Development of an evidence-based global consensus for diabetic foot disease:

The 2015 guidance of the International Working Group on the Diabetic Foot

ABSTRACT
Background
Foot complications are a frequent and severe complication of diabetes. To prevent, or at least reduce, the incidence and adverse outcomes of these foot problems, the International Working Group on the Diabetic Foot (IWGDF) develops and updates evidence-based global consensus guidance documents.

Aim
To describe the development of the 2015 IWGDF Guidance documents on the prevention and management of foot problems in persons with diabetes.

Methods
The IWGDF empanelled five working groups of international experts to undertake seven systematic reviews of the literature. These were designed to provide evidence to support development of guidance documents on five topics: prevention; footwear and offloading; diagnosis, prognosis and management of peripheral artery disease; diagnosis and management of foot infections; and interventions to enhance healing.

Results
The five 2015 IWGDF guidance documents make a total of 77 recommendations, each of which was assigned a Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) rating. These documents are now published and available for free on the IWGDF website.

Conclusions
We believe clinician compliance with the recommendations of the 2015 IWGDF Guidance documents will likely result in a reduction in, or better outcomes of, foot problems in persons with diabetes, helping to reduce the morbidity and mortality associated with this problem.

INTRODUCTION
The International Diabetes Federation estimates that by 2035 the global prevalence of diabetes mellitus will rise to almost 600 million, and around 80% of these people will live in low- and middle-income countries. Foot problems are a frequent consequence of diabetes and a major cause of morbidity, mortality, and financial costs. The frequency, type, and severity of foot problems varies within and among geographical regions, largely due to differences in socioeconomic conditions, prevalence of various comorbidities, type of footwear worn, and standards of foot care. Ulcers of the foot, usually related to peripheral neuropathy, are the most common foot complication, with a yearly incidence of around 2-4% in high-income countries and likely even higher in developing countries.

Managing diabetic foot ulcers requires local, and often systemic, treatments given by knowledgeable providers to adherent patients. This is not a “one doctor disease” – optimising outcomes requires multidisciplinary care. Furthermore, as a...
notoriously unglamorous problem, appropriate care of the diabetic foot depends on dedicated clinicians working together in a team of health-care providers to care for a complex patient – a scenario some clinicians prefer to avoid, but others relish.3

When a foot complication develops in a person with diabetes, it not only represents a major personal tragedy, but also affects that person’s family and places a substantial financial burden on the patient, the healthcare system, 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 families.4 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.5,6

The International Working Group on the Diabetic Foot (IWGDF) was founded in 1996 and includes experts from virtually all of the many disciplines involved in the care of patients with diabetes and consequent foot problems. Among the goals of the IWGDF are to prevent, or at least reduce, the adverse effects of foot problems in persons with diabetes in part by developing and continuously updating international guidance documents for use by all health care providers involved in diabetic foot care.7 In 1999, the IWGDF first published “International Consensus on the Diabetic Foot” and “Practical Guidelines on the Management and the Prevention of the Diabetic Foot.” Various versions of these documents have been translated into 26 languages, and more than 100,000 copies have been distributed globally. In 2015, the most recent version of the “IWGDF Guidance on the Prevention of Foot Problems in Diabetes” was published.7–20

METHODS
The IWGDF Editorial Board selected chairs and, in collaboration with the chairs, a secretary and about a dozen international expert members for each of five working groups. Each group was assigned to produce a guidance document on one of the following topics:

- Prevention of foot ulcers in at-risk patients with diabetes,
- Footwear and offloading to prevent and heal foot ulcers in diabetes,
- Diagnosis, prognosis, and management of peripheral artery disease in diabetic patients with foot ulcers,
- Diagnosis and management of foot infections in persons with diabetes, and
- Interventions to enhance healing of chronic ulcers of the foot in diabetes.

Each of the five working groups followed the same methods in producing its guidance document. First, each group performed a systematic review of a selected aspect of the available literature on its topic. The working groups produced seven systematic reviews (the peripheral-arterial-disease group produced three) that included over 80,000 articles for screening, of which they selected 429 for final analyses.15–20 Following the systematic review, the working group members formulated recommendations that they developed based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system for grading evidence.21 This system allowed the experts to link the available scientific evidence to specific recommendations for daily clinical practice. Each recommendation was rated as either strong or weak, and the quality of the evidence underlying this recommendation as high, moderate, or low. Interested readers are referred to reference 7 for further information on the grading system used. When the five guidance documents were completed, the Editorial Board sent them to over 100 IWGDF expert representatives, asking for their comments and, after revision of the documents, to obtain their approval. Finally, the IWGDF Editorial Board produced a “Summary Guidance for Daily Practice” based on these five documents; this summary was designed to serve as a short outline of the essential approaches to the prevention and management of foot problems in diabetes.

RESULTS
The IWGDF Guidance on the Prevention and Management of Foot Problems in Diabetes consists of seven chapters: the five guidance documents discussed above;8–12 the summary on the development of the guidance;7 and the summary guidance for daily practice.13

These documents make clear the factors involved in the pathogenesis of diabetic foot disease, particularly peripheral sensory (and motor) neuropathy and peripheral arterial disease. Treatment is most effective when it involves clinicians who are experts in medical, surgical, podiatric, nursing, and other specialties. It is also crucial that these specialists use an integrated, interdisciplinary approach to optimise clinical and technological methods for management.3 From the five cornerstones of prevention, to an effective and well-organised team, prevention and management of foot problems in diabetes requires a multidisciplinary approach that covers all bases.8

At the core of the 2015 IWGDF guidance are the 77 total recommendations provided in the seven different guidance documents. Rather than outline these recommendations in
The principles and recommendations outlined in this new guidance will now have to be adapted or modified for different countries, taking into account local and regional differences in the socioeconomic situation, accessibility to and sophistication of healthcare resources, and various cultural factors. Once modified into a local guideline, the next crucial step is implementation. Only when the guidelines are used in daily clinical practice throughout the world will they be able to contribute to improvement in outcomes for diabetic patients with foot problems.

On a pre-planned Consensus-Implementation Day immediately prior to the 7th International Symposium on the Diabetic Foot, held May 19th 2015 in The Hague, the leaders of the IWGDF invited all of the international representatives of the organisation to convene to discuss implementation of the IWGDF Guidance documents. Nearly 100 representatives from six continents attended and discussed the next steps. These local “champions” are the trailblazers, bringing back home their knowledge, ideas, and enthusiasm to inspire others. Some of them have already made major steps in implementation, such as with national diabetic foot care programs in the United Kingdom, Belgium and Germany, and with “Step-by-Step,” a program developed by the International Diabetes Federation, IWGDF, and the World Diabetes Federation, in close cooperation with many local frontrunners to help less technologically advanced countries improve diabetic foot care. With the worldwide diabetes epidemic, it is now more imperative than ever that more countries and clinicians follow these, or other, paths to improved foot care. All people with diabetes, regardless of their age, geographic location, and socioeconomic status, need access to quality, evidence-based foot care. Norwithstanding 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 diabetic foot problems and a subsequent worldwide reduction in the largely preventable tragedies they cause.

REFERENCES


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