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SUPPLEMENT ARTICLE

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Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update)

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Abstract

The International Working Group on the Diabetic Foot (IWGDF) has published evidence-based guidelines on the prevention and management of diabetic foot disease since 1999. This guideline is on the prevention of foot ulceration in persons with diabetes and updates the 2015 IWGDF prevention guideline. We followed the GRADE methodology to devise clinical questions and critically important outcomes in the PICO format, to conduct a systematic review of the medical-scientific literature, and to write recommendations and their rationale. The recommendations are based on the quality of evidence found in the systematic review, expert opinion where evidence was not available, and a weighing of the benefits and harms, patient preferences, feasibility and applicability, and costs related to the intervention. We recommend to screen a person at very low risk for ulceration annually for loss of protective sensation and peripheral artery disease and persons at higher risk at higher frequencies for additional risk factors. For preventing a foot ulcer, educate the at-risk patient about appropriate foot self-care and treat any pre-ulcerative sign on the foot. Instruct moderate-to-high risk patients to wear accommodative properly fitting therapeutic footwear, and consider instructing them to monitor foot skin temperature. Prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking to prevent plantar foot ulcer recurrence. In patients that fail non-surgical treatment for an active or imminent ulcer, consider surgical intervention; we suggest not to use a nerve decompression procedure. Provide integrated foot care for high-risk patients to prevent ulcer recurrence. Following these recommendations will help health care professionals to provide better care for persons with diabetes at risk of foot ulceration, to increase the number of ulcer-free days, and to reduce the patient and health care burden of diabetic foot disease.

KEYWORDS

diabetic foot, education, foot ulcer, footwear, guidelines, prevention, self-care, self-management

List of recommendations

1. Examine a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of loss of protective sensation and peripheral artery disease, to determine if they are at increased risk for foot ulceration. (GRADE recommendation: Strong; Quality of evidence: High)
2. Screen a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) for: a history of foot ulceration or lower-extremity amputation; diagnosis of end-stage renal disease; presence or

progression of foot deformity; limited joint mobility; abundant callus; and any pre-ulcerative sign on the foot. Repeat this screening once every 6-12 months for those classified as IWGDF risk 1, once every 3-6 months for IWGDF risk 2, and once every 1-3 months for IWGDF risk 3. (Strong; High)

3. Instruct a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors. (Strong; Low)
4. Instruct, and after that encourage and remind, a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to: inspect daily the entire surface of both feet and the inside of the shoes that will be worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toe nails straight across; and, avoid using chemical agents or plasters or any other technique to remove callus or corns. (Strong; Low)
5. Provide structured education to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer. (Strong; Low)
6. Consider instructing a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference is above-threshold between similar regions in the two feet on two consecutive days, instruct the patient to reduce ambulatory activity and consult an adequately trained health care professional for further diagnosis and treatment. (Weak; Moderate)
7. Instruct a person with diabetes who is at moderate risk for foot ulceration (IWGDF risk 2) or who has healed from a non-plantar foot ulcer (IWGDF risk 3) to wear therapeutic footwear that accommodates the shape of the feet and that fits properly, to reduce plantar pressure and help prevent a foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing custom-made footwear, custom-made insoles, or toe orthoses. (Strong; Low)
8. Consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration (IWGDF risk 1-3). (Weak; Low)
9. In a person with diabetes who has a healed plantar foot ulcer (IWGDF risk 3), prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the patient to consistently wear this footwear. (Strong; Moderate).
10. Treat any pre-ulcerative sign or abundant callus on the foot, ingrown toe nail, and fungal infection on the foot, to help prevent a foot ulcer in a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3). (Strong; Low)
11. In a person with diabetes and abundant callus or an ulcer on the apex or distal part of a non-rigid hammertoe that has failed to heal with non-surgical treatment, consider digital flexor tendon tenotomy for preventing a first foot ulcer or recurrent foot ulcer once the active ulcer has healed (Weak; Low).
12. In a person with diabetes and a plantar forefoot ulcer that has failed to heal with non-surgical treatment, consider Achilles tendon lengthening, single or pan metatarsal head resection, metatarsophalangeal joint arthroplasty or osteotomy, to help prevent a recurrent plantar forefoot ulcer once the active ulcer has healed. (Weak; Low)
13. We suggest not to use a nerve decompression procedure, in preference to accepted standards of good quality care, to help prevent a foot ulcer in a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) and who is experiencing neuropathic pain. (Weak; Low)
14. Consider advising a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) to perform foot and mobility-related exercises with the aim of reducing risk factors of ulceration, that is, decreasing peak pressure and increasing foot and ankle range of motion, and with the aim of improving neuropathy symptoms. (Weak; Moderate)
15. Consider communicating to a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) that a moderate increase in the level of walking-related weight-bearing activity (ie, an extra 1.000 steps/day) is likely to be safe. Advise this person to wear appropriate footwear when undertaking weight-bearing activities, and to frequently monitor the skin for pre-ulcerative signs or breakdown. (Weak; Low)
16. Provide integrated foot care for a person with diabetes who is at high risk of foot ulceration (IWGDF risk 3) to help prevent a recurrent foot ulcer. This integrated foot care includes professional foot care, adequate footwear and structured education about self-care. Repeat this foot care or re-evaluate the need for it once every one to three months, as necessary. (Strong; Low)

1 | INTRODUCTION

Foot ulceration is a major complication of diabetes mellitus and is associated with high levels of morbidity and mortality, as well as significant financial costs.[1-3] The lifetime incidence rate of diabetic foot ulceration is 19% to 34%, with a yearly incidence rate of 2%.[4] After successful healing, the recurrence rates of diabetic foot ulcers (DFU) are 40% within a year and 65% within 3 years.[4] Therefore, the prevention of DFU is paramount to reduce the risks to the patient and the resultant economic burden to society.

Not all patients with diabetes are at-risk for ulceration. Key risk factors include a loss of protective sensation (LOPS), peripheral artery disease (PAD), and foot deformity. Additionally, a history of foot ulceration and any level of lower extremity amputation further increase risk for ulceration.[4-6] In general, patients without any of these risk factors do not appear to be at risk for ulceration. For the current guideline, we define the at-risk patient as one with diabetes who does not have an active foot ulcer but who has at least LOPS or PAD. Table 1 shows the IWGDF system for stratifying risk for foot ulceration.

If patients have no risk factors, incidence of developing a foot ulcer is very low. Therefore, only interventions aimed specifically at the

TABLE 1 The IWGDF Risk Stratification System and corresponding foot screening and examination frequency

Category	Ulcer Risk	Characteristics	Frequency[a]
0	Very low	No LOPS and No PAD	Once a year
1	Low	LOPS or PAD	Once every 6-12 months
2	Moderate	LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity	Once every 3-6 months
3	High	LOPS or PAD, *and* one or more of the following: • history of a foot ulcer • a lower-extremity amputation (minor or major) • end-stage renal disease	Once every 1-3 months

Abbreviations: LOPS, loss of protective sensation; PAD, peripheral artery disease.

[a]Screening frequency is based on expert opinion, since no evidence is available to support these intervals. When the screening interval is close to a regular diabetes check-up, consider to screen the foot at that check-up.

prevention of foot ulcers in at-risk patients are included in this guideline. Within this group, those patients with a history of DFU or amputation are considered at higher risk for ulceration when compared with those without these problems.[6] Thus, we consider the first incidence of DFU and recurrent incidences of DFU separate outcomes of interest.

Various interventions for the prevention of foot ulcers are either used in clinical practice or have been studied in scientific research.[7] We identify five key elements of prevention: (a) identifying the at-risk foot; (b) regularly inspecting and examining the at-risk foot; (c) educating the patient, family, and health care providers; (d) ensuring routine wearing of appropriate footwear; and 5) treating risk factors for ulceration. Integrated foot care is a combination of these elements, and concerns the sixth element covered in this guideline.

The aim of this guideline is to provide evidence-based recommendations for the prevention of foot ulcers in people with diabetes and includes a rationale of how we came to each recommendation. This guideline is part of the IWGDF guidelines on the prevention and management of diabetic foot disease[8-12] and updates our previous guideline.[13] The rationale provided is based on a systematic review of the literature that underlies this guidance,[14] together with a consideration of the benefits and harm, patients' values and preferences, and the costs related to the intervention. We also provide general considerations and propose an agenda for future research.

2 | METHODS

In this guideline, we have followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, which is structured around clinical questions in the PICO-format (Patient-Intervention-Comparison-Outcome), systematic searches, and assessment of the available evidence, followed by developing recommendations and their rationale.[15,16]

First, a multidisciplinary working group of independent experts (the authors of this guideline) was installed by the IWGDF Editorial Board. The members of the working group devised the clinical questions, which were revised after consultation with external experts from various geographical regions and the IWGDF Editorial Board. The aim was to ensure the relevance of the questions for clinicians and other health care professionals in providing useful information on the prevention of foot ulcers in at-risk people with diabetes. We also formulated what we considered critically important outcomes relevant for daily care, using the set of outcomes defined by Jeffcoate et al[17] as a reference guide.

Second, we systematically reviewed the literature to address the agreed upon clinical questions. For each assessable outcome, we graded the quality of evidence based on the risk of bias of included studies, effect sizes, presence of inconsistency, and evidence of publication bias (the latter where appropriate). We then rated the quality of evidence as "high," "moderate," or "low." The systematic reviews supporting this guideline are published separately.[14,18]

Third, we formulated recommendations to address each clinical question. We aimed to be clear, specific, and unambiguous on what we recommend, for which persons, and under what circumstances. Using the GRADE system, we provided the rationale for how we arrived at each recommendation, based on the evidence from our systematic reviews,[14,18] expert opinion where evidence was not available, and a careful weighing of the benefits and harms, patient preferences, and financial costs (resource utilization) related to the intervention or diagnostic method.[15,16] Based on these factors, we graded the strength of each recommendation as "strong" or "weak", and for or against a particular intervention or diagnostic method. All our recommendations (with their rationales) were reviewed by the same international experts who reviewed the clinical questions, as well as by the members of the IWGDF Editorial Board.

We refer those seeking a more detailed description on the methods for developing and writing these guidelines to the "IWGDF Guidelines development and methodology" document.[19]

3 | RECOMMENDATIONS

3.1 | Identifying the at-risk foot

PICO:

In people with diabetes, is structured annual screening for risk factors of foot ulceration, compared with less frequent or unstructured screening, effective for preventing a first-ever or recurrent DFU?

Recommendation 1

Examine a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of loss of protective

sensation and peripheral artery disease, to determine if they are at increased risk for foot ulceration. (GRADE recommendation: Strong; Quality of evidence: High).

Rationale

Targeting people with diabetes for foot ulcer prevention requires identification of those at risk. We found no evidence in the literature on the effect of screening for preventing a DFU. However, we recommend an annual foot screening for all persons with diabetes with no additional risk factors (IWGDF risk 0). Foot screening identifies those at risk and should specifically include screening for LOPS caused by diabetic peripheral neuropathy and for signs or symptoms of PAD. Foot screening should be performed by an adequately trained health care professional (see glossary for definition). LOPS can be assessed with a 10-g Semmes Weinstein monofilament[20]: a recent meta-analysis of individual patient data found consistent results using this assessment to predict risk of foot ulcer.[6] If a 10-g monofilament is unavailable, use the Ipswich Touch Test.[21] While outcomes of this test were not included in the aforementioned meta-analysis, the Ipswich Touch Test has shown results similar to testing with the 10-g monofilament.[22] Because limited vibratory sensation may also predict risk of foot ulceration,[4] we suggest to screen for this with a tuning fork or biothesiometer/neurothesiometer, if outcomes from monofilament testing do not show LOPS. Screening for PAD is discussed in the IWGDF Guidelines on PAD.[9] In short, this includes taking a cardiovascular history, palpating for foot pulses, obtaining pedal Doppler arterial waveforms and blood pressure measurements.[9] Although evidence for a screening interval is non-existent, we recommend an annual screening for a person with diabetes in whom LOPS or PAD have not yet been identified.

Based on a meta-analysis,[6] the quality of the evidence that LOPS and PAD are predictive of foot ulceration is high. We suggest that there are no harms associated with yearly foot screenings, the benefits of foot screening outweigh the harms. We also suggest positive value to persons with diabetes of such yearly screenings as part of their regular diabetes check-ups. While foot screening is generally feasible, acceptable, and inexpensive on the individual level, it can be more complex and costly to organize on the societal level, given the growing number of people with diabetes and the limited time allotted for primary care visits. However, early identifying persons at risk of foot ulceration is highly important and is needed to target those who require preventative treatment. Therefore, the recommendation for an annual structured foot screening is strong.

3.2 | Regularly inspecting and examining the at-risk foot

PICO:

In people with diabetes at-risk for foot ulceration, what are the risk factors that should be screened for, for preventing a first-ever or recurrent DFU?

Recommendation 2

Screen a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) for a history of foot ulceration or lower-extremity amputation; diagnosis of end-stage renal disease; presence or progression of foot deformity; limited joint mobility; abundant callus; and any pre-ulcerative sign on the foot. Repeat this screening once every 6 to 12 months for those classified as IWGDF risk 1, once every 3 to 6 months for IWGDF risk 2, and once every 1 to 3 months for IWGDF risk 3 (Strong; High).

Rationale

When either LOPS or PAD is identified in a person with diabetes, more extensive and more frequent foot examination is needed, as the ulcer risk is higher.[4,6] For these patients, this examination should consist of taking a detailed history of foot ulceration, lower-extremity amputation, and determining a diagnosis of end-stage renal disease. Physically examine the foot for presence of deformities or progression thereof; abundant callus and pre-ulcerative signs, such as blisters, fissures and haemorrhage; and limited joint mobility.[5,6] A history of a previous foot ulcer or amputation are important predictive factors for a new ulceration, as identified in a meta-analysis of individual patient data.[6] Foot deformities, abundant callus, pre-ulcerative signs, and limited joint mobility may increase the risk of foot ulceration[4,23] and are important determinants of treatment in people with LOPS or PAD.

Notwithstanding the lack of evidence, other factors that we suggest taking a history of are the presence of social isolation, poor access to health care and financial constraints; foot pain (with walking or at rest); and numbness or claudication. We also suggest examining the presence of ill-fitting, inadequate, or lack of footwear; abnormal skin colour, temperature or oedema; poor foot hygiene, for example, improperly cut toenails, unwashed feet, superficial fungal infection, or unclean socks; physical limitations that may hinder foot self-care (eg, visual acuity, obesity); and foot care knowledge.[23-26] Lacking footwear, or having Ill-fitting or inadequate footwear can be a cause of ulceration,[24] and poor hygiene may be reflective of poor self-care. Appropriate interventions can potentially improve these modifiable risk factors when they are identified.

Any foot ulcer identified during screening should be treated according to the principles outlined in the other IWGDF guidelines.[8-12]

3.3 | IWGDF risk stratification

Based on the findings of the foot screening, patients can be stratified according to their risk for foot ulceration (Table 1). The risk categories defined are based on a meta-analysis and a systematic review of

prospective risk factor studies on foot ulceration; quality of evidence is therefore high.[6]

Someone without LOPS and without PAD is classified as IWGDF risk 0 and is at very low risk for ulceration. This person requires only annual screening. All other categories are considered "at risk" and require more frequent foot screening, regular inspection, and foot examination than patients who are not at risk.

A person with either LOPS or PAD, but no additional risk factors, is stratified as IWGDF risk 1 and is considered at low risk. They should be screened once every 6-12 months. When a combination of risk factors is present, a person is stratified as IWGDF risk 2 and is considered to be at moderate risk. As their risk is higher, they should be screened every 3 to 6 months. All persons with either LOPS or PAD *and* a history of foot ulcer or lower-extremity amputation are stratified as IWGDF risk 3 and considered to be at high risk of ulceration. These persons should be screened once every 1 to 3 months. We also regard people with LOPS or PAD in combination with end-stage renal disease[27-29] as being at high risk, irrespective of their ulcer history, and have therefore added these to IWGDF risk 3.

A person's risk status may change over time, thus requiring continual monitoring. The screening frequencies we have provided help guide such monitoring. If findings lead to a change in risk status, screening frequency should be adjusted accordingly. As someone's course of diabetes progresses, upgrading is the most likely change. Downgrading risk status might occur after (surgical) interventions that normalize foot structure or improve lower extremity blood flow. Further, in patients with longstanding LOPS, it is not required to repeat the assessment of LOPS at each screening visit.

In view of the lack of evidence for the effectiveness of a screening interval in at-risk patients, we recommend these intervals based on expert opinion. The aim of more frequent screening is early identification of risk factors that can increase the chances of developing a foot ulcer. This should then be followed by providing appropriate preventative foot care. For example, early diagnosis and treatment of pre-ulcerative signs on the foot may prevent foot ulcers, as well as more severe complications such as infection and hospitalization. Screening for all these factors should help increase awareness; while it might also raise concern or feelings of anxiety in some patients, we think that in general the potential for harm is limited. All screening can be done without the need for intrusive interventions and may also provide an opportunity to provide patient education, counselling, and support. We suggest that the benefits associated with targeted preventative treatment following screening likely outweigh potential harms, provided appropriate treatment is given by an adequately trained health care professional. Screening takes relatively little time, and while this is feasible, acceptable, and inexpensive at the individual level, it may be harder to organize and costlier on a societal level. Taking all evidence together, we strongly recommend such screening.

4 | EDUCATING THE PATIENT, FAMILY, AND HEALTH CARE PROVIDERS

4.1 | Instructions on foot self-care

PICO

In people with diabetes at risk for foot ulceration, is foot self-care compared with no self-care effective for preventing a first-ever or recurrent DFU?

Recommendation 3

Instruct a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors (Strong; Low).

Rationale

The feet of an at-risk person with diabetes need to be protected against high mechanical stresses, as well as external physical trauma, as both may cause foot ulcers.[20] To protect their feet, these patients should therefore not walk barefoot, in socks without shoes, or in thin-soled slippers, either at home or outside. This also includes any other open type footwear that increases risk for direct skin damage by a foreign object. While no studies have been performed on the effect of walking barefoot, in socks, or in thin-soled standard slippers, on risk of foot ulceration, there are many large prospective studies that show that at-risk patients with diabetes have elevated levels of plantar pressure during walking barefoot, in socks and in thin-soled slippers.[30,31] These high pressures are a significant independent risk factor for foot ulceration and should therefore be avoided.[4] In addition, walking under these conditions has other harmful effects in at-risk patients with diabetes, such as lack of protection against thermal or external mechanical trauma. Thus, despite the lack of direct evidence for this recommendation, we feel strongly that patients should be advised to avoid these walking conditions to reduce risk of damaging the foot.

Patients might prefer not to adhere to this recommendation, especially inside their house.[32,33] However, given the harms of walking unprotected outweigh patient preferences, we strongly recommend to instruct at-risk patients with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside.

Recommendation 4

Instruct, and after that encourage and remind, a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to inspect daily the entire surface of both feet and the inside of the shoes that will be

worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toe nails straight across; and avoid using chemical agents or plasters or any other technique to remove callus or corns (Strong; Low).

Rationale

Although no direct evidence is available for the effect of these self-care interventions in preventing foot ulcers, they enable a person to detect early signs of DFU and contribute to basic foot hygiene. This is likely to help prevent a foot ulcer, although it may pose some burden to patients. It can be expected that people will generally accept basic foot hygiene and that the benefits outweigh potential harms associated with either inappropriate or inadequate or no foot self-care at all. These foot self-care behaviours are feasible, accessible and come at a low cost per person who is at risk for DFU. Despite the limited evidence for the effect of these self-care activities on ulcer prevention, this is a strong recommendation.

4.2 | Providing structured education about foot self-care

PICO

In people with diabetes at risk of foot ulceration, is providing structured education about foot specific self-care compared with not providing it, effective for preventing a first-ever or recurrent DFU?

Recommendation 5

Provide structured education to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer (Strong; Low).

Rationale

Structured education is considered an essential and integral part of foot ulcer prevention, as it is widely thought that patients with diabetes at-risk for foot ulceration need to understand their disease in order to engage in foot self-care.[34-36] Structured education is defined as any educational modality that is provided to patients in a structured way. This can take many forms, such as one-to-one verbal education, motivational interviewing, educational group sessions, video education, booklets, software, quizzes, and pictorial education via animated drawing or descriptive images. Despite this myriad of forms available and education being ingrained in clinical practice all over the world, research on its effectiveness is limited. There is insufficient robust evidence that limited patient education alone is effective in achieving clinically relevant ulcer risk reduction.[37,38] However, education may improve knowledge and foot self-care behaviour.[38] Therefore, education should aim to improve the patients foot care knowledge and self-care behaviour and encourage the patient to adhere to the foot self-care education provided.

Structured foot care education should consist of information on:

- Foot ulcers and their consequences
- Preventative foot self-care behaviours, such as: not walking barefoot or in socks without shoes or in thin-soled slippers
- Wearing adequately protective footwear
- Undergoing regular foot checks
- Practicing proper foot hygiene
- Seeking professional help in a timely manner after identifying a foot problem (see recommendations 3 and 4).

As there is evidence of the benefits of treatment adherence on ulcer outcomes,[39,40] encourage people at risk of DFU to adhere to the foot self-care education provided. It is best if such education is integrated with regular foot screenings (see recommendations 1 and 2) and is part of integrated foot care (see recommendation 16). Structured education should be culturally appropriate, account for gender differences, and align with a patient's health literacy and personal circumstances. It is therefore not possible to provide globally applicable recommendations on the best form of education. We suggest that structured foot self-care education should be provided individually or in small groups of patients. It should be provided over several sessions and with periodical reinforcement, to maximize effect.

Despite low quality of evidence, we strongly recommend providing structured education on foot self-care. While education could potentially lead to harm such as an increased fear of complications,[41] it may also provide an opportunity for patients to clarify misunderstandings and seek answers to questions they have.[26] Overall, we assess that the benefits outweigh the potential harms. Patients will probably prefer structured education when it is appropriate to their circumstances, feasible, equitable, and accessible. While structured education is inexpensive at the individual level, it may be harder to organize and costlier on a societal level. Taken together, we strongly recommend providing structured education.

4.3 | Instructions about foot self-management

PICO

In people with diabetes at risk for foot ulceration, is foot self-management compared with no self-management, effective for preventing a first-ever or recurrent DFU (O)?

Recommendation 6

Consider instructing a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin

temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference is above threshold between similar regions in the two feet on two consecutive days, instruct the patient to reduce ambulatory activity and consult an adequately trained health care professional for further diagnosis and treatment (Weak; Moderate).

Rationale

Foot self-management differs from foot self-care as it involves more advanced interventions that are specifically designed for ulcer prevention, such as home-monitoring tools and telemedicine approaches. Self-management can include many interventions, but we found no evidence to support the use of any specific intervention, with the exception of home monitoring of foot skin temperature.[42-45] We found evidence that home monitoring of plantar foot skin temperature once per day with an easy to use infrared thermometer, combined with subsequent preventative action when above-threshold (2.2°C) temperatures were noted for two consecutive days, is more effective than standard treatment for preventing foot ulcers in high risk-patients (IWGDF risk 2-3).[42-45] These preventative actions include reduction of ambulatory activity, consultation with an adequately trained health care professional to discuss the findings, and further preventative treatment as per the health care professional's assessment. For this recommendation to be effective, a person needs to have ready access to and the ability to use an appropriate thermometer and be in communication with an adequately trained health care professional.

Professionals may value home monitoring of foot temperatures as an easy to use and relatively inexpensive method that may have high clinical value and helps empower people in their care of their own feet. However, the available evidence shows that adherence to measuring foot temperatures was an important factor in its effectiveness, and people, in particular those who have not had a foot ulcer, may find the requirement for daily assessment a burden.[43,46] False-positive and false-negative outcomes of temperature measurements may unnecessarily concern people and affect their confidence in using this approach.[47,48] To our knowledge, home monitoring of foot temperature is currently not implemented in foot care of people with diabetes at moderate to high risk of DFU. This may be due to how people value the need for and ease of use of daily temperature measurements, lack of easy access to calibrated equipment, or lack of information on cost-effectiveness and implementation feasibility. Because of these potential limitations, the recommendation is graded as weak.

5 | ENSURING ROUTINE WEARING OF APPROPRIATE FOOTWEAR

PICO

In people with diabetes at risk for foot ulceration, is any one specific orthotic intervention, including therapeutic footwear (eg, shoes, insoles or orthoses) and walking aid, compared with no intervention or another type of orthotic, effective for preventing a first-ever or recurrent DFU?

Recommendation 7

Instruct a person with diabetes who is at moderate risk for foot ulceration (IWGDF risk 2) or who has healed from a non-plantar foot ulcer (IWGDF risk 3) to wear therapeutic footwear that accommodates the shape of the feet and that fits properly, to reduce plantar pressure, and help prevent a foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing custom-made footwear, custom-made insoles, or toe orthoses (Strong; Low).

Recommendation 8

Consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration (IWGDF risk 1-3) (Weak; Low).

Rationale

People at moderate or high risk for foot ulceration (IWGDF risk 2-3) have often lost their ability to feel pain or pressure and may not adequately judge the fit of their footwear or the level of pressure on their feet. Being at increased risk for ulceration, it is important that their footwear fits, protects, and accommodates the shape of their feet; this includes having adequate length, width, and depth.[49] When a foot deformity or pre-ulcerative sign is present, it becomes even more important to change foot biomechanics and reduce plantar pressure on at-risk locations. This may require custom-made footwear, custom-made insoles, or toe orthoses. For people who have healed from a plantar foot ulcer, follow recommendation 9. Based on three RCTs,[50-52] therapeutic footwear, including shoes, insoles, or orthoses may reduce the risk of a first-ever foot ulcer in a person at moderate risk for foot ulceration (IWGDF risk 2). Additionally, such footwear can reduce the plantar pressure during walking.[53,54] High plantar pressures are a significant independent risk factor for foot ulceration and should therefore be avoided.[4,55] Because patients with LOPS cannot adequately judge footwear fit, footwear should be evaluated by appropriately trained professionals. Evaluate the fit with the patient in the standing position, preferably at the end of the day.[49]

To reduce abundant callus and the associated increased foot pressure, patients at risk of ulceration (IWGDF risk 1-3) can be provided with toe silicone and (semi-)rigid orthoses or felted foam in addition to therapeutic footwear.

Persons with diabetes may value the role of properly fitting footwear to prevent ulcers, but some still consider their footwear to be the cause of their problems, especially when the footwear does not fit

properly. Properly fitting footwear may also not align with personal comfort and style preferences, while in some countries wearing footwear is not customary at all or may lead to inconvenience (eg, in warmer or wet climates). However, we know little about the adherence of patients at moderate risk for ulceration to wearing properly fitting footwear. Therapeutic footwear or adequately trained professionals may also not be present in all countries, which limits access to orthotic interventions. However, with the additional benefit of protection against thermal and mechanical trauma, and the evidence of reducing ulcer risk, we judge the benefits to outweigh the harms and therefore assign a strong recommendation.

Recommendation 9

In a person with diabetes who has a healed plantar foot ulcer (IWGDF risk 3), prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the patient to consistently wear this footwear (Strong; Moderate).

Rationale

For people with a healed plantar foot ulcer (IWGDF risk 3), therapeutic footwear needs to reduce plantar pressure at high-risk areas, including the previous ulcer location. Two RCTs with very low risk of bias have demonstrated a reduction in ulcer risk with custom-made orthopaedic footwear[56] or custom-made insoles[57] that were demonstrably optimized for pressure reduction, provided the patient wears the footwear. Demonstrated plantar pressure-relieving effect means that at high-pressure locations, there should be either a ≥ 30% reduction in the peak pressure during walking (compared with the current (therapeutic) footwear), or a peak pressure < 200 kPa (if measured with a validated and calibrated pressure measuring system with sensor size of 2 cm^2).[56,57] The way to achieve such a pressure relief or level is by applying available state-of-the-art scientific knowledge on footwear designs that effectively offload the foot.[49,56-65]

The benefits of continuously wearing optimized footwear or insoles with a proven offloading effect outweigh the potential harm, as available trials have infrequently reported any harm related to such therapeutic footwear.[56,57,66-70] On the other hand, non-appropriate footwear (inadequate length or width) increases the risk of ulceration,[71] and we again stress the importance of ensuring adequate fit.[49] Clinicians should also encourage patients to wear their prescribed footwear at all times. The costs of prescribing therapeutic footwear with demonstrated offloading effect may be quite high, as it requires the measurement of barefoot or in-shoe plantar pressure, which to date is relatively expensive. However, these costs should always be considered in association with the clinical benefit of ulcer prevention. Cost-effectiveness has not been studied to date but, in our opinion, footwear designed or evaluated using plantar pressure measurement is likely to be cost-effective when it can reduce ulcer risk by 50%, a risk reduction demonstrated in most of the above-mentioned trials on this topic.[46] This is therefore a strong recommendation.

Note that this recommendation is predicated on the availability of both therapeutic footwear and accurate technology for pressure measurement. We acknowledge that the technology and expertise for such measurements are not yet widely available. For regions and settings where this can be made available, we encourage services to invest in regular plantar pressure measurements. For regions and clinical setting where this cannot yet be accommodated, we suggest to prescribe therapeutic footwear using available state-of-the-art scientific knowledge on footwear designs that effectively offload the foot.[49,56-65]

6 | TREATING RISK FACTORS FOR ULCERATION

6.1 | Treatment of risk factors or pre-ulcerative signs on the foot

PICO

In people with diabetes at risk for foot ulceration, is treating pre-ulcerative signs on the foot compared with not treating them, effective for preventing a first-ever or recurrent DFU (O)?

Recommendation 10

Treat any pre-ulcerative sign or abundant callus on the foot, ingrown toe nail, and fungal infections on the foot, to help prevent a foot ulcer in a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) (Strong; Low).

Rationale

Pre-ulcerative signs on the foot, such as blisters, fissures, or haemorrhage appear to be strong predictors of future ulceration.[4,23,25] Other risk factors that require treatment include abundant callus, ingrown or thickened toe nails, and fungal infections. These signs require immediate treatment by an appropriately trained health care professional. This means removing abundant callus; protecting blisters and draining them when necessary; treating fissures; treating ingrown or thickened toe nails; treating cutaneous haemorrhage; and prescribing antifungal treatment for fungal infections. The effectiveness of treating these signs on the prevention of a foot ulcer has not been directly investigated. Indirect evidence of benefit is that removal of callus reduces plantar pressure, an important risk factor for ulceration.[72,73]

The benefit-harm ratio of treatment of pre-ulcerative signs by an appropriately trained foot care professional will likely be positive and come at relatively low costs. However, these treatments do have the potential to harm when improperly performed and should therefore only be done by an appropriately trained health care professional. It can be expected that persons educated to the dangers of pre-ulcerative signs prefer that they be treated. Despite a lack of evidence, we consider this standard practice and therefore the recommendation is strong.

6.2 | Surgical interventions

PICO

In people with diabetes who are at risk of foot ulceration, is performing surgical interventions in comparison to non-surgical intervention, effective for preventing a first-ever or recurrent DFU?

Recommendation 11

In a person with diabetes and abundant callus or an ulcer on the apex or distal part of a non-rigid hammertoe that has failed to heal with non-surgical treatment, consider digital flexor tendon tenotomy for preventing a first foot ulcer or recurrent foot ulcer once the active ulcer has healed (Weak; Low).

Rationale

While controlled studies on this topic are lacking, various studies have shown that a digital flexor tendon tenotomy may reduce the risk of a recurrent plantar foot ulcer in selected patients with initially nonhealing ulcers when compared with non-surgical treatment for these ulcers.[74-80] Flexor tenotomy may also reduce the risk of ulcer development in patients with abundant callus on the tip of their toes or thickened nails.[76,77,79] We consider flexor tenotomy a promising procedure in a patient who has a toe ulcer, or a pre-ulcerative sign on the toe, that fails to respond to non-surgical treatment, and requires normalization of foot structure to prevent ulceration. Preventative surgery should only be considered after full evaluation of non-surgical treatment options by an appropriately trained health care professional.

The possible benefits of digital flexor tenotomy likely outweigh the harm, as few complications have been reported.[74-80] Patients who have pre-ulcerative lesions for which they have frequent non-surgical treatment that does not improve outcome may value and prefer treatment by flexor tenotomy. The procedure is easily performed in an outpatient setting, with no need for subsequent immobilization, and is not likely to negatively affect foot function. Costs and cost-effectiveness of this procedure have not been evaluated. Possible adverse effects of the surgery should be discussed with the patient; in patients with poor arterial supply to the foot, this includes potential non-healing of the surgical incision or wound. Taken together, the recommendation is weak.

Recommendation 12

In a person with diabetes and a plantar forefoot ulcer that has failed to heal with non-surgical treatment, consider Achilles tendon lengthening, single or pan metatarsal head resection, metatarsophalangeal joint arthroplasty or osteotomy, to help prevent a recurrent plantar forefoot ulcer once the active ulcer has healed (Weak; Low).

Rationale

Studies primarily aimed at healing recalcitrant forefoot plantar ulcers have found that Achilles tendon lengthening, single or pan-metatarsal head resection and metatarsophalangeal joint arthroplasty may reduce the risk of a recurrent plantar foot ulcer in selected patients with initially nonhealing ulcers when compared with non-surgical treatment.[81-100] While effect sizes are often large, very few well-designed controlled studies show the efficacy of these interventions.

This recommendation applies to a patient who (a) has a plantar ulcer that is unresponsive to evidence-based non-surgical treatment; (b) is expected to have a high risk of recurrence if the foot structure is not changed; (c) has elevated forefoot plantar pressures; and (d) in the case of Achilles tendon lengthening, has a limited ankle joint range of motion, not passing neutral.

Possible complications and side effects of these surgical offloading techniques include post-operative infection, new deformities, gait problems and transfer ulcers.[84,101-103] Therefore, it is not clear if the benefits outweigh the harm. In any case, these techniques should be primarily used in patients to heal a foot ulcer that is unresponsive to evidence-based non-surgical treatment and that is expected to have a high risk of recurrence if the foot structure is not changed. Patient values and preferences for these approaches are unknown, although we expect patients to value an intervention as high when it can both heal and prevent an ulcer, but as low when it causes complications such as major gait or balance problems. The costs of surgical interventions can be much higher than for non-surgical treatment, but cost-effectiveness is unknown. Clinicians should carefully discuss possible adverse effects of the surgery with the patient; in patients with poor arterial supply, this includes potential non-healing of the surgical incision or wound. We therefore offer a weak suggestion to consider these interventions.

Recommendation 13

We suggest not to use a nerve decompression procedure, in preference to accepted standards of good quality care, to help prevent a

foot ulcer in a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) and who is experiencing neuropathic pain (Weak; Low).

Rationale

While observational studies on nerve decompression procedures have demonstrated low ulcer incidence rates over extended follow-up periods in patients with or without a prior foot ulcer experiencing neuropathic pain,[104-108] there is no evidence from appropriately designed controlled studies to support an ulcer prevention effect of nerve decompression. With various non-surgical interventions available that can be considered standard of good quality care to prevent a foot ulcer in an at-risk patient, we suggest not to use nerve decompression as surgical procedure.

6.3 | Foot-related exercises and weight-bearing activity

PICO

In people with diabetes at risk for foot ulceration, are foot-related exercises compared with no foot-related exercises effective for preventing a first-ever or recurrent DFU?

Recommendation 14

Consider advising a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) to perform foot and mobility-related exercises with the aim of reducing risk factors of ulceration, that is, decreasing peak pressure and increasing foot and ankle range of motion, and with the aim of improving neuropathy symptoms (Weak; Moderate).

Rationale

There is no direct evidence to suggest that foot-related exercises prevent DFU, as studies on this topic are non-existent. Various forms of foot-related exercises are possible when aiming to improve modifiable risk factors for foot ulceration such as plantar pressure distribution, neuropathy symptoms, deficits in foot sensation, foot-ankle joint mobility, and strength.[109-118] These exercises can include stretching and strengthening of the foot and ankle musculature and functional exercises such as balance and gait exercises and are provided or supervised by physical therapists or similarly trained professionals. Multiple RCTs and non-controlled studies have shown some benefit of these exercises on a range of modifiable risk factors for foot ulceration, including plantar pressure, foot and ankle range of motion, and neuropathy symptoms.[109-118]

Foot-related exercises are relatively easy to perform autonomously, are inexpensive, and do not require intensive supervision. As people at risk will likely not know what appropriate foot-related exercises are, we recommend them to undergo a foot assessment and exercise prescription by an adequately trained health care professional prior to commencing exercise. Regular evaluation of progress with training and modification of the programme in collaboration with the professional is recommended. Persons with pre-ulcerative signs or with an active foot ulcer should not partake in foot-related exercises in which the foot is mechanically loaded.

Advising patients at low to moderate risk for foot ulceration (IWGDF risk 1 or 2) to perform foot-related exercises is based on moderate quality evidence. Any potential for harm is outweighed by both general health benefits of exercise and specific improvements to the complex musculoskeletal deficits that develop with diabetes. Minimal exercise equipment is required, for example, elastic bands or exercise balls. As adherence may be a challenge, we advise health practitioners to continue to motivate patients to complete the exercise programme as prescribed.

PICO

In people with diabetes who are at risk for foot ulceration, can the level of weight-bearing daily activities be safely increased without increasing first-ever or recurrent DFU risk?

Recommendation 15

Consider communicating to a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) that a moderate increase in the level of walking-related weight-bearing daily activity (ie, an extra 1000 steps/d) is likely to be safe. Advise this person to wear appropriate footwear when undertaking weight-bearing activities, and to frequently monitor the skin for pre-ulcerative signs or breakdown (Weak; Low).

Rationale

Exercise has general health benefits for people with diabetes, including specific improvements to the complex musculoskeletal deficits that develop with diabetes.[119] However, when this exercise is weight-bearing, it might increase the cumulative plantar tissue stress, which in turn might increase the risk for foot ulceration.[120] Based on two RCTs[121,122] where patients at risk of foot ulceration participated in a training programme that increased their weight-bearing activity, but where this did not result in increased incidence of ulceration, we suggest to consider advising people at low or moderate risk for ulceration (IWGDF 1 or 2) that a small increase in the level of weight-bearing daily activities is likely to be safe. We define a small increase as 1000 steps/day, based on the increases seen in these two studies,[121,122]

and an RCT that showed such an increase to be beneficial for glycaemic control in people with diabetes.[123] It is advisable to increase daily steps by a maximum of 10% per week, until a person reaches an overall increase of 1000 steps/day in comparison to baseline. For people at high-risk for ulceration (IWGDF 3) there is insufficient evidence to provide a recommendation on safe increase in activity, as the people in abovementioned RCTs who did develop an ulcer were all at high risk.[121,122]

The quality of the evidence to support this recommendation is low, as it is based on only two RCTs that were each not powered to detect a difference in ulcer healing.[121,122] The lack of evidence is a concern (and an important area for future research). However, we think the lack of differences in rates of ulceration between the groups in these trials and the known benefits of increasing weight-bearing exercises on general health and foot-related outcomes, outweighs the harms. However, patients should remain cautious to avoid adverse outcomes such as falls. To prevent adverse outcomes, advise patients to wear appropriate footwear when undertaking weight-bearing activities (see recommendations 8-11) and to monitor their skin for pre-ulcerative signs or breakdown (see recommendations 4-6). Increasing the level of weight-bearing daily activity as recommended can be considered feasible and acceptable to persons with diabetes. However, high drop-out rates in some trials and lack of statistical power show that this may not hold for all persons with diabetes. Exercise programmes are a relatively cheap intervention. Primarily because of the low quality of evidence in relation to ulcer prevention, this is a weak recommendation.

7 | INTEGRATED FOOT CARE

PICO

In people with diabetes at risk for foot ulceration, is providing integrated foot care compared with not providing integrated foot care, effective for preventing a first-ever or recurrent DFU (O)?

Recommendation 16

Provide integrated foot care for a person with diabetes who is at high risk of foot ulceration (IWGDF risk 3) to help prevent a recurrent foot ulcer. This integrated foot care includes professional foot care, adequate footwear, and structured education about self-care. Repeat this foot care or re-evaluate the need for it once every one to 3 months, as necessary (Strong; Low).

Rationale

We define integrated foot care as an intervention that at a minimum integrates regular foot care and examination by an adequately trained professional, structured education, and adequate footwear. One RCT, one cohort study, and four non-controlled studies all reported a significantly lower percentage of recurrent ulcers in patients who received integrated foot care compared with those who did not,[124-126] or in those patients who were adherent to a programme compared with those who were not.[127-129] None of the studies reported any complications from, or other harm related to, the programme.

Professional foot care, by an adequately trained health care professional, consists of treating risk factors and pre-ulcerative signs as described in recommendation 10; structured education about foot self-care according to recommendations 3 to 5; and providing adequate footwear following recommendations 7 to 9. The patient's feet should be regularly examined (see recommendations 1 and 2). Integrated foot care may further include foot self-management (recommendation 6), access to surgery (recommendations 11-13), and foot-related exercises and weight-bearing activity (recommendations 14 and 15).

While integrated foot care programmes have been directly investigated in the above-mentioned controlled and non-controlled studies, none included all potential components of integrated foot care. The effectiveness of a state-of-the-art integrated foot care programme that combines all recommendations from this guideline can be expected to be much higher than with the programs researched to date. The effect sizes of the various components of integrated foot care have been investigated in two reviews.[4,46] Our recommendation that integrated foot care at minimum consists of professional foot care, structured patient education, and adequate footwear, with a regular examination of a person's feet, is based on analysing these reviews.[4,46] However, the largest effect sizes in ulcer prevention can be found for self-management and surgical interventions, and a comprehensive integrated approach should include these as well. For all aspects of an integrated foot care programme, adherence to what is recommended increases the benefits,[4,46] and this should be given adequate attention in communication with the patient. Taken together, state-of-the-art integrated foot care has been suggested to be able to prevent up to 75% of all diabetic foot ulcers.[46]

We found no information on costs and cost-effectiveness of integrated foot care. However, a publication from the United States suggested that there was an increase in hospital admissions for a diabetic foot ulcer after Medicare cancelled financial coverage in one US state for preventative treatment given by podiatrists.[130] Two further studies suggested that there was a reduction in amputations following the introduction of integrated foot care that included both ulcer prevention and ulcer treatment.[131,132]

Integrated foot care should be provided by an adequately trained health care professional or a team of such professionals. People with diabetes at risk for foot ulceration who are cared for by professionals without specific expertise on diabetic foot disease should be referred by these professionals to integrated foot care services. Educational interventions targeting health care professionals to improve completion rates of yearly foot examinations and to improve knowledge of health care professionals not daily involved in diabetic foot care may be important, but the effectiveness of such education is unclear.[133-147] Teams that provide integrated foot care may perform

educational outreach activities to health care professionals in primary or secondary care. The teams should be aware, however, that the effect of such education is limited with respect to knowledge improvement and performance of yearly foot examination, and may have to be repeated frequently.

The benefits of integrated foot care by an adequately trained health care professional or a team thereof outweigh the potential harm of such treatment. We think it is likely that patients prefer integrated foot care, rather than having no integrated foot care. We consider the combined effect size of the various interventions that make up integrated foot care high. Despite the low quality of evidence, given the other advantages described, we rate our recommendation as strong.

8 | CONSIDERATIONS

1. The recommendations in this guideline are aimed at health care professionals treating people with diabetic foot disease. However, these professionals treat patients within a health care system or organization, which itself may have an effect on outcomes. Although direct evidence for this is not available, indirect evidence comes from the effect of increasing number of podiatrists and multidisciplinary teams in the Netherlands,[148] which resulted in a reduction of lower-extremity amputations. Another study showed that the discontinuation of podiatry care from Medicare in the United States[130] resulted in an increase in hospitalizations for diabetic foot disease. Both studies point to the potential importance of health care organization in diabetic foot care, including ulcer prevention. We suggest that a health care system includes the multiple levels of foot care as described in the IWGDF practical guidelines,[20] that patients can be referred from primary care to secondary care without delay, and that evidence-based preventative interventions are reimbursed within the system. Also, all health care professionals should be adequately trained to triage patients to ensure they are treated by the right professional. Investment in these aspects of the health care system is important to provide adequate preventative foot care for at-risk patients. This guideline is not written for governments or other agencies investing in health care organizations, but we do urge politicians and managers responsible to invest in health care systems that facilitate these recommendations.
2. All recommendations in this guideline are targeted at just three strata within the IWGDF risk stratification system (Table 1). Some specifications are given in relation to the location of a previous ulcer (eg, plantar vs non-plantar; toes vs forefoot) or the presence of foot deformities, when recommending orthotic or surgical interventions. However, many differences between patients in the same stratum exist, and may limit providing the right treatment for the right person at the right time. No research has been done on such personalized medicine and its effects in the prevention of diabetic foot ulcers, which means that specific personalized recommendations cannot be made. This may change in the future, as the medical community is moving more and more towards personalized solutions for medical problems.
3. An important factor in most recommendations made is that the patient is adherent to the recommendations. As we noted in our previous guideline,[13] adherence to an intervention has been shown to be crucial in preventing foot ulcers, and it is consistently reported that patients who do not adhere present with higher rates of ulceration.[46] Some pilot studies have investigated methods to improve adherence,[149] but a stronger focus on the development, evaluation and implementation of methods that improve adherence to preventative diabetic foot treatment remains urgently needed.
4. Probably the two most common preventative actions in daily clinical foot practice globally are foot screening (recommendations 1 and 2), and (structured) education (recommendation 5). Despite their widespread application in clinical foot practice, the evidence underlying these recommendations is poor. Frequency of foot screening is based on expert opinion only, and structured education has not been studied adequately. Lack of effect shown does not imply that these interventions are not effective, but more research is needed to provide a stronger evidence base.
5. Costs and cost-effectiveness have not been investigated for any of the interventions described in this guidance, and more attention to cost aspects is warranted. While some interventions are relatively inexpensive at the individual level (such as foot screening), they can be costly at a societal level, considering the millions of people with diabetes. Other interventions are costly at the individual level (such as custom-made footwear), but reduce ulcer recurrence risk to a level that they are expected to be cost-saving at a societal level. More research in this area is needed.

9 | FUTURE RESEARCH AGENDA

Based on the gaps in the evidence as identified in our systematic reviews,[14] and the recommendations and considerations made in this guideline, we consider the following topics as the most important for future research:

- An integrated foot care approach that combines state-of-the-art interventions as recommended in this guideline has not been investigated to date on efficacy to prevent foot ulcers, while the effect sizes of various interventions found suggest that up to 75% of foot ulcers may be prevented when integrated in such an approach. This needs to be investigated in well-designed randomized controlled trials.
- Current treatment recommendations are based largely on stratified health care. Future research is needed to explore the potential of a more personalized medicine approach in diabetic foot ulcer prevention, so to deliver the right treatment, to the right person, at the right time.[150]

- Organization of health care and health care setting likely plays a significant role in ulcer prevention, but this has not yet been investigated.
- Structured education is by many considered a key aspect of a foot ulcer prevention programme, but it remains unknown what the exact effect is and which educational approach is most effective. Future research should assess the effectiveness of various educational interventions, as well as the frequency of education provided. This includes but is not limited to motivational behavioural interventions, e-health applications, and (online) social support systems by peers or health care professionals.
- Adherence to treatment is crucial to achieve the best possible outcome in ulcer prevention, but it is unknown how adherence can be improved. Research on interventions that have the potential to improve adherence is needed. These interventions may include, among others, assistive technology, educational interventions or shoe technical solutions.
- The costs and the cost-effectiveness of interventions that aim to prevent foot ulcers needs to be investigated.
- Peripheral neuropathy is the most important risk factor for the development of foot ulcers in people with diabetes, but there is little research on the prevention or treatment of neuropathy. A stronger research focus in this area is needed.
- Robust data are lacking on whom, how, and when to screen for the risk of foot ulceration. High quality data on the benefit of interventions to prevent a first foot ulcer are scarce. As the event rate (foot ulceration) is relatively low in a population without a previous ulcer, large groups of patients need to be targeted, and it is unclear if the benefits will outweigh harm and costs. Studies are urgently needed to better define the categories of patients that will benefit from preventative interventions and what specific types of interventions should be included.
- While there is some evidence to support surgical interventions for the prevention of a recurrent ulcer in selected patients, these interventions are not without risk. The exact role of these surgical procedures compared with conservative approaches in the prevention of ulceration is still unclear, and requires appropriately designed controlled studies.

10 | CONCLUDING REMARKS

The global patient and economic burden of diabetic foot disease can be considerably reduced when evidence-based preventative treatment is implemented in the foot care of people with diabetes who are at risk of developing a foot ulcer. Reducing the risk of ulceration also reduces the risk of infection, hospitalization, and lower-extremity amputation in these people. While drawing only limited attention of clinicians and researchers compared with the management of foot ulcers, foot ulcer prevention is the best way to prevent severe morbidity and mortality in people with diabetes. Following the recommendations for preventative treatment in this guideline will help health care professionals and teams provide better care for diabetic patients who are at risk of ulceration.

We encourage our colleagues, both those working in primary care and in diabetic foot clinics, to consider developing forms of surveillance (eg, registries, pathways) to monitor and attempt to improve their outcomes in patients at risk of foot ulceration. We also encourage our research colleagues to consider our key controversies and considerations and future research agenda and conduct properly-designed studies[17] in areas of prevention in which we find gaps in the evidence base or to provide more robust support for existing knowledge, so to better inform the diabetic foot community on effective treatment for preventing a foot ulcer in a persons with diabetes.

11 | GLOSSARY

Abundant callus: Callus that, as assessed by an appropriately trained health care professional, requires debridement to reduce risk for ulceration.

Adherence: The extent to which a person's behaviour corresponds with agreed recommendations for treatment from a health care provider, expressed as quantitatively as possible; eg, the proportion of time, steps or instances that the prescribed intervention (or comparator) is used.[151]

Adequately trained health care professional: a person who according to national or regional standards has the knowledge, expertise, and skills to perform a specified task in screening, examining, or managing a person with diabetes who is at risk of foot ulceration.

Custom-made insole: An insole that is custom-made to the individual's foot using a 2D or 3D impression of the foot, and that is often built-up in a multi-layer construction. This may also incorporate other features, such as a metatarsal pad or metatarsal bar. The insole is designed to conform to the shape of the foot, providing cushioning and redistribution of plantar pressure. The term "insole" is also known as "insert" or "liner".

Custom-made (medical grade) footwear: Footwear uniquely manufactured for one person, when this person cannot be safely accommodated in pre-fabricated (medical grade) footwear. It is made to accommodate deformity and relieve pressure over at-risk sites on the plantar and dorsal surfaces of the foot. In-depth assessment, multiple measurements, impressions or a mould, and a positive model of a person's foot and ankle are generally required for manufacture. This footwear includes a custom-made insole. Also known as "bespoke footwear" or "orthopaedic footwear".

Extra-depth footwear: Pre-fabricated footwear constructed with additional depth and volume in order to accommodate deformity such as claw/hammer toes and/or to allow for space for a thick insole. Usually a minimum of 5 mm (~3/16″) depth is added compared with off-the-shelf footwear. Even greater depth is sometimes provided in footwear that is referred to as double depth or super extra-depth.

Foot deformity: see IWGDF definitions and criteria document.[152]

Foot-related exercises: Any physical exercise specifically targeting the foot or lower-extremity with the aim of changing foot function. These exercises can include stretching and strengthening of

the foot and ankle musculature and functional exercises such as balance and gait training. These exercises are provided and/or supervised by a physical therapist or a similarly adequately trained health care professional.

Foot self-care: Foot care interventions the patient can do at home, consisting of but not limited to: foot inspection, washing of feet, careful drying between the toes, nail cutting, using emollients to lubricate skin, footwear inspection, avoidance of using chemical agents or plasters to remove callus, avoidance of walking barefoot or on socks only or in thin-soled slippers, avoidance of wearing tight socks, and avoiding exposure to excessive cold and heat.

Foot self-management: Advanced assistive interventions the patient can use at home, consisting of but not limited to: home monitoring systems, lifestyle interventions, telehealth, technological applications, peer support programs.

Footwear: defined broadly as any shoe-gear and including insoles.

Footwear modification: Modification to existing footwear with an intended therapeutic effect, for example, pressure relief.

Hosiery: Stockings or socks of any kind. See further Stockings or Socks.

In-shoe (semi-)rigid orthosis: Term used for device put inside the shoe to achieve pressure reduction or alteration in the function of the foot. Can be pre-fabricated or custom-made.

Limited oint mobility: see IWGDF definitions and criteria document.[152]

Medical grade footwear: Footwear that meets the specific needs of a person. Can be either pre-fabricated (see "Pre-fabricated medical grade footwear") or custom-made (see "Custom-made medical grade footwear"). Also known as pedorthic footwear.

Off-the-shelf footwear: Readily available footwear that has not been modified and has no intended therapeutic functions. Preferred term is pre-fabricated footwear.

Pre-fabricated medical grade footwear: Pre-fabricated footwear that meets the specific needs of a person, on the basis of footwear that provides extra depth, multiple width fittings and features designed to accommodate a broader range of foot types. Other features may include modified soles, fastenings and smooth internal linings. This type of footwear is usually available at specialty shoe shops.

Pre-fabricated insole: An "off-the-shelf" flat or contoured insole made without reference to the shape of the individual patient's foot.

Shoe last: Last used to make footwear. The upper of the footwear is moulded or pulled over the last. The last shape defines the footwear shape including the outsole, heel pitch and toe spring. For off-the-shelf or pre-fabricated footwear generically-generated lasts in different sizes are used.

Slipper: Low-cut, open type footwear that is easily slipped onto the foot. Includes thin-soled slippers and flip-flops (thongs).

Socks: Garment for the foot and lower part of the leg, typically knitted from wool, cotton, or nylon.

Stockings: Garment that fits closely over the foot and lower leg, typically elastic. Includes compression stockings for medical purposes.

Structured education: Any educational modality that is provided in a structured way. This can take many forms, such as one-to-one verbal education, motivational interviewing, educational group sessions, video education, booklets, software, quizzes, and pictorial education via animated drawing or descriptive images.

Therapeutic footwear: Generic term for footwear designed to have some therapeutic effect that cannot be provided by or in off-the-shelf footwear. Custom-made shoes or sandals, custom-made insoles, extra-depth shoes, and custom-made or prefabricated medical grade footwear are examples of therapeutic footwear.

Toe orthosis: an in-shoe orthosis to achieve some alteration in the function of the toe.

Weight-bearing activity: Activity during which the foot is loaded by supporting the body weight of the person, and expressed as quantitatively as possible. Incudes walking and standing.

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CONFLICT OF INTEREST

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