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Evaluating and mapping the evidence that screening for diabetic foot disease meets the criteria for population-wide screening: a scoping review

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ABSTRACT

Objective To evaluate and map the evidence around diabetes-related foot screening using the World Health Organisation screening principles, which set the gold standard for determining the appropriateness of introducing population-wide screening programmes internationally.

Design A scoping review methodology in line with Arksey and O'Malley and the Joanna Briggs Institute.

Data sources Medline (EBSCO), Scopus, ScienceDirect and EMBASE between 24 May 2022 and 12 July 2022. Reference lists of the selected studies, and 'Google' and 'Google Scholar' were also searched.

Eligibility criteria Inclusion criteria were informed by the principles of screening. Articles, published in English since 2000, reporting on the impact of the diabetes-related foot ulcers, effectiveness of treatment available for those identified as being at risk, reliability of screening tests for screening for the at-risk foot and the effectiveness, cost-effectiveness, safety and ethics of diabetes-related foot screening programmes were included.

Data extraction and synthesis Data were extracted by one reviewer, with data extraction headings relating to the principles of screening. A narrative synthesis approach was used to report the information from included studies.

Results 46 articles were deemed eligible for inclusion. Diabetes-related foot ulcers are an important health condition associated with increased risk of mortality and poorer quality of life. However, there is insufficient evidence on the effectiveness of treatments to prevent disease development. Moreover, while consensus exists on what screening tools should be used to screen for risk factors, there is no agreement on threshold values. Finally, there is no available information on the potential budgetary, organisational or societal implications of a whole-population diabetes-related foot screening programme.

Conclusion Existing evidence does not support the introduction of an organised population-wide screening programme in the context of World Health Organisation screening principles. Further research on treatment and management strategies for the at-risk foot and of whole-population screening programmes is required.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Current diabetes-related foot screening recommendations may mean that not all people with diabetes are not being offered foot screening and appropriate follow-up, with some suggesting moving diabetes-related foot screening into a population-wide screening programme.

WHAT THIS STUDY ADDS

⇒ By using internationally recognised principles of screening, this study adds to the knowledge on suitability, and the potential harms and benefits of introducing diabetes-related foot screening into a population-wide screening programme.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study synthesised and mapped the current evidence surrounding diabetes-related foot ulcers and screening for risk factors. The findings inform those involved in decision-making of screening programmes on the impact of the disease while also highlighting evidence gaps that need to be addressed before screening for this disease will likely be considered for introduction into such a programme.

INTRODUCTION

The prevalence of diabetes is increasing internationally, and with this comes an increase in diabetes-related macrovascular and microvascular complications which increase a person's risk of limb loss, vision loss and loss of kidney function.[1] Diabetes-related lower extremity amputations are a complication of diabetes, preceded by a diabetes-related foot ulcer (DFU) in approximately 80% of cases.[2] Both amputations and DFUs have been identified as leading causes of the global burden of disability, accounting for 2.1% of global years lived with a disability.[3]

DFU development follows a typical trajectory where a person with diabetes develops risk factors, placing them at an increased risk for DFUs. The International Working Group for the Diabetic Foot (IWGDF), an international consortium of clinical and academic experts in diabetes-related foot disease, recommends that persons with diabetes be screened for these risk factors at least annually and depending on risk factors identified, be risk stratified and referred to the most appropriate healthcare professional allowing for treatment and management to reduce the risk of diabetes-related lower extremity complications.[4] This annual screening and pathway of care is recommended within many health systems.[5–10] However, many patients are not receiving an annual diabetes related foot screening, meaning guidelines are not being adhered to and patients risk not receiving timely referral to specialist foot care services.[11–13]

Screening is defined as the 'testing of people who either do not have or have not recognised the signs or symptoms of the condition being tested for'.[14] The purpose of screening an asymptomatic individual is to detect early evidence of abnormalities, thus allowing for implementation of preventive strategies or treatment and better health outcomes, than if the disease were diagnosed at a later stage. In the case of diabetes-related foot screening, this includes identification of risk factors so appropriate treatment and management strategies can be put in place to prevent progression to ulceration and subsequent amputation. Screening may be offered to a population group opportunistically, which is often the case for the foot in diabetes, or it can be conducted as part of an organised screening programme. Opportunistic and organised screening programmes typically have different characteristics, which can influence the level of uptake of screening. For example, invitations to opportunistic screening tend to be sporadic and screening is often only carried out when patients either request screening or healthcare professionals recommend it. Whereas organised screening programmes often maintain a central register from which invitations are extended to offer a screening appointment at a specific time and place, usually annually. Another difference is the lack of quality assurance when screening is carried out opportunistically. Quality assurance processes are necessary to minimise error and improve performance using explicit standards.[14] In the case of diabetes-related foot screening, this lack of quality assurance may be a contributing factor to why many patients do not receive annual diabetes-related foot screening or are only being referred for specialist services when they present with a 'foot concern'.[15]

A potential alternative to current approaches is to move diabetes-related foot screening into an organised screening programme, like how retinopathy screening is organised in many health systems.[16] For this review, we will use the term targeted, as opposed to population screening, because we are screening for a disease in a defined population (ie, those with diabetes) who are at an increased risk for the condition being screened for.[17] From a public health perspective, there are principles to consider when deciding whether to implement a targeted programme for a given disease or health problem. These were first outlined by Wilson and Jungner[18] for the World Health Organisation (WHO) and have been used to inform decisions on screening programme internationally. Efforts have been made to update them, yet many aspects of Wilson and Jungner's principles are still relevant today.[19] However, there has been a shift towards principles that focus on operational or implementation issues of whole screening programmes, rather than just screening for the disease in question. These include a screening programme's acceptability and ethics, benefits and harm, and quality and performance management.[18 19]

Although there has been increased attention on the possibility of introducing diabetes-related foot screening into an organised screening programme, little is known about whether DFUs, and screening for risk factors, meet the principles outlined by Wilson and Jungner or the operational or implementation issues outlined by Dobrow and colleagues. Therefore, this scoping review aims to evaluate and map the evidence on DFUs and screening for risk factors, using these principles.

MATERIALS AND METHODS

Study protocol

A protocol for this scoping review was previously published, and it was performed in line with Arksey and O'Malley's six-stage methodological framework and the Joanna Briggs Institute.[20–22] It is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (see online supplemental file 1).[23]

Deviations from study protocol

In the original protocol, the authors noted the scoping review process may not be linear, and the researchers would need to engage with each stage in a reflexive way making changes to what was originally stated.[22] As a result, there were variations to what was originally stated. All variations, and rationale for them, were discussed by JAP, SFD, CMB and PK before implementation. Deviations can be found in online supplemental file 2.

Identifying the research question

The overarching aim of this review was to evaluate and map the evidence on DFUs, and screening for risk factors, using the Wilson and Jungner screening principles and the operational and implementation issues outlined by Dobrow *et al*. As outlined in table 1, the research questions were guided by the principles of screening.

Search strategy

Database searches were carried out between 24 May 2022 and 12 July 2022 and repeated in June 2023 by one reviewer. In line with JBI recommendations, a three-step

Table 1 The principle of screening, corresponding research question and inclusion criteria

Principles of screening	Research question	Inclusion criteria: Population	Inclusion criteria: Intervention or comparator	Inclusion criteria: Outcome	Exclusion criteria
► The condition should be an important health problem.	Are DFUs an important health problem? (ie, increasing prevalence or incidence, or causing substantial morbidity and/or mortality).	People with diabetes	None	Incidence Prevalence	Studies where DFUs were grouped with other diabetes-related lower extremity complications (eg, amputations, infection) and could not be separated from them.
			Comparator: Mortality in those without a DFU	Mortality in those with a DFU	
			Comparator: Quality of life in those without a DFU	Quality of life in those with a DFU	
► There should be a recognisable latent or early symptomatic stage. ► The natural history of the condition, including development from latent to declared disease, should be adequately understood.	Is the natural history of DFUs clearly understood?	People with diabetes	None	Variables associated with an increased risk of ulceration	Studies reporting on risk factors for ulcer reoccurrence.
► There should be an acceptable treatment for patients with recognised disease. ► There should be an agreed policy on who to treat as patients. ► Facilities for diagnosis and treatment should be available.	Are there effective interventions for those identified as at-risk, with evidence that intervention at a presymptomatic phase leads to better outcomes for the screened individual compared with usual care?	People with diabetes	Intervention: ► Treatment of the at-risk (IWGDF 1 or 2)*. Foot in diabetes ► Management of the at-risk foot in diabetes	Effectiveness in primary prevention of DFUs.†	Studies where interventions reported on secondary prevention of DFUs‡ or where those with and without a history of ulceration were grouped together and could not be separated.
► There should be a suitable test or examination. ► The test should be acceptable to the population.	Are the screening test(s) for risk factors for DFUs safe, simple, reliable, validated and acceptable to the population?	People with diabetes	Intervention: Screening tests as recommended by the IWGDF.§ Comparator: Reference test	Sensitivity, specificity, reliability of screening test	Studies that had no reference tests. Where the included population did not have diabetes.
► The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole. ► Case finding should be a continuing process and not a 'once and for all' project.	Is there evidence that diabetes-related foot screening is cost-effective?	People with diabetes who have received diabetes-related foot screening	Intervention ► Diabetes-related foot screening ► Diabetes-related foot screening programme	Effectiveness of primary prevention strategies in the at-risk foot in diabetes.	Studies reporting on effectiveness of amputation prevention.
► Implementation and operationalisation issues identified by Dobrow *et al*[19]	Is there evidence that a diabetes-related foot screening programme would be clinically, socially and ethically acceptable to screening participants, health professionals and society?	People with diabetes who have received diabetes-related foot screening. HCPs who have provided diabetes-related foot screening.	Intervention ► Diabetes-related foot screening ► Diabetes-related foot screening programme	► Clinically, social and/or ethical acceptability	None

*International working group for the DFU risk 1 (having loss of protective sensation **OR** peripheral artery disease) or 2 (having loss of protective sensation + peripheral arterial disease **OR** loss of protective sensation+foot deformity **OR** peripheral artery disease + foot deformity).[4]
†Primary prevention: prevention of a person's first ever foot ulcer.
‡Secondary prevention: prevention of ulcer reoccurrence.
§These include pulse palpation, Doppler waveform analysis, 10g monofilament, 128htz tuning fork, vibratip and biothesiometer.
DFU, diabetes-related foot ulcer; HCP, healthcare professional; IWGDF, International Working Group for the Diabetic Foot.

process for applying a search strategy was employed.[24] Step 1 was carried out in consultation with a research librarian and involved a broad search on Medline (EBSCO) to identify key search terms. This is described elsewhere.[22] Search terms were associated with the concepts of DFUs and diabetes-related foot screening, and selection was informed by previous research, the principles of screening and the authors' clinical knowledge. Boolean operators AND, OR and proximity operators were used to combine search terms. Step 2 involved using the identified key words on the Scopus, ScienceDirect and EMBASE databases. Key words and search terms were adapted to suit the relevant databases. Step 3 involved a search of the reference lists of the selected studies to identify any additional relevant studies. In addition, a web search was conducted on "Google" and "Google Scholar". Full search strategies, dates conducted and number of results can be found in online supplemental file 2.

Eligibility criteria

Eligible articles were those published from 1 January 2000 to 30 June 2023, and in English. Professional stakeholders were consulted to inform inclusion criteria, which as outlined in table 1, depended on the principle of screening being addressed, and the corresponding research question. Studies had to include people with a diabetes diagnosis. For studies reporting on the importance of the condition, participants had to have a history of DFUs and not be grouped with those who had other diabetes-related lower extremity complications. For studies reporting on the effectiveness of DFU prevention interventions, studies reporting secondary prevention of DFUs or where those with and without a history of ulceration were grouped together and could not be separated were excluded. Studies reporting on reliability of screening test, had to include tests recommended by the IWGDF. Rationale for these is outlined elsewhere.[22]

Study selection

Identified studies were imported into the bibliographic reference manager, Mendeley, and duplicates and triplicates were removed. The online tool Covidence (www.covidence.org) was used for screening against eligibility criteria. Title and abstract screening were carried out by two researchers. The adaptations to inclusion and exclusion criteria (see online supplemental file 2) were added following title and abstract screening. Full-text screening was carried out on all articles by JAP, and 10% were screened by a second reviewer. All screening was carried out independently, and disagreements were resolved by consensus.

Data extraction

A data-charting form was developed in Microsoft Excel by the research team. As this study involved mapping the evidence to principles of screening, data extraction headings differed depending on the research question being answered. Data extraction headings, and their operationalisation, are available in online supplemental file 2. The form was piloted on three full-text articles for each category by one reviewer. The same reviewer extracted data from all included articles.

Synthesis of results

A narrative synthesis approach was used to report the information from the included studies. As the aim was to map and evaluate the evidence on DFUs against the principles of screening, findings from studies were not aggregated. In line with Arksey and O'Malley and the Joanna Briggs Institute for scoping reviews, a risk of bias assessment was not conducted.[20 24]

Patient and public involvement

None.

RESULTS

Results are presented in line with the PRISMA-ScR. As outlined in figure 1, after removal of duplicates, 1033 articles were identified as potentially relevant. On title, abstract and full-text screening, 45 were selected for inclusion. One additional article was included after a Google search. The characteristics of all included studies are summarised in online supplemental tables 1–8.

Category 1: the condition

Research question: are DFUs an important health problem?

To ascertain the impact of DFUs, we identified articles reporting on DFU incidence, prevalence and their effect on mortality and quality of life. As outlined in online supplemental table 1, reported incidence ranged from 0.15% to 8.8% depending on study design and setting, inclusion criteria, methods of data collection, length of follow up and presence of other microvascular complications.[25–36] In the community setting, reported incidences were 0.42%, 0.34%–1.08%, 2.2% and 2.6%.[25 27 32 36] Higher incidences were seen where community and hospital-based patients were grouped together,[25] and where patients with a history of ulceration were included.[27] In the outpatient hospital setting incidence ranged from 0.15% to 2.8%.[25 26 29–31 33] One study found ulcer incidence increased as individuals developed retinopathy and nephropathy.[30] One study found that incidence decreased over time, which may be because of faster access to foot protection services.[31]

We identified five systematic reviews reporting on prevalence of DFUs in the Arab world,[37] Ethiopia,[38] Africa,[39] Australia[40] and globally[41] (see online supplemental table 2). Reported pooled global prevalence was 6.3% (95% CI 5.4% to 7.3%), with North America having a prevalence of 13.0% (95% CI 10.0% to 15.9%), Oceania 3.0% (95% CI 0.9% to 5.0%), Africa 7.2% (95% CI 5.1% to 9.3%), Asia 5.5% (95% CI 4.6% to 6.4%) and Europe 5.1% (95% CI 4.1% to 6.0%). In

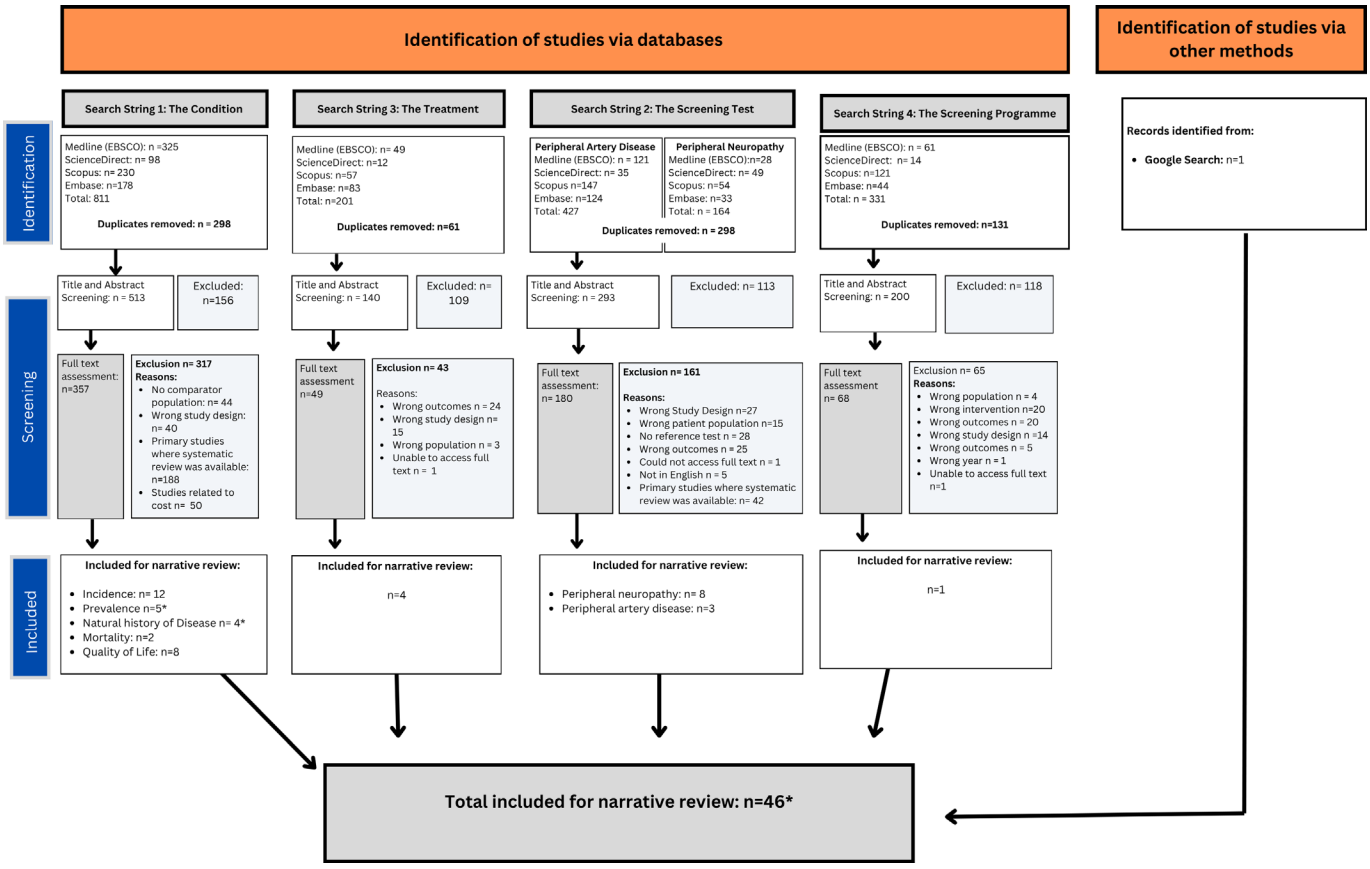

Figure 1 PRISMA fow diagram. *One study reported on both prevalence and natural history of disease. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Africa and Ethiopia, the prevalence was higher than those reported by Zhang *et al*[41] with the pooled prevalence in Ethiopia reported as 12.98% (95% CI 7.81% to 18.15%) and in Africa as 13.0% (95% CI 10.5% to 15.8%).[38 39] In Australia, three studies reported on DFU prevalence, two of which had a high risk of bias and one with a moderate risk of bias. Reported prevalence was 1.2%–1.5% in community settings, and 3.5% in hospital-based settings. In their global systematic review, Zhang *et al*[41] explored prevalence of DFUs by setting and reported highest prevalence in hospital-based settings (7.1%), followed by public health centres (5.6%), population-based studies (4.6%) and community settings (2.9%). Finally, all studies found that DFUs were more prevalent in males, those with type 2 diabetes, longer diabetes duration and with complications including retinopathy and nephropathy.

DFUs are associated with an increased risk of all-cause mortality when compared with those with diabetes but who have never experienced a DFU.[42 43] As outlined in online supplemental table 3, Brownrigg *et al*[43] reported a pooled relative risk of 1.89 (95% CI 1.60 to 2.23), and in their updated version, Saluja *et al* reported a pooled relative risk of 2.45[42] (95% CI 1.85 to 2.85) suggesting the risk of death has increased over time. Eight studies (See online supplemental table 4) reported poorer quality of life in those with DFUs compared with those without.[44–51] The greatest differences were seen in physical functioning and role limitations caused by physical limitations.[44 45 47 48] When compared with those without DFUs, patients with DFUs typically had more hospital stay days,[48] reported statistically significant poorer ability in using stairs and walking distance and speed[44] and higher levels of anxiety and depression.[50]

Research question: is the natural history of DFUs clearly understood?

We identified four systematic reviews reporting on risk factors for DFU development in those with no history of ulceration,[52 53] with two including meta-analysis (see online supplemental table 5).[38 54] Most common risk factors for ulceration were neuropathy, peripheral artery disease, longer diabetes duration and the presence of microvascular complications nephropathy and retinopathy.[38 52–54] One meta-analysis reported an inability to feel a 10g monofilament (OR 3.184, 95% CI 2.654 to 3.82), at least one absent pedal pulse (OR 1.968, 95% CI 1.624 to 2.386) and a longer diabetes duration (OR 1.024, 95% CI 1.011 to 1.036) were associated with a greater risk of DFU development.[54] Another meta-analysis including studies conducted in Ethiopia reported living rurally (OR 2.72, 95% CI 1.84 to 4.01), having callus (OR 12.67, 95% CI 6.47 to 24.79)

and a BMI≥24.5 kg/m^2 (OR 2.68, 95% CI 1.58 to 4.56) increased a person's risk of developing a DFU. Whereas shorter diabetes duration and younger age decreased a person's risk.[38]

Category 2: the treatment

Research question: are there effective interventions for those identified as at risk, with evidence that intervention at a presymptomatic phase leads to better outcomes

We identified four systematic reviews,[55] three of which were published by the IWGDF.[56–58] All reviews included studies where participants were at risk for recurrent ulcers and for first ever DFUs, however, only results relating to prevention of first ever DFU were extracted for this scoping review. As outlined in online supplemental table 6, few primary studies reported on interventions for primary prevention, and all found there was insufficient evidence to the support the effectiveness of interventions for primary DFU prevention.

Category 3: the screening test

Research question: are the screening test(s) for risk factors for DFUs safe, simple, reliable, validated and acceptable to the population?

We identified three articles (see online supplemental table 7) evaluating screening tests for peripheral artery disease, including one systematic review[59] and two observational articles.[60 61] The observational studies reported on pulse palpation and the systematic review reported on the Doppler waveform. Results indicated pulse palpation was prone to a high false-positive rate, poor specificity and relatively poor accuracy.[60] However, the cut-off for peripheral artery disease using the reference test, colour duplex ultrasound, differed between both studies.[60 61] Regarding Doppler waveform analysis, the systematic review reported that sensitivity and specificity ranged from 69% to 100% and 66% to 92.86%, respectively. They also used positive likelihood ratio (PLR) and negative likelihood ratio (NLR) as primary endpoints, reporting a NLR of 0.09-0.28, and a PLR 3 to 13. In addition, each of the included studies within the systematic review (n=4) used different cut-off points to diagnose peripheral artery disease. In addition, although each study used colour duplex ultrasound as the reference test, only three used the same cut-off point for diagnosis.[59] Furthermore, when sensitivity was explored by level of arterial stenosis, lowest sensitivities were found in the least severe disease groups (>50% to 74% stenosis), suggesting that Doppler waveform may not be a suitable diagnostic tool in the early or less severe stages of peripheral artery disease.[59]

Eight articles (see online supplemental table 8) evaluated screening tests for peripheral neuropathy, including three systematic reviews evaluating the 10g monofilament,[62–64] six observational studies evaluating the 128htz tuning fork[65–69] and four observational studies evaluating the vibratip.[67–69] No study included the biothesiometer as an index test. The biothesiometer and nerve conduction studies were the most used reference tests, and the 10g monofilament and tuning fork were used in one study evaluating the vibratip.[69]

Results from the systematic reviews suggest that the reliability of the 10g monofilament vary depending on the number of sites tested and cut-off points for diagnosis. There was also a lack of consensus in application of the monofilament, number of sites tested, study populations, use of reference tests and threshold for neuropathy diagnosis.[62–64] In addition, quality of included studies was low. In their review of 16 primary studies, Feng *et al*[62] reported large variations in sensitivity (57%–93%), specificity (75%–100%), PPV (84%–100%) and NPV (36%–94%) when compared against the gold standard nerve conduction studies. However, they did find the most sensitive method involved testing the third and fifth metatarsal heads on each foot with a positive test defined as the inability to sense either site, resulting in a sensitivity of 93% (95% CI 77% to 99%). Following their review of three studies, Dros *et al* reported sensitivity ranged from 41% to 93%, and specificity ranged from 68% to 100%. They also found differences in the number of sites tested and cut-off points for diagnosis among included studies. The most recent systematic review and meta-analysis by Wang et al. (2017), of nineteen primary studies also found variability in a number of sites tested and threshold for diagnosis.[64] However, different to the two previous articles, the authors enrolled a hierarchical summary receiver operating characteristic (HSROC) model for pooled analyses for eight of the identified studies, allowing for pooled sensitivity and specificity while considering the threshold effect. When compared with nerve conduction studies, they found the pooled sensitivity and specificity were 0.53 and 0.88, and the pooled PLR and NLR values were 4.56 and 0.53.

For the 128htz tuning fork, there was a lack of consensus among included studies on the reference test, the number of test sites and threshold for diagnosis. The biothesiometer was used as the reference test in four studies,[65–68] and the 10g monofilament was used in one.[69] In addition, where the biothesiometer was used, there was also a lack of consensus on test sites and diagnosis threshold. For studies where the biothesiometer was used, sensitivity and specificity ranged from 40% to 69% and 90% to 100%, respectively. The lower sensitivity of 40% was seen in a study where the cut-off for the tuning fork was the patient stating they felt a vibration sensation on the medial malleolus when the device was inactive and reported being unable to feel ≥20V on one site"the pulp of the hallux" with the biothesiometer.[67] Whereas the higher sensitivity of 69% was reported where the tuning fork was applied to the hallux and medial malleolus, and the cut-off point was ≥1 insensate site and being unable to feel ≥ 25 tested at the "pulp of the hallux".[68] We identified three studies reporting on the reliability of the vibratip diagnosing peripheral neuropathy, with two using the biothesiometer as the reference test[67 68] and one using the 10g monofilament.[69] Sensitivity ranged

from 70.5% to 92%, and specificity ranged from 82% to 94%. For studies involving the biothesiometer, the same test site ("the pulp of the hallux") was used but there were different cut off limits (inability to feel ≥20V vs ≥25V) for neuropathy diagnosis, and with different cut off points resulting in different sensitivities and specificities.

Category 4: the screening programme

Research question: is there evidence that diabetes-related foot screening is cost-effective?

Research question: Is there evidence that a diabetes-related foot screening programme would be clinically, socially and ethically acceptable to screening participants, health professionals and society?

We did not find any studies reporting on the cost-effectiveness, clinical, ethical or social acceptability of foot screening in preventing DFUs. However, we identified one systematic review reporting on the effectiveness of screening programmes.[16] It found that where structured screening had been introduced into a population at high risk for ulceration, it led to reduced amputations and hospitalisations. They did not report on whether introduction led to a reduction in DFUs. However, they stated both the evidence and the applicability of included studies to the general population was weak.[16]

DISCUSSION

This scoping review identifies existing evidence on screening for the at-risk foot, mapping the evidence to international screening principles. There is overwhelming evidence of the importance of DFUs in terms of morbidity and mortality providing a clear rationale for potential benefit of providing diabetes-related foot screening within an organised screening programme. However, evidence is lacking on the effectiveness and cost-effectiveness of these programmes. In addition, there is a lack of consensus on cut-off points for screening tests used to detect peripheral neuropathy and peripheral artery disease, two significant risk factors for DFU development. Here, we discuss the scoping review findings, how they related to the principles of screening and what further research is needed. Table 2 provides a summary of points outlined in the discussion and how the evidence aligns with arguments for and against the principles of screening.

First, Wilson and Jungner state '*to be considered an important problem, a disease need not necessarily have a high degree of prevalence, though that would be a usual requirement'*. In this review, we found that the reported global prevalence of DFUs is 6.3%, with some regions having higher prevalence than others, and prevalence being higher in the hospital setting.[38 39 41] For comparison, the global prevalence of vision-threatening diabetes-related retinopathy is estimated to be slightly lower at 6.17%, and the global prevalence for all diabetes-related retinopathies is 22.27%.[70] Although not explored in the current study, the prevalence of diabetes-related peripheral neuropathy and peripheral artery disease, significant risk factors for ulceration, is estimated to be between 6% to 51% for neuropathy and 20% to 30% for peripheral artery disease. Both diabetes-related foot ulceration, which is a limb threatening condition, and vision-threatening diabetes-related retinopathy have similar prevalence, as does the at-risk foot (i.e., those with neuropathy and/or peripheral artery disease) and diabetes-related retinopathy. Annual screening, at a minimum, for risk factors for both conditions is recommended internationally. However, how they are operationalised within health systems differs. We have seen internationally the benefit of structured population diabetes-related retinopathy screening programmes, with retinopathy no longer being the leading cause of blindness in working-age adults in some regions.[71 72] Regarding the incidence of DFUs, we found no changes in incidence rates, however, no study was nationally representative, and no study accounted for the increasing prevalence of diabetes. Therefore, although incidence rates may stay the same, the number of people experiencing DFUs may be increasing because of the continuous rise of people being diagnosed with diabetes. However, it is important to note that where more structured care was introduced, one study did find that over time incidence decreased.[31] Leading to Wilson and Jungner's next point, that '*the importance of the problem needs to be considered from the point of view both of the individual and of the community'*. We found that DFUs are associated with a two-fold increased risk of mortality, and poorer quality of life, especially in areas relating to physical limitations, role limitations and social functioning.

Next, Wilson and Jungner state that '*in order to usefully detect and treat disease at an early stage there must clearly be a reasonable period in the natural history of the condition during which symptoms are either not present or at any rate not clamant'*. As outlined within the current study, there are specific risk factors that increase a person's risk of developing a DFU. Their role has been well described throughout the literature, with the term 'stairways to amputation' often being used to describe the stepwise process from developing diabetes, risk factors and ultimately ulceration and amputation.[73] Furthermore, their role towards DFUs is reflected in the development of internationally agreed risk stratification systems, which use these risk factors to indicate a person's level of risk (ie, low, moderate, high) of developing a DFU and provide recommendations on referral pathways to appropriate prevention services.[74] In terms of understanding the natural history, and progression from latent to early symptomatic stages and eventually declared disease, we know those identified as being high-risk have an 83-fold increased risk of developing an ulceration, those at moderate risk have a 6-fold increased risk, and those at low-risk have a 99.7% (95% CI 99.6% to 99.8%) chance of remaining 'ulcer free' after 2.4 years follow-up,[75] thus providing an insight into the absolute risk of developing a DFU once screened and risk stratified. In addition, a recent study found that after 2 years follow-up, 5.1% (95% CI 4.7% to 5.6%) of people

Table 2 Mapping arguments for and against diabetes-related foot screening, against the Wilson and Jungner principles of screening

Principles of screening	Arguments for targeted population screening	Arguments against targeted population screening
The condition should be an important health problem	Diabetes-related foot ulcers are associated with increased risk of death, poorer quality of life and a natural history of disease that is clearly defined throughout the literature, with specific risk factors leading to increased risk of ulceration. In addition, once screened patients can be risk stratified, with the level of care required depending on the level of risk of ulceration. Although not included within this review, evidence suggests that diabetes-related foot ulcers are associated with increased costs to health system, with the costs continuously increasing.	Although this review reports on the incidence of diabetes-related foot ulcers, it does not show whether incidence is increasing over time or with an increase in diabetes prevalence.
There should be an accepted treatment for patients with recognised disease	The need for a multidisciplinary approach towards treatment and management of the at-risk foot, and active foot disease is widely recognised within international guidelines.	The level and quality of evidence on the effectiveness of treatment strategies is poor. Increased research focus is needed on strategies for primary prevention.
Facilities for diagnosis and treatment should be available	Currently, diabetes-related foot screening is carried out within the primary care setting in many health systems.	Where not already established, facilities for treatment may be expensive to establish. There is little evidence to inform policy-makers on the costs associated.
There should be a recognisable latent or early symptomatic stage	Risk factors for ulceration are clearly defined, and level of risk can be classified to inform treatment and management strategies.	None identified.
There should be a suitable test or examination	There is an internationally agreed consensus on screening tests for identifying peripheral neuropathy and peripheral vascular disease by trained healthcare professionals.	For peripheral neuropathy, there is a lack of consensus on number the sites that should be tested and the number of times they should be tested. In addition, screening tests explored during this review are prone to high false positive rates which may lead to increased anxiety among screened individuals, and increased burden on health services as there is a risk of unnecessary referrals to foot protection services.
The test should be acceptable to the population	There are no reported consequences of screening tests.	There are no available studies that have explored patient and healthcare professional's perceptions of screening tests.
The natural history of the condition, including development from latent to declared disease, should be adequately understood	The pathophysiology and risk factors that lead to ulceration is clearly defined within the literature.	None identified.
There should be an agreed policy on whom to treat as patients	Once risk factors have been identified, guidelines (national and international) clearly define which patients require treatment and management for both the at-risk foot and active foot disease.	Health systems will need to make decision relevant to their local context and availability of resources.
The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole	Screening has shown to be effective in reducing amputation rates when carried out as part of a structured management pathway.	There is insufficient evidence to support the effectiveness and cost-effectiveness of a structured diabetes-related foot screening programme in reducing diabetes-related foot ulcer incidence.
Case finding should be a continuing process and not a 'once for all' project	There is international consensus on the importance of annual diabetes-related foot screening for the at-risk foot in diabetes.	None identified.

classified as low risk at their first visit had progressed to moderate risk, and the cumulative incidence of ulceration and amputation and death among the low-risk cohort of people with diabetes was 0.4% (95% CI 0.3% to 0.6%) and 0.1% (95% CI 0.1% to 0.2%).[76] DFUs are associated with increased risk of death, significant poorer quality of life and evidence suggests their prevalence is on par with diabetes-related retinopathy, a complication of diabetes that has long-since been recognised as a disease that should sit within an organised screening programme.

Third, Wilson and Jungner state '*Of all the criteria that a screening test should fulfil, the ability to treat the condition adequately, when discovered, is perhaps the most important*' while also adhering to the rule of '*do no harm*'. We found the level and quality of evidence to be low regarding the effectiveness of primary prevention interventions. However, this may be a consequence of poor study design in primary studies,[57] and possibly of systematic reviews.[77] In addition, DFU prevention is an under-researched area, whereby for every thirty-six articles published on wound healing, only one is published on prevention and so adding to the lack of evidence surrounding treatment and/or management of the at-risk foot.[78] However, although there is uncertainty on the effectiveness of DFU prevention strategies, there is international agreement on who to treat as patients, aligning with Wilson and Jungner's next principle that '*There should be an agreed policy on whom to treat as patients*'. International guidelines, developed in line with the best available evidence provide recommendations on whom to treat and in which setting they should be treated.[74] Many health systems have adopted these recommendations and implemented them into policy recommendations.[8 79 80] For those with an active DFU, the role of a multi-disciplinary approach is well recognised[81–83], and is reflected in diabetes related foot guidelines internationally.[8 80 84]

Fourth, a key difference between screening and diagnostic tests, is that screening involves attempts to detect asymptomatic disease to differentiate those at high risk from those at low risk of developing a disease, whereas diagnostic tests establish a diagnosis of the disease or condition under investigation. To accurately identify a person at increased risk for the condition being screened for, a test should have a high degree of sensitivity. Regarding screening tests for peripheral artery disease and peripheral neuropathy, we found variability in terms of sensitivity, specificity and application of screening tests and cut-off points for diagnosis for both index tests and reference tests. Others have highlighted the need for agreed consensus on test sites and cut-off points to identify these risk factors,[85] and we argue the same based on our results especially if foot screening is to be considered for introduction into an organised screening programme. Although the screening tests included within this review are recommended for use internationally, based on a review using the Grading of Recommendations Assessment, Development and Evaluation evidence-to-decision framework and have been shown to predict those at risk for ulceration,[86] it is important to consider these are currently used in settings by medical practitioners trained in disease detection and management (eg, primary care physicians or podiatrists) and may not be suitable, given the current level of evidence, for an organised screening programme where screening is typically carried out by trained technicians. On one hand, false positives may lead to an increased burden on finite health resources and unnecessary psychological consequences if individuals unnecessarily undergo further diagnostic tests and may endure the anxiety accompanied by testing positive. On another hand, false negatives will mean screening may miss a large proportion of those who are at risk and require further testing and care. These potential harms and risks would need to be considered by those involved in decision-making around screening programmes.

Fifth, evidence relating to Wilson and Jungner's principles around the cost of screening programmes, and their effectiveness is lacking. This review did not identify any studies that met the inclusion criteria reporting on the effectiveness, cost-effectiveness, clinical, ethical, or social acceptability of diabetes related foot screening in preventing DFUs. A previous systematic review also found no evidence on the effect of screening for preventing a diabetes related foot ulceration.[4] However, these may be down to study designs and study endpoints, as studies appear to use lower extremity amputations as study endpoints. For example, two studies found that after implementing a lower extremity disease management program consisting of screening and treatment protocols for people with diabetes, the incidence of amputations, number of foot-related hospitalisations and average in-patient length of stay all decreased suggesting screening combined with a diabetes related foot management pathway is effective in reducing incidences of amputations.[87 88]

Finally, regarding Wilson and Jungner's principle '*Case-finding should be a continuing process and not a 'once and for all' project*', we did not set out to explore the evidence on this. However, it is internationally agreed that people with diabetes should be screened at least annually, suggesting the importance of a continuous cycle of screening.[4 74] Where combined with a person-centred integrated model of care for surveillance of those at risk, screening has been shown to reduce incidence of ulceration and subsequent amputation.

Strengths and limitations

This study systematically evaluates and maps the evidence surrounding DFUs and screening for risk factors, providing a comprehensive overview of potential risks and benefits of introducing diabetes-related foot screening into a targeted and organised screening programme.

It highlights where evidence surrounding DFUs meets these principles while also highlighting where further evidence may be needed to inform relevant policymakers on the potential harms and benefits of such programmes. However, this study has several limitations.

First, the primary aim of screening is to prevent DFUs, and subsequent amputation. Therefore, when evaluating the potential role of carrying out diabetes related foot screening in the public health context, it is important to consider the impact of other diabetes related foot complications (e.g., Charcot Neuro-oesto-arthropathy, infections) and lower extremity amputations, and this review only included studies reporting on DFUs. In terms of methodological limitations, first, due to the nature of scoping reviews, we did not assess publication bias or study quality, and so there is an increased risk that the quality of evidence may be low. Second, while efforts were made to include all relevant studies, some may have been missed due to the electronic databases used, limiting the inclusion criteria to systematic reviews when addressing certain principles of screening, and the decision to only include studies published in English. Third, only one reviewer extracted the data from all included studies and so there was an increased risk of missing data and introducing bias. However, the development of a data extraction tool that was piloted in studies helped eliminate this risk. In addition, co-authors were consulted throughout the data extraction process, if any queries arose. Fourth, we acknowledge there have been deviations from what was specified in the protocol. However, it is recognised that scoping reviews are often an iterative process and researchers need to engage with each stage of the review in a reflexive way.[20] This was the case in the current review, and we have outlined in online supplemental file 2 what the deviations were, and the rationale for them. Finally, although this review found specific areas where further evidence may be needed before diabetes-related foot screening can be introduced into an organised screening programme, it is important to note that in line with a scoping review methodology, this review only maps the evidence to the principles of screening. It did not explore the potential budget, organisational or societal impact that could arise from a targeted diabetes-related foot screening programme, but we argue that this is something that should be done on a health system level. Ideally, by those involved in decision-making around screening programmes, with input from multidisciplinary research, clinical and public bodies, so they can systematically weigh up all possible benefits and harms that would arise within the context of their own health system.

Research and policy implications

In the context of the growing burden of non-communicable disease, there is increased interest in population-wide screening for these diseases and their complications. However, such programmes are significant undertakings requiring substantial resources (including financial, human and infrastructure) and engagement from multiple organisations both within and beyond the health system to maximise potential benefits and minimise potential harms that could arise.[89] When making decisions around the introduction of population screening for a disease or condition, relevant policy-makers are typically guided by available evidence and how it relates to specific screening principles. This includes any potential harms or controversies that could arise from such programmes. Regarding DFUs, there is overwhelming evidence that they are an important health condition, with population-wide targeted screening being a potential method of identifying the at-risk foot to reduce their burden. However, there is little published evidence on the effectiveness of population-wide diabetes-related foot screening programmes. From a research perspective, there is a need for high-quality studies investigating the effectiveness of interventions on primary prevention for DFUs and effectiveness of diabetes-related foot screening programmes, including any barriers or facilitators of such programmes.

CONCLUSION

This is the first study to evaluate and map the evidence surrounding DFUs, and screening for risk factors, against principles of screening. While there is evidence to suggest that DFUs, and screening for risk factors, meet many of the principles of screening, our findings suggest that further evidence is needed to weigh up the potential benefits and harms of an organised population-wide diabetes-related foot screening programme before policymakers may be willing to invest in such programmes.

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