



Australian evidence-based guidelines for the prevention and management of diabetes-related foot disease: a guideline summary

Peter A Lazzarini^{1,2} , Anita Raspovic³, Jenny Prentice⁴, Robert J Commons^{5,6} , Robert A Fitridge^{7,8}, James Charles⁹, Jane Cheney¹⁰, Nytasha Purcell¹¹, Stephen M Twigg^{12,13}

Diabetes-related foot disease (DFD) — foot ulcers, infection and ischaemia — is a leading cause of hospitalisation, amputation, disability, and health care costs.¹⁻⁶ In Australia each year, DFD affects around 50 000 people, causing 28 000 hospitalisations, 5000 amputations and \$1.6 billion in costs.¹⁻⁵ Further, 300 000 Australians are at risk of DFD, and Aboriginal and Torres Strait Islander Peoples have up to a 38-fold risk of developing DFD and ensuing amputations.^{1-4,7}

Despite the large national DFD burden, Australian regions implementing guideline-based care have demonstrated large reductions in their regional DFD burdens and costs.^{4,8-11} However, the most recent Australian guideline on DFD was published in 2011,¹² many of its recommendations are now outdated,^{1,13} and the body of research on DFD has since expanded considerably.¹⁴ Therefore, the recent Australian DFD Strategy recommended an urgent update of Australian DFD guideline to inform contemporary evidence-based practice and help reduce the large burden of DFD.^{1,2}

To address this gap, Diabetes Feet Australia (DFA; a division of the Australian Diabetes Society) recently developed and published a suite of six new guidelines that make up the new Australian evidence-based guidelines for the prevention and management of DFD. The six full guidelines are available at <https://jfootankleres.biomedcentral.com/>.¹⁵⁻²¹

Methods

The methodology for developing these guidelines is detailed in a published protocol.¹⁵ In brief, as the funding necessary to develop guidelines *de novo* was unavailable, DFA appointed a guidelines development group comprising multidisciplinary clinical, research, guideline, consumer and Aboriginal and Torres Strait Islander experts in DFD to adapt suitable international guidelines to the Australian context.¹⁵ Experts were defined as having nationally or internationally recognised track records in DFD research, guideline development, or lived experience. This group developed the protocol following eight key steps adhering to the ADAPTE and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approaches as recommended by the National Health and Medical Research Council (NHMRC) guidelines for adopting or adapting international guidelines.²²⁻²⁴

First, the scope was defined to develop new evidence-based guidelines that informed the practice of the multidisciplinary health professionals that provide prevention or management for populations with or at risk of DFD in the Australian context.

Abstract

Introduction: Diabetes-related foot disease (DFD) — foot ulcers, infection, ischaemia — is a leading cause of hospitalisation, disability, and health care costs in Australia. The previous 2011 Australian guideline for DFD was outdated. We developed new Australian evidence-based guidelines for DFD by systematically adapting suitable international guidelines to the Australian context using the ADAPTE and GRADE approaches recommended by the NHMRC.

Main recommendations: This article summarises the most relevant of the 98 recommendations made across six new guidelines for the general medical audience, including:

- prevention — screening, education, self-care, footwear, and treatments to prevent DFD;
- classification — classifications systems for ulcers, infection, ischaemia and auditing;
- peripheral artery disease (PAD) — examinations and imaging for diagnosis, severity classification, and treatments;
- infection — examinations, cultures, imaging and inflammatory markers for diagnosis, severity classification, and treatments;
- offloading — pressure offloading treatments for different ulcer types and locations; and
- wound healing — debridement, wound dressing selection principles and wound treatments for non-healing ulcers.

Changes in management as a result of the guideline: For people without DFD, key changes include using a new risk stratification system for screening, categorising risk and managing people at increased risk of DFD. For those categorised at increased risk of DFD, more specific self-monitoring, footwear prescription, surgical treatments, and activity management practices to prevent DFD have been recommended. For people with DFD, key changes include using new ulcer, infection and PAD classification systems for assessing, documenting and communicating DFD severity. These systems also inform more specific PAD, infection, pressure offloading, and wound healing management recommendations to resolve DFD.

DFD was defined as infection, ulceration, or tissue destruction of the foot in a person with diabetes.^{25,26} Second, a systemic search was undertaken to identify all international DFD guidelines in international and Australian guideline registers by three independent authors (PAL, AR and JP). Third, all international guidelines identified were assessed independently by four authors (PAL, AR, JP and RJC) for quality using a 23-item Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument, plus suitability and currency using a 22-item instrument customised from the NHMRC table of factors to consider when adapting guidelines.^{15,22,27} The suite of six International Working Group on the Diabetic Foot (IWGDF)

¹Queensland University of Technology, Brisbane, QLD. ²Allied Health Research Collaborative, Metro North Hospital and Health Service, Brisbane, QLD. ³La Trobe University, Melbourne, VIC. ⁴Hall and Prior Health and Aged Care Group, Perth, WA. ⁵Grampians Rural Health Alliance, Ballarat, VIC. ⁶Menzies School of Research, Charles Darwin University, Darwin, NT. ⁷Royal Adelaide Hospital, Adelaide, SA. ⁸University of Adelaide, Adelaide, SA. ⁹First Peoples Health Unit, Griffith University, Gold Coast, QLD. ¹⁰Diabetes Victoria, Melbourne, VIC. ¹¹Diabetes Feet Australia, Australian Diabetes Society, Sydney, NSW. ¹²University of Sydney, Sydney, NSW. ¹³Royal Prince Alfred Hospital, Sydney, NSW. ✉ peter.lazzarini@qut.edu.au • doi: 10.5694/mja2.52136

guidelines,²⁸⁻³⁴ along with their accompanying systematic reviews of all relevant studies in the field,³⁵⁻⁴⁴ were identified as the only international DFD guidelines with appropriate quality, suitability and currency to adapt.

Fourth, all 100 recommendations (and associated rationale) in the IWGDF guidelines were systematically evaluated.²⁸⁻³⁴ This was undertaken by six panels each comprising six to eight nationally and internationally recognised experts in the DFD fields of prevention, classification, peripheral artery disease (PAD), infection, offloading, and wound healing interventions.¹⁵ Collectively, the panels comprised 30 experts from endocrinology, infectious diseases, vascular surgery, orthopaedic surgery,

wound care nursing, podiatry, pedorthics, consumers, and Aboriginal and Torres Strait Islander peoples. Each panel rated all recommendations in their field for acceptability and applicability in the Australian context using a seven-item ADAPTE form by consensus.²⁴ Where panels rated all seven items as acceptable or applicable, the recommendation was adopted. Where panels rated any item as unsure or not acceptable or applicable, the panel performed a full re-evaluation of the recommendation using the GRADE Evidence to Decision framework to facilitate judgements on eight important criteria: the problem, desirable effects, undesirable effects, quality of evidence, values, balance of effects, acceptability, and feasibility.^{15,23} A decision was made to adopt, if all panel and IWGDF criteria judgements

1 Summary of key prevention recommendations

Recommendation	GRADE	
	Strength*	Quality†
Examine a person with diabetes at very low risk (IWGDF system) of foot ulceration annually for loss of protective sensation and PAD to determine if they are at risk of ulceration.	Strong	Low
Screen a person determined at risk of ulceration (low to high risk) also for history of ulceration or amputation, end-stage renal disease, foot deformity, limited joint mobility, abundant callus, and pre-ulcerative signs on the foot. Repeat every 6–12 months for people at low risk, every 3–6 months for moderate risk, and every 1–3 months for high risk.	Strong	Low
Consider instructing a person who is at moderate or high risk to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent an ulcer; contingent on systems approved in Australia.	Weak	Moderate
Instruct a person who is at moderate risk to wear medical-grade footwear to reduce plantar pressure and help prevent ulcers.	Strong	Low
Consider prescribing orthotic interventions, such as toe silicone or rigid or semi-rigid orthotic devices, to help reduce abundant callus in a person at risk.	Weak	Low
In a person who has a healed plantar ulcer, prescribe medical-grade footwear that has a demonstrated a plantar pressure-relieving effect to help prevent recurrent ulcers.	Strong	Moderate
Treat any pre-ulcerative sign or abundant callus on the foot, ingrown toenail, and fungal infection to help prevent ulcers in a person at risk.	Strong	Low
In a person with abundant callus (and ulcer history), consider digital flexor tendon tenotomy for preventing ulcer recurrence.	Weak	Low
In a person with a plantar forefoot ulcer (history), consider Achilles tendon lengthening, single or pan-metatarsal head resection, metatarsophalangeal joint arthroplasty or osteotomy to prevent ulcer recurrence.	Weak	Low
Consider communicating to a person at risk that any increase in weight-bearing activity should be gradual, ensuring appropriate footwear is worn and the skin is frequently monitored for pre-ulcerative signs or injury.	Weak	Low

GRADE = Grading of Recommendations, Assessment, Development and Evaluation; IWGDF = International Working Group on the Diabetic Foot; PAD = peripheral artery disease. * The GRADE strength of recommendation rating is defined as the extent the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention/recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty), or very low (very low certainty).^{15,23} Source: Table adapted with permission from Kaminski et al.¹⁶ ◆

2 Summary of key classification recommendations

Recommendation	GRADE	
	Strength*	Quality†
In a person with a foot ulcer, as a minimum, use the SINBAD wound classification system.	Strong	Moderate
In a person with an infected ulcer, use the IDSA/IWGDF infection classification system.	Weak	Moderate
In a person with an ulcer managed where expertise in vascular intervention is available, use the Wifi classification system.	Weak	Moderate
As a minimum, use the SINBAD system for any regional/national/international audits.	Strong	High

GRADE = Grading of Recommendations, Assessment, Development and Evaluation; IDSA = Infectious Diseases Society of America; IWGDF = International Working Group on the Diabetic Foot; SINBAD = Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth; Wifi = Wound, Ischaemia, and foot Infection. * The GRADE strength of recommendation rating is defined as the extent the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention or recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty), or very low (very low certainty).^{15,23} Source: Table adapted with permission from Hamilton et al.¹⁷ ◆

were in agreement; adapt, if some disagreements; or exclude, if substantial disagreements.¹⁵

Fifth, panels redrafted recommendations (and rationale) using the GRADE approach.^{15,23} For adopted recommendations, the wording, strength of recommendation and quality of evidence remained the same. For adapted recommendations, the wording was redrafted to be clear, specific and unambiguous on what was recommended.^{15,23} The strength of recommendation was re-evaluated as “strong” or “weak”, based on the extent to which the panel was confident that the desirable effects (benefits) of the intervention clearly outweighed the undesirable effects (harms), based on the available evidence, applicability and feasibility in the Australian context.^{15,23} A strong recommendation implies the desirable effects of the intervention clearly outweigh the undesirable effects, and most people in this situation would be best served using this recommendation.^{15,23} A weak recommendation implies the desirable effects probably outweigh the undesirable effects, but there is a need to carefully consider each person’s situation before using.^{15,23} Quality of evidence was re-evaluated as high, moderate, low or very low, based on the extent the panel could be certain that the true effect was close to the effect estimates found for the critical outcomes in the available evidence supporting the recommendation and further research was unlikely to change their certainty.^{15,23} For excluded recommendations, the panel stated the recommendation was

excluded. The panel then drafted rationale for all decisions, plus considerations on implementing the recommendation in Australia (including specifically for geographically remote and Aboriginal and Torres Strait Islander peoples), monitoring and future research priorities.^{15,23}

Sixth, panels drafted and incorporated all recommendations and rationale in a full guideline consultation manuscript. Seventh, each panel sought four to six weeks of public consultation on their consultation manuscript, collated feedback, transparently revised and sought endorsement from national peak bodies.¹⁵ Finally, panels incorporated all recommendations into pathways to aid implementation into practice,¹⁵ with pathways further developed into interactive online decision-assisting pathways and a practical toolkit, available in full at <https://www.diabetesfeetaustralia.org/new-guidelines/>.

Recommendations

Here we summarise the key recommendations considered most relevant for the general medical audience, with a focus on prevention and classification.^{16-21,45} In doing so, we highlight that many PAD, infection, offloading and wound healing management recommendations that are considered most relevant for specialist medical audiences have been omitted.¹⁶⁻²¹ Thus, we strongly suggest people with DFD are referred to

3 Summary of key peripheral artery disease recommendations

Recommendation	GRADE	
	Strength*	Quality [†]
Examine all patients annually for PAD by taking a relevant history and palpating foot pulses.	Strong	Low
As examination does not reliably exclude PAD in persons with an ulcer, evaluate pedal Doppler arterial waveforms with ABI or TBI. PAD is less likely in presence of ABI of 0.9–1.3, TBI \geq 0.75, and triphasic waveforms.	Strong	Low
Perform at least one of the following in a patient with an ulcer and PAD, as any increases the probability of healing by > 25%: skin perfusion pressure \geq 40 mmHg, toe pressure \geq 30 mmHg, or TcPO ₂ \geq 25 mmHg.	Strong	Moderate
Use the WIfI classification system in a patient with an ulcer and PAD.	Strong	Moderate
Always consider urgent vascular imaging/revascularisation in a patient with an ankle pressure < 50 mmHg, ABI < 0.5, toe pressure < 30 mmHg, or TcPO ₂ < 25 mmHg.	Strong	Low
Always consider vascular imaging/revascularisation in patients, irrespective of the results of tests, when the ulcer is not healing within 6 weeks. [‡]	Strong	Low
Use any of the following when considering revascularisation: colour duplex ultrasound, computed tomography angiography, magnetic resonance angiography, or intra-arterial digital subtraction angiography.	Strong	Low
When performing revascularisation, aim to restore direct blood flow to at least one foot artery, preferably the artery that supplies the ulcer.	Strong	Low
As evidence is inadequate to establish which revascularisation technique is superior, make decisions based on individual factors, such as morphological distribution of PAD, availability of autogenous vein, the patient’s comorbid conditions, and local expertise.	Strong	Low
Any centre treating patients with ulcers should have expertise in, and/or rapid access to, facilities necessary to diagnose and treat PAD.	Strong	Low
Ensure that after a revascularisation procedure, the patient is treated by a multidisciplinary team.	Strong	Low
Urgently assess patients with signs of PAD and foot infection, as they are at particularly high risk for amputation.	Strong	Moderate
Avoid revascularisation in patients in whom the risk–benefit ratio for success is unfavourable.	Strong	Low
Provide intensive cardiovascular risk management for any patient with an ischaemic ulcer.	Strong	Low

ABI = ankle brachial index; GRADE = Grading of Recommendations, Assessment, Development and Evaluation; PAD = peripheral artery disease; TBI = toe brachial index; TcPO₂ = transcutaneous oxygen pressure; WIfI = Wound, Ischaemia, and foot Infection. * The GRADE strength of recommendation rating is defined as the extent to which the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention/recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent to which the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty) or very low (very low certainty).^{15,23} ‡ Recommendation applying specifically to people with non-healing diabetes-related foot ulcers, defined as foot ulcers reducing in size by < 50% after four to six weeks of receiving best standard of foot ulcer care,²⁶ in alignment with the applicable recommendations in these guidelines.¹⁶⁻²¹ Source: Table adapted with permission from Chuter et al.¹⁸ ◆

4 Summary of key infection recommendations

Recommendation	GRADE	
	Strength*	Quality†
Diagnose soft tissue foot infection based on local or systemic signs and symptoms of inflammation.	Strong	Low
Assess the severity of infection using the IWGDF/IDSA classification scheme.	Strong	Moderate
Consider admitting to hospital all persons with severe infection (IWGDF/IDSA) and those with moderate infection that is complex.	Strong	Low
In a person with possible infection for whom examination is equivocal, consider an inflammatory serum biomarker for diagnosis, such as C-reactive protein, erythrocyte sedimentation rate, or procalcitonin.	Weak	Low
In a person with suspected osteomyelitis, use probe-to-bone test, erythrocyte sedimentation rate (or C-reactive protein and/or procalcitonin), and x-rays as initial studies to diagnose osteomyelitis.	Strong	Moderate
In a person with suspected osteomyelitis, if plain x-ray and clinical and laboratory findings are compatible, we recommend no further imaging to establish diagnosis.	Strong	Low
If osteomyelitis remains in doubt, consider an advanced imaging study, such as magnetic resonance imaging, ¹⁸ F-FDG PET/CT, or leukocyte scintigraphy (with or without CT).	Strong	Moderate
In a person with suspected osteomyelitis in whom making a definitive diagnosis or determining the causative pathogen is necessary for treatment, collect a bone sample for culture and histopathology.	Strong	Low
Collect an appropriate specimen for culture for almost all clinically infected ulcers.	Strong	Low
For soft tissue infection, obtain a sample for culture by aseptically collecting a tissue specimen from the ulcer.	Strong	Moderate
Treat a person with infection with an antibiotic shown to be effective in a randomised controlled trial that is appropriate for the individual.	Strong	High
Select an antibiotic for treating infection based on causative pathogen(s) and antibiotic susceptibilities; clinical severity of infection; evidence of efficacy; risk of adverse events, including damage to commensal flora; likelihood of drug interactions; availability; and costs.	Strong	Moderate
Administer antibiotic(s) initially by parenteral route to any patient with severe soft tissue infection. Switch to oral therapy if the patient is clinically improving, has no contraindications and if an appropriate agent is available.	Strong	Very low
Treat patients with mild and most with moderate infections with oral antibiotic(s), either at presentation or when improving with intravenous therapy.	Weak	Low
We suggest not using topical antimicrobial(s) for treating mild infection.	Weak	Moderate
Administer antibiotic(s) to a patient with soft tissue infection for 1–2 weeks.	Strong	High
Consider continuing for up to 3–4 weeks if the infection is improving but is extensive, resolving slower than expected, or if the patient has severe PAD.	Weak	Low
If infection has not resolved after 4 weeks, re-evaluate and reconsider the need for further diagnostic studies or alternative treatments.‡	Strong	Low
For patients who have not recently received antibiotic(s) and have acute infection, consider targeting empiric antibiotic(s) at aerobic gram-positive pathogens for mild infection.	Weak	Low
For patients who have been treated with antibiotic(s) within a few weeks, have a chronic infection, a severely ischaemic limb, or moderate or severe infection, we suggest selecting an empiric antibiotic that covers gram-positive pathogens, commonly isolated gram-negative pathogens, and possibly obligate anaerobes.	Weak	Low
Empiric treatment aimed at <i>Pseudomonas aeruginosa</i> is not usually necessary but consider it if <i>P. aeruginosa</i> has been isolated from the site within the previous few weeks or in tropical/subtropical climates (at least for moderate or severe infection).	Weak	Low
Do not treat clinically uninfected ulcers with antibiotics.	Strong	Low
Urgently consult with a surgical specialist in cases of severe infection or moderate infection complicated by extensive gangrene, necrotising infection, deep abscess, compartment syndrome, or severe PAD.	Strong	Low
In a patient with uncomplicated forefoot osteomyelitis, with no other indication for surgical treatment, consider treating with antibiotic(s) without surgical resection.	Strong	Moderate
In a patient with probable osteomyelitis with soft tissue infection, urgently evaluate the need for surgery.	Strong	Moderate
Select antibiotic(s) for treating osteomyelitis from those that have demonstrated efficacy in clinical studies.	Strong	Low
Treat osteomyelitis with antibiotic(s) for just a few days if there is no soft tissue infection and all infected bone has been surgically removed.	Weak	Low
For osteomyelitis that initially requires parenteral therapy, consider switching to an appropriate oral antibiotic that has high bioavailability after 5–7 days.	Weak	Moderate
During surgery to resect bone for osteomyelitis, consider obtaining a bone specimen for culture (and, if possible, histopathology) at the stump of the resected bone to identify residual infection.	Weak	Moderate

Continues

4 Continued

Recommendation	GRADE	
	Strength*	Quality [†]
If an aseptically collected culture specimen obtained during surgery grows pathogen(s) or if histology demonstrates osteomyelitis, administer appropriate antibiotic(s) for up to 6 weeks.	Strong	Moderate
To specifically address infection, we suggest not using hyperbaric oxygen therapy nor topical oxygen therapy.	Weak	Low
To specifically address infection, we suggest not using adjunctive granulocyte colony-stimulating factor treatment.	Weak	Moderate
To specifically address infection, we suggest not routinely using topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy.	Weak	Low

CT = computed tomography; ¹⁸F-FDG = fluorine-18 fluorodeoxyglucose; GRADE = Grading of Recommendations, Assessment, Development and Evaluation; IDSA = Infectious Diseases Society of America; IWGDF = International Working Group on the Diabetic Foot; PAD = peripheral artery disease; PET = positron emission tomography. * The GRADE strength of recommendation rating is defined as the extent the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention/recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty), or very low (very low certainty).^{15,23} ‡ Recommendation applying specifically to people with non-healing diabetes-related foot ulcers, defined as foot ulcers reducing in size by < 50% after four to six weeks of receiving best standard of foot ulcer care,²⁶ in alignment with the applicable recommendations in these guidelines.¹⁶⁻²¹ Source: Table adapted with permission from Commons et al.¹⁹ ◆

5 Summary of key offloading recommendations

Recommendation	GRADE	
	Strength*	Quality [†]
In a person with a neuropathic plantar forefoot/midfoot ulcer:		
Use a non-removable knee-high offloading device:	Strong	Moderate
• either a total contact cast or non-removable knee-high walker	Weak	Low
When the above is contraindicated/not tolerated, consider a removable knee-high offloading device	Weak	Low
When the above is contraindicated/not tolerated, use a removable ankle-high offloading device	Strong	Very low
When the above is contraindicated/not tolerated, use medical-grade footwear	Strong	Low
If the best recommended offloading device option fails to heal a:		
Neuropathic plantar metatarsal head ulcer, consider Achilles tendon lengthening, gastrocnemius recession, metatarsal head resection(s), or joint arthroplasty [‡]	Weak	Low
Neuropathic plantar ulcer on a non-rigid toe, consider a digital flexor tenotomy [‡]	Weak	Low
In a person with a neuropathic plantar forefoot/midfoot ulcer (complicated) with:		
Mild infection and mild ischaemia, moderate infection or moderate ischaemia, consider a removable knee-high offloading device	Weak	Low
Moderate infection and moderate ischaemia, severe infection or severe ischaemia, consider a removable offloading intervention	Weak	Low
In a person with a neuropathic plantar heel ulcer, consider a knee-high offloading device	Weak	Low
In a person with a non-plantar ulcer use a removable offloading device, medical-grade footwear, felted foam, toe spacers or orthoses, depending on the ulcer type and location	Strong	Very low

GRADE = Grading of Recommendations, Assessment, Development and Evaluation. * The GRADE strength of recommendation rating is defined as the extent the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention/recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty), or very low (very low certainty).^{15,23} ‡ Recommendation applying specifically to people with non-healing diabetes-related foot ulcers, defined as foot ulcers reducing in size by < 50% after four to six weeks of receiving best standard of foot ulcer care,²⁶ in alignment with the applicable recommendations in these guidelines.¹⁶⁻²¹ Source: Table adapted with permission from Fernando et al.²⁰ ◆

interdisciplinary High Risk Foot Services or equivalent for management where possible.¹⁶⁻²¹

We also tabulated recommendations that are new or changed from the previous 2011 guideline along with their GRADE strength of recommendation and quality of evidence (Box 1, Box 2, Box 3, Box 4, Box 5 and Box 6). We further edited the tabulated recommendations for brevity and flow, and we refer the reader to the full guidelines for complete details on

each recommendation, including rationale, implementation, monitoring, and research considerations.¹⁶⁻²¹ Otherwise, we highlight that most recommendations for DFD apply to healing or non-healing DFD; we denote recommendations specifically for non-healing DFD in Box 3, Box 4, Box 5 and Box 6.²⁶

The most obvious change in the new guidelines is that they contain 98 recommendations across six DFD fields, whereas the previous guideline contained 25 recommendations across four

6 Summary of key wound healing recommendations

Recommendation	GRADE	
	Strength*	Quality [†]
Remove slough, necrotic tissue, and callus of an ulcer with sharp debridement, taking relative contraindications into account.	Strong	Low
Dressings should be selected principally on exudate control, comfort and cost.	Strong	Low
Do not use dressings/applications containing surface antimicrobial agents with the sole aim of accelerating the healing of an ulcer.	Strong	Low
Consider sucrose octasulfate-impregnated dressing in non-infected, neuro-ischaemic ulcers that are difficult to heal. [‡]	Weak	Moderate
Consider systemic hyperbaric oxygen therapy in non-healing ischaemic ulcers. [‡]	Weak	Moderate
We suggest not using topical oxygen therapy.	Weak	Low
Consider negative pressure wound therapy in patients with a surgical wound.	Weak	Low
We suggest not using negative pressure wound therapy in non-surgical ulcers.	Weak	Low
Consider placental-derived products in ulcers that are difficult to heal. [‡]	Weak	Low
We suggest not using growth factors, autologous platelet gels, bioengineered skin products, ozone, topical carbon dioxide, and nitric oxide.	Weak	Low
Consider autologous combined leucocyte, platelet and fibrin in non-infected ulcers that are difficult to heal, if approved in Australia. [‡]	Weak	Moderate
We suggest not using agents including electricity, magnetism, ultrasound and shockwaves.	Weak	Low
We suggest not using interventions aimed at correcting nutritional status (including supplementation of protein, vitamins, trace elements).	Weak	Low

GRADE = Grading of Recommendations, Assessment, Development and Evaluation. * The GRADE strength of recommendation rating is defined as the extent the panel is confident that the desirable effects (ie, benefits, such as improved health outcome) of an intervention/recommendation considerably outweigh the undesirable effects (ie, harms, such as adverse events) based on the available evidence. Strength is rated as strong (highly confident) or weak (less confident).^{15,23} † The GRADE quality of evidence rating is defined as the extent the panel can be certain that the true effect lies close to the effect estimates from a body of evidence supporting the recommendation and that further research is unlikely to change their confidence in the certainty. Quality is rated as high (high certainty), moderate (moderate certainty), low (low certainty), or very low (very low certainty).^{15,23} ‡ Recommendation applying specifically to people with non-healing diabetes-related foot ulcers, defined as foot ulcers reducing in size by < 50% after four to six weeks of receiving best standard of foot ulcer care,²⁶ in alignment with the applicable recommendations in these guidelines.^{16–21} Source: Table adapted with permission from Chen et al.²¹ ◆

DFD fields. The new guidelines also used the recommended GRADE methodological approach, whereas the previous used the historical NHMRC approach. Finally, these new guidelines have been endorsed by ten national peak bodies, including the Australian Diabetes Society, the Australian and New Zealand Society for Vascular Surgery, the Australasian Society for Infectious Diseases, the Australian Podiatry Association, and Wounds Australia.^{16–21,45}

Prevention

There are 15 prevention recommendations covering screening, education, self-care, footwear and treatments for people at risk of DFD (Box 1 and Box 7).¹⁶ It is recommended that people with diabetes are screened at least annually for loss of protective sensation (LOPS) and PAD to determine any increased risk of diabetes-related foot ulcers (DFU). For LOPS, this can be performed using a 10g Semmes–Weinstein monofilament or Ipswich Touch Test; and for PAD, by taking a relevant history and palpating foot pulses.^{16,18} People identified to not have LOPS or PAD can be categorised at very low risk of DFU and rescreened in 12 months. Individuals identified to have LOPS or PAD should be further examined according to the IWGDF risk stratification system for foot deformities, abundant callus, pre-ulcerative lesions, DFU history, amputation history, end-stage renal disease, and DFU (Box 7). This examination categorises if the person is at low risk (and re-examined every six to 12 months), moderate risk (re-examined every three to six months), or high risk of DFU (re-examined every one to three

months) according to the IWGDF risk stratification system.¹⁶ For people with DFU, see the Classification section.¹⁷ These categories are based on systematic reviews finding increasing combinations of these risk factors (and risk categories) correspond with increasing likelihood of developing DFU.^{42,43} We note the IWGDF system is a change to the system in the previous guideline,¹² as it includes end-stage renal disease as an additional risk factor found to predict DFU development, and four risk categories with different combinations of risk factors instead of three in the previous guideline.¹⁶ The IWGDF risk stratification system should be considered the minimum standard to document and communicate risk of DFU with other health professionals (Box 7).¹⁶

For individuals identified at risk (low, moderate or high), education is recommended on DFU risk, foot self-care (including daily inspection for foot problems), foot protection (including wearing well fitting footwear), regular foot examinations (as per above re-examination recommendations), and how to seek care if a DFU is identified. In people looking to increase activity, a gradual increase in weight-bearing activity while wearing appropriate well fitted footwear and daily inspection for foot problems is recommended. Further, treatment is recommended for any pre-ulcerative lesions, callus, ingrown toenails and fungal infections, and prescription of orthotic interventions considered to reduce abundant callus.¹⁶

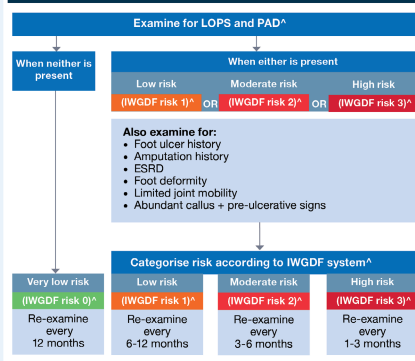
For people at moderate or high risk, prescribing medical-grade footwear and instructing patients to self-monitor foot skin temperatures daily to detect signs of pre-ulcerative lesions (when

7 Prevention pathway for a person with diabetes at risk of foot ulceration*

Prevention

Prevention pathway for a person with diabetes at-risk of foot ulceration

1. Screening



Category	Ulcer risk	Characteristics
0	Very low risk (IWGDF risk 0)	No LOPS + No PAD
1	Low risk (IWGDF risk 1)	LOPS or PAD
2	Moderate risk (IWGDF risk 2)	LOPS + PAD or LOPS + Foot deformity or PAD + Foot deformity
3	High risk (IWGDF risk 3)	LOPS or PAD and one or more of: • Foot ulcer history • Amputation history • ESRD

Adapted from Bus SA, Lavery LA, Monteiro-Sousa M, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36 Suppl 1:e3269. Pp 3.

LEGEND

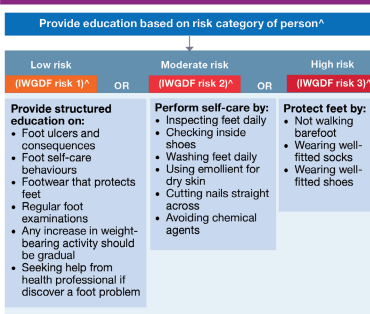
■ Prevention categories ■ Prevention recommendations ■ Not recommended for prevention ■ IWGDF risk stratification *Contingent on device approval and availability in Australia. To be used in conjunction with the other guideline pathways from the 2021 Australian Guidelines for diabetes-related foot disease. Please refer to the Australian guideline on prevention of foot ulceration for full details about this pathway.

ABBREVIATIONS

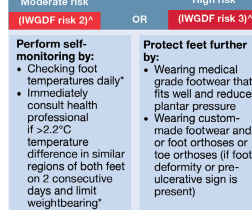
IWGDF: International Working Group on the Diabetic Foot LOPS: Loss of protective sensation PAD: Peripheral artery disease ESRD: End-stage renal disease

Development of the Diabetes & Feet Toolkit was funded through the National Diabetes Services Scheme (NDSS). The NDSS is an initiative of the Australian Government and is administered by Diabetes Australia

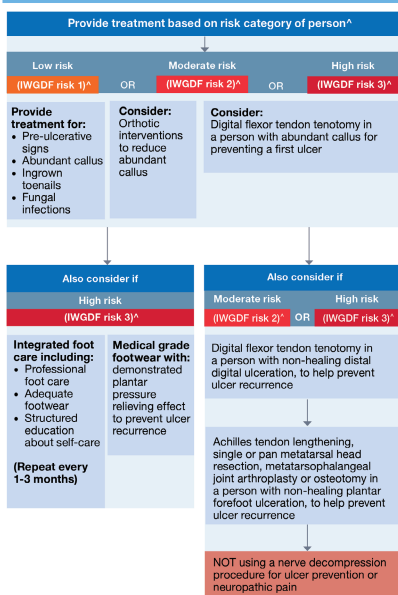
2. Education



Consider additional education for person if



3. Treatments



* Using this pathway: This figure incorporates all 15 recommendations made in the Australian guideline on prevention of foot ulceration¹⁶ into an evidence-based clinical pathway. The pathway aims to guide the health professional through screening, education and treatment according to the person's risk category for developing foot ulceration (very low, low, moderate or high risk). This pathway should be read in the following order: **1. Screening (left column):** Examine for stated risk factors for developing foot ulceration (higher boxes). Use identified risk factors to categorise the person's risk category according to the IWGDF Risk Stratification System (lower box). Use the person's risk category to determine the frequency of re-examination (middle boxes). **2. Education (middle column):** Provide stated education to all persons at-risk (low, moderate or high risk; higher boxes), plus also consider additional stated education for persons at moderate or high risk (lower boxes). **3. Treatment (right column):** Provide stated treatments to all persons at-risk (low, moderate or high risk) (higher boxes), plus also consider additional stated treatments for persons at moderate or high risk (lower boxes). Source: Figure reproduced with permission from the Diabetes and Feet Toolkit (version 1; February 2022); National Diabetes Services Scheme (NDSS), an initiative of the Australian Government and is administered by Diabetes Australia (<https://www.ndss.com.au/about-diabetes/resources/find-a-resource/diabetes-and-feet-toolkit>).⁴⁵ ♦

systems become available in Australia) are also recommended. Further, for individuals at high risk, it is strongly recommended that medical-grade footwear with demonstrated plantar pressure-relieving effects be prescribed. Otherwise, if the above recommended non-surgical treatment fails to reduce ongoing abundant callus or recurrent DFU, the use of various surgical interventions for the prevention of DFU should be considered.¹⁶

Classification

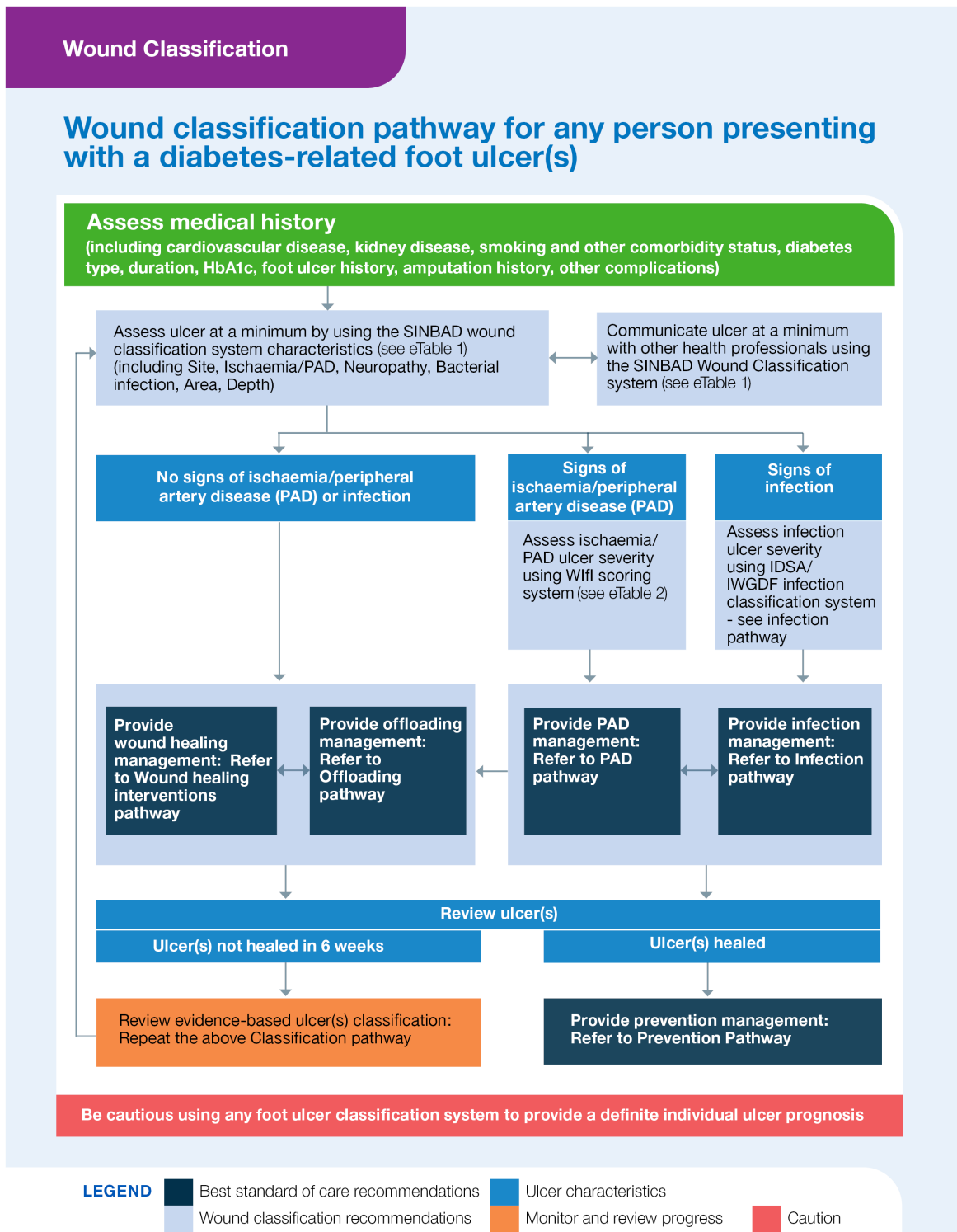
There are five classification recommendations covering ulcer, infection, ischaemia and auditing (Box 2 and Box 8).¹⁷ The Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth (SINBAD) wound classification system is strongly recommended as the minimum standard to document and communicate DFU characteristics with other health professionals (Box 8 and Supporting Information, eTable 1).¹⁷ We note that SINBAD is a change to the previous guideline that recommended the University of Texas wound classification system,¹² as SINBAD has demonstrated more effective communication between health professionals, does not require any specialised equipment, and has higher quality of evidence. Thus, there should be no barriers

to using SINBAD in the primary care context, including when referring people with DFU to interdisciplinary High Risk Foot Services. Further, it is recommended that SINBAD also be used as a minimum for any service audits to allow comparisons between institutions on DFU outcomes.¹⁷

In people with infected DFU, the Infectious Diseases Society of America (IDSA)/IWGDF infection classification system is recommended to classify severity and guide infection management (see Infection section).^{17,19} Additionally, in people with DFU who are being managed in settings with appropriate vascular expertise (such as interdisciplinary High Risk Foot Services), the Wound, Ischaemia and foot Infection (WIFI) classification system is recommended to aid decision making in the assessment of perfusion and likelihood of revascularisation benefit (see PAD section and Supporting Information, eTable 2).^{17,18}

Otherwise, we highlight that classification using the above recommended systems is critical to achieving optimal outcomes for people with DFU, and important to facilitate effective communication among health professionals, referral, triage, and guide management decisions.¹⁷ Further, we point out

8 Wound classification pathway for any person presenting with a diabetes-related foot ulcer*



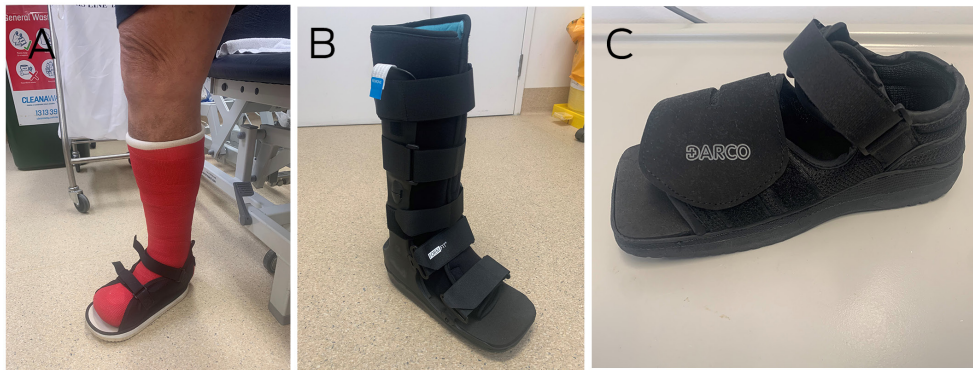
LEGEND ■ Best standard of care recommendations ■ Ulcer characteristics
 ■ Wound classification recommendations ■ Monitor and review progress ■ Caution

NOTE To be used in conjunction with the other guideline pathways from the 2021 Australian Guidelines for diabetes-related foot disease. Please refer to the Australian guideline on wound classification of diabetes-related foot ulcers for full details about this pathway.

Development of the Diabetes & Feet Toolkit was funded through the National Diabetes Services Scheme (NDSS). The NDSS is an initiative of the Australian Government and is administered by Diabetes Australia

IDSA = Infectious Diseases Society of America; IWGDF = International Working Group on the Diabetic Foot.* Using this pathway: This figure incorporates all five recommendations made in the Australian guideline on wound classification of diabetes-related foot ulcers into an evidence-based clinical pathway.¹⁶ The pathway aims to guide the health professional through assessing and classifying a person presenting with a diabetes-related foot ulcer, and also refers to the management pathways needed. This pathway should be read in the following order: **1. Assessing medical history (first row):** Obtain stated medical history factors relevant for a person with a diabetes-related foot ulcer. **2. Classifying ulcer (second row):** Examine for stated ulcer characteristics that are required at a minimum to classify the person's ulcer according to the SINBAD classification system (left box). Use identified characteristics to communicate ulcer status with other health professionals (right box). Further examine people with signs of peripheral artery disease or infection according to the Wound, Ischaemia, and foot Infection (WIFI) or IDSA/IWGDF classification systems respectively (third row). **3. Providing management (fourth row):** Provide all persons with diabetes-related foot ulcers management according to the wound healing intervention and offloading management pathways (left boxes), plus, also provide people with signs of PAD or infection management according to the PAD and infection management pathways respectively (right boxes). Source: Figure reproduced with permission from the Diabetes and Feet Toolkit (version 1; February 2022); National Diabetes Services Scheme (NDSS), an initiative of the Australian Government and is administered by Diabetes Australia (<https://www.ndss.com.au/about-diabetes/resources/find-a-resource/diabetes-and-feet-toolkit/>).⁴⁵ ♦

9 Offloading devices: (A) non-removable knee-high device, (B) removable knee-high device, and (C) removable ankle-high device



that appropriate DFU classification is central to the below PAD, infection, offloading and wound healing management recommendations.¹⁸⁻²¹

Peripheral artery disease

There are 17 PAD recommendations covering diagnosis, severity classification, medical and surgical treatments for people with DFU (Box 3 and Supporting Information, eFigure 1).¹⁸ We note all are new, as no PAD recommendations were made in the previous guideline.¹² In brief, it is recommended that all people with diabetes and DFU undergo at minimum a clinical examination for PAD, including relevant history and palpation of foot pulses.¹⁸ As clinical examination does not reliably exclude PAD, it is also strongly recommended that further non-invasive bedside testing is performed, including pedal Doppler arterial waveforms, ankle systolic pressure, ankle brachial index (ABI) and/or toe systolic pressure. Vascular imaging and referral for possible revascularisation should always be considered for patients with a DFU and an ankle pressure below 50 mmHg, ABI below 0.5, or toe pressure below 30 mmHg. People with less severe ischaemia may also require revascularisation. Otherwise, it is strongly recommended that all centres treating DFU should have expertise in and/or rapid access to facilities necessary to diagnose and treat PAD.¹⁸

Infection

There are 35 infection recommendations covering diagnosis, severity classification, and medical and surgical treatments for people with DFU (Box 4 and Supporting Information, eFigures 2A and 2B).¹⁹ Again, we note all are new, as no infection recommendations were made in the previous guideline.¹² In brief, it is recommended that foot infection is diagnosed clinically based on the presence of at least two signs and symptoms of local inflammation, including swelling/induration, erythema, tenderness/pain, warmth, or purulent discharge. If infection is diagnosed, it is strongly recommended that the IDSA/IWGDF classification system is used to classify severity as mild (involves only skin or subcutaneous tissue without erythema that extends >2 cm around the DFU), moderate (involves deeper tissues and/or erythema that extends >2 cm around the DFU) or severe (involves systemic manifestations of systemic inflammatory response syndrome). If osteomyelitis is suspected, a combination of the probe-to-bone test, erythrocyte sedimentation rate (or C-reactive protein and/or procalcitonin) and plain x-rays are recommended as the initial diagnostic studies. If the diagnosis

remains in doubt, it is then recommended that advanced imaging studies be considered, such as magnetic resonance imaging scans. Diagnosis of foot infection severity informs the specific infection management recommendations (Box 4 and Supporting Information, eFigures 2A and 2B).¹⁹

Offloading

There are 13 recommendations covering offloading for different situations in people with DFU (Box 5, Box 9 and Supporting Information, eFigure 3).²⁰ Offloading is defined as the relief of mechanical stress (pressure) from a specific area of the foot.^{20,31} We note nearly all recommendations are new, as only two offloading recommendations were made in the previous guideline.¹² We also highlight that offloading management now has the strongest evidence to effectively heal DFU and should always be considered.^{15,46} In brief, for people with plantar DFU, it is strongly recommended that non-removable knee-high offloading devices (total contact cast or non-removable knee-high walker) should be provided as first line treatment unless contraindicated or not tolerated. If contraindicated (such as moderate infection) or not tolerated by the patient (such as unable to use for employment), then consider removable knee-high offloading devices as second line treatment, removable ankle-high offloading devices as third line, and medical-grade footwear as last line. Otherwise, felted foam (or other pressure offloading insole) in combination with the chosen offloading device can be considered to further reduce plantar pressure. For people with non-plantar DFU, depending on the DFU type and location, removable offloading devices, felted foam, toe spacers, or medical-grade footwear are recommended. If non-surgical offloading fails to heal a person with plantar DFU, various surgical offloading procedures should be considered, including Achilles tendon lengthening, gastrocnemius resections, metatarsal head resections, joint arthroplasty, or digital flexor tenotomies.^{20,38}

Wound healing

There are 13 wound healing recommendations covering debridement, wound dressing selection, and other wound treatments in people with DFU (Box 6 and Supporting Information, eFigure 4).²¹ We note half of these recommendations are new compared with the previous guideline.¹² The similar recommendations include:

- regular sharp debridement if not contraindicated;
- using wound dressings initially based on controlling exudate, comfort and cost;
- considering systemic hyperbaric oxygen therapy for ischaemic DFU; and
- considering negative pressure wound therapy for post-surgical DFU.

The new recommendations for non-healing DFU include considering the use of sucrose octasulfate-impregnated dressings, placental-derived products, or autologous combined

leucocyte, platelet and fibrin dressings.²¹ However, we note these products have only been recently approved in Australia.²¹

Conclusion

For the first time in a decade, we have developed new Australian evidence-based guidelines for DFD. These new guidelines have been endorsed by ten national peak bodies and we encourage all Australian medical professionals caring for people at risk of, or with DFD, to implement the recommendations contained in these new guidelines to help reduce the large patient and national burden of DFD in Australia.

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Supporting Information

Additional Supporting Information is included with the online version of this article.