9	71.4	25.0	
Mean domain score	42.9	82.9	36.8	

- ➤ 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 the usual workflow of the care setting in which they would be applied.
- ▶ Measurability: While 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.

DISCUSSION

Our documentary analysis has identified aspects of 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 immediately 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.³¹

Our results indicate that referring clinicians may not have been considered as the principal audience for the guidance documents. The AGREE II tool, which assesses the quality and reporting of guidelines, 15 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, while 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 primary care society or college websites. The lack of community representation in author groups and endorsing bodies may act as a barrier to primary care clinicians viewing the guidelines as applicable to them.³²

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. The A need for new knowledge has also been shown to act as a barrier to adherence to guidance. The support of the support of

Three of the six documents containing guidance on the 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 UK with reference to cancer referrals, where it indicates a 2-week wait for hospital assessment.³⁶ This is not appropriate in the context of CLTI and may lead community clinicians to delay referrals unnecessarily. A lack of precision in behavioural instructions may result in fewer community clinicians following guidance.³³ The use of specific concrete statements increases the understanding and remembering of information,³⁷ and this could help where a lack of knowledge or skill is a barrier to referral.³⁸ It also allows the clinical audit of whether recommendations have been followed.³⁹ Guidance written in simple, concise terms allows the identification and manipulation of antecedents and consequences of said behaviour. 40

The lack of information on the consequences of delays in the management of CLTI (namely major limb amputation and mortality) may also contribute to delayed referral. Beliefs about consequences have been seen to affect referrals both positively and negatively in other conditions, 42 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. 33

Just 4 of the 93 available behavioural change techniques were used in the guidance documents analysed. This shows that an opportunity exists to consider the application of other behavioural change techniques in future guidance.⁴⁰ Specific behavioural change techniques have been identified as leading to higher success rates in behaviour change interventions such as smoking cessation services, 43 and further research is required to evaluate their effectiveness in wider contexts. 44 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 previously been used to assess guidelines for pharmacological management and screening and diagnosis of PAD. ^{17 45 46} Uyagu *et al*, Chen *et al* and Barriocanal *et al* similarly found guidelines to score poorly in stakeholder



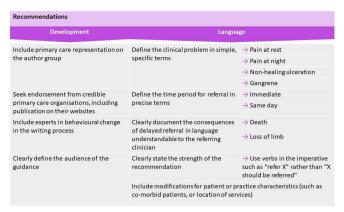


Figure 2 Recommendations for future guidance documents.

involvement and applicability domains compared with clarity of presentation. The Global Vascular Guidelines²⁹ were only included in Uyagu *et al*'s review of screening and diagnosis of PAD,⁴⁵ but in agreement with our results, found them to score higher in two of the three relevant domains than the NICE guidelines,²⁶ the American Heart Association/American College of Cardiology (AHA/ACC) guidelines²⁸ and the ESC guidelines.¹⁸ 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 recommendations 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 2).

Strengths and limitations

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. 47–49 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 were within the parameters suggested in the tool guidance. While the author group was multidisciplinary, including a surgeon, a public health physician, an implementation science expert, a professor of health psychology and a professor of health services research, there are no primary care clinicians in the author group. Including a primary care clinician may have added further perspective to the findings of the study. 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 vascular surgeon assessment. In order to reduce delay in the management of CLTI, patient, process, clinician and system factors must be considered in addition to improving the guidance available.

CONCLUSIONS

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 are 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 the use of a shared language. The wording of the guidance is vague and non-specific. In order to create effective guidance, it is vital that vascular surgery clinicians consider these aspects when updating these guidance documents, and work with professional bodies in the community and behavioural change experts to create concise, clearly defined guidance specifically for primary care clinicians.

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Patient consent for publication Not applicable.

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