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ORIGINAL DATA

A Critical Evaluation of Existing Diabetic Foot Screening Guidelines

Cynthia Formosa[1,2], Alfred Gatt[1,2], and Nachiappan Chockalingam[1,2]

[1] *Faculty of Health Sciences, University of Malta, Tal-Qroqq, Msida, MSD 2080, Malta.* [2] *Faculty of Health Sciences, Staffordshire University, UK. Address correspondence to: Cynthia Formosa, e-mail: cynthia.formosa@um.edu.mt*

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■ Abstract

AIM: To evaluate critically the current guidelines for foot screening in patients with diabetes, and to examine their relevance in terms of advancement in clinical practice, improvement in technology, and change in socio-cultural structure. **METHODS**: A structured literature search was conducted in Pubmed/Medline, CINAHL, Cochrane Register of Controlled Trials, and Google between January 2011 and January 2015 using the keywords '(Diabetes) AND (Foot Screening) AND (Guidelines)'. **RESULTS**: Ten complete diabetes foot screening guidelines were identified and selected for analysis. Six of them included the full-process guidelines recommended by the International Diabetes Federation. Evaluation of the existing diabetes foot screening guidelines showed substantial variability in terms of different evidence-based methods and grading systems to achieve targets, making it difficult to compare the guidelines. In some of the guidelines, it is unclear how the authors have derived the recommendations, i.e. on which study results they are based, making it difficult for the users to understand them. **CONCLUSIONS**: Limitations of currently available guidelines and lack of evidence on which the guidelines are based are responsible for the current gaps between guidelines, standard clinical practice, and development of complications. For the development of standard recommendations and everyday clinical practice, it will be necessary to pay *m*ore attention to both the limitations of guidelines and the underlying evidence.

Keywords: diabetic foot · screening · guideline · diabetes complication · primary care

1. Introduction

Diabetes contributes to approximately 80% of the 120,000 non-traumatic amputations performed yearly in the US. While some studies reported that every 20 seconds a limb is amputated somewhere in the world, others highlighted that the implementation of a structured diabetes foot screening program could achieve a 75% reduction in amputation rates [1].

Screening for diabetes involves the identification of asymptomatic individuals who are at high risk of developing the disease or its complications through appropriate screening tests. Guidelines are an essential component of achieving quality in the care of diabetes [2]. These guidelines are devised to define standards for care. They should use evidence-based interventions to provide health care professionals, policy makers, administrators, and people living with diabetes with a set of recommendations for prevention, diagnosis, and management of type 2 diabetes and its complications. A number of studies have demonstrated that patient outcomes improve when evidence-based guideline recommendations are applied in clinical practice [3].

Serious diabetic foot complications can be delayed and even prevented with appropriate, careful, and reliable screening and management standards. Several countries and organizations such as WHO and IDF have made suggestions with the aim of reducing the rate of amputations by up to 50%. It is speculated that implementing a foot screening and protection program for patients at

Abbreviations:

ABI	ankle brachial index
ABPI	ankle brachial pressure index
ADA	American Diabetes Association
AHCPR	Agency for Health Care Policy and Research
CDA	Canadian Diabetes Association
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DDG	Deutsche Diabetes Gesellschaft
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
ICSI	Institute for Clinical Systems Improvement
IDF	Interntional Diabetes Federation
IWGDF	International Working Group on the Diabetic Foot
NG19	National Guideline 19
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NZSSD	New Zealand Society for the Study of Diabetes
PAD	peripheral arterial disease
PPG	photoplethysmography
QUADAS	Quality Assessment Tool for Diagnostic Accuracy Studies
RCT	randomized controlled trial
SIGN	Scottish Intercollegiate Guidelines Network
TCPO2	transcutaneous oxygen
WHO	World Health Organization

risk of ulceration may reduce both morbidity and cost [4]. However, a diabetic foot screening tool needs to be evidence-based and relevant to the characteristics of the target population [5]. Despite the advancement in technology, biomechanical modeling, and other treatment innovations, the refinement of current foot screening guidelines is paramount to prevent amputations and to preserve limb function in high-risk patients.

During the last decade, a number of diabetes foot screening guidelines and expert consensus documents have been formulated by various organizations and experts in the field. It is normally expected that effective implementation of guidelines requires 3 interrelated aspects:

1. An explicit assessment of the quality of the available medical evidence.
2. Application of clinical judgment in the care of individual patients.
3. Elicitation and acceptance of patient preferences via shared decision-making.

However, most of the current guidelines address only the first of these 3 aspects (quality of evidence). In this regard, it is important to note that effective implementation requires the tailoring of guidelines to the individual patient because "*evidence alone is never sufficient to make a clinical decision*." [6]. Except a few examples, current guidelines do not address patient preferences or include tools for shared decision-making. Although patient preferences have not historically been at the heart of evidence-based medicine [7], an emerging consensus is that patient preferences should be included [8], particularly when evidence is weak or incomplete.

2. Justification for the study

The practice of diabetes care is still not optimal, and it is far from being consistent both within and between countries [2]. The high number of different and partly contradictory recommendations and guidelines existing today, and the discrepancies between different organizations and countries, may cause confusion on the part of both practicing health care professionals and organizations which attempt to develop local clinical guidelines. Further confusion in clinical care is generated by the high number of proposed diabetes foot screening methods that may be useful in the identification of high-risk patients [9]. On the other hand, changes in the pattern of disease progression and outcome, environment, and anthropometry, in combination with new developments in technology for both measurement and treatment advocate for more accurate and refined diabetes foot screening guidelines.

The aim of this study was to evaluate critically the existing foot screening guidelines, with a view to examining their completeness in terms of advancement in clinical practice, improvements in technology, and changes in socio-cultural structure. This should result in the improvement of existing screening guidelines and eventually save limbs. Whilst analyzing the similarities and differences within various guidelines, this report aims particularly to highlight the deficiencies in guidelines. It should help to identify aspects for which there is sufficient agreement, highlight specific limitations in present guidelines, and address future changes and research which may support the development of more accurate and reliable guidelines.

3. Methods

3.1 Protocol

In this study, the following protocol was adopted, as recommended by the IDF [2]:

Table 1. List of guidelines for diabetic foot screening included in the study

Guideline	Guideline provider	Year	Reference to guideline	Grading system used	Reference to grading system
National evidence-based guideline	National Health and Medical Research Council (NHMRC), Australia	2011	NHMRC, 2011 [9]	Own (NHMRC)	NHMRC, 2011, pp. 10-12 [9]
Clinical practice guidelines for the prevention and management of diabetes in Canada	Canadian Diabetes Association (CDA), Canada	2013	CDA, 2013 [10]	Own (CDA)	CDA, 2013 [11]
Diabetic foot problems: prevention and management. NICE guideline NG19	National Institute for Health and Care Excellence (NICE), England and Wales	2014, updated 2016	NICE, 2014 [12]	Own (NICE). Adapted from: US Agency for Healthcare Policy and Research Classification and Clinical Outcomes Group of the NHS Executive (1996)	NICE, 2005 [13]
Clinical practice guidelines: diabetic foot care	Deutsche Diabetes Gesellschaft (DDG), Germany	2014	DDG, 2014 [14]	According to: Agency for Health Care Policy and Research (AHCPR), 1992, and SIGN, 1996	DDG, 2006 [15]
Management of diabetes: a national clinical guide	Scottish Intercollegiate Guidelines Network (SIGN), Scotland	2013	SIGN, 2014, pp. 104 ff [16]	Own (SIGN)	SIGN, 2014, p. 1 [16]
Diagnosis and management of type 2 diabetes mellitus in adults	Institute for Clinical Systems Improvement (ICSI), USA	2014	ICSI, 1014 [17]	Grading of Recommendations Assessment, Development and Evaluation (GRADE) system	Kavanagh, 2009 [18]
Foot Screening Guidelines	American Diabetes Association (ADA), USA	2014, updated 2016	ADA, 2014, S47-S49 [19]	Own (ADA)	ADA, 2014, S15 [19]
IWGDF Guidance on the management and prevention of foot problems in diabetes	International Working Group on the Diabetic Foot (IWGDF)	2015	IWGDF, 2015 [20]; Bakker *et al.*, 2011 [21] (short version of the guideline which is based on 7 reviews)*	GRADE, SIGN*	Kavanagh (GRADE), 2009 [18], SIGN, 2014, p. 1 [16].
Global guideline for type 2 diabetes	International Diabetes Federation (IDF)	2012, updated 2015	IDF, 2012 [29]	Own (IDF)	IDF, 2003 [2]
Diabetes Foot Screening and Risk Stratification Tool	New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group	2014	http://www.nzssd.org.nz/healthprofs/14%2007%20Primary%20diabetes%20foot%20screening%20and%20referral%20pathways.pdf	Guideline and grading adopted from SIGN risk stratification system	

Legend: * Guideline based on 7 systematic reviews created by IWGDF working groups. The reviews are related to different topics: 1) prevention [22], 2) footwear [23], 3) PAD diagnosis [24], 4) PAD prognosis [25], 5) PAD therapy [26], 6) infection [27], and 7) wound healing [28]. Each group applied its own grading system, usually either the GRADE or the SIGN system. See http://iwgdf.org/guidelines-2/systematic-reviews/. *Abbreviations*: GRADE – Grading of Recommendations Assessment, Development, and Evaluation, PAD – peripheral artery disease.

1. Development of the research question. The proposed question for this study was as follows: Are the currently available foot screening guidelines sufficient to identify reliably patients at risk of amputations?
2. Use of the full-process diabetes foot screening guidelines, as proposed by the IDF, as reference guideline [2].
3. Search for other guidelines relating to the research question.
4. Search for recent evidence in reviews, meta-analyses, and major research studies.
5. Evaluation of the quality and relevance of the available evidence and guidelines.
6. Comparison of relevant guidelines in relation to their ability in identifying patients at risk and preventing severe diabetes foot complications.

3.2 Search strategy and guidelines included

Six full-process guidelines were automatically included in the study. These guidelines involved a complete and systematic development of the clinical questions addressed, and provided recommendations supported by scientific and formal evidence, even if at different degrees of quality.

After including the six guidelines, searches were performed to identify other possible guidelines and research evidence that are available for diabetes foot screening protocols. All searches were limited to the English language. The following electronic databases were retrieved between January 2011 and January 2015: Pubmed/Medline, CINAHL, Cochrane Register of Controlled Trials, and Google Scholar. The search term '(Diabetes) AND (Foot Screening) AND (Guidelines)' was used, and studies involving adult human participants living with diabetes were pre-selected. Guidelines and research evidence were considered for inclusion if they addressed aspects of diabetes foot screening, management, prevention, and education relating to the foot care of people with type 2 diabetes. The titles and abstracts of the articles containing the guidelines identified by the search strategy were screened by one author (CF) to identify potentially eligible articles. If it was unclear from the title or abstract whether an article should be included, the full-text article was retrieved, and a consensus between the three authors (CF, AG, NC) was induced.

The search for full-text articles and guidelines resulted in the following outcome:

- Sixty-eight documents were found in Pubmed and 4 documents in Cochrane Register of Controlled Trials. However, when manually searched and evaluated there was no relevant citations amongst these articles which reported diabetes foot screening guidelines. So, these 72 articles were excluded.
- Four relevant diabetes foot screening guidelines were identified by manual search in Google Scholar.
- Six full-process guidelines proposed by the IDF (see section 3.1) were included.

Thus, ten relevant foot screening guidelines were finally included. **Table 1** lists the ten guidelines on foot screening along with the details of the publishing organization, and shows the references to the guidelines and the evidence-grading systems used by the organizations [2, 10-29].

3.3 Evidence-grading

Recommendations included in guidelines are usually based on scientific and clinical evidence, which may result from clinical studies or experience. However, evidence may by be regarded as strong or less strong based on the kind of study it results from. Therefore, ranking/grading systems have been developed to rate the underlying evidence of guidelines. As a rough and general reference scale, evidence may be ranked as follows:

- High: large-scale clinical trials, randomized controlled trials (RCTs), meta-analyses of RCTs
- Medium: non-randomized clinical studies with control group
- Low: case series, clinical experience, expert opinion, and suggestions without verification in large clinical trials

Table 1 also includes references to the grading systems that were used by the guideline providers to rate the underlying evidence on which their recommendations were based. However, it is important to note that there are several rating systems, which use different scales and methods, and that the guideline-providing organizations have applied different systems. Thus, the ratings provided by the organizations are not easily comparable.

3.4 Assessment of guideline relevance and evidence used

Once a guideline was assessed as being relevant, the evidence presented was evaluated according to the usual methodological requirements. Two experienced reviewers evaluated the guidelines independently. Data were extracted into evidence tables by one reviewer (CF) and a second reviewer (AG) checked the extracted data.

Keywords were derived from each guideline for further comparison. These keywords included:

- Neuropathy (sensory, motor, autonomic)
- Peripheral arterial disease
- Foot deformation
- Limited joint mobility
- Patient foot care education
- Multi-disciplinary diabetic foot care service
- Adequate training for healthcare professionals
- Self- monitoring/inspection of feet
- Footwear provision and orthoses
- Frequency of assessment/screening

Table 2. Comparison of evidence-grading schemes

Agency for Health Care Policy and Research (AHCPR)		Scottish Intercollegiate Guidelines Network (SIGN)	
Level of evidence	Description	Level of evidence	Description
I	Evidence obtained from a systematic review of all relevant randomized controlled trials.	1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
II	Evidence obtained from at least one properly-designed randomized controlled trial.	1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
III-1	Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method).	1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomized, cohort studies, case-control studies, or interrupted time series with a control group.	2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.	2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
IV	Evidence obtained from case series, either post-test or pre-test/post-test.	2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
		3	Non-analytic studies, e.g. case reports, case series
		4	Expert opinion

Tables A1-A10 (in the Appendix) include the recommendation for each identified keyword for each organization, and the level of evidence that each guideline is based on, as reported by the organization, if this was available.

4. Results

We first evaluated whether recommendations for the different complications associated with the diabetic foot and relevant screening and care aspects are included in the guidelines.

4.1 Evaluation of the completeness of guidelines

The following aspects to be considered in diabetes foot screening were included in all 10 guideline documents as part of the screening guideline (the tables that show the recommendations by each organization and the level of evidence on which the organization based the proposal are given in parentheses):

- Peripheral neuropathy (**Table A1**)
- Peripheral vascular disease (**Table A2**)
- Inspection and provision of footwear (**Table A3**)
- Foot deformation (**Table A4**)
- Patient foot care education (**Table A5**)
- Frequency of assessment and screening (**Table A6**)

The following aspects of diabetes foot screening were **not** included in all 10 guideline documents:

- Evaluation of limited joint mobility (**Table A7**)
- Training for health care professionals (**Table A8**)
- Self-monitoring and inspection of feet by healthcare personnel (**Table A9**)
- Multi-disciplinary team within a diabetic foot care service for the inspection of diabetic feet (**Table A10**)

The findings indicate that the guidelines vary in their recommendations for screening, and more

importantly, there is little or no evidence for some of the recommendations (see tables and section 4.2). There are some agreements between the guidelines, but also clear differences. In particular, it is obvious that the quality of the underlying evidence used to create the guidelines varies considerably. While some guidelines used controlled trials with or without randomization and/or meta-analyses as evidence, others abstained from providing evidence completely. In this regard, it may be borne in mind that individuals who develop guidelines may employ different methodologies, and that the creation of a guideline may be influenced by the aims, practices, and possibly ideas of the organization or professional body that has commissioned it. These are factors that may be responsible for the present differences.

Another concern relates to the validity of the grading systems applied. The use of different grading systems, the disagreement between the guidelines regarding the grading of the evidence, and the different methods and scales of the grading systems make it difficult to compare the guidelines and to understand the recommendations [30].

The following two examples illustrate the differences between the grading systems (**Table 2**):

- The Scottish Intercollegiate Guidelines Network (SIGN) rated evidence from 1++ (least likely to be biased) to 4 (greatest potential for bias), using a scale of 8 levels. Studies were assessed on the basis of critically appraisal checklists.
- The levels of evidence used by the Australian National Health and Medical Research Council (ANHMRC) were arranged so that they correspond to the methods and designs of the clinical studies.

4.2 Qualitative evaluation of the guidelines – rating of evidence

Peripheral neuropathy. Recommendations for the screening for peripheral neuropathy were included in all 10 foot screening guideline documents, as illustrated in **Table A1**. Recommended screening tests included the 10 g monofilament test in combination with vibration perception testing using a tuning fork or biothesiometer. However, although all guidelines highlighted the importance of screening for peripheral neuropathy to identify the insensate foot, the level of evidence, as assessed by the organizations themselves, supporting this recommendation differed considerably. Whilst some organizations such as the American Diabetes Association (ADA) graded this recommendation as grade B level of evidence [19], other organizations such as the Australian National Health and Medical Research Council (NHMRC) attached grades C or D to the same recommendation, advocating for caution when applying these recommendations [10]. This inconsistency is irritating since the aim of evidence-based guidelines is to improve the value of healthcare by recommending the best screening and treatment modalities to facilitate decision-making and improve care [31]. Inconsistencies among systems for grading the quality of evidence and the strength of recommendations contribute to the degree of non-transparency, and reduce their potential to facilitate critical assessment and improved application.

Peripheral vascular disease. A guideline for the screening for peripheral vascular disease was also included in all 10 foot screening guideline documents, as shown in **Table A2**. All guidelines emphasized the importance of palpation of foot pulses, but the evidence grading for this recommendation (provided by the organizations themselves) is poor in some guidelines. Some organizations such as the ADA assigned only grade C or D level of evidence [19], meaning that the supportive evidence is derived from poorly controlled or uncontrolled studies only, while other organizations such as the National Institute for Health and Care Excellence (NICE) gave an A rating [4], which means that the evidence is based directly on at least one RCT or a meta-analysis of RCTs.

Clinicians need to be attentive to the validity of guidelines that claim to be evidence-based since some guidelines may contain information that has not been critically assessed for evidence quality [30]. **Table A2** shows that some guidelines rely on expert opinion or clinical experience only (e.g. those from the Australian NHMRC, the Canadian Diabetes Association, the Institute for Clinical Systems Improvement, and the ADA) as randomized controlled trials were not available or unreliable because of the nature of the research conducted to date. Guidelines that are based on either poorly controlled or non-controlled studies suggest that these recommendations should be adopted with caution due to the possibility of arterial calcification, as shown in **Table A2** (and discussed in more detail in the next paragraph). Other guideline providers, including the IDF and the New Zealand Guidelines Group, refer to evidence, but it is unclear how the recommendations were derived. Due to the deficit of information on a reliable method to screen for PAD in the high-risk foot new

structured studies and randomized control trials should be conducted to create sufficient evidence.

Ankle-brachial pressure index (ABPI) is recommended as an additional test for the diagnosis of peripheral arterial disease in some of the guidelines analyzed. However, the evidence for this recommendation is controversial. A recent clinical study conducted by our group demonstrated the limitations of ABPI as a diagnosis tool in peripheral arterial disease (PAD) and patients with diabetes mellitus [32]. ABPI thresholds of less than 0.9 and more than 1.3 are highly suggestive of PAD. However, when there is concomitant clinical peripheral neuropathy or a high risk of arterial calcification (Monckberg's sclerosis), the efficiency of ABPI is limited because a falsely elevated ABPI may be generated. Based on these new findings, it is recommended that peripheral arterial disease in people with diabetes should be assessed using both ABPI and Doppler waveform in combination. When the findings from both test modalities do not correlate, then subjects should be monitored or the examination continued. Additional physiological testing could include toe pressure and toe brachial pressure indices to determine whether PAD is actually present. Despite the evidence that Doppler waveform is an important additional test modality for the diagnosis of PAD as ABPI may give false values in calcified arteries, the 10 guidelines analyzed do not refer to Doppler waveform analysis.

Inspection and provision of footwear. Recommendations for the inspection and provision of footwear were included in all 10 foot screening guideline documents, as illustrated in **Table A3**. However, the evidence on the importance of inspection and provision of footwear in the guidelines varies considerably. This issue has also been analyzed by Healy *et al.*, indicating that no research has examined the effectiveness of footwear in preventing ulceration to date [33]. The authors also reported conflicting findings on the effectiveness of footwear interventions to prevent re-ulceration, and recommended that further studies were performed to explore the type of therapeutic footwear required to reduce ulceration in patients with neuropathy and deformities. It is striking that only 1 of the 10 guidelines analyzed included acceptable evidence on the effectiveness of footwear interventions to prevent ulceration (CDA) [11]. Two cited rather old studies from the 90s only (NICE and SIGN) [4, 16], 4 referred to other guidelines or a single review article only (NHMRC, ADA, IWGDF, IDF) [10, 19-21, 29], and 3 included no evidence at all (DDG, ICFSI, NZSSD) [14, 17]. This shows that the guidelines lack sufficient evidence. Given this situation, it is impossible to identify an appropriate recommendation that warrants adoption in clinical practice. It is necessary that more adequately powered research is conducted on the inspection and provision of therapeutic footwear to safeguard the high-risk foot. Given the advances in material science and measurement techniques, such studies could employ quantitative outcome measures that are reliable and repeatable.

Limited joint mobility and foot deformations. Recommendations for the inspection of limited joint mobility and foot deformities in patients living with diabetes did not form part of the screening guidelines included in all the 10 foot screening guideline documents (**Table A4**). Studies have reported that foot morphology and foot deformations have been associated with ulcer development [34]. It is known that even slight pressure over a fixed bony deformation such as a prominent metatarsal head or a hammer toe can lead to necrosis and ulceration of the skin. However, the clinical guidelines lack sufficient evidence on these problems and provide poor information. Those guidelines that do include a recommendation for the evaluation of existing foot deformations support their recommendations with by low-quality evidence that is not based on well-defined or well-conducted studies (i.e. poorly controlled or uncontrolled studies, case reports, clinical experience, or expert opinion).

There has been technological and scientific progress relating to the clinical assessment and intervention of foot deformities, including wearable sensors and advanced materials with an option of 3D printing, which should be reflected in the guidelines. However, such changes in guidelines can happen only if enough clinically acceptable evidence through structured investigations is available. We recommend that potential guidelines should compile and make use of existing experimental evidence rather than anecdotal and opinion-based evidence.

The current state of research to date in this area does not allow robust recommendations to be made for the screening of limited joint mobility, which is due to the lack of randomized controlled trials. Well-designed studies need to be carried out to provide strong evidence in this area. Foot morphology and foot deformity have been previously identified in other studies as potential risks of ulceration [34]. Thus, healthcare professionals need to inspect and evaluate these deformations systematically both before and after ulcers occur to

prevent recurrence, especially in countries with a high rate of amputations. Such systematical inspection is possible only if reliable guidelines are available, and this in turn requires the performance of well-designed studies to provide the necessary evidence as basis for optimal healthcare. Studies highlight the importance of increased attention on part of the clinical personnel coupled with the intensification of existing screening efforts and introduction of reliable clinical guidelines including the biomechanical assessment of the feet [35]. These efforts could reduce the incidence of diabetic foot complications, but we are still far from realizing them. This problem is reflected by the existing guidelines and the limited or lacking evidence needed to justify them. As shown in **Table A4**, most guidelines are based on poorly controlled or non-controlled studies. For example, the Australian NHMRC graded the evidence as C, which is described as evidence that provides some support for the recommendation, but not enough to apply the recommendation without further observation and caution.

Patient foot care education. A recommendation advocating the importance of patient foot care education for patients living with diabetes as part of the screening guidelines was included in all 10 foot screening guideline documents, as shown in **Table A5**. Although all guidelines emphasize the importance of foot care education, they fail to identify the best methodological approach, making it difficult for guideline users to adopt this recommendation. Previous studies have reported conflicting results regarding outcomes of diabetes education programs [36]. It is known that improving knowledge alone is not sufficient to improve adherence to treatment and care regimens that involve behavioral change, although a few studies have shown that diabetes education programs produce statistically significant health benefits, at least in the short-term.

Patient education activities are currently implemented in various ways in different countries. Most countries use didactic education primarily, but remain at an experimental stage as far as the different ways of developing patient education are concerned [37]. Diabetes education is often prescriptive, offered on an *ad hoc* basis, and is not continuous so that the patient is not provided with new knowledge on a timely basis. It is even more problematic that current education programs are not based on scientifically proven educational or behavioral principles that may result in better outcomes [38]. These problems limit the effectiveness of such programs considerably. Therefore, well-conducted, generalizable RCTs are necessary to explore new psychosocial intervention strategies in diabetes care for preventing diabetic foot ulcerations and amputations.

A general reconsideration of the traditional biomedical model of care is necessary to develop a biopsychosocial model. This may be the first step in achieving a positive change. Other recommendations included in some of the guidelines advocated the "importance of self-monitoring and inspection of feet" and "the importance of having a multi-disciplinary foot care service". However, the organizations provided these two important recommendations by using different levels of evidence. While NICE attached grade 'A' level of evidence to their recommendation, and provided evidence directly based on meta-analysis of RCTs [4], the Australian NHMRC based their recommendation on expert opinion only [10]. This discrepancy is mirrored by the inconsistency of the evidence on educational programs for the prevention of ulcer recurrence and amputation, suggesting that more research is necessary on this issue.

Frequency of assessment/screening. A recommendation regarding the frequency of assessing and screening patients living with diabetes by both patients and healthcare professionals as part of the screening guidelines was included in all 10 foot screening guideline documents, as shown in **Table A6**. Although all guidelines analyzed uniformly emphasized the importance and frequency of assessing and screening people living with type 2 diabetes, the evidence provided in support of this recommendation was of poor quality.

More attention should be paid to the limitations of the guidelines and underlying evidence from which they were devised as this might be the reason for the current gap between recommendation and practice. An evidence-grading system based on relevant populations, patient-oriented outcomes, and shared decision-making could improve physician information and patient guideline adherence, and thus improve diabetes foot screening outcomes [31]. Furthermore, new structured research with appropriately designed trials needs to be conducted to remedy the lack of evidence. These efforts could be of great benefit to the increasing number of people with and at risk of type 2 diabetes and its complications.

5. Discussion

The aim of this study was to evaluate critically the guidelines currently adopted by different or-

ganizations to facilitate foot screening in patients with diabetes, with a view to providing ways of improving existing screening methods, which could save limbs. Given the dynamic nature of the research into this topic, the WHO emphasized the need for new evidence from randomized controlled trials and observational studies to evaluate and improve the screening for diabetes [39]. However, to date, such new research and screening efforts have not been achieved in the area of the diabetic foot, in contrast to screening for several other chronic conditions, e.g. various types of cancers.

The overall goal of screening guidelines is to prevent diabetic foot complications or at least to halt or decelerate their development. This requires that the feet diabetes patients are inspected regularly and treated by skilled healthcare professionals. However, our evaluation of the existing diabetes foot screening guidelines revealed huge variability in the recommended methods and conflicting or missing evidence on which the recommendations were based. Also, the guidelines used different grading systems to grade their recommendations, making it difficult to compare the guidelines. It is inappropriate to publish recommendations that are not based on any scientific evidence, which is the case with some of the guidelines analyzed, as discussed above. Diabetic foot complications are increasing at alarming rates. Therefore, looking at endocrine functions and treatment procedures alone is not sufficient to stop the trend. The literature advocates for more prevention [39]. However, preventive measures are sometimes impractical and corresponding recommendations lack robust evidence [40, 41].

Since the 1970s, different organizations have employed various systems to grade the quality (level) of evidence and the strength of their recommendations. Unfortunately, organizations use different systems to grade evidence and recommendations. The same evidence and recommendation could be graded as II-2, B, C+, 1, “strong evidence”, or “strongly recommended” depending on the system used. This is confusing and impedes effective communication [30]. Furthermore, it has been reported that most of the currently used approaches to grade evidence and the strength of recommendations have important shortcomings. This diversity makes comparisons and syntheses of findings difficult.

Our findings show that guidelines are inconsistent in how they rate quality of evidence and grade strength of recommendations. As a result, guideline users may be irritated and find it difficult to understand the messages that rating systems are trying to communicate. Evidence rating systems are included in most foot screening guidelines. They aim to establish a hierarchy of evidence that usually acknowledges the primacy of randomized controlled trials, followed by observational studies, and expert opinion when sufficiently sound evidence on a particular issue is not available. However, some guidelines contain considerable material that has not been critically assessed for evidence quality or reference to evidence has not been provided by the guideline publishers. Such guidelines rely on expert consensus or non-randomized clinical experience only (see **Tables A1-A10**). Most of these guidelines have not used rigorously the guideline methodologies for identification and analysis of evidence. Those which lack sufficient evidence behind their recommendations should be revised thoroughly by adjusting the recommendations and using the latest and most robust research findings. New evidence should be created where recommendations are needed to achieve better clinical outcomes (such as reduction in ulcerations and amputations, and improved quality of life), but findings from well-conducted studies are missing (such as for screening for neuropathy and peripheral artery disease, inspection and provision of footwear, and inspection of foot deformations). The revision of guidelines should be carried out in such a way that inconsistencies are reduced and new evidence is included, while the evidence should be carefully analyzed regarding study type, quality, and relevance of the findings both clinical and for the target population [2].

It is therefore suggested that more attention should be paid to the limitations of these guidelines and the underlying evidence on the basis of which they were devised as this may be one reason for the current gap between recommendation and standard practice. In this regard, special attention should be given to the evaluation of foot biomechanics, training of healthcare professionals, self-monitoring, and the importance of a multidisciplinary team approach, as highlighted in **Tables A7-A10**, since these aspects of diabetes foot screening were not included in all 10 guidelines analyzed in this article. With advances in technology, modeling, and other treatment innovations, refining current foot screening guidelines could preserve functional limbs in high-risk patients.

6. Conclusions and recommendations

This study highlighted that the current guidelines lack evidence in one or more of their recom-

mendations. As the global prevalence of diabetes is increasing because of population growth, ageing of populations, and lifestyle changes associated with urbanization screening guidelines need to include the latest advances in clinical management. Proper screening and management in the prevention of diabetes complications is essential. Whilst the recommendations included in the guidelines are mostly similar, there are substantial differences in the grading of these recommendations. Although this may not impact policy development and implementation of recommendations in a specific setting, it is necessary to include current developments in science and information technology when revising the guidelines. It should be acknowledged that there could be practical reasons for the differences in the guidelines for screening procedures, depending on what is possible and available in a particular country.

Based on the results, future research in diabetes foot screening should also be oriented to the needs of physicians and patients to improve healthcare. Furthermore, large-scale, randomized trials are needed to demonstrate convincingly the benefit of various foot screening recommendations and improve outcomes. Detailed information regarding the sources of the evidence used in each guideline should be clearly reported within the guidelines. This will enable new guideline developers to refer to the work performed and published by others as 'source' guidelines, and to optimize and standardize diabetes foot screening guidelines.

It will also be important that guidelines are more explicit and accurate so that recommendations are addressed clearly to facilitate adoption, adherence, and improve outcomes. When formulating screening guidelines, the aim of any screening policy should be clearly stated. Epidemiological considerations, issues of health system capacity, economic considerations, the assessment of tests taking into account sensitivity and specificity, competing priorities, and ethical and political considerations need to be considered and clearly stated [39]. Evidence needs to be reviewed on a regularly basis as new evidence accumulates. A paradigm shift on how to screen for risk factors in the high-risk population using high-quality evidence is urgently needed should the risks of foot ulceration and its devastating consequences be reduced.

Author contributions: All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors have made a substantial contribution to the conception and design of this review. CF conceptualized this study, led and prepared this manuscript. CF and AG designed the study and researched/evaluated the data. NC made contributions to the design of the study and reviewed/edited the manuscript.

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■ Appendix

Table A1. Peripheral neuropathy screening recommendations included in the guidelines analyzed

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	**Neuropathy disability score**: ankle (Achilles) reflexes and the sensory modalities of pinprick, vibration and temperature perception **Vibration perception**: using tuning fork, biothesiometer or 10 g monofilament sensitivity	Evidence-based recommendation set up according to a systematic review of the literature. Grade C using the NHMRC grading system. The body of evidence provides some support for these recommendations (Boulton 2005 [42], Leese *et al.* 2006 [43]), but recommendation should be applied with caution.
Canadian Diabetes Association (Canada), 2013	**Evaluation of neuropathy**: 10 g monofilament over the distal plantar surface of the foot	Grade D, level 4, using CDA system. Evidence cited: Boulton *et al.* 2008 [8], Feng *et al.* 2011 [44] Evidence should meet 1 or 2 of the following criteria: a) Independent interpretation of test results (without knowledge of the result of the diagnostic or gold standard) b) Independent interpretation of the diagnostic standard c) Selection of people suspected to have the disorder d) Reproducible description of both the test and diagnostic standard e) At least 50 patients with and 50 patients without the disorder

Table A1 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
National Institute for Clinical Excellence, England and Wales (NICE), 2014	Testing of **foot sensation** using 10 g monofilament (changed every 10 patients in one session and left for at least 24 hr to recover buckling strength) or **vibration** using biothesiometer or calibrated tuning fork.	**Foot sensation**: grade C (evidence from non-experimental descriptive studies or extrapolated recommendation from meta-analysis of RCTs or at least one RCT), but no reference to evidence was given by the guideline publisher. **Vibration**: grade A, III (evidence from meta-analysis of RCTs or from at least one RCT), but no reference to evidence was given by the guideline publisher.
Deutsche Diabetes Gesellschaft (Germany), 2014	10 g monofilament (for **foot sensation**) and/or **vibration** testing using a Rydell-Sieffer tuning fork.	No grading and no evidence provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	10 g monofilament, **neuropathy disability score**. A neurothesiometer can be used as part of a more formal assessment.	Grade 2++ (evidence results from findings from a study of strong design, but with some uncertainty because of inconsistent results or other issues). Relevant citation: Abbott *et al*., 2002 [45].
Institute for Clinical Systems Improvement, (USA), 2014	Assessed by 5.07 Semmes-Weinstein monofilament or by testing vibration using 128-Hz tuning fork at the dorsum of the interphalangeal joint of the great toe to detect loss of protective sensation.	Low-quality evidence (the guideline publisher indicated that further research is very likely to have an important impact on the confidence in the estimate of the effect). No reference to evidence provided by the guideline publisher.
American Diabetes Association (USA) 2014	10 g monofilament plus any of the following: vibration using 12-Hz tuning fork, pinprick sensation, ankles reflexes, vibration perception threshold.	Grade B (only supportive evidence from well-conducted cohort studies). No reference to evidence given for this recommendation; only cited Boulton *et al*., 2008 [8], but not next to the recommendation.
International Working Group on the Diabetic Foot, 2015	Examine the feet annually to look for symptoms of peripheral neuropathy.	GRADE recommendation: strong. Quality of evidence: low (no reference to evidence provided).
	Sensory loss due to diabetic polyneuropathy should be assessed using the following techniques: 10 g monofilament (pressure perception), 128 Hz tuning fork (vibration), pin prick and tactile sensation (discrimination), cotton wool on dorsum of the foot (sensation), and Achilles tendon reflexes (reflexes).	No specific evidence or grading provided for this recommendation. *Note*: evidence provided in the guideline paper (Bakker *et al*., 2012 [21]) but not clearly assigned to the recommendation. Articles cited in the guideline paper have been regarded as the evidence, which has been assessed according to the 'QUADAS tool', and graded according to the GRADE system. However, grades are not provided for all recommendations).
International Diabetes Federation, 2012 (updated 2015)	Detection of neuropathy by 10 g monofilament (or 128 Hz tuning fork). Biothesiometer as option for quantitative assessment (cut-off point for risk of ulcer > 25 volts). Non-traumatic pin-prick test.	Evidence-based, but unclear from where the recommendations were derived. Cited are only other guidelines: NHMRC 2011 [9], SIGN 2013 [16], Bakker *et al*. 2012 [21], ADA 2014 [19], NICE 2014 [12], CDA 2013 [11] (partly newer versions of the papers).
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	Neuropathy screening using 10 g monofilament, vibration test using 128 Hz tuning fork, perception thresholds using a biothesiometer.	Grade C (low-quality observational studies or extrapolated evidence). No reference to evidence provided by the guideline publisher.

Legend: GRADE - Grading of Recommendations Assessment, Development, and Evaluation, QUADAS – Quality Assessment Tool for Diagnostic Accuracy Studies.

Table A2. Peripheral artery screening recommendations included in the guidelines analyzed

Guideline provider	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	Palpation of peripheral foot pulses	Evidence-based recommendation set up according to a systematic review of the literature. Grade C. Body of evidence provides some support for the recommendation, but should be applied with caution. Cited: McCabe *et al*., 1998 [46].
	Ankle brachial pressure index (ABPI) using Doppler ultrasound recommended as useful adjunct to assess arterial perfusion of the foot. Can be falsely elevated in the presence of arterial calcification. The toe-brachial pressure index or toe pressures are useful adjuncts for assessing arterial perfusion of the foot if the ABPI is falsely elevated.	Evidence from a systematic review and expert opinions in the absence of evidence. Cited: Abott *et al*. 2002 [45]; Pham *et al*. 2000 [47]; Leese *et al*. 2006 [43].
Canadian Diabetes Association (Canada), 2013	Palpation of foot pulses	Grade D, level 4 (for description see Table A1). Cited: Kalani *et al*. 1999 [48], Faglia *et al*. 2005 [49]
	ABPI useful adjunct to assess arterial perfusion of the foot + Determination of systolic toe pressures by photoplethysmography (PPG), transcutaneous oxygen (TCPO2), and spectral Doppler waveform analysis.	Grade D, level 4. Kalani *et al*. 1999 [48], Faglia *et al*. 2005 [49]
National Institute for Clinical Excellence, England and Wales (NICE), 2014	Palpation of foot pulses	Grade A (from meta-analysis of RCTs or from at least one RCT). However, no reference to evidence is provided by the guideline publisher for this recommendation.
	Patients who may benefit from revascularization should be referred promptly.	Grade D (from expert committee reports, opinions and/or clinical experience). However, no reference to evidence is provided by the guideline publisher for this recommendation.
Deutsche Diabetes Gesellschaft (Germany), 2014	- Foot Pulses - Measurement of arterial occlusion pressure over the dorsalis pedis and tibial posterior arteries - Determination of the ABPI	No grading and no evidence provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Palpation of pulses using Doppler ultrasound. ABPI can be used to assess PAD.	Grade 2++. Evidence consisting of results from studies of strong design, but with some uncertainty regarding the results.
	All patients with critical limb ischemia, including rest pain, ulceration, and tissue loss, should be considered for arterial reconstruction.	Grade B, 2++
Institute for Clinical Systems Improvement (USA), 2014	Pedal pulses, record history of claudication, or ischemic skin changes	Low-quality evidence. No reference to evidence is provided by the guideline publisher.
	Consider obtaining an ABPI if clinically indicated. PAD slowed by smoking cessation and treatment of hypertension and dyslipidmia. Consider referral of patients with claudication and/or absent pedal pulses for vascular surgery.	

Table A2 continued

Guideline provider	Recommendation	Grading of evidence, as provided by the guideline publisher
American Diabetes Association (USA), 2014	Assessment of foot pulses, dorsalis pedis, and posterior tibial characterized as present or absent.	Grade C. Cited: ADA, 2003 [50] (part of guideline)
	Inclusion of initial screening for peripheral artery disease (PAD), history for claudication, and assessment of pedal pulses. Obtain ABPI. In presence of incompressible calf or ankle arteries, toe pressure or transcutaneous oxygen tension may be performed.	Grade C. Cited: ADA, 2003 [50] (part of guideline)
	Initial screening for PAD should include a history of claudication and an assessment of pedal pulses. A diagnostic ankle-brachial index (ABI) system should be used in any patient with symptoms of PAD. Due to the highly estimated prevalence of PAD in patients with diabetes, and the fact that many patients with PAD are asymptomatic, an ADA consensus statement on PAD [47] suggested that a screening ABI should be performed in patients over 50 years of age, and be considered in patients under 50 years of age who have other PAD risk factors (e.g., smoking, hypertension, hyperlipidemia, or duration of diabetes >10 years). Refer patients with significant symptoms or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options.	Grade C. Cited: ADA, 2003 [50] (part of guideline)
International Working Group on the Diabetic Foot, 2015	Examine the feet annually to look for symptoms of peripheral artery disease.	GRADE recommendation: strong. Quality of evidence: low (no reference to evidence provided).
	Pedal pulses, claudication, rest pain. In patients with ABPI of <0.6, toe pressures <50 mmHg, or TCPO2 <30 mmHg revascularization should be considered.	No specific evidence or grading provided for this recommendation (see **Table A1**).
International Diabetes Federation, 2012 (updated 2015)	Palpation of foot pulses (dorsalis pedis and posterior tibial). Doppler ankle/brachial pressure ratio (< 0.9 for occlusive vascular disease) may be used where pulses are diminished to quantify the abnormality.	Evidence-based, but unclear from where recommendations were derived, obviously collected from other guidelines. Cited are other guidelines: NHMRC 2011 [9], SIGN 2013 [16], Bakker *et al.* 2012 [21], ADA 2014 [19], NICE 2014 [12], CDA 2013 [11] (partly newer versions).
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	Assessment of peripheral circulation through evaluation of symptomatic claudication and/or rest pain, and palpation of pedal pulses.	It is not known from where this guideline was derived. No grading and no evidence provided.

Legend: ABI – ankle-brachial index, ABPI – ankle brachial pressure index, PAD – peripheral artery disease, PPG – photoplethysmography, TCPO2 – transcutaneous oxygen.

Table A3. Inspection and provision of footwear screening guidelines

Guideline provider	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	Appropriate footwear and hosiery	Grade C. Cited: McCabe *et al*., 1998 [46]. Evidence-based recommendation set up according to a systematic review of the literature. A body of evidence provides some support for the recommendation, but should be applied with caution.
	Therapeutic footwear	Two average quality trials (not referenced in the guideline paper next to the recommendation). Insufficient evidence to determine the effectiveness of therapeutic footwear.
Canadian Diabetes Association (Canada), 2013	People at high risk of foot ulceration or amputation should have professionally fitted therapeutic footwear.	Grade C, level 3. Meets 3 of the following criteria: a) Independent interpretation of test results. b) Independent interpretation of the diagnostic standard, c) Selection of people suspected to have the disorder, d) Reproducible description of both the test and diagnostic standard, e) At least 50 patients with and 50 patients without the disorder. Cited: Bus *et al*., 2008 [51]; Arad *et al*., 2011 [52], Valk *et al*., 2002 [53], McCabe *et al*., 1998 [46].
National Institute for Clinical Excellence, England and Wales (NICE), 2014	Inspection of footwear	Grade A (from meta-analysis of RCTs or from at least one RCT).
	In people with diabetes and previous ulceration, footwear should be inspected at each examination, specialist footwear and insoles should be provided. However, the guideline indicates that there is conflicting evidence about the impact of therapeutic footwear on the risk of further ulceration.	Grade 1b (evidence obtained from at least one well-designed quasi- experimental study). Cited (rather old articles): Colagiuri *et al*., 1995 [54]; Litzelman *et al*., 1997 [55]; McCabe *et al*., 1998 [46]; Reiber *et al*., 2002 [56]; Uccioli *et al*., 1995 [57].
Deutsche Diabetes Gesellschaft (Germany), 2014	Footwear of all diabetics should be examined periodically. Footwear provision according to risk class.	No grading provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Preventative footwear and orthoses. Patients with diabetic foot disease should be advised to wear running-style, cushion-soled trainers rather than ordinary shoes.	Grade B (high-quality case-control or cohort studies with a very low risk of bias or extrapolated evidence from high-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias). Cited: (rather old articles): Colagiuri *et al*., 1995 [54], Edmonds *et al*., 1986 [58], Uccioli *et al*., (1995) [57].
	Custom-built footwear or orthotic insoles should be used to reduce callus severity and ulcer recurrence.	Grade B. Cited: Dargis *et al*., 1999 [59].
	Patients who routinely wear their prescription shoes and orthoses are less likely to have ulcer relapse.	Grade 3 (defined as non-analytic study, e.g. case report, case series). Cited: Breuer, 1994 [60].
Institute for Clinical Systems Improvement (USA), 2014	Inspection of footwear for excessively worn, ill fitting, or inappropriate shoes.	Low-quality evidence. No reference to evidence provided by guideline publisher.

Table A3 continued

Guideline provider	Recommendation	Grading of evidence, as provided by the guideline publisher
American Diabetes Association (USA), 2014	People with neuropathy or evidence of increased plantar pressure (e.g., erythema, warmth, callus, or measured pressure) may be adequately managed with well-fitted walking shoes or athletic shoes that cushion the feet and redistribute pressure. Callus can be debrided with a scalpel by a foot care specialist or other health professional with experience and training in foot care.	No grading and no evidence provided. Cited: Boulton *et al*., 2008 [8] (part of guideline).
	People with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions) may need extra-wide or -deep shoes. People with extreme bony deformities (e.g., Charcot foot) who cannot be accommodated with commercial therapeutic footwear may need custom-molded shoes.	
International Working Group on the Diabetic Foot, 2015	Appropriate footwear both indoor and outdoor should be used to accommodate the altered biomechanics and deformities. Plantar pressure reduction can be achieved with footwear that includes a molded insole, although the amount of reduction is not certain.	No grading provided for this recommendation. Cited: Bus *et al*., 2008 [51] (other guideline paper only, no evidence).
	Patients without loss of protective sensation can select off-the-shelf footwear. Patients with neuropathy and/or ischemia need extra care for fitting footwear, in particular when deformities are present [49]	See above.
	Insole material and soft padding alone do not seem to have a great effect on plantar pressure, although some studies have found significant differences.	See above
International Diabetes Federation, 2012 (updated 2015)	Evaluate footwear: provide advice, specialist insoles, and shoes if indicated in the high-risk diabetic foot.	Evidence-based, but unclear from where recommendations were derived. Cited are only other guidelines (no evidence): NHMRC 2011 [9], SIGN 2013 [16], Bakker *et al*., 2012 [21], ADA 2014 [19], NICE 2014 [12], CDA 2013 [11].
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	People with diabetic foot disease should be advised to wear high-quality, cushioned running or sports shoes rather than ordinary shoes.	Grade B (well-designed observational studies or extrapolated evidence from RCTs). It is not known from where this recommendation was derived.
	People with high-risk feet, deformation, or previous amputation, should use custom-built footwear or orthotic insoles to reduce callus severity and ulcer recurrence.	Grade B. It is not known from where this recommendation was derived. No reference to evidence provided.

Table A4. Foot deformation guidelines

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	Use of the "Foot Deformity Score" to assess foot deformation. This includes, but is not limited to the following conditions: hallux deformity, hammer/claw toe, callus, previous amputations, excessively flat or high-arched feet, abnormally wide feet, and Charcot's neuroarthropathy.	Evidence-based recommendation set up according to a systematic review of the literature. Grade C using the NHMRC grading system. The body of evidence provides some support for these recommendations, but should be applied with caution (Pham *et al.*, 2000 [47]; Abott *et al*., 2002 [45]; Boulton, 2005 [42]; Leese *et al.* 2006 [43]).
Canadian Diabetes Association (Canada), 2013	Assessment by healthcare providers should include assessment of bony foot deformations.	Grade D, level 4 (for description see Table A1). Cited: Boulton *et al*., 2008 [8].
NICE, 2014	Inspection and assessment of any foot deformation.	Grade 1b. Evidence derived from at least one RCT (Pham *et al*., 2000 [47]).
Deutsche Diabetes Gesellschaft (Germany), 2014	Examination of both feet for foot deformations.	No grading and no evidence provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Simple tests to assess the presence of significant structural abnormalities.	Grade 2++ (evidence from a study of strong design, but with some uncertainty because of inconsistent results or other issues). Relevant citation: Abbott *et al*., 2002 [45].
Institute for Clinical Systems Improvement (USA), 2014	A foot examination should include an assessment of structural deformations such as bunions, hammer toes, Charcot deformity, and prior amputation.	Guideline publisher indicated low-quality evidence, but provided no reference to evidence.
American Diabetes Association (USA), 2014	Common foot deformations are known to increase plantar pressure, and are associated with skin breakdown or amputations. Therefore, they need to be recorded during the screening process.	Grade B. Cited: Boulton *et al*., 2008 [8].
International Working Group on the Diabetic Foot, 2015	Deformations, including claw toes, hammer toes, or bony prominences, should be recorded during history taking.	No specific evidence or grading provided for this recommendation (see **Table A1**).
International Diabetes Federation, 2012	Assessment of foot deformation, including hammer toes, clawed toes, and bone prominences.	No grading provided. Cited other guideline: ADA, 2014 [19].
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	Identify and manage foot deformations. Significant structural foot deformations should be marked as present or absent.	No grading of evidence provided. Cited: Litzelman *et al*., 1997 [61]; Rith-Najarian *et al*., 1992 [62]; Klenerman *et al*., 1996 [63].

Table A5. Patient foot care education guidelines

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	Foot care education should be provided to all people with diabetes to assist in the prevention of foot complications.	Expert opinion used to derive the recommendation, because of the inconsistent nature of the currently available evidence on educational programs for the prevention of ulcer recurrence and amputation. No reference to evidence provided.
Canadian Diabetes Association (Canada), 2013	People at high risk of foot ulceration and amputation should receive foot care education.	Grade C, level 3 (see Table A3). Cited: Arad *et al*., 2011 [52]; Valk *et al*., 2002 [53]; McCabe *et al*., 1998 [46].
NICE, 2014	Offer patient education on an ongoing basis.	Grade A (directly based on evidence from meta-analysis of randomized controlled trials; reference to the meta-analysis not clearly indicated).
	Use of different patient education approaches until optimal methods available.	Grade B (evidence from at least one controlled study without randomization or from one other type of quasi-experimental study or extrapolated recommendation from meta-analysis of RCTs or at least one RCT; reference to the evidence not clearly indicated).
Deutsche Diabetes Gesellschaft (Germany), 2014	Repeat training of patients with the objective of preventing ulcers.	No evidence and no grading provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Foot care education is recommended as part of a multidisciplinary approach in all patients with diabetes.	Grade B (see Table A3), 1+, 1++ (extrapolated evidence from studies rated as 1++ or 1+, high quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias). Relevant citations provided: Dargis *et al*., 1999 [60], Rönnemaa *et al*., 1997 [64].
Institute for Clinical Systems Improvement (USA), 2014	Diabetes education should be offered to all patients with diabetes on diagnosis.	Grade: high. Cited: Gillett *et al*., 2010 [65].
	Foot care education should be tailored to patients' current knowledge, individual needs, and risk factors.	Guideline publisher indicated low-quality evidence, but no reference to evidence provided.
	Physical activity. 150 minutes a week of moderate-intensity activity and resistance training 3 times a week unless contraindicated.	No grading and no reference to evidence provided next to this recommendation.
American Diabetes Association (USA), 2014	Provide general foot self-care education to all patients with diabetes.	Grade B (only supportive evidence from well-conducted cohort studies). No reference to the cohort study provided; only cited another guideline / review paper: Haas *et al*., 2012 [66].
International Working Group on the Diabetic Foot, 2015	Patient education should be presented in a structured and organized manner. Education should be provided in several sessions over time, and preferably using a mixture of methods. It is essential to evaluate whether the person with diabetes has understood the messages, is motivated to act, and has sufficient self-care skills.	No specific evidence or grading provided for this recommendation (see **Table A1**).

Table A5 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
International Diabetes Federation, 2012	Make patient-centered self-management education an integral part of all people with type 2 diabetes from time of diagnosis. On an ongoing basis, based on routine assessment of need.	No grading provided. Cited: Norris *et al*., 2001 [67], Colagiuri *et al*., 2009 [68], NICE 2003 [69] (*note*: these are partly other guidelines).
	Use an appropriate multidisciplinary team to provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Use modern communication technologies to advance methods of diabetes education.	See above.
	Provide ongoing self-management support.	See above.
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	Foot care education is recommended as part of a multi-disciplinary approach in all people with diabetes.	Grade B (very well-designed observational studies or extrapolated evidence from RCTs). Unknown from where this recommendation was derived. No reference to evidence provided.

Table A6. Frequency of assessment/screening/risk stratification guidelines

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
National Health and Medical Research Council (Australia), 2011	Assess all people with diabetes and stratify their risk of developing foot complications as follows: 1. Low-risk people with no risk factors and no previous history of foot ulcer/amputation: examine annually (expert opinion). 2. Intermediate risk people with one risk factor (e.g. neuropathy, peripheral arterial disease, or foot deformity) and no previous history of foot ulcer/amputation: examine at least every 3 to 6 months (expert opinion). 3. High-risk people with two or more risk factors (neuropathy, peripheral arterial disease, or foot deformity) and/or a previous history of foot ulcer/amputation: include in foot protection program, including foot care education, podiatry review, and appropriate footwear (expert opinion).	Grade C. Body of evidence provides some support for recommendations, but caution should be applied. Cited: McCabe *et al*., 1998 [46].
Canadian Diabetes Association (Canada), 2013	In people with diabetes, foot examination by healthcare providers should be an integral part of diabetes management to identify persons at risk of ulceration and amputation.	Grade C, level 3 (see **Table A3**). Cited: Feng *et al*., 2011 [44]
	Foot examinations should be performed at least annually and at more frequent intervals in those at high risk.	Grade D, level 1 (see **Table A1**). Cited: Boulton *et al*., 2008 [8].

Table A6 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
NICE, 2014	Low current risk with normal sensation, palpable pulses: arrange management plan, including foot care education and annual review.	Grade A (see **Table A1**). No specific evidence provided.
	Increased risk with neuropathy, absent pulses, or another risk factor: every 3-6 months (at each review) inspect patients' feet, consider need for vascular assessment, evaluate footwear, and enhance foot care education.	Grade C (see **Table A1**). No specific evidence provided.
	High risk with neuropathy or absent pulses plus deformity, skin changes, or previous ulcer: every 1-3 months (at each review): inspect patients' feet, consider need for vascular assessment, evaluate and ensure the appropriate provision of intensified foot care education, specialist footwear and insoles, and skin and nail care.	Grade C (see **Table A1**). No specific evidence provided.
	Ulcerated foot or foot care emergencies (new ulceration, swelling, discoloration): refer to multidisciplinary foot care team within 24 hours (as a minimum, investigate and treat vascular insufficiencies, initiate and supervise wound management, use dressings and debridement as indicated, use systemic antibiotic therapy for cellulitis or bone infection as indicated, ensure an effective means of distributing foot pressures, including specialist footwear, orthotics, and casts, try to achieve optimal glucose levels, and control risk factors for cardiovascular disease).	Grade D (see **Table A2**). No specific evidence provided.
	The team should comprise highly trained specialist podiatrist and orthotist, nurses with training in dressing of diabetic foot wounds, and diabetologist with expertise in lower limb complications. They should have unhindered access for managing major wounds, urgent inpatient facilities, antibiotic administration, community nursing, microbiology, diagnostic and advisory services, orthopedic/podiatric surgery, vascular surgery, radiology, and orthotics. Patients who may benefit from recvascularization should be referred promptly.	Grade D (see **Table A2**). No specific evidence provided.
	Patients with non-healing ulcers should receive intensive systemic antibiotic therapy.	Grade C, 1b (extrapolated evidence from meta-analysis of RCTs or at least one RCT). No reference to evidence provided.
	Use of best wound dressings, closely monitored, and dressings changed regularly dead tissue should be carefully removed. Total contact casting may be considered for people with ulcers, unless there is severe ischemia.	Grade B, 1b (evidence from at least one controlled study without randomization, or from at least one other type of quasi-experimental study, or extrapolated recommendation from meta-analysis of RCTs or one RCT). No reference to evidence provided.

Table A6 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
Deutsche Diabetes Gesellschaft (Germany), 2014	Feet and footwear should be checked as follows: Risk category 0: no sensory neuropathy, no PAD: annual examination. Risk category 1: sensory neuropathy with or without deformation: examination every 3-6 months. Risk category 2: PAD with or without sensory neuropathy: examination every 2-3 months by a specialist. Risk category 3: previous ulcer or amputation: examination every 1-2 months by specialist.	No evidence and no grading provided by guideline publisher.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	All patients with diabetes should be screened to assess their risk of developing a foot ulcer.	Grade A (at least one meta-analysis, systematic review, or RCT rated as 1++, directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.). Relevant citation provided: Crawford *et al*., 2007 [70].
	Low risk (absence of risk factors, i.e. no loss of sensation, no signs of peripheral vascular disease, and no other risk factors): annual screening by a trained healthcare professional, agreed self-management plan, provision of written and verbal education with emergency contact numbers, provision of appropriate access to podiatrist if required.	Grade C (a body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++). Relevant citation provided: Abbott *et al*., 2002 [45].
	Moderate risk (one risk factor present, e.g. loss of sensation or signs of peripheral vascular disease (PVD) without callus or deformation): annual assessment by a podiatrist, agreed and tailored management/treatment plan by podiatrist according to patient's needs, provision of written and verbal education with emergency contact numbers.	Grade C (see above, Abbott *et al*., 2002 [45].
	High risk (previous ulceration or amputation or more than one risk factor present, e.g. loss of sensation, signs of PVD with callus or deformation): annual assessment by a specialized podiatrist, agreed and tailored management/treatment plan by podiatrist according to patient's needs, provision of written and verbal education with emergency contact numbers, referral for specialist intervention if required.	Grade C (see above, Abbott *et al*., 2002 [45].
	Active: referral to and management by a member of a multidisciplinary foot team, agreed and tailored management/treatment plan by podiatrist according to patient's needs, provision of written and verbal education with emergency contact numbers, referral for specialist intervention if required.	Grade C (see above, Abbott *et al*., 2002 [45].
Institute for Clinical Systems Improvement (USA), 2014	**Prevent microvascular complications** through annual and biannual foot risk assessments and foot care counseling. **Foot care specialist**: consultation of a specialist is suggested if the patient 1) is unable to care properly for his own feet, 2) needs prescriptive footwear, or 3) has more serious problems such as foot deformations (e.g. Charcot), infected lesions, ulcers, deformed nails, or thick calluses. **Vascular specialist/surgeon**: consider referral if patient has symptoms of PVD such as loss of pulses and/or claudicaton.	No grading and no reference to evidence provided next to the recommendations.

Table A6 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
American Diabetes Association (USA), 2014	All patients with diabetes should receive annual foot examinations to identify risk factors predictive of ulcers and amputations. Examinations should include inspection and assessment of foot pulses and loss of protective sensation testing.	Grade B (supportive evidence from well-conducted cohort studies). No reference to the cohort study provided; only cited another guideline/review paper: Haas *et al*., 2014 [66].
	Provide foot self-care education to all patients.	Grade B (see above, Haas *et al*., 2014 [66]).
	For patients with foot ulcers and high-risk feet, use multidisciplinary approach. Refer patients to foot care specialist for lifelong surveillance if they smoke, have LOPS, structural abnormalities, or history of prior lower extremity complications.	Grade B (see above, Haas *et al*., 2014 [66]).
	Include history of claudication and assessment of pedal pulses in initial PVD screening. Also, consider obtaining ABPI.	Grade C (as supportive evidence from poorly controlled or uncontrolled studies). No reference to evidence provided.
	Refer further vascular assessment patients with positive ABPI or significant claudication. Consider exercise, medications, and surgical options.	Grade C. No reference to evidence provided.
International Working Group on the Diabetic Foot, 2015	5 key elements: 1. **Regular inspection and examination of the at-risk foot**. All people with diabetes should be examined at least once a year for potential foot problems. Patients with risk factors should be examined more frequently (1-6 mo). Patients should be examined in lying and standing position. Shoes and socks should be inspected. 2. **Identification of the at-risk foot**: patients should be assigned to a risk category. Neuropathy assessed using 10 g monofilament, 128 Hz tuning fork, pin prick, cotton wool, and reflexes. Also, vascular status check for claudication, rest pain, and pedal pulses. **Skin**: color, temperature, edema. **Bones and joints**: deformations or bony prominences. **History**: previous ulceration/amputation, previous foot education, social isolation, poor access to healthcare, bare-foot walking. 3. **Education of patient and family**: should be provided in several sessions over time, preferably using a mixture of methods, including evaluation of persons with diabetes for sufficient self-care skills, motivation, and knowledge. Healthcare providers should receive periodic education to improve care for high-risk individuals. 4. **Appropriate footwear**. 5. **Treatment of non-ulcerative pathology**: in high-risk patients, callus and nail and skin pathology should be treated regularly by foot care specialist. Foot deformations should be treated by orthosis. **3 levels of foot care management needed**: Level 1: general practitioner, podiatrist, diabetic nurse. Level 2: diabetologist, surgeon, podiatrist diabetic nurse. Level 3: specialized foot center with multiple disciplines specialized in diabetic foot care.	No specific evidence or grading provided for this recommendation (see **Table A1**).

Table A6 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
International Diabetes Federation, 2012	Assess feet of people with diabetes as part of an annual review for lesions, which require active treatment, and for risk factors, ulcers, and amputations: 1. History of previous foot ulceration or amputation, symptoms of peripheral arterial disease, physical or visual difficulty in self-foot- care. 2. Foot deformation (hammer or clawed toes, bone prominences); visual evidence of neuropathy (dry skin, dilated veins) or incipient ischemia; callus; nail deformity or damage; footwear. 3. Detection of neuropathy by 10 g monofilament (or 128 Hz tuning fork); a biothesiometer is an option for quantitative assessment (cut-off point for ulcer risk > 25 volts); non-traumatic pin-prick. 4. Palpation of foot pulses (dorsalis pedis and posterior tibial). Doppler ankle:brachial pressure ratio (< 0.9 for occlusive vascular disease) may be used where pulses are diminished to quantify the abnormality. Discuss reasons for foot review with each person with diabetes as part of the foot-care educational process. Agree on a foot-care plan based on the findings of the annual foot review with each person with diabetes. Assess and provide necessary foot-care education according to individual needs and risks of ulcer and amputation. Classify risk of ulcer and amputation according to findings of the foot assessment: 1. No added risk: no risk factors and no previous history of foot ulcer or amputation. 2. At risk: one risk factor and no previous history of foot ulcer or amputation. 3. High risk: two or more risk factors. Previous ulcer or amputation (very high risk). Manage according to risk classification level: No added risk: provide foot-care education. At risk: arrange regular review, approximately every 6 months, by foot-care team. At each review: 1. Inspect both feet: ensure provision of local management. 2. Evaluate footwear: provide appropriate advice. 3. Enhance foot-care education. High-risk patients: arrange frequent review every 3-6 months by foot-care team. At each review: 1. Inspect both feet: ensure provision of local management, as indicated. 2. Evaluate footwear: provide advice and specialist insoles and shoes if indicated. 3. Consider need for vascular assessment or referral if indicated. 4. Evaluate and ensure the appropriate provision of intensified foot-care education. People with foot ulceration or infection should receive the following management: refer to multidisciplinary foot-care team within 24 hours for: 1. Appropriate wound management, dressings, and debridement if indicated. 2. Classify infections as follows: mild (superficial with minimal cellulitis), moderate (deeper than skin or more extensive cellultis), severe (accompanied by systemic signs of sepsis). Consideration of systemic antibiotic therapy (often longer term) for extensive cellulitis or bone infection if indicated, generic penicillins, macrolides, clindamycin and/or metronidazole if indicated as first-line medications, with ciprofloxacin or co-amoxicllin as examples of second-line medications. 3. Probing of bone, radiology and scans, magnetic resonance imaging, and biopsy if indicated for suspected osteomyelitis. 4. Reduce weight, relief of pressure (walking with crutches, rest), and optimal pressure distribution (casting if indicated and not contraindicated) 5. Investigation and treatment (referral) for vascular insufficiency. 6. Specialist footwear and orthotic care (e.g. insoles), and individualized discussion on prevention of recurrence, when ulcer has healed. 7. Optimal blood glucose control.	No grading and no evidence provided by the guideline publisher. Cited are only other guidelines: NHMRC 2011 [9], SIGN 2013 [16], Bakker *et al*. 2012 [21], ADA 2014 [19], NICE 2014 [12], CDA 2013 [11] (partly newer versions of the papers).

Table A6 continued

Guideline	Recommendation	Grading of evidence, as provided by the guideline publisher
	Limited care: Risk assessment and classification as for recommended care, but with sensory assessment by 10 g monofilament or tuning fork, with or without non-traumatic disposable pin-prick, and peripheral circulation assessment by palpation of pedal pulses. Classification of infection as for recommended care, but antibiotic therapy with generic penicillins, macrolides, and/or metronidazole, given intravenously for deep tissue infections, and adjusted by response or culture results. Vascular referral according to findings and local revascularization facilities. **Comprehensive care**: The principles are as for recommended care, but the multidisciplinary foot-care team can be enhanced by on-site inclusion of vascular surgeons, orthopedic surgeons, orthotists, social workers, and psychologists. Foot pressure distribution measurements may be carried out. Sophisticated vascular scanning and angiography should be available to the foot-care team.	
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	All people with diabetes should be screened for foot disease by a health care professional. Screening should occur from the time of diagnosis on, and then at least once per year, if there are no features indicating a high-risk foot. More frequent examinations (every 3-6 mo) should be carried out if there are features of a high-risk foot.	Grade D (evidence by non-analytical studies or expert opinion). However, no reference to evidence provided next to the recommendation.

Legend: ABPI – ankle brachial pressure index. LOPS – loss of protective sensation. PVD – peripheral vascular disease.

Table A7. Limited joint mobility guidelines

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
National Health and Medical Research Council (Australia), 2011	Use foot deformity score to assess limited joint mobility.	Grade C (body of evidence provides some support for recommendation, but should be applied with caution). Cited: Abbott *et al*., 2002 [45]; Pham *et al*., 2000 [47]; Leese *et al*., 2006 [43].
Canadian Diabetes Association (Canada), 2013	Assessment by healthcare providers should include assessment of structural abnormalities, including range of motion of ankles and toe joints.	Grade D, level 4 (see **Table A1**). Cited: Boulton *et al*., 2008 [8].
NICE, 2014	Evaluation of musculoskeletal conditions on an annual basis is important for the detection of feet at elevated risk of ulceration.	Level of evidence: 1b (evidence from at least one RCT). Cited: Pham *et al*., 2000 [47].
Deutsche Diabetes Gesellschaft (Germany), 2014	Examination of both feet for limited joint mobility.	No evidence and no grading provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Simple tests to assess presence of significant structural abnormalities.	Grade 2++ (see **Table A1**). Relevant citation: Abbott *et al*., 2002 [45].
Institute for Clinical Systems Improvement (USA), 2014	Foot examination should include assessment of limited joint mobility.	Low-quality evidence. No reference to evidence provided by guideline publisher.
American Diabetes Association (USA), 2014	Musculoskeletal assessment should include evaluation of any deformation.	No grading provided. Cited: Boulton *et al*., 2008 [8].
International Working Group on the Diabetic Foot, 2015	Evaluate loss of joint mobility.	No specific evidence or grading provided for this recommendation (see **Table A1**).
International Diabetes Federation, 2012		No specific guideline provided
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014		No specific guideline provided

Table A8. Recommendations for training of health care professionals

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
National Health and Medical Research Council (Australia), 2011	Any suitably trained healthcare professional may perform the risk assessment.	Lowest level of evidence; expert opinion (evidence was absent or unreliable and advice was formulated based on clinical experience by experts in the field).
Canadian Diabetes Association (Canada), 2013	Education for caregivers and healthcare professionals.	No grading provided. Cited: IWGDF, 2012/2015 [20].
NICE, 2014	Health care professionals and other personnel involved in the assessment of diabetic feet should receive adequate training.	Grade D (evidence from expert committee reports or opinions, clinical experience of respected authorities, or extrapolated evidence of categories I, II, III). No reference to evidence provided.
Deutsche Diabetes Gesellschaft (Germany), 2014	Repeat training of caregivers.	No grading and no evidence provided.
Scottish Intercollegiate Guidelines Network (Scotland), 2013	No clear recommendation provided.	
Institute for Clinical Systems Improvement (USA), 2014	No clear recommendation provided.	
American Diabetes Association (USA), 2014	No clear recommendation provided.	
International Working Group on the Diabetic Foot, 2015	Physicians and other healthcare professionals should receive periodic education to improve care for high-risk individuals.	No grading and no evidence provided.
International Diabetes Federation, 2012	Include in education teams healthcare professionals with specialist training in diabetes and delivery of education for people with diabetes.	Level of evidence not clearly stated.
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	No clear recommendation provided.	

Table A9. Self-monitoring and inspection of feet guidelines

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
National Health and Medical Research Council (Australia), 2011	Visual inspection of feet for structural abnormalities and ulceration.	Grade C (evidence-based recommendation set up according to a systematic review of the literature. Body of evidence provides some support for recommendation, but it should be applied with caution. *Note*: no reference to evidence given by the guideline publisher).
Canadian Diabetes Association (Canada), 2013	Visual inspection of feet for skin changes, callus pattern, skin temperature, and evidence of infection.	Grade D, level 4 (see **Table A1**). Cited: Boulton *et al*., 2008 [8].
NICE, 2014	Self- monitoring and visual inspection of feet by people with diabetes should be encouraged.	Grade D (evidence from expert committee reports or opinions, clinical experience of respected authorities, or extrapolated evidence of categories I, II, III). No reference to evidence provided.
Deutsche Diabetes Gesellschaft (Germany), 2014	No clear recommendation provided.	
Scottish Intercollegiate Guidelines Network (Scotland), 2013	All patients should be assessed and screened to assess their risk of developing foot ulcer.	Grade B (see **Table A3**).

Table A9 continued

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
Institute for Clinical Systems Improvement (USA), 2014	Diabetes self-management or education by a qualified healthcare professional team (which may include a clinician, dietitian, nursing staff, and a pharmacist) should be offered to patients diagnosed with diabetes. Inspection of feet for dermatological conditions, including color, sweating, infection, ulceration, callus, and blistering. Daily self-inspection of feet for cuts, bruises, bleeding, redness, and nail problems.	Quality of evidence: high Strength of recommendation: strong (further research is very unlikely to change confidence in the estimate of the effect). *Note*: the grading by the guideline publisher is based on evidence that is not fully suitable to the recommendations as the evidence is on diabetes self-monitoring in general, but not the diabetic foot (e.g. Guicciardi *et al*., 2014 [71], Steinsbekk *et al*., 2012 [72]).
American Diabetes Association (USA), 2014	Patients with diabetes and high-risk foot should understand the importance of foot monitoring on a daily basis, and the proper care of the foot including nail and skin care. Hand palpation and visual inspection for surveillance of early foot problems. Patients with visual difficulties, physical constraints, or cognitive problems, which impair their ability to assess the condition of the foot, will need other people such as family members to assist in their care.	No grading and no evidence provided next to the recommendation, only cited: ADA, 2003 [50] (review article, part of guideline).
International Working Group on the Diabetic Foot, 2015	Regular callus removal appears to have a beneficial effect on the reduction of plantar pressure in the neuropathic diabetic foot.	No specific evidence or grading provided for this recommendation (see **Table A1**).
International Diabetes Federation, 2012	No clear recommendation provided.	
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	No clear recommendation provided.	

Table A10. Multi-disciplinary diabetic foot care service guidelines

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
National Health and Medical Research Council (Australia), 2011	Patients with active diabetic foot disease should be referred to multidisciplinary diabetic foot care service. The team should comprise podiatrist, diabetes physician, ortotist, diabetes nurse specialist, vascular surgeon, orthopedic surgeon, radiologist, wound care nurse, and footwear technician.	Grade C (body of evidence provides some support for the recommendation, but caution should be applied). Cited: Horswell *et al*., 2003 [73]; Rerkasem *et al*., 2009 [74]; Yesil *et al*., 2009 [75].
Canadian Diabetes Association (Canada), 2013	Individuals who develop a foot ulcer should be managed by a multidisciplinary healthcare team with expertise in the management of foot ulcers to prevent recurrent foot ulcers and amputation.	Grade C, level 3 (see **Table A3**). Cited: Dargis *et al*., 1999 [76].
NICE, 2014	Patients with active diabetic foot disease should be referred to multidisciplinary diabetic foot care service. The team should comprise a highly trained specialist, podiatrist, and orthotist, nurses with training in dressing of diabetic foot wounds, and a diabetologist with expertise in lower limb complications. They should have unhindered access to management of major wounds, urgent inpatient facilities, antibiotic administration, community nursing, microbiology, diagnostic and advisory services, orthopedic/podiatric surgery, vascular surgery, radiology, and orthotics.	Grade D (evidence from expert committee reports or opinions, clinical experience of respected authorities, or extrapolated evidence of categories I, II, III). No reference to evidence provided.

Table A10 continued

Guideline	Recommendation	Grading of evidence, as provided by guideline publisher
Deutsche Diabetes Gesellschaft (Germany), 2014	No recommendation provided.	
Scottish Intercollegiate Guidelines Network (Scotland), 2013	Patients with active diabetic foot disease should be referred to a multidisciplinary diabetic foot care service.	Grade C, 2+, 2++ (a body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++). No reference to evidence provided.
Institute for Clinical Systems Improvement (USA), 2014	In case of claudication and/or absent pedal pulses, refer appropriately to foot-care specialist or vascular surgeon if required.	Low-quality evidence. No reference to evidence provided.
American Diabetes Association (USA), 2014	A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially for those with a history of prior ulcer or amputation.	Grade B (see **Table A1**). No reference to evidence provided for this recommendation.
International Working Group on the Diabetic, 2015	No clear recommendation provided.	
International Diabetes Federation, 2012	Refer to multidisciplinary foot-care team within 24 hours for following inspection and treatment: 1. Appropriate wound management, dressings, and debridement if indicated. 2. Infections should be classified as mild (superficial with minimal cellulitis), moderate (deeper than skin or more extensive cellulitis), or severe (accompanied by systemic signs of sepsis). Consideration of systemic antibiotic therapy (often longer term) for extensive cellulitis or bone infection if indicated, generic penicillin, macrolides, and clindamycin and/or metronidazole if indicated as first-line medications, with ciprofloxacin or co-amoxicllin as examples of second-line medications. 3. Probing of bone, radiology and scans, magnetic resonance imaging, and biopsy where indicated for suspected osteomyelitis. 4. Weight reduction, relief of pressure (walking with crutches, rest), and optimization of pressure distribution (casting if indicated and not contraindicated) 5. Investigation and treatment (referral) for vascular insufficiency. 6. Specialist footwear and orthotic care (e.g. insoles), and individualized discussion on prevention of recurrence, when ulcer has healed. 7. Improvement of blood glucose control.	No grading of evidence provided. Cited: Shaper *et al*., 2012 [77].
New Zealand Society for the Study of Diabetes (NZSSD) - Podiatry Special Interest Group, 2014	People with diabetes and high-risk feet should be referred to a specialist diabetic foot clinic or multidisciplinary foot-care team	Grade C (see **Table A1**).

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