

The 2015 IWGDF Guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus

Prepared by the IWGDF Editorial Board

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Summary

Foot problems complicating diabetes are a source of major patient suffering and societal costs. Investing in evidence-based, internationally appropriate diabetic foot care guidance is likely among the most cost-effective forms of healthcare expenditure, provided it is goal-focused and properly implemented.

The International Working Group on the Diabetic Foot (IWGDF) has been publishing and updating international Practical Guidelines since 1999. The 2015 updates are based on systematic reviews of the literature, and recommendations are formulated using the Grading of Recommendations Assessment Development and Evaluation (GRADE) system. As such, we changed the name from “Practical Guidelines” to “Guidance”.

In this article we describe the development of the 2015 IWGDF Guidance documents on prevention and management of foot problems in diabetes. This Guidance consists of five documents, prepared by five working groups of international experts. These documents provide guidance related to foot complications in persons with diabetes on: prevention; footwear and offloading; peripheral artery disease; infections; and, wound healing interventions. Based on these five documents, the IWGDF Editorial Board produced a summary guidance for daily practice.

The resultant of this process, after review by the Editorial Board and by international IWGDF members of all documents, is an evidence-based global consensus on prevention and management of foot problems in diabetes. Plans are already under way to implement this Guidance.

We believe that following the recommendations of the 2015 IWGDF Guidance will almost certainly result in improved management of foot problems in persons with diabetes and a subsequent worldwide reduction in the tragedies caused by these foot problems.


Keywords:

Diabetic foot, foot ulcer, guidelines, guidance, IWGDF, implementation

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It is estimated that by 2035 the global prevalence of diabetes mellitus will rise to almost 600 million, and around 80% of these people will live in developing countries (1). Foot problems complicating diabetes are a source of major patient suffering and societal costs (2). The frequency and severity of foot problems varies from region to region, largely due to differences in socio-economic conditions, type of footwear, and standards of foot care. Foot ulcers are the most prevalent problem, with a yearly incidence of around 2-4% in developed countries (2) and likely even higher in developing countries.


The most important factors underlying the development of foot ulcers are peripheral sensory neuropathy, foot deformities related to motor neuropathy, minor foot trauma, and peripheral artery disease. Once the skin is ulcerated, it is susceptible to becoming infected, an urgent medical problem. Only two-thirds of foot ulcers will eventually heal (3,4), and up to 28% may result in some form of lower extremity amputation (5). Every year, more than 1 million people with diabetes lose at least a part of their leg as a consequence of the complications of diabetes. This translates into the estimate that every 20 seconds a lower limb is lost to diabetes somewhere in the world (2).

Foot problems in persons with diabetes not only represent a major personal tragedy, they also affect that person's family and place a substantial financial burden on healthcare systems and society in general. In low-income countries the cost of treating a complex diabetic foot ulcer can be equivalent to 5.7 years of annual income, potentially resulting in financial ruin for these patients and their family (6). Investing in evidence-based, internationally appropriate diabetic foot care guidance is likely among the most cost-effective forms of healthcare expenditure, provided it is goal-focused and properly implemented (7,8).

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International Working Group on the Diabetic Foot

The International Working Group on the Diabetic Foot (IWGDF; www.iwgdf.org) was founded in 1996, and consists of experts from almost all disciplines involved in the care of patients with diabetes and foot problems. The IWGDF aims to prevent, or at least reduce, the adverse effects of foot problems in diabetes, in part by developing and continuously updating international guidance documents for use by all health care providers involved in diabetic foot care. In 1999, the IWGDF published its first version of “International Consensus on the Diabetic Foot” and “Practical Guidelines on the Management and the Prevention of the Diabetic Foot”. This publication has been translated into 26 languages, and more than 100,000 copies have been distributed globally. These documents have since been updated four times, including the versions published in this supplement (9-12).

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The initial Practical Guidelines, and each subsequent update, were developed by a consensus process: all texts were written by a panel of experts in the field and (since 2007) informed by systematic reviews of the literature. These texts were reviewed and revised by the IWGDF Editorial Board, then sent for critical evaluation to IWGDF representatives throughout the world, culminating in an agreed upon text. Finally, the IWGDF recruited local “champions,” representing over 100 countries around the world, to implement the recommended practices.


However, these Practical Guidelines were not based on high-quality evidence only. Developing such guidelines on foot problems in diabetes that are applicable all over the world and relevant for all disciplines involved is still a “bridge too far”. In many areas solid evidence is lacking, resources and expertise differ widely in various parts of the world, cost-effectiveness of approaches may vary between health care systems, and what is self-evident to experts of one discipline may be debatable for others.

For the 2015 update we have taken our methodological process a step further. Not only did we perform a systematic review on each topic, we have also formulated recommendations of key points for daily practice using the GRADE system (see below), based on both the available evidence and expert opinion. These recommendations should be adapted to local circumstances in each country. For these reasons we changed the name from Practical Guidelines to Guidance. We recommend that this Guidance be used as the basis for developing local guidelines in each country.

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For the 2015 IWGDF Guidance documents, the IWGDF invited five working groups of international experts to produce guidance on the following topics:

- Prevention of foot ulcers in at-risk patients with diabetes (13)
- Footwear and offloading to prevent and heal foot ulcers in diabetes (14)
- Diagnosis, prognosis and management of peripheral artery disease in patients with foot ulcers in diabetes (15)
- Diagnosis and management of foot infections in persons with diabetes (16)
- Interventions to enhance healing of chronic ulcers of the foot in diabetes (17)

The IWGDF Editorial Board produced a “Summary Guidance for Daily Practice,” based on these five documents, that is intended to serve as a short outline of the essential parts of prevention and management of foot problems in diabetes (18). We advise interested clinicians to read the full Guidance on each topic for more detailed recommendations, as well as the systematic review for detailed discussion of the evidence. These are, together with the “Summary Guidance”, published as freely accessible articles in this issue of Diabetes / Metabolism Research and Reviews (13-17,19-25).

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Each of the five working groups followed the same methods in the design of their Guidance document. First, they performed a systematic review of a selected aspect of the available literature on their topic. The reviewers only included controlled studies that drew from the target population of people with diabetes. As might be expected, some papers published by members of the committee were included in the review, but they used strict rules to guard against any conflict of interest. The design and risk of bias of all intervention studies included in the systematic reviews were assessed using the Scottish Intercollegiate Grouping Network (SIGN) algorithm (<http://www.sign.ac.uk/pdf/studydesign.pdf>) and score sheets from the Dutch Cochrane Centre (www.cochrane.nl). Assessment of methodological quality for the Guidance document on diagnosis of peripheral artery disease was performed using the quality assessment for diagnostic accuracy studies (QUADAS) instrument (26), and for the Guidance document on prognosis of peripheral artery disease using the Quality in Prognostic Studies (QUIPS) instrument (27). Evidence from included studies was summarized in evidence tables.

Following the systematic review, the experts in the working groups formulated recommendations based on the Grading of Recommendations Assessment Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline (28). The GRADE system allows the experts to provide a rating for each recommendation based on both the strength with which it is recommended and the quality of the evidence underlying it. In this manner the link is made between scientific evidence and recommendations for daily clinical practice. We assessed the strength of each recommendation as either 'strong' or 'weak', based on the quality of evidence, balance between benefits and harms, patient values and preferences, and costs (resource utilization). We rated the quality of evidence as 'high', 'moderate', or 'low' based on the risk of bias of included studies, the effect size, and expert opinion. Many of the older papers identified in the systematic reviews lacked data for the reviewers to calculate or assess for inconsistency, indirectness or imprecision. Ideally, these items help to fully assess the quality of evidence, but unfortunately they could not usually be taken into account. The rationale behind each recommendation is described in the Guidance documents.

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The members of the IWGDF Editorial Board met in person on a number of occasions to thoroughly review the systematic reviews and the Guidance documents, which were then revised by the working groups based on this editorial review. When found satisfactory, the Editorial Board sent the Guidance documents to the IWGDF representatives for comments; the editorial board processed all comments received and made changes where needed in collaboration with the chair of each working group. Finally, the five Guidance documents were the basis for the ‘Summary Guidance for daily practice’, written by the members of the IWGDF Editorial Board. The result of this process is a series of evidence-based global consensus documents.

On a pre-planned “Consensus-Implementation Day” prior to the 7th International Symposium on the Diabetic Foot, held May 19th 2015 in The Hague, all international representatives were invited to discuss implementation of the IWGDF Guidance documents. Implementation of these Guidance documents is a crucial step, as only when they are used in daily clinical practice throughout the world will they contribute to improvement in outcomes.

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Plans are already under way to ensure continued implementation and evaluation of the IWGDF Guidance on the prevention and management of foot problems in persons with diabetes into the future. With the world-wide diabetes epidemic, it is now more imperative than ever that appropriate action be taken to ensure access to quality care for all people with diabetes, regardless of their age, geographic location, economic or social status. The evidence base for the prevention and management of foot ulcers in diabetes is progressively growing, but it remains a challenge how to use these data to optimize outcomes in different health care systems, in countries with different resources and in different cultures. The IWGDF hopes to see an increase in global awareness of foot problems in persons with diabetes and aims to stimulate this process of transforming global guidance to local guidelines, leading to improved foot care throughout the world. Notwithstanding the limited published evidence of improved outcomes associated with using these Guidance documents, we believe that following the recommendations of the 2015 IWGDF Guidance will almost certainly result in improved management of foot problems in diabetes and a subsequent worldwide reduction in the tragedies caused by these foot problems.

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We are deeply grateful to the many authors and members of the working groups who have collaborated tirelessly, lending their time, expertise and passion to the realization of this huge project. In addition, we sincerely thank the sponsors who, by providing generous and unrestricted educational grants, made development of this Guidance possible.

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All authors declare no conflict of interest.

The IWGDF Guidance is developed by working groups of independent experts. These documents are written without any influence from commercial, political, academic or other interest groups.

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Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015, based on the IWGDF Guidance documents

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