DFA Guides You Through

Australian and International Guidelines on Diabetic Foot Disease

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Introduction

Diabetic Foot Australia (DFA) aims to end avoidable diabetes-related amputations within a generation.

DFA has engaged with multiple partner organisations across Australia to create a national body for people suffering diabetic foot disease. A multidisciplinary approach to the patient with diabetic foot disease is critical to the delivery of a gold standard of treatment. DFA also advocates a coordinated approach by health professionals, researchers, government and industry as critical to achieving our vision of ending avoidable amputations in a generation.

A key objective of DFA is supporting health professionals to improve clinical and quality of life outcomes for people with diabetic foot disease. One method to support clinicians is the "DFA Guides You Through" series. In this series, DFA translates an important diabetic foot disease research topic to help support for clinicians to provide the best evidence-based care available for their patients.

The current "DFA Guides You Through" document discusses Australian and international guidelines on diabetic foot disease.

In 2011, the National Health and Medical Research Council published the Australian "National Evidence-Based Guideline: Prevention, Identification and Management of Foot Complications in Diabetes". You can find this document here.

In 2015, the International Working Group on the Diabetic Foot (IWGDF) published the International "2015 IWGDF Guidance Documents on the Prevention and Management of Foot Problems in Diabetes". You can find these documents here.

With all the new evidence from the last four years, it is inevitable that these guidelines differ. But what exactly are the differences and similarities, and who has time to sit down and read them both?

DFA guides you through these guidelines in seven sections, discussing their history, development, prevention and management recommendations, implementation strategies and research directions.

Contents

1. History and development of the Australian and International Guidelines

In 2011, the Australian National Evidence-Based Guideline "Prevention, Identification and Management of Foot Complications in Diabetes" was published. This guideline updated and replaced a foot-related chapter in the 2005 general diabetes management guidelines, and as such was the first standalone guideline completely dedicated to diabetic foot disease in Australia.

The Australian guidelines were written by three organisations experienced in guideline development, with clinical guideline input from a foot expert panel, guidelines advisory committee, and an online survey including various health professionals. For these guidelines, the literature up to 10 December 2009 was searched, based on seven research questions. The full methodology and all answers to these questions can be found in an impressively extensive (1777 pages) technical report. Using these literature search findings and following the NHMRC Grading method, 11 expert opinion and 14 evidence-based recommendations were formulated. The 25 recommendations are described in sections B-D of the Australian guidelines, preceded by an introductory chapter, and followed by chapters on research and implementation.

It is advised in the guidelines to "fully review and update them within five years". However, the literature search is now more than 6 years old, and to our knowledge a new process has yet to be started. This makes comparison with the IWGDF guidelines published in 2015 a useful undertaking for this "DFA guides you through" series.

The International Working Group on the Diabetic Foot (IWGDF) was founded in 1996. With the absence at that time of any guideline on diabetic foot disease anywhere in the world, a group of experts decided to produce an expert opinion document with practical guidelines for the prevention and management of diabetic foot disease. This resulted in the first IWGDF guidelines, published in 1999. This document has since been updated every four years, with improvements in the methodological process accompanying each update. The fifth version of the "IWGDF Guidance on the Prevention and Management of Foot Problems in Diabetes" was published in May 2015.

Contrary to the Australian guidelines, which involves professional guideline developing institutes, the IWGDF Guidance was written solely by experts in the clinical and research field of diabetic foot disease. The 2015 Guidance is based on seven systematic reviews, following literature searches in July 2014. Five working groups of 7-10 international experts formulated recommendations following the GRADE system. Both the systematic reviews and recommendations were reviewed by the editorial board, and by over 100 international IWGDF members. An article describing the IWGDF methods can be found here.

The IWGDF Guidance boils down to a total of 77 recommendations, described in five different chapters. Each recommendation is graded as “strong” or “weak” to indicate the strength with which it is made. The quality of the evidence upon which the recommendation is based is graded as “high”, “moderate”, or “low”. Descriptions as to how the working groups came to these recommendations are given in each chapter.

The next update of the IWGDF Guidance will be published in May 2019, with the first steps of this process being undertaken.

2. Overview of current Australian and International Guidelines on diabetic foot disease

Both the Australian and the International Working Group on the Diabetic Foot (IWGDF) Guidelines on diabetic foot disease use clearly formulated recommendations based on well-defined grading systems and extensive systematic literature searches, resulting in two documents that can be directly compared. This chapter aims to present a general comparison between the two guidelines. A detailed comparison will be made in the following chapters.

Let's start with the titles. These are very similar, concentrating on the "prevention and management of foot problems/complications in diabetes". The Australian version adds in the process of "identification". This seemingly minor addition points to the first difference between the guidelines. Five of the seven research questions that form the basis for the literature review of the Australian guideline, concern themselves with identification or assessment, separated from treatment interventions. In contrast, identification and assessment are integral parts of the IWGDF chapters on (interventions for) prevention, peripheral artery disease and infection, but their literature searches are less extensive.

Another difference between the two guidelines is the absence of recommendations with regard to interventions for peripheral artery disease or infection in the Australian guideline. The IWGDF dedicates a chapter to each of these components of treatment of diabetic foot ulcers, whereas they were outside the scope of work carried out for the Australian guideline. For the Australian situation, a therapeutic guideline exists for antibiotic use, which can be applied to patients with diabetic foot disease. An international group is currently working on a vascular surgery guideline for the management of severe limb ischemia. However, with the multidisciplinary nature of diabetic foot disease, the specific focus of the IWGDF chapters on that population makes it a useful endeavour as an Australian clinician to familiarize with them.

The IWGDF calls their document "Guidance", rather than "Guideline", to underline that these documents are written for a general situation. As acknowledged in their summary guidance, principles in the IWGDF Guidance need to be adapted to local circumstances. Specific recommendations in the Australian guideline concerning the Indigenous population or rural and remote areas exemplify such "local translation".

An overview of the contents and the number of recommendations of both guidelines is given in Appendix 1.

3. Prevention of diabetic foot ulcers

Prevention has long been the Cinderella of diabetic foot disease, receiving scant attention in research and guidelines. While it is still underrepresented in research (of the last 100 published RCTs on diabetic foot disease only 6 focus on prevention, yet 62 target healing), the new IWGDF guidance finally makes up for this with a chapter dedicated to this topic. While the Australian guideline appears to focus more heavily on prevention, with chapter B on risk assessment and chapter C on prevention, the content and the recommendations of these two chapters provide less detail compared to the IWGDF Guidance. The aim of this chapter is to present the similarities and differences in both guidelines with regard to risk assessment and prevention of diabetic foot ulcers.

Both guidelines are largely similar in their approach to risk assessment and screening frequencies. Peripheral neuropathy, peripheral artery disease, foot deformities, and ulcer/amputation history are identified as the most important risk factors in both. Based on these risk factors, 3 (Australian) or 4 (IWGDF) risk stratification groups are identified. IWGDF advocates a screening frequency of 1-3 months for people in the highest risk group, compared to 3-6 months in the Australian guideline. However, both acknowledge that this frequency is based predominantly on expert opinion as no evidence is available to indicate superiority of one screening frequency over another.

Although the risk assessment and screening recommendations are very similar, the recommendations with regard to prevention interventions show some differences. The IWGDF has 11 recommendations that deal with the topics of foot care, education, footwear, self-management and surgical interventions; whilst the Australian guideline has 3 recommendations concerning foot care and education.

For each of these topics, similarities and differences are:

Foot care: both guidelines stress the importance of an integrated foot protection program that includes education, treatment and footwear. The specific components of protective treatment by a podiatrist or other suitably trained health care worker are described in a little more detail in the IWGDF guideline, based on expert opinion.

Education: both guidelines provide cautious recommendation that patient education should be provided for the prevention of foot ulcers, based on expert opinion due to the absence of high-quality evidence on patient education. Although, we do not know what the best form of education is, both guidelines have placed it as part of integrated foot care (see above).

Footwear: while no recommendation was made in 2011 in the Australian guideline, new evidence has appeared in the last four years driving the IWGDF recommendations. Based on this evidence, therapeutic footwear with a demonstrated plantar pressure relieving effect is recommended for the

prevention of recurrent plantar foot ulcers. This adds weight to the need to update the Australian guideline on this specific topic.

Self-management: the only self-management intervention supported by any evidence in either guideline is home-based foot skin temperature monitoring. Three RCTs support its effectiveness in the prevention of foot ulcers. The translation of this evidence into recommendations, however, differs between guidelines. A positive recommendation supporting home-based foot skin temperature monitoring is made in the IWGDF guidance, whilst no recommendation is made in the Australian guideline. The Australian guideline's technical report sheds light on why no recommendation was made, stating: "the expert working group felt there was insufficient evidence (due to small sample sizes)". This appears a little unusual, as the sample sizes in these RCTs were 225, 173 and 85, which is larger compared to various other interventions that are recommended in the Australian guideline. As this self-management intervention could be suitable for Australia's vast rural and remote areas, this intervention should perhaps be reconsidered in any update of the Australian guideline.

Surgical interventions: no recommendations are made on surgical interventions in the Australian guideline, as these were not part of their scope of work. However, the IWGDF positively recommends considering Achilles tendon lengthening and flexor tenotomy, and a recommendation against nerve decompression is given. Any surgical intervention presents the risk of complications, but also the advantage of permanently changing foot shapes to reduce plantar pressure without the need for any treatment adherence. With increasing evidence on this topic, it should perhaps be considered for inclusion in the scope of work of any Australian update.

The overview of all recommendations in both guidelines can be found in Appendix 2.

In conclusion, both guidelines recommend similar risk assessment, stratification schemes and integrated foot protection programs. The main differences result from additional IWGDF recommendations based on new evidence or evidence in fields outside the scope of work of the Australian guideline; particularly for footwear, home-based foot skin temperature monitoring and some surgical interventions. The new evidence behind these IWGDF recommendations suggests these should be very relevant areas for consideration in any future Australian guideline update.

4. Management of diabetic foot disease

In this chapter, we compare the Australian guideline and IWGDF Guidance on the management of diabetic foot disease. Management of diabetic foot disease is divided in three topics: organization of care and ulcer assessment; footwear and offloading; and wound healing interventions.

The importance of a multidisciplinary team to organize diabetic foot care is stressed in both guidelines. Evidence is limited on this topic, but expert opinion is clear. Both guidelines recommend treatment of diabetic foot disease by a multidisciplinary team including diabetologist, (orthopaedic) surgeon, vascular surgeon, endovascular interventionist/radiologist, podiatrist, diabetes nurse, and pedorthist / orthotist. There is no agreed definition for a multidisciplinary team, so no further recommendations to the specific organization of this team is made in either guideline. When access to a multidisciplinary team is limited, or for uncomplicated ulcers, both guidelines describe that a first level of treatment consisting of general practitioner with podiatrist and/or wound care nurse may suffice.

Various systems are available for assessment of foot ulcers, such as the University of Texas, PEDIS, WIfI, and SINBAD. Each system has its advantages and disadvantages, as nicely described in this paper by Dr. Game. The University of Texas is one of the longest standing classification systems, and is recommended in the Australian guideline. No specific system is recommended in the IWGDF guidance, they only list the items that should minimally be assessed (type, cause, site, depth, and infection). The bottom line is the same in both: to understand outcomes of treatment, we need careful assessment and classification of each ulcer.

Offloading is paramount to heal plantar diabetic foot ulcers. Non-removable knee-high offloading devices are considered the gold standard in both guidelines. However, that can be contraindicated for various reasons, such as the need for regular dressing changes or the risk of falls. Both guidelines recommend considering other devices in such cases. IWGDF specifies this further, recommending a trapped approach: non-removable knee-high devices are the preferred method of offloading, when contra-indicated a removable knee-high device should be provided, and when these are contra-indicated as well an offloading shoe or cast shoe can be chosen. In addition, IWGDF recommends using shoe modifications or felted foam in combination with adequate footwear as last resort, while clearly recommending against the use of conventional or standard therapeutic to heal an ulcer.

A difference between both guidelines is surgical offloading, as these are only included in the IWGDF guidance. When conservative treatment fails, Achilles tendon lengthening, single or pan metatarsal head resection, or joint arthroplasty are suggested to heal a plantar neuropathic ulcer, and digital flexor tenotomy for a toe ulcer. However, high-quality evidence in this area is scarce, and surgery should only be considered in selected patients while taking potential complications into account.

The last part concerns wound healing interventions. These can be separated in basic interventions and advanced adjunctive interventions. Recommendations for basic interventions are primarily based on expert opinion, advocating sharp debridement and the use of topical hydrogel dressings, with exudate control, comfort and costs as principal criteria to guide dressing selection. Both guidelines, however, stress the insufficient evidence for superiority of one dressing over another.

Advanced adjunctive interventions are only recommended as part of a comprehensive wound management program in specialist centres. Both guidelines agree that topical negative pressure therapy and hyperbaric oxygen therapy may be considered for specific ulcers, although the debate surrounding these interventions is reflected in the cautious texts following these recommendations. A difference exists with regard to larval therapy and skin replacement therapies. These receive the same cautious recommendations as topical negative pressure and hyperbaric oxygen in the Australian guideline, but IWGDF recommends against their use. This seems to result from a more strict assessment of the evidence by the IWGDF working group, as well as the inclusion of some more recent publications. Other advanced adjunctive interventions (growth factors, electricity, magnetism, ultrasound, shockwaves, and systemic treatments such as drugs and herbal therapies) are recommended against in the IWGDF guidance, and not recommended due to the limited evidence in the Australian guideline.

The overview of all recommendations in both guidelines can be found in Appendix 3.

In conclusion, the Australian guideline and IWGDF guidance are similar on the vast majority of topics. Diabetic foot disease needs to be managed by a multidisciplinary team, standardized ulcer assessment is a key first step of treatment, non-removable devices are the gold standard for offloading but when contra-indicated other options are available, and advanced adjunctive wound healing interventions should only be provided by specialized centres when accepted standards of good quality care do not heal an ulcer.

5. IWGDF recommendations on peripheral artery disease and infection

As discussed in chapter 2, peripheral artery disease and infection were outside the scope of the Australian guidelines. For the Australian situation, a therapeutic guideline exists for antibiotic use, which can be applied to patients with diabetic foot disease. An international group is currently working on a vascular surgery guideline for the management of severe limb ischemia. With the multidisciplinary nature of diabetic foot disease, the specific focus of the IWGDF chapters on that population makes it a useful endeavour as an Australian clinician to familiarize with them. In this article, we will guide you through the IWGDF Guidance on these two topics.

Peripheral artery disease

The IWGDF Guidance on peripheral artery disease (PAD) is backed by three systematic reviews, on diagnosis, prognosis and treatment of PAD.

Identifying PAD among patients with a diabetic foot ulcer is important because its presence is associated with worse outcomes. In a person with a foot ulcer, the following non-invasive bedside tests are recommended to exclude PAD: measuring ankle-brachial index (values 0.9-1.3 exclude PAD), measuring toe-brachial index (values ≥0.75 exclude PAD) and the presence of triphasic pedal Doppler arterial waveforms. All of these bedside techniques should be performed in a standardised manner by trained healthcare professionals. It should be noted that there is insufficient evidence to support selecting any one of the bedside non-invasive diagnostic modalities for the detection of PAD across a spectrum of patients with diabetes. Healthcare professionals should be aware of the limitations of each modality and must decide which, either singly or in combination, to use, given their local expertise and test availability.

The second step is the prognosis of the outcome of an ulcer. Unfortunately, in patients with a diabetic foot ulcer and PAD, no specific symptoms or signs of PAD reliably predict healing of the ulcer. However, one of the following simple bedside tests should be used to inform the patient and healthcare professional about the healing potential of the ulcer, as any of the following findings increases the pre-test probability of healing by at least 25%: a skin perfusion pressure ≥40mmHg; a toe pressure ≥30mmHg; or, a TcPO2 ≥25mmHg. When a toe pressure below 30mmHg, a TcPO2 value below 25mmHg, an ankle pressure <50mmHg or an ankle brachial index <0.5 is found, urgent vascular imaging revascularization should be considered. The same holds for any ulcer that does not improve within six weeks despite optimal management.

Treatment of PAD starts with vascular imaging to obtain anatomical information. Techniques to define the lower limb arterial system in patients with diabetes include duplex ultrasound, MR

angiography, CT angiography and digital subtraction angiography, with each having its own (dis)advantages. Most important is visualization of the entire lower extremity arterial circulation, especially of below-the-knee and pedal arteries. The aim of revascularization should be to restore direct flow to at least one of the foot arteries. There is inadequate evidence to establish superiority of one revascularization technique over another. Decisions should be made in a multidisciplinary team, this team should have access to both endovascular techniques and bypass surgery, and follow-up care should be provided by this team after revascularization. When PAD and infection are both present, a patient requires emergency treatment. On the other hand, when the risk-benefit ratio for the probability of surgical success is unfavourable, revascularization should be avoided.

Diabetic foot infection

The chapter on the diagnosis and management of foot infection is the longest chapter of the IWGDF guidance, with 26 recommendations in six different areas.

Diabetic foot infection should be diagnosed clinically, using the IWGDF classification system (Appendix 4). Clinicians should evaluate a diabetic patient presenting with a foot wound at three levels: the patient as a whole (e.g., cognitive, metabolic, fluid status), the affected foot or limb (e.g., presence of neuropathy, vascular insufficiency), and the infected wound. Clinical diagnosis rests on the presence of at least two local findings of inflammation: redness (erythema or rubor), warmth (calor), pain or tenderness (dolour), induration (swelling or tumour) or purulent secretions.

Wound cultures serve to determine the causative organisms and their antibiotic sensitivities, to select the most appropriate antimicrobial therapy. A tissue specimen rather than a swab is recommended to obtain cultures. Cultures should not be repeated, unless the patient is not clinically responding to treatment, or occasionally for infection control surveillance of resistant pathogens.

Diabetic foot osteomyelitis can present the clinician with formidable diagnostic and therapeutic challenges. Clinicians should suspect osteomyelitis when an ulcer lies over a bony prominence, particularly when it fails to heal despite adequate off-loading, or when a toe is erythematous and indurated (the so-called “sausage toe’). For an infected open wound, perform a probe-to-bone test; in a patient at low risk for osteomyelitis a negative test largely rules out the diagnosis, while in a high risk patient a positive test is largely diagnostic. For blood tests, markedly elevated serum inflammatory markers, especially erythrocyte sedimentation rate, are suggestive of osteomyelitis in suspected cases. For imaging, obtain plain X-rays of the foot in all cases of non-superficial diabetic foot infection and use MRI when an advanced imaging test is needed to diagnose osteomyelitis.

Surgical treatment of diabetic foot infection should be discussed in selected moderate and all severe cases of infection. Urgent surgical intervention is necessary in most cases of deep abscesses, compartment syndrome and virtually all necrotizing soft tissue infections.

Antimicrobial therapy should only be given to infected ulcers; non-infected ulcers should not be treated with antimicrobials. In case of infection, the specific antibiotic agents for treatment should be selected based on the likely or proven causative pathogens, their antibiotic susceptibilities, the clinical severity of the infection, and evidence of efficacy for DFI and costs. A course of antibiotic therapy of 1-2 weeks is usually adequate for most soft tissue diabetic foot infections. Parenteral antibiotic therapy should be administered for most severe and some moderate infections, with a switch to oral therapy when the infection is responding. For diabetic foot osteomyelitis, 6 weeks of antibiotic therapy is recommended for patients who do not undergo resection of infected bone; no more than a week of antibiotic therapy is recommended if all infected bone is resected. IWGDF recommendations on selecting an empiric antibiotic regimen for diabetic foot infections can be found in Appendix 5.

All IWGDF recommendations on PAD and infection can be found in Appendix 6.

6. Where to go from here?

In the previous five sections, we have guided you through the two most important evidence-based diabetic foot disease documents available for Australian clinicians: the Australian and International guidelines. However, the journey does not end here; this is where it begins as we need to put these research recommendations into clinical practice, and look to the future. So where do we go from here?

There are three directions we will follow in this chapter: implementation of the guidelines, topics for future research, and future updates of the guidelines.

Implementation of the guidelines

Only when recommendations made in guidelines are implemented in daily clinical practice do they lead to the best outcomes in care for people with diabetic foot disease. However, little is known about the situation in Australia. Two questionnaire-based studies have been performed in Australia, one on general guideline adherence and one specifically on offloading. However, both studies used questionnaires that were not validated, and the formulation of the questions has likely resulted in over-reporting of guideline adherence. Further, response rates were relatively low, and sampling bias resulting in over-representation of adherent clinicians can be expected. Finally, only podiatrists were targeted, rather than all multidisciplinary clinicians.

Despite these limitations, both articles do provide some useful insights. The most important finding of both studies is the discrepancy between the limited use of gold standard non-removable offloading in clinical practice versus the "over-use" of mostly felted foam, for which very limited evidence is available, to offload diabetic foot ulcers. This has also been reported in other nations (e.g. America or specialized European centres). Improving offloading practices, with more frequent application of non-removable knee high devices, is one the most important areas where guidelines can be better implemented in daily clinical practice to improve outcomes for our patients.

For other aspects, such as prevention, screening, the organization of multidisciplinary foot care, or the use of dressings and advanced adjunctive therapies, we basically do not know if Australian clinicians follow the guidelines. Rather than relying on questionnaires to obtain this information, two other ways forward seem more promising.

The first is the Australian Diabetic Foot Ulcer Minimum Dataset. DFA developed this dataset in consultation with multiple stakeholders, and its use is endorsed by Australian peak bodies. If all clinicians who treat diabetic foot ulcers collect the data-items outlined in the minimum dataset, this will provide truly unique insights into the clinical practice of diabetic foot care in Australia. The

dataset is not only designed to obtain diabetic foot disease outcomes such as ulcer healing, hospitalization and amputation, but also provides the opportunity to capture if care is provided in line with (inter)national guidelines.

The second way forward for Australia is the path followed by other nations such as Scotland, Belgium and Germany. These countries have created accreditation systems, where treatment of people with diabetic foot disease is only funded or reimbursed when provided by fully accredited multidisciplinary foot clinics. This system has forced clinics to either demonstrate they are providing evidence-based practice, or to stop treating people with diabetic foot disease. This is not an easy road to follow, as nicely described in these two articles, but looking at the results of these countries this may well be the best way forward for Australia as well.

In addition to these top-down approaches, bottom-up approaches should be pursued at the same time. One worthy approach, which is already described in the NHMRC guidelines, could be the creation of a "diabetic foot kit". One kit may target foot screening and ulcer prevention, and contain the necessary equipment for evidence-based foot examinations, as well as state of the art evidence-based instruction materials. Another kit might target "first-aid ulcer treatment", containing equipment for debridement and basic offloading. This kit should also contain instruction materials and information on multidisciplinary foot clinics for referral. These kits seem especially useful in Australia's rural and remote areas, but may come in handy in first line health clinics in metropolitan areas as well.

Another bottom-up approach is continuous education of health care professionals involved in diabetic foot disease. With the bi-annual DFA conference (next up in September 2017), and the "What's New in DFU" events, DFA will continue to support health professionals in keeping their knowledge up to date with the best and most recent evidence available.

Future research

The body of evidence available seems large, especially if you read the extensive NHMRC technical report or the seven IWGDF systematic reviews, but the high numbers of recommendations that are based on a low quality of evidence or expert opinion in both guidelines tell a different story. More research is needed to answer the many questions for which no evidence is currently available.

As this document is primarily aimed at clinicians, we will not extensively discuss the topics where new research is most urgently needed. However, the Australian guideline has a one page chapter (Part E) on future research topics needed, and the 5 IWGDF guidance chapters each have a "key controversies" section that describe the urgent topics for new research. Interested readers are referred to these parts of the guidelines.

Both guidelines primarily argue for more good quality, large-scale studies. A steady increase in publications on diabetic foot disease can be seen on Medline in the last 15-20 years. However, the number of randomised controlled trials published in high-impact journals does not show a similar increase. If anything, this seems to be dropping. Such studies require effort from large consortia willing to work together. It is hoped that the Diabetic Foot Australia Clinical Trials Network will stimulate this development in Australia.

Guideline updates

Guidelines need regular updating as new evidence emerges, clinical practice changes and the methodology for guideline development improves. The IWGDF have a standard four-year update process. The next update will be produced in 2019, and this process has already begun. However, an update seems much more imperative for the Australian guideline, as it was published in 2011, based on a 2009 literature review, and a new update process to our knowledge has yet to be started.

Perhaps the most important step in the process of updating guidelines is the development of the clinical questions that form the basis of the systematic reviews. In the Australian guideline, surgical offloading, peripheral artery disease and foot infections were outside the scope of work. However, with the importance of multidisciplinary treatment (involving vascular surgeons and infectiologists as well), and the critical nature of ischemia and infection on diabetic foot ulcer outcomes, future Australian recommendations are needed to cover all bases of diabetic foot disease treatment. Further, the large number of clinical questions on risk assessment factors may be worth reconsidering. Various high-quality systematic reviews and meta-analyses are already available on this topic. While these are informative, assessment of risk alone does not lead to improved clinical outcomes, only subsequent targeted treatment does. Risk assessment based treatment is not included in any guideline and probably should be considered in future updates.

The IWGDF, on the other hand, would do well to include risk assessment factors in their new guidance documents, as this was not included in their documents apart from peripheral artery disease. Similar to the points made above, the clinical questions would be best if they include risk assessment based treatment. Another topic of debate concerns the outcome measures used to answer in these clinical questions. The IWGDF systematic reviews focus rather strictly on ulcer development, ulcer healing (primarily at 12 weeks) and some on amputation. However, some interventions (such as specific dressings) may be targeted at short-term outcomes or patient-related outcomes (such as pain reduction), and will not result in significant changes in 12 week healing outcomes. If more specific outcomes are included, more specific recommendations may be given in future.

7. Conclusions

Providing evidence-based care is the cornerstone of treatment of diabetic foot disease. To support clinicians, we have summarized the Australian and International guidelines on the prevention and management of diabetic foot disease. To prevent diabetic foot ulcers, all people with diabetes should receive at least yearly foot screenings. People identified to be at high-risk of diabetic foot ulcers should receive integrated foot care by knowledgeable clinicians with an expertise in foot disease. Both guidelines advocate multidisciplinary management of diabetic foot ulcers, consisting of standardized ulcer assessment, offloading and wound debridement and dressings. Specific recommendations for peripheral artery disease and infection are also made in the IWGDF guidance.

We hope that this overview will further add to the implementation of evidence-based care in daily clinical practice. Because only when the recommendations made in these guidelines are implemented will they lead to improved outcomes for people with diabetic foot disease and bring us closer to ending avoidable amputations in Australia.

Appendices

Appendix 1: Overview of the Australian and IWGDF Guidelines on diabetic foot disease

Appendix 2: An overview of recommendations on risk assessment and preventative interventions in the Australian guideline and IWGDF guidance

Appendix3: An overview of recommendations on management of diabetic foot disease in the Australian guideline and IWGDF guidance

Appendix 4: IWGDF classification of clinical signs of infection

Appendix 5: IWGDF recommendations on selecting an empiric antibiotic regimen for diabetic foot infections

Appendix 6: IWGDF recommendations on peripheral artery disease and infection

Appendix 1: Overview of the Australian and IWGDF Guidelines on diabetic foot disease

AUSTRALIAN GUIDELINE	IWGDF GUIDANCE
Published in 2011	Published in 2015
Executive summary *List of the 25 recommendations*	**Summary guidance** *Information summarized as one basic document with the essentials for daily clinical practice, based on five chapters and additional expert opinion on ulcer classification and organization of care*
B - Risk assessment *7 recommendations on assessing and defining risk, and frequency of risk assessment* **C – Prevention** *3 recommendations on preventive interventions*	**1 – Prevention** *2 recommendations on assessing and defining risk, and frequency of risk assessment* *11 recommendations on preventive interventions*
D - Management *2 recommendations on (outcome) assessment*	
3 recommendations on footwear and offloading	**2 – Footwear and Offloading** *13 recommendations on footwear and offloading*
-	**3 – Peripheral Artery Disease (PAD)** *3 recommendations on diagnosis of PAD* *5 recommendations on prognosis of PAD* *8 recommendations on treatment for PAD*
-	**4 – Infection** *7 recommendations on diagnosis / severity assessment / microbiology* *8 recommendations on osteomyelitis* *11 recommendations on treatment of infection*
2 recommendations on debridement *1 recommendation on dressings* *4 recommendations on wound healing interventions* *3 recommendations on types of care*	**5 – Wound Healing Interventions** *2 recommendations on debridement* *2 recommendations on dressings* *5 recommendations on wound healing interventions* -

Appendix 2: An overview of recommendations on risk assessment and preventative interventions in the Australian guideline and IWGDF guidance

AUSTRALIAN GUIDELINE	IWGDF GUIDANCE
Part A – Risk Assessment	
EBR 1: Assess all people with diabetes and stratify their risk of developing foot complications. (Grade C)	1. To identify a person with diabetes at risk for foot ulceration, examine the feet annually to seek evidence for signs or symptoms of peripheral neuropathy and peripheral artery disease. (GRADE recommendation: strong; Quality of evidence: low)
EO 1: Any suitably trained healthcare professional may perform the risk assessment.	
EBR 2: Assess risk stratification by inquiring about previous foot ulceration and amputation, visually inspecting the feet for structural abnormalities and ulceration, assessing for neuropathy using either the Neuropathy Disability Score or a 10g monofilament and palpating foot pulses. (C)	2. In a person with diabetes who has peripheral neuropathy, screen for: a history of foot ulceration or lower-extremity amputation; peripheral artery disease; foot deformity; pre-ulcerative signs on the foot; poor foot hygiene; and ill-fitting or inadequate footwear. (Strong; Low)
EBR 3: Stratify foot risk in the following manner (C): - "low risk"- people with no risk factors and no previous history of foot ulcer/amputation - "intermediate risk"- people with one risk factor (neuropathy, peripheral arterial disease or foot deformity) and no previous history of foot ulcer/amputation - "high risk" - people with two or more risk factors (neuropathy, peripheral arterial disease or foot deformity) and/or a previous history of foot ulcer/amputation	IWGDF risk classification: 0 - No peripheral neuropathy 1 - Peripheral neuropathy 2 - Peripheral neuropathy with peripheral artery disease and/or a foot deformity 3 - Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation
EO 2: Until adequately assessed all Aboriginal and Torres Strait Islander people with diabetes are considered to be at high risk of developing foot complications and therefore will require foot checks at every clinical encounter and active follow-up.	
EO 3: In people stratified as having low-risk feet	Screening based on risk classification:

(where no risk factors or previous foot complications have been identified), foot examination should occur annually.	IWGDF 0: Once a year
EO 4: In people stratified as having intermediate-risk or high-risk feet (without current foot ulceration), foot examination should occur at least every 3 to 6 months.	Screening based on risk classification: IWGDF 1: Once every 6 months IWGDF 2: Once every 3-6 months IWGDF 3: Once every 1-3 months
Part B – Prevention Interventions	
EBR 4: People assessed as having "intermediate risk" or "high risk" feet should be offered a foot protection program. A foot protection program includes foot care education, podiatry review and appropriate footwear. (C)	9. To prevent a recurrent foot ulcer in an at-risk patient with diabetes, provide integrated foot care, which includes professional foot treatment, adequate footwear and education. This should be repeated or re-evaluated once every one to three months as necessary. (Strong; Low)
EO 5: Podiatry review is an important component of a foot protection program. However, in settings where this is not possible, a suitably trained health care worker may undertake a review of the feet.	3. Treat any pre-ulcerative sign on the foot of a patient with diabetes. This includes: removing callus; protecting blisters and draining when necessary; treating ingrown or thickened toe nails; treating haemorrhage when necessary; and prescribing antifungal treatment for fungal infections. (Strong; Low)
EO 6: Foot care education should be provided to all people with diabetes to assist with prevention of foot complications.	8. To prevent a first foot ulcer in an at-risk patient with diabetes, provide education aimed at improving foot care knowledge and behaviour, as well as encouraging the patient to adhere to this foot care advice. (Weak; Low)
	4. To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside. (Strong; Low)
	5. Instruct an at-risk patient with diabetes to: daily inspect their feet and the inside of their shoes; daily wash their feet (with careful drying particularly between the toes); avoid using chemical agents or plasters to remove callus or corns; use emollients to lubricate dry skin; and cut toe nails straight across. (Weak; Low)
	6. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis. (Strong; Low)

"There was insufficient evidence to determine the effectiveness of therapeutic footwear (2 average quality trials) for the prevention of foot complications."	7. To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking (i.e. 30% relief compared to plantar pressure in standard of care therapeutic footwear), and encourage the patient to wear this footwear. (Strong; Moderate)
"Expert working group felt there was insufficient evidence (due to small sample sizes) and concerns regarding feasibility to make a recommendation for home-based temperature monitoring."	10. Instruct a high-risk patient with diabetes to monitor foot skin temperature at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation. (Weak; Moderate)
Not included in the systematic review.	11. Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the toe. (Weak; Low)
"Given the limited clinical impact and small numbers studied, no recommendation has been developed."	12. Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar foot ulcer. (Weak; Low)
Nerve decompression studies excluded from the systematic review.	13. Do not use a nerve decompression procedure in an effort to prevent a foot ulcer in an at-risk patient with diabetes, in preference to accepted standards of good quality care. (Weak; Low)

Note: EBR = Evidence-Based Recommendation; EO = Expert Opinion. Text in *Italics* refers to the guidelines, but is not a specific recommendation.

Appendix3: An overview of recommendations on management of diabetic foot disease in the Australian guideline and IWGDF guidance

AUSTRALIAN GUIDELINE	IWGDF GUIDANCE
Organization of care and ulcer assessment	**Organization of care and ulcer assessment**
EBR 9: People with diabetes-related foot ulceration are best managed by a multi-disciplinary foot care team. (Grade C)	Successful efforts to prevent and manage foot problems in diabetes depend upon a well-organized team, using a holistic approach in which the ulcer is seen as a sign of multi-organ disease, and integrating the various disciplines involved. (EO – summary guidance)
EO 7: A foot ulcer is serious and needs to be managed immediately. EO 11: The following factors should always precipitate referral to a multidisciplinary foot care team: - deep ulcers (probe to tendon, joint or bone) - ulcers not reducing in size after 4 weeks despite appropriate treatment - the absence of foot pulses - ascending cellulitis and - suspected Charcot's neuroarthropathy (e.g. unilateral, red, hot, swollen, possibly aching foot) If access to a multi-disciplinary foot care team is limited, foot ulceration or foot complications other than those above should be managed by a GP together with a podiatrist and/or wound care nurse.	There should be at least three levels of foot-care management. - Level 1: GP, podiatrist, diabetic nurse - Level 2: multidisciplinary team - Level 3: specialized multidisciplinary team acting as tertiary reference centre (EO – summary guidance)
EBR 10: Remote expert consultation with digital imaging should be made available to people with diabetic foot ulceration living in remote areas who are unable to attend a multi-disciplinary foot care team/service for management. (C)	
EBR 5: Foot ulcer severity can be graded on the basis of wound depth, presence of infection (local, systemic or bone) and presence of peripheral arterial disease. Ulcer grading helps determine the degree of risk to the person and	Health care providers should follow a standardized and consistent strategy for evaluating a foot wound. The following items should be addressed: type, cause, site and depth, signs of infection. (EO – summary guidance)

limb. The University of Texas (UT) wound classification system is the most useful tool for grading foot ulcers. (C)	
Footwear and offloading	**Footwear and offloading**
Offloading	*Offloading*
EBR 7: Pressure reduction, otherwise referred to as redistribution of pressure or offloading, is required to optimise the healing of plantar foot ulcers. (B) EBR 8: Offloading of the wound can be achieved with the use of a total contact cast or other device rendered irremovable. (B)	1. To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface. (GRADE recommendation: strong, Quality of evidence: high)
EO 10: Other removable offloading devices may be considered in particular settings (e.g. wounds that require more regular debridement and dressing changes) or where patient factors (e.g. significant risk of falls) do not allow the use of an irremovable device.	2. When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider offloading with a removable knee-high walker with an appropriate foot-device interface to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the device. (Weak; Moderate)
	3. When a knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only and when the patient can be expected to be adherent to wearing the shoes. (Weak; Low)
	Therapeutic footwear
	4. Do not prescribe, and instruct a patient with diabetes not to use, conventional or standard therapeutic shoes to heal a plantar foot ulcer. (Strong; Low)
	5. Consider using shoe modifications, temporary footwear, toe spacers or orthoses to offload and heal a non-plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. The specific modality will depend on the type and location of the foot ulcer. (Weak; Low)
	13. If other forms of biomechanical relief are not available, consider using felted foam in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection in a patient with

	diabetes. (Weak; Low)
	Surgical offloading interventions
	11. To heal a neuropathic plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes, consider Achilles tendon lengthening, single or pan metatarsal head resection, or joint arthroplasty when conservative treatment fails. (Weak; Low)
	12. To heal a toe ulcer without ischemia or uncontrolled infection in a patient with diabetes and hammertoes, consider digital flexor tenotomy when conservative treatment fails. (Weak; Low)
Wound-healing interventions	**Wound-healing interventions**
Basic interventions	*Basic interventions*
EO 8: Local sharp debridement of non-ischaemic wounds should be performed as it improves ulcer healing.	1. Clean ulcers regularly with clean water or saline, debride them when possible in order to remove debris from the wound surface and dress them with a sterile, inert dressing in order to control excessive exudate and maintain a warm, moist environment in order to promote healing. (Strong; Low) 2. In general remove slough, necrotic tissue and surrounding callus with sharp debridement in preference to other methods, taking relative contra-indications such as severe ischemia into account. (Strong; Low)
EBR 6: Topical hydrogel dressings may be considered for autolytic debridement to assist the management of non-ischaemic, nonhealing ulcers with dry, non-viable tissue. (B) EO 9: There is insufficient evidence to demonstrate the superiority of any one wound dressing over another in management of ulcers. This means that the dressing plan will need to be tailored to the specific characteristics of the wound. In non-ischaemic ulcers, create a moist wound environment. In ischaemic ulcers maintain a dry wound environment using a dry, non-adherent dressing, until the wound has been reviewed by someone with experience in peripheral arterial disease.	3. Select dressings principally on the basis of exudate control, comfort and cost. (Strong; Low) 4. Do not use antimicrobial dressings with the goal of improving wound healing or preventing secondary infection. (Strong; Moderate)

Advanced adjunctive interventions	*Advanced adjunctive interventions*
The following may be considered for foot ulcers in specialist centres, as part of a comprehensive wound management program: EBR 11: Topical negative pressure therapy (B) EBR 12: Hyperbaric oxygen therapy (B) EBR 13 Larval therapy (C) EBR 14 Skin replacement therapies - Cultured skin equivalents. (B) - Skin grafting. (D)	5. Consider the use of systemic hyperbaric oxygen therapy, even though further blinded and randomised trials are required to confirm its cost-effectiveness, as well as to identify the population most likely to benefit from its use. (Weak; Moderate) 6. Topical negative pressure wound therapy may be considered in post-operative wounds even though the effectiveness and cost-effectiveness of the approach remains to be established. (Weak; Moderate)
	7. Do not select agents reported to improve wound healing by altering the biology of the wound, including growth factors, bioengineered skin products and gases, in preference to accepted standards of good quality care. (Strong; Low) 8. Do not select agents reported to have an impact on wound healing through alteration of the physical environment, including through the use of electricity, magnetism, ultrasound and shockwaves, in preference to accepted standards of good quality care. (Strong; Low) 9. Do not select systemic treatments reported to improve wound healing, including drugs and herbal therapies, in preference to accepted standards of good quality care. (Strong; Low)
Peripheral artery disease	**Peripheral artery disease**
Outside the scope of the Australian guidelines	IWGDF recommendations can be found here
Infection	**Infection**
Outside the scope of the Australian guidelines	IWGDF recommendations can be found here

Note: EBR = Evidence-Based Recommendation; EO = Expert Opinion.

Appendix 4: IWGDF classification of clinical signs of infection

1 – Uninfected	No systemic or local symptoms or signs of infection
2 - Mild infection	At least 2 of the following items are present: • Local swelling or induration • Erythema > 0.5 cm* around the wound • Local tenderness or pain • Local warmth • Purulent discharge - Other causes of an inflammatory response of the skin should be excluded (e.g., trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis) - Infection involving only the skin or subcutaneous tissue (without involvement of deeper tissues and without systemic manifestations as described below). - Any erythema present extends < 2 cm* around the wound - No systemic signs or symptoms of infection
3 - Moderate infection	: Infection involving structures deeper than skin and subcutaneous tissues (e.g., bone, joint, tendon, muscle) or erythema extending >2 cm* from the wound margin. No systemic signs or symptoms of infection (see below).
4 - Severe infection	Any foot infection with the systemic inflammatory response syndrome (SIRS), as manifested by ≥2 of the following: • Temperature >38 or <36C • Heart rate >90 beats/minute • Respiratory rate >20 breaths/minute or PaCO2 < 4.3 kPa (32 mmHg) • White blood cell count >12,000 or <4,000/mm3, or >10% immature (band) forms.

Appendix 5: IWGDF recommendations on selecting an empiric antibiotic regimen for diabetic foot infections

Infection Severity	Additional Factors	Usual Pathogen(s)	Potential Empirical Regimens [a]
Mild	No complicating features	GPC	S-S pen; 1st gen ceph
	ß -lactam allergy or intolerance	GPC	Clindamycin; FQ; T/S; macrolide; doxy
	Recent antibiotic exposure	GPC + GNR	ß -L-ase-1; T/S; FQ
	High risk for MRSA	MRSA	Linezolid; T/S ; doxy; macrolide; FQ
Moderate	No complicating features	GPC ± GNR	ß -L-ase 1; 2nd /3rd gen ceph
and Severe [b]	Recent antibiotics	GPC ± GNR	ß -L-ase 2; 3rd gen ceph, group 1 carbapenem (depends on prior therapy; seek advice)
	Macerated ulcer, warm climate	GNR, including *Pseudomonas*	ß -Lase-2; S-S pen + ceftazidime, S-S pen + cipro, group 2 carbapenem
	Ischemic limb/ necrosis/ gas forming	GPC ± GNR ± anaerobes	ß -L-ase 1 or 2; group 1 or 2 carbapenem; 2nd /3rd gen ceph + clindamycin or metronidazole
	MRSA risk factors	MRSA	Consider addition of, or substituting with, glycopeptides; linezolid; daptomycin; fusidic acid; T/S (±rif)*; doxycycline; FQ
	Risk factors for resistant GNR	ESBL	Carbapenems, FQ, aminoglycoside, colistin

GPC = gram positive cocci (staphylococci and streptococci); GNR = gram negative rod; MRSA = methicillin-resistant *Staphylococcus aureus*; ESBL = extended spectrum beta lactamase producing organism; S-S pen = semisynthetic penicillinase-resistant penicillin; ß -L-ase= ß-lactam, ß-lactamase inhibitor; ß -L-ase 1= amoxicillin/clavulanate, ampicillin / sulbactam; ß -L-ase 2= ticarcillin/clavulanate, piperacillin/tazobactam; doxy = doxycycline; Group 1 carbapenem= ertapenem; Group 2 carbapenem= imipenem, meropenem, doripenem; Ceph= cephalosporin; gen= generation; Pip / tazo=piperacillin/tazobactam; FQ=fluoroquinolone with good activity against aerobic gram-positive cocci (e.g., levofloxacin or moxifloxacin); Cipro = antipseudomonal fluoroquinolone e.g. ciprofloxacin; T/S=trimethoprim / sulfamethoxazole; T/S (±rif) = trimethoprim/sulfamethoxazole with or without *rifamp(ic)in (200) (for now we think rifamp(ic)in should only be used for osteomyelitis).[a] Given at usual recommended doses for serious infections. Modify doses or agents selected for azotaemia, liver dysfunction, etc. Recommendations based upon theoretical considerations and available clinical trials. [b] Oral antibiotic agents should generally not be used for severe infections, except as follow-on (switch) after initial parenteral therapy.

Appendix 6: IWGDF recommendations on peripheral artery disease and infection

Peripheral artery disease

Diagnosis

1. Examine a patient with diabetes annually for the presence of peripheral artery disease (PAD); this should include, at a minimum, taking a history and palpating foot pulses. (GRADE recommendation: strong; Quality of evidence: low)
2. Evaluate a patient with diabetes and a foot ulcer for the presence of PAD. Determine, as part of this examination, ankle or pedal Doppler arterial waveforms; measure both ankle systolic pressure and systolic ankle brachial index (ABI). (Strong; Low)
3. We recommend the use of bedside non-invasive tests to exclude PAD. No single modality has been shown to be optimal. Measuring ABI (with <0.9 considered abnormal) is useful for the detection of PAD. Tests that largely exclude PAD are the presence of ABI 0.9-1.3, toe brachial index (TBI) ≥0.75 and the presence of triphasic pedal Doppler arterial waveforms. (Strong; Low)

Prognosis

4. In patients with a foot ulcer in diabetes and PAD, no specific symptoms or signs of PAD reliably predict healing of the ulcer. However, one of the following simple bedside tests should be used to inform the patient and healthcare professional about the healing potential of the ulcer. Any of the following findings increases the pre-test probability of healing by at least 25%: a skin perfusion pressure ≥40mmHg; a toe pressure ≥30mmHg; or, a TcPO2 ≥25 mmHg. (Strong; Moderate)
5. Consider urgent vascular imaging and revascularisation in patients with a foot ulcer in diabetes where the toe pressure is <30mmHg or the TcPO2 <25 mmHg. (Strong; Low)
6. Consider vascular imaging and revascularisation in all patients with a foot ulcer in diabetes and PAD, irrespective of the results of bedside tests, when the ulcer does not improve within 6 weeks despite optimal management. (Strong; Low).
7. Diabetic microangiopathy should not be considered to be the cause of poor wound healing in patients with a foot ulcer. (Strong; Low)
8. In patients with a non-healing ulcer with either an ankle pressure <50mm Hg or ABI <0.5 consider urgent vascular imaging and revascularisation. (Strong; Moderate)

Treatment

9. Colour Doppler ultrasound, CT-angiography, MR-angiography or intra-arterial digital subtraction angiography can each be used to obtain anatomical information when revascularisation is being considered. The entire lower extremity arterial circulation should be evaluated, with detailed visualization of below-the-knee and pedal arteries. (Strong; Low)
10. The aim of revascularisation is to restore direct flow to at least one of the foot arteries, preferably the artery that supplies the anatomical region of the wound, with the aim of achieving a minimum skin perfusion pressure ≥40mmHg; a toe pressure ≥30mmHg; or, a TcPO2 ≥25 mmHg (Strong; Low)
11. A centre treating patients with a foot ulcer in diabetes should have the expertise in and rapid access to facilities necessary to diagnose and treat PAD; both endovascular techniques

and bypass surgery should be available. (Strong; Low)

12. There is inadequate evidence to establish which revascularisation technique is superior and decisions should be made in a multidisciplinary team on a number of individual factors, such as morphological distribution of PAD, availability of autogenous vein, patient co-morbidities and local expertise. (Strong; Low)
13. After a revascularisation procedure for a foot ulcer in diabetes, the patient should be treated by a multidisciplinary team as part of a comprehensive care plan. (Strong; Low)
14. Patients with signs of PAD and a foot infection are at particularly high risk for major limb amputation and require emergency treatment. (Strong; Moderate)
15. Avoid revascularisation in patients in whom, from the patient perspective, the risk-benefit ratio for the probability of success is unfavourable. (Strong; Low)
16. All patients with diabetes and an ischemic foot ulcer should receive aggressive cardiovascular risk management including support for cessation of smoking, treatment of hypertension and prescription of a statin as well as low-dose aspirin or clopidogrel. (Strong; Low)

Foot infection

Classification / diagnosis

1. Diabetic foot infection must be diagnosed clinically, based on the presence of local or systemic signs or symptoms of inflammation (Strong; Low).
2. Assess the severity of any diabetic foot infection using the Infectious Diseases Society of America/International Working Group on the Diabetic Foot classification scheme (Strong; Moderate)

Osteomyelitis

3. For an infected open wound, perform a probe-to-bone test; in a patient at low risk for osteomyelitis a negative test largely rules out the diagnosis, while in a high risk patient a positive test is largely diagnostic (Strong; High)
4. Markedly elevated serum inflammatory markers, especially erythrocyte sedimentation rate, are suggestive of osteomyelitis in suspected cases (Weak; Moderate)
5. A definite diagnosis of bone infection usually requires positive results on microbiological (and, optimally, histological) and examinations of an aseptically obtained bone sample, but this is usually required only when the diagnosis is in doubt or determining the causative pathogen's antibiotic susceptibility is crucial (Strong; Moderate)
6. A probable diagnosis of bone infection is reasonable if there are positive results on a combination of diagnostic tests, such as probe-to-bone, serum inflammatory markers, plain X-ray, MRI or radionuclide scanning (Strong; Weak)
7. Avoid using results of soft tissue or sinus tract specimens for selecting antibiotic therapy for osteomyelitis as they do not accurately reflect bone culture results (Strong; Moderate)
8. Obtain plain X-rays of the foot in all cases of non-superficial diabetic foot infection. (Strong; Low)
9. Use MRI when an advanced imaging test is needed for diagnosing diabetic foot osteomyelitis (Strong; Moderate)
10. When MRI is not available or contraindicated, consider a white blood cell-labelled radionuclide scan, or possibly SPECT/CT or 18 F- FDG PET/CT scans (Weak; Moderate)

Assessing severity

11. At initial evaluation of any infected foot, obtain vital signs and appropriate blood tests, debride the wound, probe and assess the depth and extent of the infection to establish its severity (Strong; Moderate)
12. At initial evaluation assess arterial perfusion and decide whether and when further vascular assessment or revascularization is needed (Strong; Low)

Microbiological considerations

13. Obtain cultures, preferably of a tissue specimen rather than a swab, of infected wounds to determine the causative microorganisms and their antibiotic sensitivity (Strong; High)
14. Do not obtain repeat cultures unless the patient is not clinically responding to treatment, or occasionally for infection control surveillance of resistant pathogens (Strong; Low)
15. Send collected specimens to the microbiology laboratory promptly, in sterile transport containers, accompanied by clinical information on the type of specimen and location of the wound (Strong; Low)

Surgical treatment

16. Consult a surgical specialist in selected cases of moderate, and all cases of severe, DFI (Weak; Low)
17. Perform urgent surgical interventions in cases of deep abscesses, compartment syndrome and virtually all necrotizing soft tissue infections (Strong; Low)
18. Consider surgical intervention in cases of osteomyelitis accompanied by: spreading soft tissue infection; destroyed soft tissue envelope; progressive bone destruction on X-ray, or bone protruding through the ulcer (Strong; Low)

Antimicrobial therapy

19. While virtually all clinically infected diabetic foot wounds require antimicrobial therapy do not treat clinically uninfected wounds with antimicrobial therapy (Strong; Low)
20. Select specific antibiotic agents for treatment based on the likely or proven causative pathogens, their antibiotic susceptibilities, the clinical severity of the infection, evidence of efficacy of the agent for DFI and costs (Strong; Moderate)
21. A course of antibiotic therapy of 1-2 weeks is usually adequate for most mild and moderate infections (Strong; High)
22. Administer parenteral therapy initially for most severe infections and some moderate infections, with a switch to oral therapy when the infection is responding (Strong; Low)
23. Do not select a specific type of dressing for a diabetic foot infection with the aim of preventing an infection or improving its outcome (Strong; High)
24. For diabetic foot osteomyelitis we recommend 6 weeks of antibiotic therapy for patients who do not undergo resection of infected bone and no more than a week of antibiotic treatment if all infected bone is resected. (Strong; Moderate)
25. We suggest not using any adjunctive treatments for diabetic foot infection. (Weak; Low)
26. When treating a diabetic foot infection, assess for use of traditional remedies, previous antibiotic use, and consider local bacterial pathogens and their susceptibility profile. (Strong; Low)