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National Diabetes Services Scheme

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Diabetes and feet

A practical toolkit for health professionals using the Australian diabetes-related foot disease guidelines.

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The 2021 Australian guidelines for diabetes-related foot disease were developed by Diabetes Feet Australia and the Australian Diabetes Society. An expert multi-disciplinary guideline working group was appointed, followed by the development of six multi-disciplinary national panels to enact the plan to develop the six guidelines.

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Introduction

Diabetes-related foot disease (DFD) is a leading cause of morbidity, mortality and healthcare cost burdens in Australia. DFD is defined as foot ulceration, infection, or tissue destruction in people with diabetes, accompanied by the risk factors of peripheral neuropathy (PN) and/or peripheral artery disease (PAD).

Each year DFD affects approximately 50,000 Australians, with a further 300,000 having risk factors for developing DFD. As a leading cause of hospitalisation, disability and cost burdens in Australia, DFD has been labelled Australia's least known major health problem. However, studies show these burdens can be considerably reduced when using guideline-recommended DFD care.

The most recent Australian DFD guideline was published in 2011 and a considerable amount of new research has been published since. In 2020, an expert multi-disciplinary guideline working group was appointed by Diabetes Feet Australia to develop a best practice plan to adapt the 2019 International Working Group on the Diabetic Foot (IWGDF) international guidelines into the Australian context to become the new Australian DFD guidelines. These new 2021 Australian evidence-based DFD guidelines considerably update the 2011 guidelines and when used should further help reduce the national DFD burden.

How were the guidelines developed?

Following the appointment of the expert multi-disciplinary guideline working group, the group invited multi-disciplinary national panels to enact the plan to develop a new guideline in six fields:

- **prevention**
- **wound classification**
- **peripheral artery disease**
- **infection**
- **offloading**
- **wound healing interventions**

The methodology to develop these new guidelines involved systematically identifying and adapting suitable international source guidelines based on NHMRC-recommended ADAPTE and GRADE-ADOLPMENT processes.

Each panel systematically screened, assessed and judged all IWGDF recommendations in the Australian context from their sub-field using ADAPTE and GRADE frameworks. For each recommendation, the panel re-evaluated the wording, quality of evidence and strength of recommendation, and provided rationale, justifications and implementation considerations in Australia (including for geographically remote and Aboriginal and Torres Strait Islander Peoples).

Each panel also consulted with our consumer and Aboriginal and Torres Strait Islander Peoples representatives when drafting the recommendations and considerations. In 2021, the six new DFD guidelines underwent public consultation, revision and approval by multiple peak national bodies before being launched as the new 2021 Australian evidence-based guidelines for the prevention and management of diabetes-related foot disease.

In this toolkit, we explain what's in the new guidelines, what's new, tips on how to use the guidelines in daily practice and provide practical pathways to make guideline-recommended DFD care easier to use.

For further information about how the guidelines were developed and to access each full guideline, please visit diabetesfeetaustralia.org/new-guidelines/

Who should use the guidelines?

The new guidelines and this toolkit is designed for health professionals and disciplines caring for Australians with diabetes-related foot disease and diabetes-related foot ulcers in secondary and tertiary health care settings in Australia.

What's in the new guidelines?

In total, the guidelines make 98 evidence-based recommendations for Australian situations that address 51 common clinical questions across six DFD fields.

For each recommendation, we provide the reasons for the recommendation, how certain we are of the supporting evidence (very low, low, moderate or high).

We suggest how strongly to use the recommendation (weak or strong) and how to implement the recommendation in Australia, including for geographically remote and Aboriginal and Torres Strait Islander Peoples.

Guideline	
Prevention	Screening, risk classification, education, self-care, self-monitoring, footwear and treatments to prevent DFD.
Wound classification	Systems to use to classify ulcers, infection, ischaemia, and auditing.
Peripheral artery disease	Examinations and imaging for PAD diagnosis, severity classification, and medical and surgical treatments.
Infection	Examinations, cultures, imaging and inflammatory markers for infection diagnosis, severity classification, and medical and surgical treatments.
Offloading	Pressure offloading treatments to use for different ulcers, infection, ischaemia, and other hard-to-heal ulcers.
Wound healing interventions	Debridement, initial wound dressing selection principles and wound treatments for hard-to-heal ulcers.

The new 2021 Australian guidelines for diabetes-related foot disease contains 6 guidelines that includes 98 evidence-based recommendations for Australian situations that address 51 common clinical questions.

What's changed from the previous guidelines?

The 2011 guideline made 25 recommendations covering 4 fields in one 50-page guideline. Whereas the new 2021 guideline makes 98 recommendations covering 6 fields in 6 guidelines over 300 pages. The 2021 guidelines also contain practical pathways to help use the recommendations in daily practice.

Guideline	New or changed recommendations
Prevention	In risk classification, self-monitoring, footwear prescription, surgical treatments and weight-bearing activity advice.
Wound classification	In all classification systems to now use.
Peripheral artery disease	For all areas as the 2011 guideline did not cover PAD.
Infection	For all areas as the 2011 guideline did not cover infection.
Offloading	For offloading treatments to use when non-removable knee-high offloading devices are contraindicated or not tolerated.
Wound healing interventions	In wound treatments to use for hard-to-heal ulcers.

How to use the new guidelines and pathways?

We have designed the toolkit to help busy multi-disciplinary health professionals use guideline-recommended DFD care at any time and place and with the person with DFU right there in front of them.

The pathways should assist health professionals to decide on the recommended evidence-based assessment, diagnosis, management and follow-up care needed for people living with DFD and DFU.

When more detailed information on a clinical question or a recommendation is required, we suggest you then refer to the full guidelines at diabetesfeetaustralia.org/new-guidelines/

You can do this by quickly browsing the contents of each guideline, identifying the question you are most interested in and then read the recommendations made, the reasons why those recommendations were made and considerations on how to implement the recommendation in practice.

The 2021 guidelines also contain practical pathways to help use the recommendations in daily practice.

The toolkit includes:

- **an overview of each guideline**
- **recommendations for each guideline**
- **implementation and monitoring considerations**
- **considerations for the Australian context**
- **practical pathways for each guideline to help optimise the implementation of the recommendations.**



Prevention

Australian guideline on prevention of foot ulceration.

In Australia, it is estimated that 50,000 people are living with diabetes-related foot ulcers (DFU), while 300,000 people are considered at-risk of DFU. Aboriginal and Torres Strait Islander Peoples have disproportionately high rates of foot-related complications, with a 3 to 6-fold increased likelihood of developing DFU and requiring amputation.

The lifetime incidence of DFU is between 19% to 34%, with an annual incidence of around 2%. DFU recurrence is also very common, with 40% of people re-ulcerating within one year, and 65% within three years.

Interventions aimed at the prevention of DFU have been found to have contrasting benefits and risks, varying levels of evidence to support their benefits and risks, and global differences in their feasibility and clinical uptake.

To interpret these benefits and risks, the quality of the supporting evidence, and the acceptability and feasibility of these interventions, evidence-based prevention guidelines have been developed to guide optimal care for people at-risk of DFU.

These prevention interventions more specifically relate to:

- examining and inspecting the feet
- structured education pertaining to foot self-care and management principles
- early treatment of pre-ulcerative signs or injuries
- surgical interventions (particularly to prevent ulcer recurrence)
- and the provision of integrated foot care.

This toolkit provides a practical and condensed overview of the Australian prevention guideline designed to assist health professionals in the implementation of these recommendations in daily practice.

Prevention recommendations

1	Examine a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of loss of protective sensation and peripheral artery disease, to determine if they are at increased risk for foot ulceration. (GRADE recommendation: Strong; Quality of evidence: Low)
2	Screen a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) for: a history of foot ulceration or lower-extremity amputation; diagnosis of end-stage renal disease; presence or progression of foot deformity; limited joint mobility; abundant callus; and any pre-ulcerative sign on the foot. Repeat this screening once every 6-12 months for those classified as IWGDF risk 1, once every 3-6 months for IWGDF risk 2, and once every 1-3 months for IWGDF risk 3. (Strong; Low)
3	Instruct a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors. (Strong; Low)
4	Instruct, and after that encourage and remind, a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to: inspect daily the entire surface of both feet and the inside of the shoes that will be worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toe nails straight across; and, avoid using chemical agents or plasters or any other technique to remove callus or corns. (Strong; Low)
5	Provide structured education to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer. (Strong; Low)
6	Consider instructing a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. The implementation of this recommendation is contingent on validated, user-friendly and affordable systems becoming approved and available in Australia. If the temperature difference is above-threshold between similar regions in the two feet on two consecutive days, instruct the patient to reduce ambulatory activity and consult an adequately trained health care professional for further diagnosis and treatment. (Weak; Moderate)
7	Instruct a person with diabetes who is at moderate risk for foot ulceration (IWGDF risk 2) or who has healed from a non-plantar foot ulcer (IWGDF risk 3) to wear medical grade footwear that accommodates the shape of the feet and that fits properly, to reduce plantar pressure and help prevent a foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing custom-made footwear, custom-made foot orthoses, or toe orthoses. (Strong; Low)
8	Consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration (IWGDF risk 1-3). (Weak; Low)

- | | |
|----|--|
| 9 | In a person with diabetes who has a healed plantar foot ulcer (IWGDF risk 3), prescribe medical grade footwear that has a demonstrated plantar pressure relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the patient to consistently wear this footwear. (Strong; Moderate) |
| 10 | Treat any pre-ulcerative sign or abundant callus on the foot, ingrown toenail, and fungal infection on the foot, to help prevent a foot ulcer in a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3). (Strong; Low) |
| 11 | In a person with diabetes and abundant callus consider digital flexor tendon tenotomy for preventing a first foot ulcer. Where there is an ulcer on the apex or distal part of a non-rigid hammertoe that has failed to heal with evidence-based non-surgical treatment, consider this procedure to help prevent future ulcer recurrence. (Weak; Low) |
| 12 | In a person with diabetes and a plantar forefoot ulcer that has failed to heal with evidence-based non-surgical treatment, consider Achilles tendon lengthening, single or pan metatarsal head resection, metatarsophalangeal joint arthroplasty or osteotomy, to help prevent future ulcer recurrence. (Weak; Low) |
| 13 | We suggest not to use a nerve decompression procedure, in preference to accepted standards of good quality care, to help prevent a foot ulcer in a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) and who is experiencing neuropathic pain. (Weak; Low) |
| 14 | Consider communicating to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) that any increase in weight-bearing activity should be gradual, ensuring appropriate footwear and/or prescribed offloading device(s) are worn, and that the skin is frequently monitored for pre-ulcerative signs or injury. (Weak; Low) |
| 15 | Provide integrated foot care for a person with diabetes who is at high risk of foot ulceration (IWGDF risk 3) to help prevent a recurrent foot ulcer. This integrated foot care includes professional foot care, adequate footwear, and structured education about self-care. Repeat this foot care or re-evaluate the need for it once every one to three months, as necessary. (Strong; Low) |

Using the Australian prevention guideline and pathway

By health professionals following these recommendations and pathway, it should:

- Encourage evidence-based consistency of care among health services and health professionals, which may in turn improve clinical pathways of care and reduce any confusion for health professionals and their patients at risk of DFU.
- Help guide and give confidence to clinicians providing evidence-based DFU prevention strategies.
- As the guideline has been designed to be evidence-based, yet pragmatic, it is likely that these best practice recommendations can be implemented by all health professionals involved in DFU prevention in Australia, providing that they are adequately trained.
- Promote better prevention and overall outcomes for people living with DFU in Australia.

The guideline also includes specific considerations for Australian health professionals to help optimise implementation (including in special subgroups) of these prevention recommendations in clinical practice.

All 15 recommendations have been developed into a practical prevention pathway (over page) to optimise the implementation of recommendations by the multiple health professionals and disciplines caring for Australians with DFU in secondary and tertiary health care settings in Australia.

The recommendations are displayed in order according to their prevention category:

- A** Identifying the at-risk foot.
- B** Regularly inspecting and examining the at-risk foot.
- C** Instructions on foot self-care.
- D** Providing structured education about foot self-care.
- E** Instructions about foot self-management.
- F** Ensuring routine wearing of appropriate footwear.
- G** Treatment of risk factors or pre-ulcerative signs on the foot.
- H** Surgical interventions.
- I** Foot-related exercises and weight-bearing activity
Integrated foot care.
- J** Integrated foot care.

All fifteen recommendations are included in the prevention pathway that focuses on:



Screening



Education



Treatment

For the prevention of DFU we recommend:

Screening all people with diabetes at increased risk of foot ulceration at intervals corresponding to the IWGDF risk ratings.

Providing structured education about foot protection, inspection, footwear, weight-bearing activities, and foot self-care.

Self-monitoring of foot skin temperatures (contingent on validated user-friendly and affordable systems becoming approved and available in Australia).

Prescription of orthotic interventions and/or medical grade footwear.

Providing integrated foot care.

If the above recommended non-surgical treatments fails, we recommend considering the use of various surgical interventions for the prevention of DFU.



Key risk factors contributing to the development of DFU include peripheral neuropathy, peripheral arterial disease, and foot deformity. Empirical evidence has shown that history of foot ulceration, amputation and/or end-stage renal disease (ESRD) further increases the risk.

For those without risk factors for DFU, the incidence of ulceration is very low, so prevention strategies should be targeted more specifically to people considered at increased risk ('at-risk') for DFU.

To learn more about each individual prevention recommendation refer to the Australian guideline on the prevention of foot ulceration.

Prevention considerations for the Australian context

Health services and clinicians should continue to strive for effective, equitable and culturally appropriate clinical environments to all Australians with diabetes at risk of foot ulceration. This is particularly important for those groups needing better service such as Aboriginal and Torres Strait Islander Peoples and those living in rural and remote regions of Australia.

Providing culturally responsive health care through the provision of a safe and welcoming clinical environment that is professional, humble, inclusive, transparent, respectful, empathetic, non-judgemental, and that gives a 'voice' which encourages client choice and informed consent, may result in improved health outcomes in the Aboriginal and Torres Strait Islander Peoples population.

Awareness and preparation

Prior to the implementation of these guidelines, it is important for health professionals to understand and reflect on the health disparities that still exist between geographically remote and metropolitan populations and importantly Aboriginal and Torres Strait Islander Peoples and non-Indigenous Australians.

Health professionals should determine the best approach to provide culturally sensitive education and treatment, and how best to meet the needs of people living with diabetes and DFU.

Developing partnerships and engaging with local Aboriginal and Torres Strait Islander health care workers, Liaison Officers and/or community members, such as family and Elders, may assist in promoting these recommendations by determining the best approach for providing education and to ensure it is culturally sensitive. This may optimise understanding and in turn outcomes for people living with diabetes and DFU.

Providing education about foot self-care

Structured education on foot self-care practices is an essential component of foot ulcer prevention in an at-risk person with diabetes. Those living in geographically remote locations, where Aboriginal

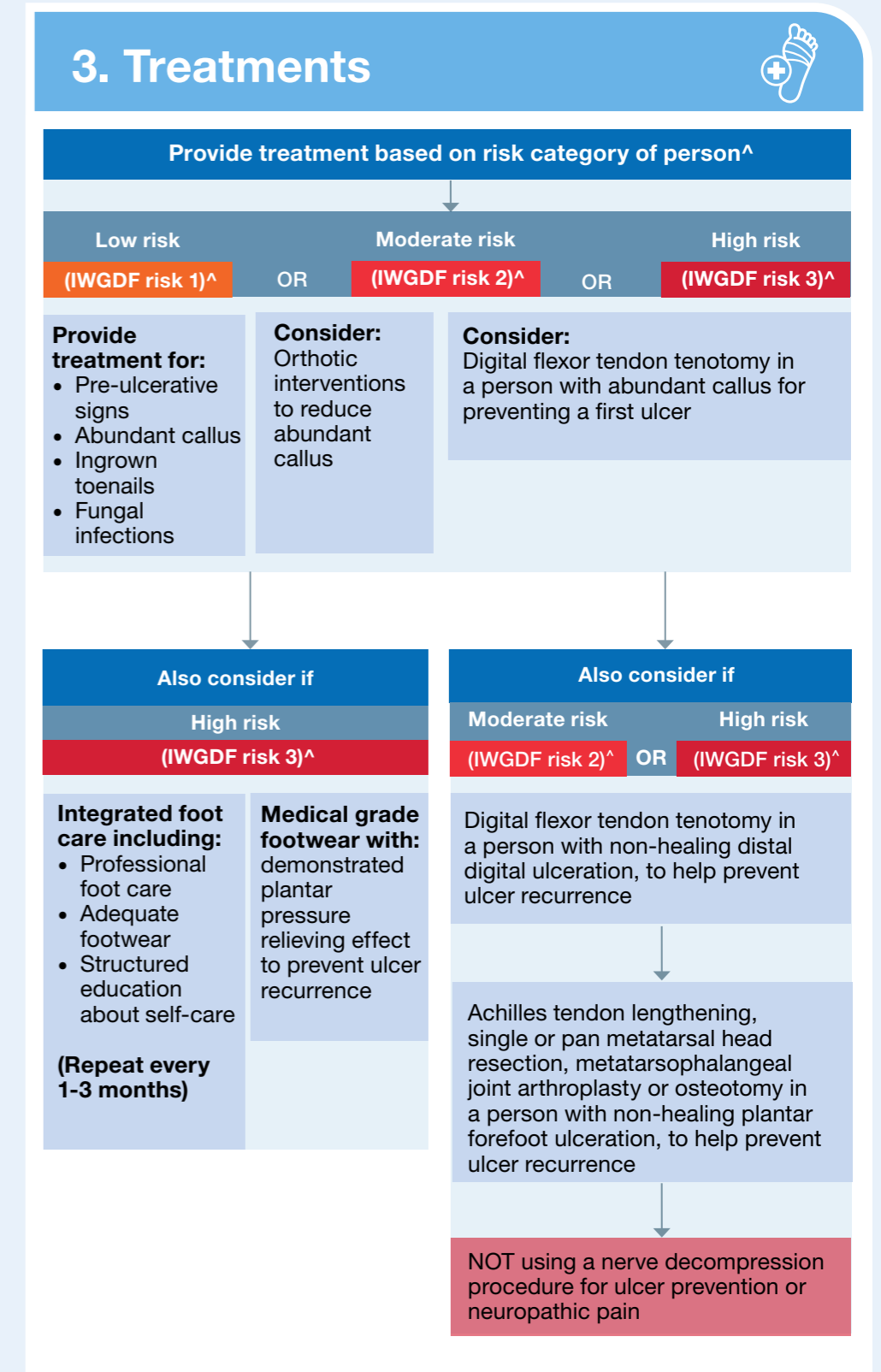
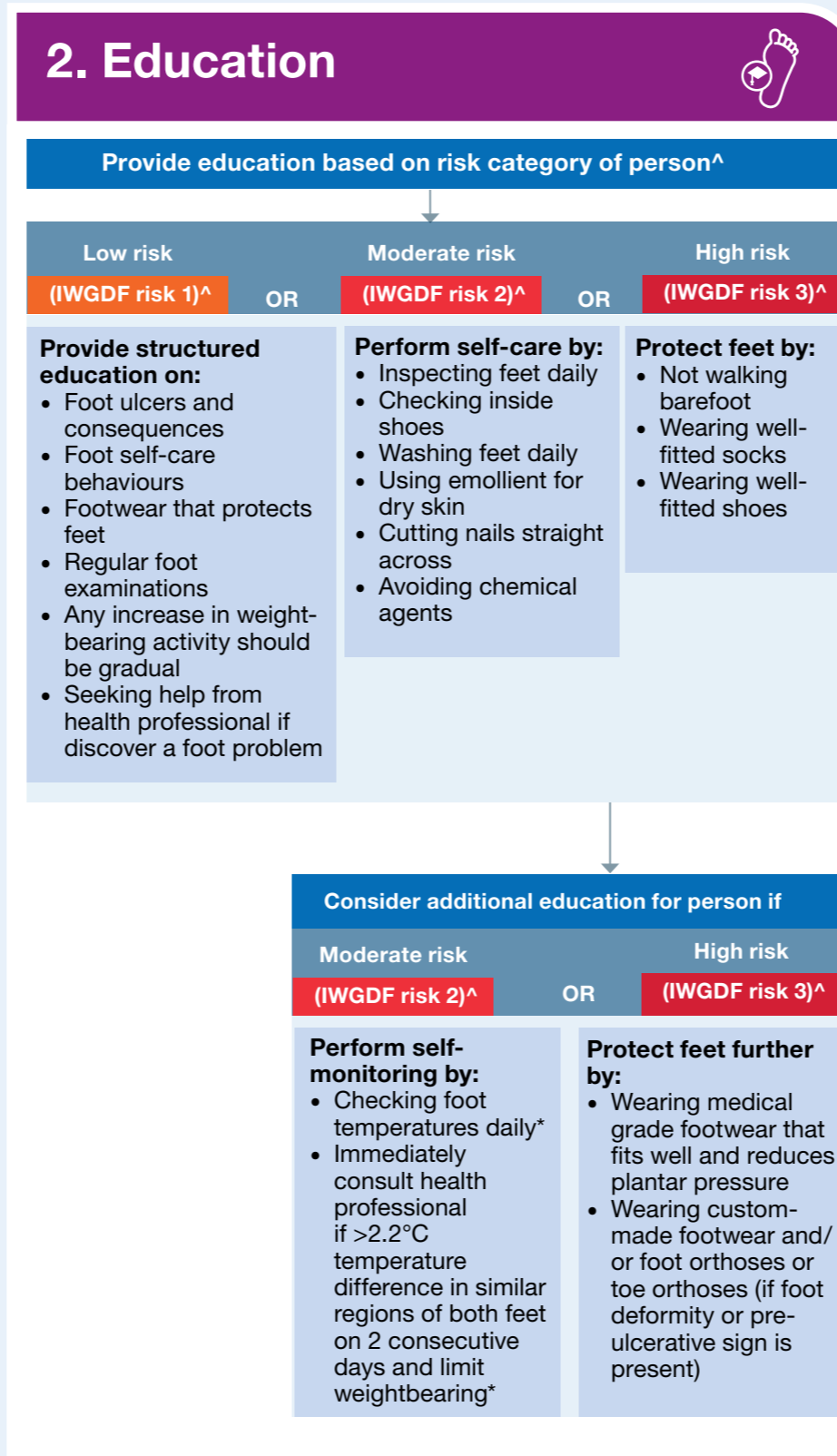
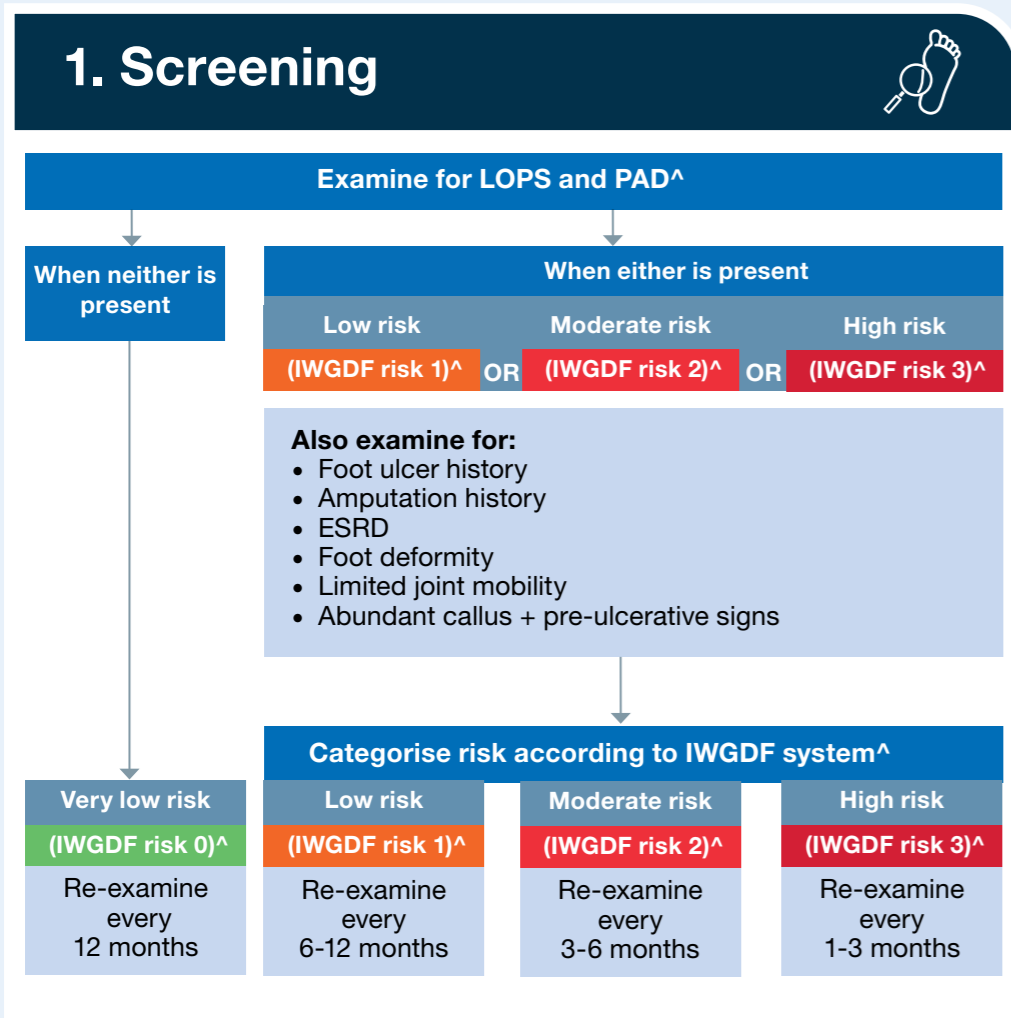
and Torres Strait Islander Peoples account for a higher proportion of this population, may have limited availability of health services and adequately trained health professionals to provide such education. Likewise, these individuals may also have infrequent access or limited ability to attend for medical care to receive this foot care education; all of which may act as potential barriers for implementing these recommendations.

Structured education should also account for gender differences and align with health literacy, preferences and values, and personal circumstances of the person living with DFU. Structured education (a component of integrated foot care) should be performed in collaboration with local Aboriginal and Torres Strait Islander health care workers and/or with input from family and Elders to optimise understanding and individual outcomes.

To learn more about each individual prevention recommendation and how they can be implemented in the Australian context, please refer to the Australian guideline on the prevention of foot ulceration.

- **Performing foot self-care practices is particularly important for those living in rural or remote areas of Australia with hot climates; as this may precipitate perspiration and increased risk of blistering and/ or ulceration.**
- **For dry and dusty environments, people may need to wash their feet more regularly and check for any abrasions, sunburn, or injuries from foreign objects, particularly if people are wearing open type footwear or walking barefoot.**
- **Health professionals are encouraged to have discussions regarding whether there is regular sharing of shoes and socks within the community. We suggest that this should be avoided as to reduce spreading of infections (e.g. fungal infections), and to reduce risk of trauma to the feet related to poor shoe fit or excessively worn footwear.**

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



IWGDF Risk Stratification System[^]

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: <ul style="list-style-type: none"> Foot ulcer history Amputation history ESRD

Adapted from: Bus SA, Lavery LA, Monteiro-Soares 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

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 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



Wound classification

Australian guideline on wound classification of diabetes-related foot ulcers.

Effective assessment, documentation and communication of clinical information and audit of patient outcomes is central to achieving optimal outcomes for people living with diabetes-related foot disease.

Wound classification systems are useful tools to characterise diabetes-related foot ulcers that:

- support clinical assessment
- aid effective communication between health professionals
- assist with timely triage of referrals to specialist services such as interdisciplinary high-risk foot service (iHRFS)
- guide clinical decision making and prognosis in certain settings
- support clinical audit and benchmarking.

This toolkit provides a practical and condensed overview of the Australian wound classification guideline designed to assist health professionals use the recommendations in daily practice.

All recommendations have also been developed into a practical wound classification pathway (over page) to optimise the implementation of recommendations by the multiple health professionals and disciplines caring for Australians with DFU in secondary and tertiary health care settings in Australia.

To learn more about each individual recommendation, please refer to the Australian guideline on wound classification of diabetes-related foot ulcers.

Wound classification recommendations

1	In a person with diabetes and a foot ulcer, as a minimum, use the SINBAD wound classification system for communication among health professionals about the characteristics of the ulcer. (strength of recommendation: strong; quality of evidence: moderate)
2	Be cautious in the application of any of the currently available classification/scoring systems to offer an individual prognosis for a person with diabetes and a foot ulcer. (weak; low)
3	In a person with diabetes and an infected foot ulcer, use the IDSA/IWGDF infection classification to characterise and guide infection management. (weak; moderate)
4	In a person with diabetes and a foot ulcer who is being managed in a setting where appropriate expertise in vascular intervention is available, use WIfI scoring to aid decision making in the assessment of perfusion and likelihood of benefit from revascularisation. (weak; moderate)
5	As a minimum, use the SINBAD system for any regional/national/international audits to allow comparisons between institutions on the outcomes of patients with diabetes and an ulcer of the foot.(strong; high)

Implementing the Wound classification guideline

In Australia, we recommend the use of the SINBAD system as a minimum standard to document the characteristics of a DFU for the purposes of communication among health professionals and for regional/ national/ international audit.

It is important the individual components of SINBAD (rather than the total score) are used for the purposes of communication between health professionals. Refer to the wound classification pathway (over page) for further information.

Key factors that may predict DFU:

- Patient factors (end-stage renal disease)
- Limb factors (presence of peripheral arterial disease, loss of protective sensation)
- Ulcer factors (area, depth, location, number of ulcers and presence of infection)

Wound classification considerations for the Australian context

Each year, Australia experiences close to 28,000 hospitalisations, 4,500 amputations, 1,700 deaths, and \$AU1.6 billion in health care expenditure for the treatment of diabetes-related foot disease (DFD). Aboriginal and Torres Strait Islander Australians have a 38-fold elevated risk of developing DFD, including diabetes-related peripheral neuropathy, DFU and amputations.

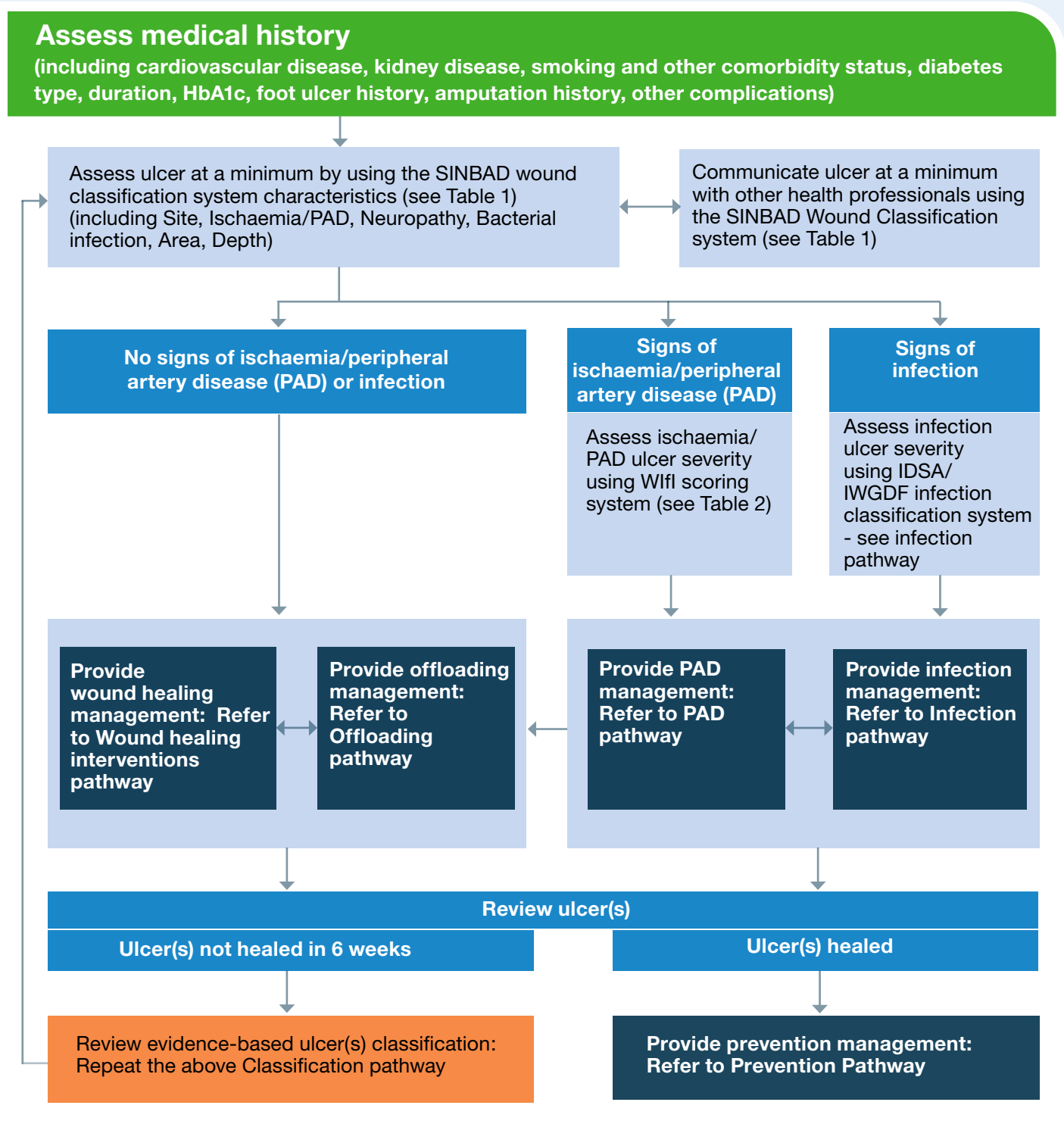
Foot health complications in Aboriginal and Torres Strait islander communities is historic and this impacts on social and emotional well-being. People living in rural and remote locations also experience poorer DFD outcomes, with up to 10-fold differences in amputation rates between people with diabetes living in rural areas compared to urban settings.

The SINBAD system is simple, reliable and requires no specialised equipment. As a minimum standard, the SINBAD wound classification system would be acceptable and readily implemented in diverse health care settings in an Australian context, including in health settings where Aboriginal and Torres Strait Islander populations are managed and rural and regional health services.

- People in geographically remote sites are at increased risk of ulcer non-healing by conservative measures and the greater likelihood of the need for LEA compared with those in urban areas.
- When assessment is being made, and if revascularisation is being considered, there must be adequate consultation with the person and engagement with family explaining why the assessment is being conducted and if hospitalisation is needed provide the approximate length of stay required.
- There must also be consideration of language barriers with consultation, especially where English may be a second, third or fourth language, in these situations a professional interpreter should be considered.

A diabetes-related foot ulcer (DFU) is a break in the skin of the foot in a person with diabetes which does not promptly heal. DFUs may vary in regard to precipitant, characteristics such as location, size and depth and there are a number of different factors which may influence DFU outcomes, such as healing time and risk of lower extremity amputation (LEA).

Wound classification pathway for any person presenting with a diabetes-related foot ulcer(s)



Be cautious using any foot ulcer classification system to provide a definite individual ulcer prognosis

- 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.

Table 1: SINBAD System

Category	Definition	Score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischaemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area	Ulcer <1 cm ²	0
	Ulcer ≥1 cm ²	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total possible score		6

Adapted from Ince P et al. Use of the SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. *Diabetes Care*. 2008;31(5):964-7.

Table 2: Wound, ischaemia and foot infection system

Wound

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
	Clinical description: ischaemic rest pain (requires typical symptoms + ischaemia grade 3); no wound	
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage	
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
	Clinical description: major tissue loss salvageable with multiple (≥ 3 digital amputations or standard TMA \pm skin coverage	
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer \pm calcaneal involvement	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis \pm calcaneal involvement
	Clinical description: extensive tissue loss salvageable only with complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management for large soft tissue defect	

Ischaemia

Grade	Ankle-brachial index	Ankle Systolic Pressure (mmHg)	Toe pressure, transcutaneous oxygen pressure (mmHg)
0	≥ 0.80	>100 mmHg	≥ 60 mmHg
1	0.60 - 0.79	70 - 100 mmHg	40 - 59 mmHg
2	0.4 - 0.59	50 - 70 mmHg	30 - 39 mmHg
3	≤ 0.39	< 50 mmHg	< 30 mmHg

Foot infection

Grade	Clinical manifestation of infection	IDSA/PEDIS infection severity
0	No symptoms or signs of infection	Uninfected
1	Infection present, as defined by the presence of at least two of the following items: <ul style="list-style-type: none"> Local swelling or induration Erythema > 0.5 to ≤ 2 cm around the ulcer Local tenderness or pain Local warmth Purulent discharge (thick, opaque to white, or sanguineous secretion) 	Mild
	Local infection involving only the skin and the subcutaneous tissue (without systemic signs).	
	Exclude other causes of an inflammatory response of the skin (e.g. trauma, gout, acute Charcot Neuro-osteoarthropathy, fracture, thrombosis, venous stasis)	
2	Local infection (as described above) with erythema > 2 cm, or involving structures deeper than skin and subcutaneous tissues (e.g. abscess, osteomyelitis, septic arthritis, fasciitis)	Moderate
	No systemic inflammatory response signs (as described below)	
3	Local infection (as described above) with the signs of SIRS as manifested by two or more of the following: <ul style="list-style-type: none"> Temperature $> 38^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$ Heart rate > 90 beats/min Respiratory rate > 20 breaths/min or $\text{PaCO}_2 < 32$mmHg White blood cell count $> 12,000$ or < 4000cu/mm or 10% immature (band) forms 	Severe ^a

PACO₂: Partial pressure of arterial carbon dioxide, SIRS: systemic inflammatory response syndrome

^aIschaemia may complicate and increase the severity of any infection. Systemic infection may sometimes manifest with other clinical findings, such as hypotension, confusion, vomiting, or evidence of metabolic disturbances, such as acidosis, severe hyperglycaemia, new-onset azotaemia.

Adapted from Mills, J.L et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischaemia and foot Infection (WIFI). Journal of Vascular Surgery, Jan 2014 and Lew, EJ et al. Clinical Application of the Society for Vascular Surgery (SVS) Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischaemia and foot Infection (WIFI). Wound practice and research, Nov 2014





Peripheral artery disease

Australian guideline on diagnosis and management of peripheral artery disease.

Peripheral artery disease (PAD) is estimated to affect up to 15% of Australian adults. Diabetes is associated with a four-fold increase in incidence of PAD, independent of other risk factors.

PAD is estimated to be present in up to 50% of diabetes-related foot ulcers (DFU) and to be an independent risk factor in their development. PAD also contributes to delayed wound healing and increased risk of amputation, particularly when infection is present.

This new Australian guideline, adapted from the IWGDF 2019 Guideline on the diagnosis, prognosis and management of PAD in patients with foot ulcers in diabetes, provides a current and comprehensive synthesis of the literature. It has been modified to suit the Australian context, and in consideration of specific subgroups including

those in geographically remote areas and Aboriginal and Torres Strait Islander Peoples.

This toolkit provides a practical and condensed overview of the Australian PAD guideline designed to assist practitioners in primary, secondary and tertiary settings with the implementation of best practice management for people with diabetes, PAD and DFU.

To learn more about each individual recommendation, please refer to the Australian guideline on diagnosis and management of peripheral artery disease.

The recommendations include the following categories:



Diagnosis



Prognosis



Treatment

Peripheral artery disease recommendations

1	Examine the feet of all patients with diabetes annually for the presence of peripheral artery disease (PAD) even in the absence of foot ulceration. At a minimum, this should include taking a relevant history and palpating foot pulses. (Strength of the recommendation: strong; quality of the evidence: low)
2	Clinically examine (by relevant history and palpation of foot pulses) all patients with diabetes and foot ulceration for the presence of PAD. (Strong; low)
3	As clinical examination does not reliably exclude PAD in most persons with diabetes and a foot ulcer, evaluate pedal Doppler arterial waveforms in combination with ankle systolic pressure and systolic ankle brachial index (ABI) or toe systolic pressure and toe brachial index (TBI) measurement. No single modality has been shown to be optimal, and there is no definite threshold value above which PAD can reliably be excluded. However, PAD is a less likely diagnosis in the presence of ABI, 0.9-1.3; TBI, ≥ 0.75 ; and triphasic pedal Doppler waveforms. (Strong; low)
4	Perform at least one of the following bedside tests in a patient with a diabetes-related foot ulcer and PAD, any of which increases the pretest probability of healing by at least 25%: a skin perfusion pressure of ≥ 40 mmHg, a toe pressure of ≥ 30 mmHg, or a transcutaneous oxygen pressure (TcPO ₂) of ≥ 25 mmHg. (Strong; moderate)
5	Use the Wound, Ischaemia, and foot Infection (WIfI) classification system as a means to stratify amputation risk and revascularisation benefit in a patient with a diabetes-related foot ulcer and PAD. (Strong; moderate)
6	Always consider urgent vascular imaging, and revascularisation, in a patient with a diabetes-related foot ulcer and an ankle pressure of < 50 mmHg, ABI of < 0.5 , a toe pressure of < 30 mmHg, or a TcPO ₂ of < 25 mmHg. (Strong; low)
7	Always consider vascular imaging in patients with a diabetes-related foot ulcer, irrespective of the results of bedside tests, when the ulcer is not healing within 4 to 6 weeks despite good standard of care. (Strong; low)
8	Always consider revascularisation in a patient with a diabetes-related foot ulcer and PAD, irrespective of the results of bedside tests, when the ulcer is not healing within 4 to 6 weeks despite optimal management. (Strong; low)
9	Do not assume diabetes-related microangiopathy, when present, is the cause of poor healing in patients with a diabetes-related foot ulcer; therefore, always consider other possibilities for poor healing. (Strong; low)
10	Use any of the following modalities to obtain anatomical information when considering revascularising a patient's lower extremity: colour duplex ultrasound, computed tomographic angiography, magnetic resonance angiography, or intra-arterial digital subtraction angiography. Evaluate the entire lower extremity arterial circulation with detailed visualisation of below-the-knee and pedal arteries, in an anteroposterior and lateral plane. (Strong; low)

11	When performing revascularisation in a patient with a diabetes-related foot ulcer, aim to restore direct blood flow to at least one of the foot arteries, preferably the artery that supplies the anatomical region of the ulcer. After the procedure, evaluate its effectiveness with an objective measurement of perfusion. (Strong; low)
12	As evidence is inadequate to establish whether an endovascular, open, or hybrid revascularisation technique is superior, make decisions based on individual factors, such as morphological distribution of PAD, availability of autogenous vein, patient co-morbidities, and local expertise. (Strong; low)
13	Any centre treating patients with a diabetes-related foot ulcer should have expertise in, and/or rapid access to facilities necessary to diagnose and treat, PAD, including both endovascular techniques and bypass surgery. (Strong; low)
14	Ensure that after a revascularisation procedure in a patient with a diabetes-related foot ulcer, the patient is treated by a multidisciplinary team as part of a comprehensive care plan. (Strong; low)
15	Urgently assess and treat patients with signs or symptoms of PAD and a diabetes-related foot infection, as they are at particularly high risk for major limb amputation. (Strong; moderate)
16	Avoid revascularisation in patients in whom, from the patient's perspective, the risk-benefit ratio for the probability of success of the procedure is unfavourable. (Strong; low)
17	Provide intensive cardiovascular risk management for any patient with diabetes and an ischaemic foot ulcer, including support for cessation of smoking, treatment of hypertension, control of glycaemia, and treatment with a statin drug as well as low-dose clopidogrel or aspirin. (Strong; low)

PAD in DFU

PAD is estimated to be present in up to 50% of DFU and to be an independent risk factor in their development.

PAD commonly co-exists with systemic atherosclerosis and underlying generalised endothelial dysfunction due to vascular inflammation and, an abnormal metabolic state. Together these changes increase the risk of cardiovascular morbidity and mortality significantly.

When associated with diabetes, PAD is also more diffuse with increased involvement of tibial arteries, greater severity of the disease process, higher likelihood of distal ischaemic ulcer and extensive tissue loss, and increased risk of amputation.

Early diagnosis and treatment of PAD in people with DFU is critical due to the increased risk of non-healing, infection and amputation, as well as elevated rate of cardiovascular complications such as myocardial infarction and stroke, and a five-year mortality rate of more than 50%.

What's new in PAD?

This new guideline includes substantial new evidence relating to diagnosis, prognosis and management in the person with PAD and DFU including:

- New evidence demonstrating the clinical challenge of diagnosing PAD in diabetes cohorts, particularly in relation to the limited capacity of clinical examination (including pulse palpation) and various bedside testing methods to rule out the presence of disease with no single or combination of tests yet to be found to be superior (recommendations 1 to 4, 6 to 8).
- The validated Wlfl classification system to estimate risk of amputation and potential benefit of revascularisation based on the ulcer characteristics, severity of ischaemia measured via non-invasive bedside testing, and infection severity (recommendation 5).
- Additionally considers the recommendations in relation to specific subpopulations relevant to the Australian context including those in geographically remote circumstances, and for Aboriginal and Torres Strait Islander Peoples.

Implementing the Peripheral artery disease guideline

General considerations for implementation relate to the limited ability for clinical examination and bedside (ankle-brachial index and toe pressures) vascular assessments to rule out (ABI) PAD in people with diabetes with and without DFU.

This highlights the need to undertake further vascular investigation in any person with DFU where non-invasive testing confirms likely inadequate perfusion (ABI<0.5, ankle pressure<50mmHg, toe pressure <30mmHg), or, where there is evidence of delayed healing (non-healing within 4-6 weeks with optimal care).

Further main considerations relate to contraindications for specific forms of vascular imaging, for example due to contrast agent allergy or risk of nephrotoxicity, and determination of patient suitability for revascularisation. In people with DFU in whom revascularisation is required or needs to be considered, non-invasive tests of arterial disease, including colour duplex ultrasound, computed tomographic angiography, magnetic resonance (MR) angiography, or intra-arterial digital subtraction angiography (DSA) can be performed.

The modality will depend on clinical availability and local expertise as well as contraindications such as iodine contrast allergy, renal impairment and the presence of non-MR compatible devices (e.g. pacemakers). It is critical that arteries are imaged from the aorta to the foot (rather than from groin to foot). DSA is invasive and may be required for arterial imaging, as well as when endovascular intervention is planned.

Performing endovascular or open revascularisation is associated with significant risk and thus vascular specialists may defer intervention or decide not to perform revascularisation in the setting of a limb deemed unsalvageable, in patients whom are bed-bound, very frail or are at high risk of an adverse outcome associated with the intervention, and in those with limited life expectancy.

This guideline includes the implementation of the WIfI (Wound, Ischaemia, foot Infection) classification system to estimate the risk of major amputation and the potential benefit of revascularisation. WIfI is based on grading the

severity of the ulcer, the severity of ischaemia based on bedside non-invasive testing and the presence and severity of infection.

As the WIfI tool has not been validated in the Aboriginal and Torres Strait Islander populations, the following factors need to be considered in addition to the WIfI classification system to better determine risk of amputation and benefits of revascularisation:

- extrinsic and cultural barriers to care access (for example the need to stay on country, family)
- community circumstances and roles
- preference for community-delivered care.

The classification system is readily available and can be downloaded as a calculator tool to assist with application. Further information about WIfI can also be found in the Wound classification section.

Monitoring Considerations

Monitoring and evaluation is an essential component of establishing best-practice clinical management of DFU. We encourage organisations to include in their formal monitoring systems options to be able to collect, monitor and analyse revascularisation and DFU healing outcomes in accordance with national based High Risk Foot Service database monitoring systems and datasets. Within services, collection of existing monitoring data from their local hospital discharge datasets also using Australian Classification of Health Interventions codes for specific surgical interventions for PAD is encouraged.

Peripheral artery disease considerations for the Australian context

In more geographically remote areas there may be delays in access to DFU services. There may also be restricted access to appropriate expertise and equipment for diagnosis of PAD. Health services providing DFU treatment and management, should ensure they are able to provide a form of bedside testing that is consistent with their expertise and availability of equipment.

Access to advanced diagnostic services (i.e. vascular imaging) in more geographically remote areas is challenging and requires well-established clinical referral pathways to support timely access to services.

Delays in access to conservative DFU care or more extended time between appointments, as well as hot or dry and dusty environments, may reduce adherence to some conservative therapies (for example regular conservative debridement and offloading devices). This may slow healing time. Nevertheless, due to the need to diagnose PAD as soon as possible where delayed healing is occurring further imaging should be sought.

Rapid referral pathways are also required to treatment centres offering revascularisation procedures. Care models inclusive of access to appropriate follow-up assessment and care need to be established in conjunction with involved health care providers. Additional options to support health practitioners in remote areas with appropriate expertise via telehealth and other forms of remote monitoring should be also be considered.

Aboriginal and Torres Strait Islander Peoples

Despite the severity of the outcomes of PAD in Aboriginal and Torres Strait Islander Peoples with diabetes, and particularly in those with DFU, there is limited data to determine best practice treatments. As reflected by key outcomes identified in the 2020 Closing the Gap in Partnership agreement, there is an urgent need to prioritise and achieve better health outcomes for Aboriginal and Torres Strait Islander Peoples to protect against the devastating consequences of DFU in this population.

Diagnosis

Basic PAD clinical examination can be provided by a range of health professionals including appropriately trained Aboriginal Health Workers. More frequent screening may be required and further bedside testing should be used in the population due to increased risk of PAD. Aboriginal Health Workers should be involved in care delivery where possible, including conducting clinical examination where they have received sufficient training. Health practitioners should ensure the need for, and nature of, the assessment, and the assessment results are discussed with the patient and their family using a professional interpreter when required.

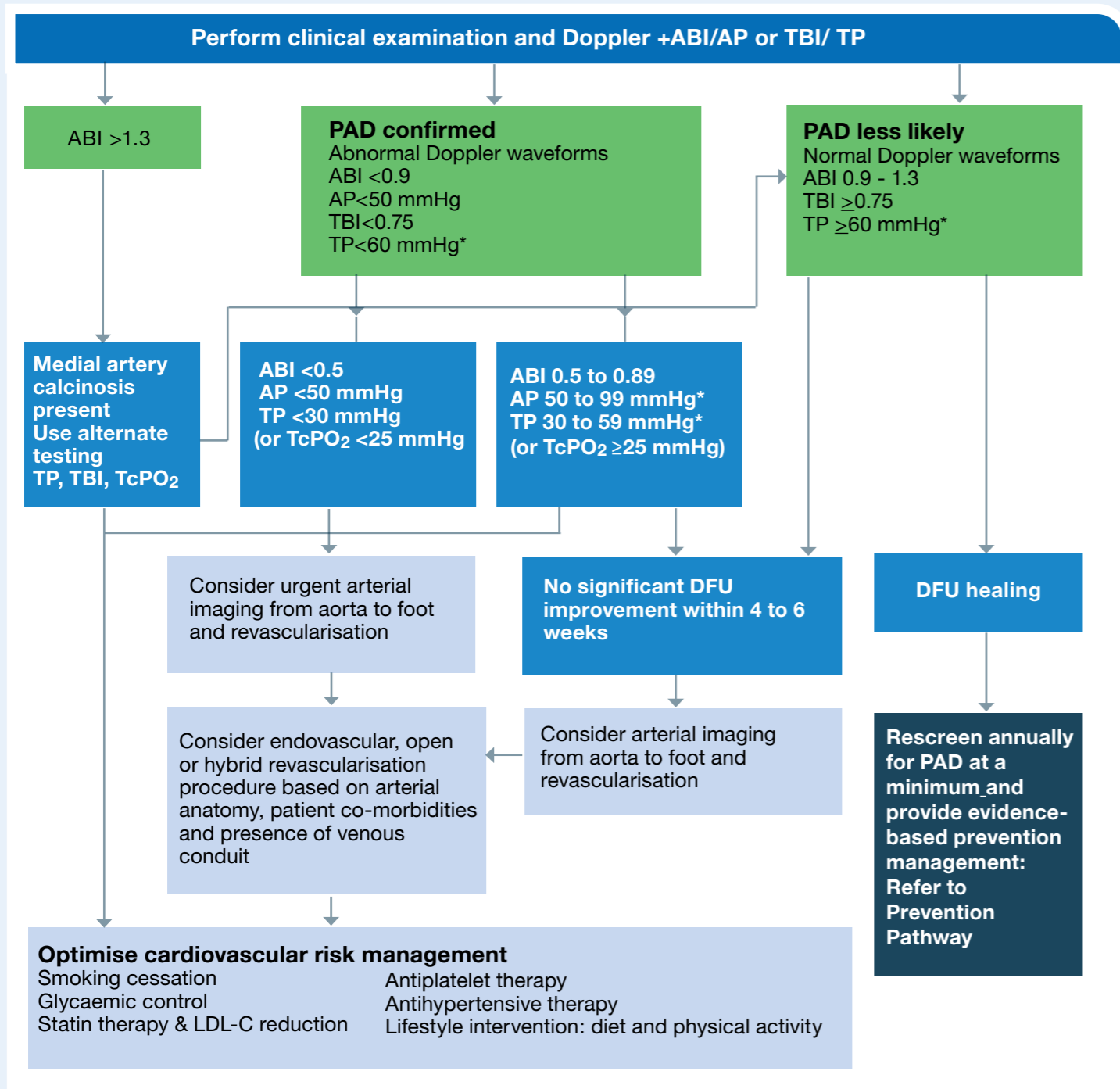
Prognosis

Due to the high incidence of PAD in Aboriginal and Torres Strait Islander Peoples, further imaging should be sought where there is practitioner concern over healing response, regardless of results of bedside testing. Consider extrinsic factors that may contribute to delayed, or non-healing in this population. These include adequate access to culturally safe care, suitability of conservative care to cultural needs, and similar potential restrictions in access to regular conservative care in geographically remote areas.

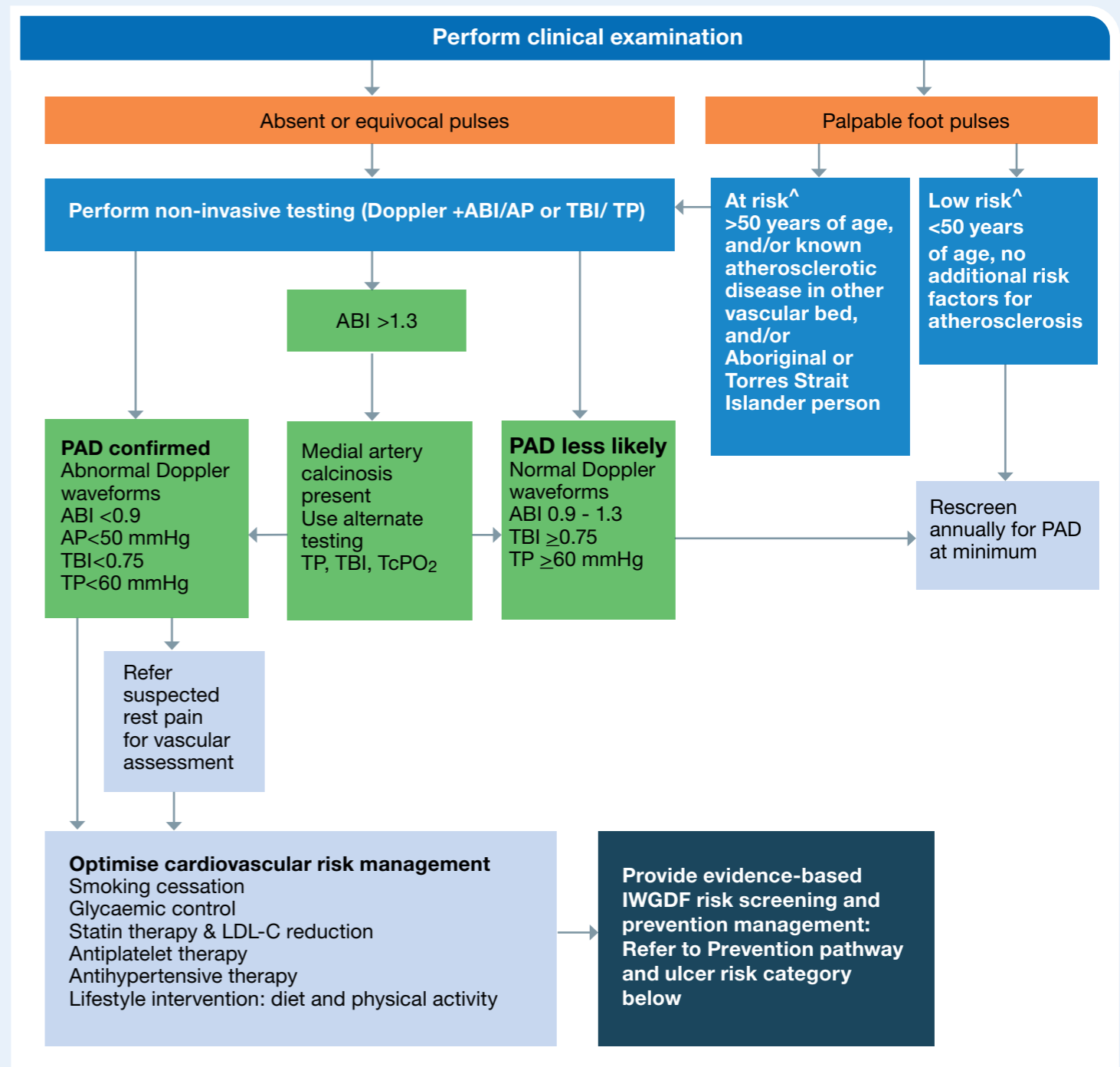
Treatment

Due to the high risk of amputation in Aboriginal and Torres Strait Islander Peoples, the extrinsic and cultural barriers to accessing care should also be considered to better determine the risk of amputation and the benefits of any revascularisation for the person, such as the need to stay on Country, family and community circumstances and preference for community-delivered care. Established referral pathways, as well as appropriate, culturally safe follow-up care, are required for Aboriginal and Torres Strait Islander people in all geographical locations. These should be developed in conjunction with community-based Aboriginal Health and Medical Services where the care access and provision is supported by an Aboriginal Health Worker and professional interpreter (where required) to optimise outcomes.

Peripheral artery disease pathway for a person presenting with diabetes and a diabetes-related foot ulcer



Peripheral artery disease pathway for a person presenting with diabetes and no foot ulcer



ABBREVIATIONS

ABI	Ankle-brachial index	LEA	Lower extremity amputation
AP	Ankle pressure	LOPS	Loss of protective sensation
DFU	Diabetes-related foot ulcer	PAD	Peripheral artery disease
ESRD	End-stage renal disease	TBI	Toe-brachial index
IWGDF	International Working Group on the Diabetic Foot	TcPO₂	Transcutaneous oxygen pressure
LDL-C	Low density lipoprotein cholesterol	TP	Toe pressure

ULCER RISK CATEGORY

ULCER RISK CATEGORY	CHARACTERISTICS	RESCREEN
0	No LOPS or PAD	Annually
1	LOPS or PAD	6-12 months
2	LOPS + PAD or LOPS + foot deformity or PAD + foot deformity	3-6 months
3	LOPS or PAD + one of more of history DFU/LEA/ESRD	1-3 months

Adapted from the 2016 American Heart Association/American College of Cardiology Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease 'at increased risk' classification.

LEGEND ■ Diagnosis ■ Prognosis ■ Pulses ■ PAD treatment(s) recommended ■ Best standard of care recommendations * Figures based on wound, ischaemia, and foot infection (WIFI) classification system Mills et al, 2014

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 diagnosis and management of peripheral artery disease for full details about these pathways.



Infection

Australian guideline on management of diabetes-related foot infection.

Diabetes-related foot ulcers currently affect around 50,000 Australians, and up to 40% of these individuals can expect to have an associated infection in the first year after presentation.

Best-practice adaptation of the 2019 IWGDF Working Group's Infection Guideline for the Australian national context was undertaken by an expert panel, leading to the development of the first multi-disciplinary, evidence-based Australian diabetes-related foot infection guidelines since 2011.

Implementation of this guideline by health professionals should:

- Provide an evidence-based framework to ensure best management of individuals with diabetes-related foot infections
- Help highlight infection considerations for implementation and monitoring
- Help improve outcomes for Australians living with diabetes.

This toolkit provides a practical and condensed overview of the Australian infection guideline designed to assist health professionals use the recommendation in daily practice. To learn more about each individual recommendation, please refer to the Australian guideline on management of diabetes-related foot infection.

A diabetes-related foot infection is defined as the presence of an infection in any tissue distal to the malleolus in an individual with diabetes mellitus.

The majority of infections are associated with a breach of the epithelium (i.e. an ulcer).

The presence of microorganisms alone does not define the presence of an infection as a wound may be colonised by microorganisms. Thus, diagnosis generally requires the clinical recognition of inflammation.

Given the severe complications that can arise from diabetes-related foot infections, all infections, even those that are mild, should be considered serious.

Infection recommendations

1a	Diagnose a soft tissue diabetes-related foot infection clinically, based on the presence of local or systemic signs and symptoms of inflammation. (GRADE strength of recommendation: Strong; Quality of evidence: low)
1b	Assess the severity of any diabetes-related foot infection using the International Working Group on the Diabetic Foot / Infectious Diseases Society of America classification scheme. (Strong; moderate)
2	Consider hospitalising all persons with diabetes and a severe (grade 4) foot infection and those with a moderate (grade 3) infection that is complex or associated with key relevant morbidities. (Strong; low)
3	In a person with diabetes and a possible foot infection for whom the clinical examination is equivocal or uninterpretable, consider ordering an inflammatory serum biomarker, such as C-reactive protein, erythrocyte sedimentation rate, and perhaps procalcitonin, as an adjunctive measure for establishing the diagnosis. (Weak; low)
4	As neither electronically measuring foot temperature nor using quantitative microbial analysis has been demonstrated to be useful as a method for diagnosing diabetes-related foot infection, we suggest not using them. (Weak; low)
5	In a person with diabetes and suspected osteomyelitis of the foot, we recommend using a combination of the probe-to-bone test, the erythrocyte sedimentation rate (or C-reactive protein and/or procalcitonin), and plain X-rays as the initial studies to diagnose osteomyelitis. (Strong; moderate)
6a	In a person with diabetes and suspected osteomyelitis of the foot, if a plain X-ray and clinical and laboratory findings are most compatible with osteomyelitis, we recommend no further imaging of the foot to establish the diagnosis. (Strong; low)
6b	If the diagnosis of osteomyelitis remains in doubt, consider ordering an advanced imaging study, such as magnetic resonance imaging scan, 18F-FDG-positron emission tomography (PET)/computed tomography (CT) or leukocyte scintigraphy (with or without CT). (Strong; moderate)
7	In a person with diabetes and suspected osteomyelitis of the foot, in whom making a definitive diagnosis or determining the causative pathogen is necessary for selecting treatment, collect a sample of bone (percutaneously or surgically) to culture clinically relevant bone microorganisms and for histopathology (if possible). (Strong; low)
8a	Collect an appropriate specimen for culture for almost all clinically infected wounds to determine the causative pathogens. (Strong; low)
8b	For a soft tissue diabetes-related foot infection, obtain a sample for culture by aseptically collecting a tissue specimen (by curettage or biopsy) from the ulcer. (Strong; moderate)
9	Do not use molecular microbiology techniques (instead of conventional culture) for the first-line identification of pathogens from samples in a patient with a diabetes-related foot infection. (Strong; low)

10	Treat a person with a diabetes-related foot infection with an antibiotic agent that has been shown to be effective in a published randomised controlled trial and is appropriate for the individual patient. Some agents to consider include penicillins, cephalosporins, carbapenems, metronidazole (in combination with other antibiotic[s]), clindamycin, linezolid, daptomycin, fluoroquinolones, or vancomycin, but not tigecycline. (Strong; high)
11	Select an antibiotic agent for treating a diabetes-related foot infection based on: the likely or proven causative pathogen(s) and their antibiotic susceptibilities; the clinical severity of the infection; published evidence of efficacy of the agent for diabetes-related foot infections; risk of adverse events, including collateral damage to the commensal flora; likelihood of drug interactions; agent availability; and, financial costs. (Strong; moderate)
12	Administer antibiotic therapy initially by the parenteral route to any patient with a severe (grade 4) skin and soft tissue diabetes-related foot infection. Switch to oral therapy if the patient is clinically improving and has no contraindications to oral therapy and if there is an appropriate oral agent available. (Strong; very low)
13	Treat patients with a mild (grade 2) diabetes-related foot infection, and most with a moderate (grade 3) diabetes-related foot infection, with oral antibiotic therapy, either at presentation or when clearly improving with initial intravenous therapy. (Weak; low)
14	We suggest not using any currently available topical antimicrobial agent for treating a mild (grade 2) diabetes-related foot infection. (Weak; moderate)
15a	Administer antibiotic therapy to a patient with a skin or soft tissue diabetes-related foot infection for a duration of 1 to 2 weeks. (Strong; high)
15b	Consider continuing treatment, perhaps for up to 3 to 4 weeks, if the infection is improving but is extensive and is resolving slower than expected or if the patient has severe peripheral artery disease. (Weak; low)
15c	If evidence of infection has not resolved after 4 weeks of apparently appropriate therapy, re-evaluate the patient, and reconsider the need for further diagnostic studies or alternative treatments. (Strong; low)
16	For patients who have not recently received antibiotic therapy and have an acute infection, consider targeting empiric antibiotic therapy at just aerobic Gram positive pathogens (beta-haemolytic streptococci and <i>Staphylococcus aureus</i>) in cases of a mild (grade 2) diabetes-related foot infection. (Weak; low)
17	For patients who have been treated with antibiotic therapy within a few weeks, have a chronic infection, have a severely ischaemic affected limb, or a moderate (grade 3) or severe (grade 4) infection, we suggest selecting an empiric antibiotic regimen that covers Gram positive pathogens, commonly isolated Gram negative pathogens, and possibly obligate anaerobes in cases of moderate (grade 3) to severe (grade 4) diabetes-related foot infections. Then, reconsider the antibiotic regimen based on both the clinical response and culture and sensitivity results. (Weak; low)
18	Empiric treatment aimed at <i>Pseudomonas aeruginosa</i> is not usually necessary but consider it if <i>P. aeruginosa</i> has been isolated from cultures of the affected site within the previous few weeks, or in tropical/subtropical climates (at least for moderate (grade 3) or severe (grade 4) infection). (Weak; low)

19	Do not treat clinically uninfected foot ulcers with systemic or local antibiotic therapy with the goal of reducing the risk of infection or promoting ulcer healing. (Strong; low)
20	Non-surgeons should urgently consult with a surgical specialist in cases of severe (grade 4) infection or of moderate (grade 3) infection complicated by extensive gangrene, necrotising infection, signs suggesting deep (below the fascia) abscess or compartment syndrome, or severe lower limb ischaemia. (Strong; low)
21a	In a patient with diabetes and uncomplicated forefoot osteomyelitis, for whom there is no other indication for surgical treatment, consider treating with antibiotic therapy without surgical resection of bone. (Strong; moderate)
21b	In a patient with probable diabetes-related foot osteomyelitis with concomitant soft tissue infection, urgently evaluate for the need for surgery as well as intensive post-operative medical and surgical follow-up. (Strong; moderate)
22	Select antibiotic agents for treating diabetes-related foot osteomyelitis from among those that have demonstrated efficacy for osteomyelitis in clinical studies. (Strong; low)
23	Treat diabetes-related foot osteomyelitis with antibiotic therapy for just a few days if there is no soft tissue infection and all the infected bone has been surgically removed. (Weak; low)
24	For people with diabetes-related foot osteomyelitis that initially require parenteral therapy, consider switching to an oral antibiotic regimen that has high bioavailability after perhaps 5 to 7 days, if the likely or proven pathogens are susceptible to an available oral agent and the patient has no clinical condition precluding oral therapy. (Weak; moderate)
25a	During surgery to resect bone for diabetes-related foot osteomyelitis, consider obtaining a specimen of bone for culture (and, if possible, histopathology) at the stump of the resected bone to identify if there is residual bone infection. (Weak; moderate)
25b	If an aseptically collected culture specimen obtained during the surgery grows pathogen(s), or if the histology demonstrates osteomyelitis, administer appropriate antibiotic therapy for up to 6 weeks. (Strong; moderate)
26	For a diabetes-related foot infection, do not use hyperbaric oxygen therapy or topical oxygen therapy as an adjunctive treatment if the only indication is specifically for treating the infection. (Weak; low)
27a	To specifically address infection in a diabetes-related foot ulcer: do not use adjunctive granulocyte colony stimulating factor treatment (Weak; moderate), and
27b	do not routinely use topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy (with or without instillation). (Weak; low)

Using the Australian guideline and infection pathway

Evidence-based guidelines are vital to ensure optimal multi-disciplinary management and outcomes of people with diabetes-related foot infections. To optimise the uptake of these new recommendations into national clinical practice, the guideline provides a comprehensive range of implementation considerations for health professionals.

In addition to general implementation considerations for the Australian population, this guideline also provides specific implementation considerations for treatment of people residing in

geographically remote areas and Aboriginal and Torres Strait Islander Peoples.

In combination with simplified clinical pathways (over page) this guideline provides an evidence-based framework to ensure best management of individuals with diabetes-related foot infections across Australia and highlight considerations for implementation and monitoring.

The infection pathway focuses on:



Diagnosis



Management

Infection implementation considerations

Specific diagnostic techniques and treatment approaches identified as having variable availability across geographical locations and secondary and tertiary centres include:

- procalcitonin
- percutaneous bone biopsy
- advanced imaging studies
- restricted antibiotics
- surgical expertise

There is reduced expertise in the use of some diagnostic tests such as procalcitonin and percutaneous bone biopsy. While alternative options for procalcitonin such as C-reactive protein (CRP) and erythrocyte sedimentation ration (ESR) are widely available, we recommended that expertise in percutaneous bone biopsy be developed more widely.

The choice of antibiotic regimen should include multiple considerations including a number that are patient-related.

Considerations include:

- likely or proven causative pathogen(s) and their antibiotic susceptibilities
- expected efficacy
- severity of infection
- route of administration
- adverse drug reactions
- local antibiotic resistance patterns
- appropriate antimicrobial stewardship
- antibiotic restrictions
- cost
- access
- likelihood of drug interactions
- patient preferences for route of administration
- risk of adverse reaction.

Infection monitoring considerations

Each service will undertake a different process. However, best-practice clinical management of diabetes-related foot infections and the principles followed should be similar for all services.

- **Monitoring and evaluation forms a vital component of best-practice clinical management of diabetes-related foot infections.**
- **Services undertake an audit of patient outcomes every 12 months at a minimum.**
- **Minimum data should be collected on patients' treatment approaches (including antibiotic and surgical management) and outcomes.**
- **Outcomes should be compared over time and to external units where possible.**

Infection considerations for the Australian context

Diabetes-related foot ulcers and infection are substantial risk factors for amputation. 85% of all amputations in Australia are associated with diabetes-related foot ulcers. In Darwin, Australia, major amputations occurred in almost 10% of individuals with diabetes-related foot infections presenting to hospital over 14 months, death in 9% over 1-year, and the median hospital stay lasted 29 days.

Risk of complications is further increased in Aboriginal and Torres Strait Islander Peoples. Addressing these risks is needed to successfully achieve key outcomes identified in the 2020 Closing the Gap in Partnership agreement.

Geographically remote people

People living in geographically remote areas face a number of barriers to effective implementation of these guidelines.

These barriers include:

- reduced access to diagnostic services including basic services such as X-ray and advanced services such as MRI or PET scan
- delays in time to results for biomarkers or pathological sampling
- reduced access to surgical and specialist foot expertise.

In addition, options for treatment may be impacted with hospitalisation unavailable locally, and reduced local access to intravenous antibiotics or surgery. In many circumstances, treatment will still be required, and it is important that remote centres have clear referral pathways (including criteria for referral and who to contact) to ensure access to timely advice and transfer mechanisms.

The use of technology such as telehealth appointments and person-centred co-management arrangements such as joint appointments with general practitioners and specialists should be considered where feasible.

Many of the potential barriers to implementation of the guidelines that relate to geographically remote people also relate to a substantial proportion of Aboriginal and Torres Strait Islander Peoples due to 20% of Aboriginal and Torres Strait Islander Peoples living rurally and a substantial proportion living in remote locations.

Aboriginal and Torres Strait Islander Peoples

Given the increased risk of complications from diabetes-related foot infections, including amputations, in Aboriginal and Torres Strait Islander Peoples, it is vital that guidelines be adjusted to ensure inclusivity of this population. Cultural and language barriers need to be carefully assessed and mitigated through the support of Aboriginal health workers, Aboriginal liaison officers and interpreters as much as possible.

Health professionals should aim to explore each individual's understanding of their diabetes-related foot infection including:

- predisposing factors
- prognosis
- potential treatment options

An inability to undergo treatment locally may impact the choice of treatment for some people living with diabetes who wish to be treated on country and/or near their local community, and health professionals should discuss alternative treatment options including associated benefits and risks.

Aboriginal and Torres Strait Islander Peoples may have a greater preference to be treated in the outpatient setting with oral antibiotics or prefer to use intravenous antibiotics through outpatient

parenteral services if available to enable them to stay on country or avoid inpatient hospital admissions.

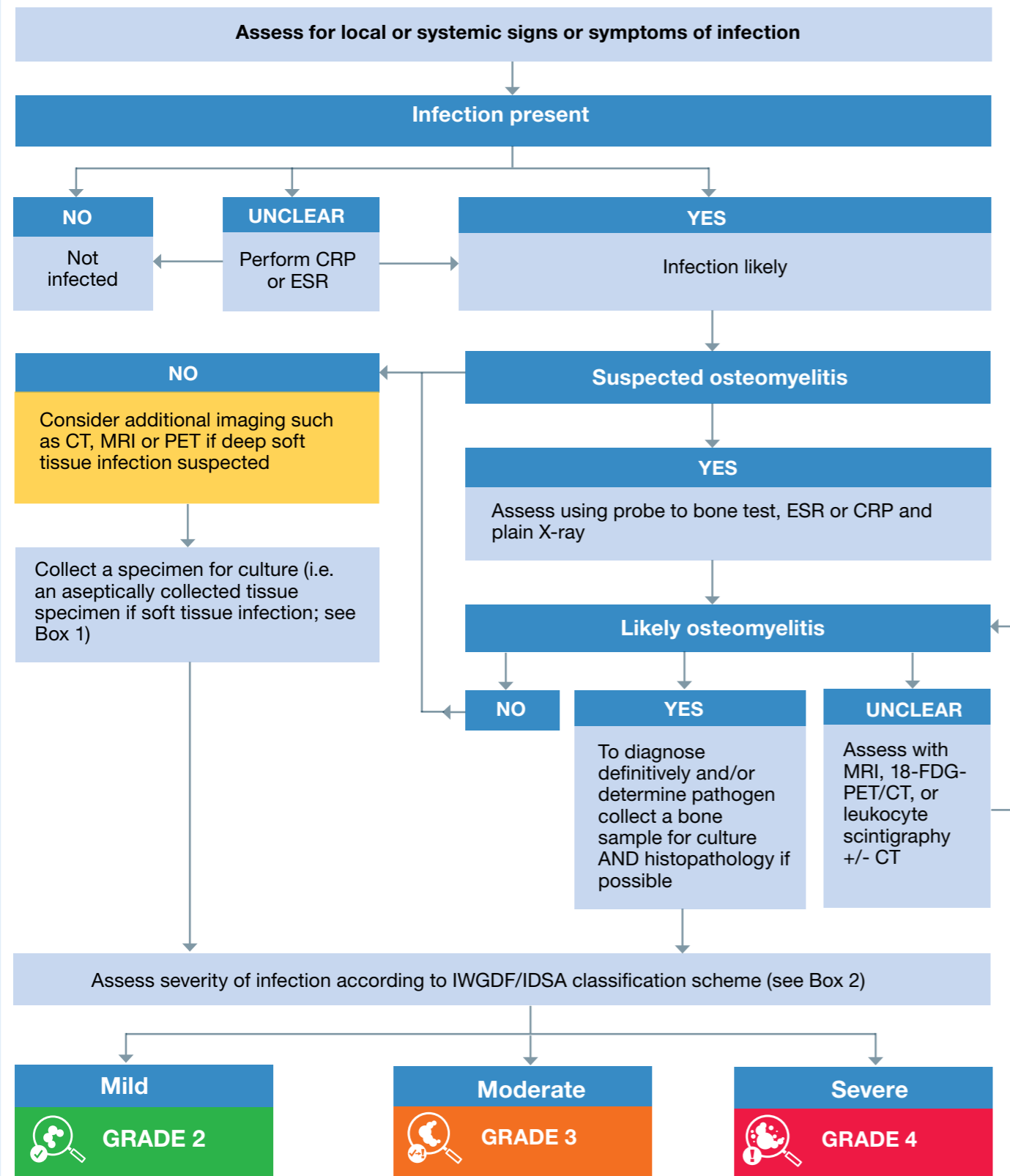
Prescribers should consider empiric methicillin resistant *Staphylococcus aureus* (MRSA) coverage in people known to be colonised with MRSA or those living in areas with a high prevalence of MRSA. An increased rate of MRSA has been identified in some Aboriginal and Torres Strait Islanders populations. For example, a study from Darwin found over 40% of Aboriginal and Torres Strait Islander patients with a diabetes-related foot infection had associated MRSA.

To learn more about each individual infection recommendation and how they relate to the Australian context, please refer to the Australian guideline on management of diabetes-related foot infection.

- **Some Aboriginal and Torres Strait Islander Peoples may wish to use a combination of traditional and western medicine. Health professionals should approach this with an open mind that positively fosters the therapeutic relationship and encourages engagement with medical services.**
- **In certain circumstances traditional medicine may be a potential harm. This should be addressed in a sensitive and culturally appropriate manner.**
- **Aboriginal and Torres Strait Islander Peoples may be located in remote areas restricting access to intravenous antibiotics and surgery.**



Infection diagnosis pathway for a person with diabetes and suspected foot infection



1. Tips for collecting diagnostic samples

- Wherever possible collect tissue, bone or pus using an aseptic technique for culture
- Histopathology should also be requested on bone specimens
- Avoid taking superficial swabs of ulcers as they will more likely identify colonising organisms than infecting pathogens
- Before collecting a sample, debride and clean (using saline) the ulcer base
- Do not sample areas of necrotic or non-viable tissue

2. IWGDF severity classification scheme for diabetes-related foot infections

Mild GRADE 2	Moderate GRADE 3	Severe GRADE 4
<ul style="list-style-type: none"> • Involves only the skin or subcutaneous tissue • Erythema extends <2cm from the wound margin. • No systemic features of infection 	<p>Infection is not associated with systemic inflammatory response syndrome (SIRS) and either:</p> <ul style="list-style-type: none"> • Involves structures deeper than the skin and subcutaneous tissues (eg. tendon, muscle, joint, bone) <p>OR</p> <ul style="list-style-type: none"> • Erythema extends ≥2cm from the wound margin 	<p>Any infection associated with systemic inflammatory response syndrome (SIRS), as manifested by ≥2 of the following:</p> <ul style="list-style-type: none"> • Temperature, >38°C or <36 °C • Heart rate, >90 beats/min • Respiratory rate, >20 breaths/min or PaCO₂ <32 mmHg • White blood cell count >12 x 10⁹/L or <4 x 10⁹/L, or >10% immature (band) forms

Osteomyelitis: Infection involving bone (add '(O)' after grade)

Contraindication

Suggest not to use

- For diagnosis**
- Foot temperature
 - Quantitative microbial analysis

Recommended not to use

- For culture**
- Molecular microbiology techniques

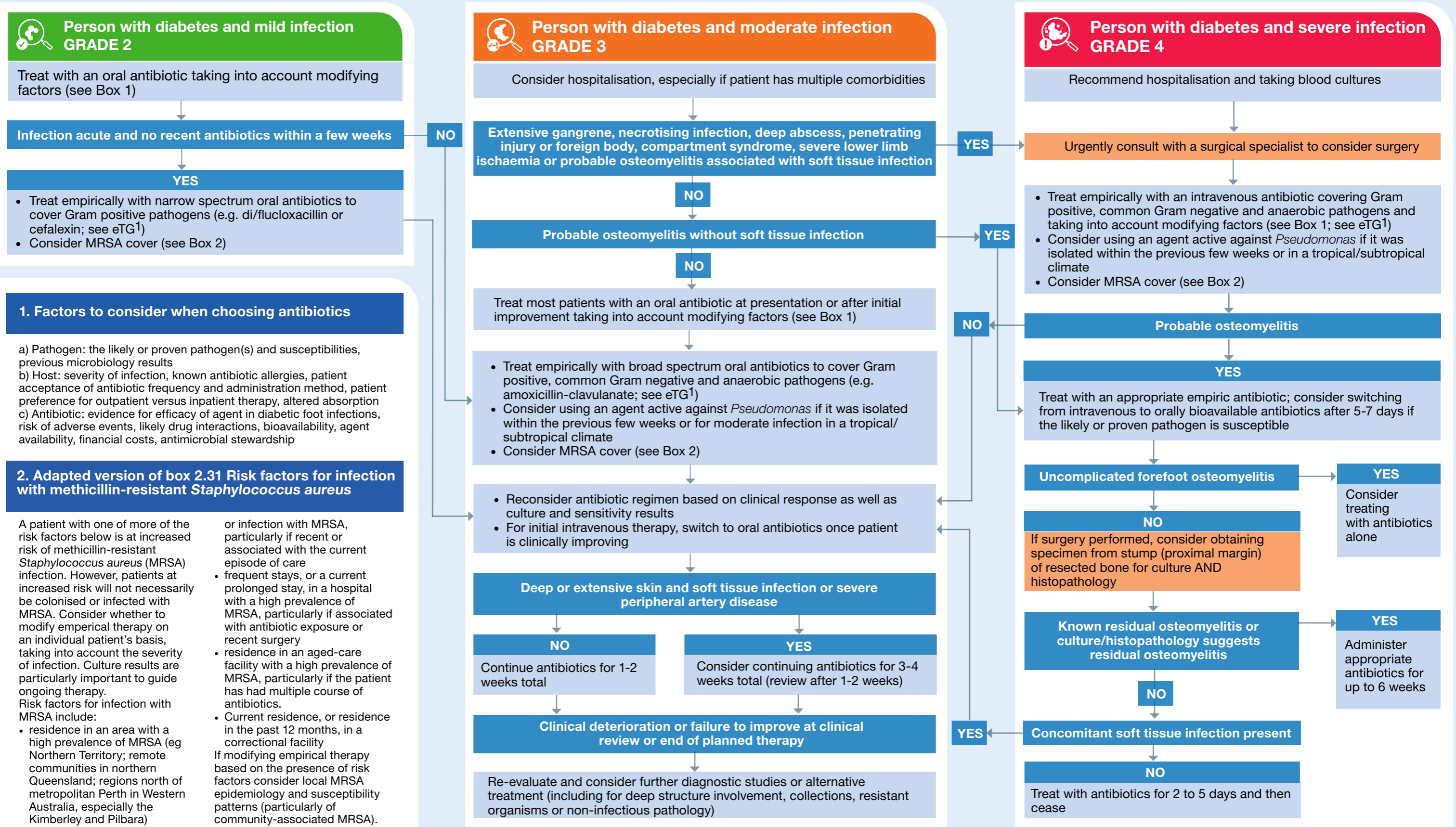
LEGEND

Infection grade
 Infection type
 Recommended good standard of care
 Suggested standard of care
 Contraindication

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 management of diabetes-related foot infections for full details about this pathway.

Infection management pathway for a person with diabetes and suspected foot infection



1. Factors to consider when choosing antibiotics

- a) Pathogen: the likely or proven pathogen(s) and susceptibilities, previous microbiology results
- b) Host: severity of infection, known antibiotic allergies, patient acceptance of antibiotic frequency and administration method, patient preference for outpatient versus inpatient therapy, altered absorption
- c) Antibiotic: evidence for efficacy of agent in diabetic foot infections, risk of adverse events, likely drug interactions, bioavailability, agent availability, financial costs, antimicrobial stewardship

2. Adapted version of box 2.31 Risk factors for infection with methicillin-resistant *Staphylococcus aureus*

A patient with one of more of the risk factors below is at increased risk of methicillin-resistant *Staphylococcus aureus* (MRSA) infection. However, patients at increased risk will not necessarily be colonised or infected with MRSA. Consider whether to modify empirical therapy on an individual patient's basis, taking into account the severity of infection. Culture results are particularly important to guide ongoing therapy. Risk factors for infection with MRSA include:

- residence in an area with a high prevalence of MRSA (eg Northern Territory; remote communities in northern Queensland; regions north of metropolitan Perth in Western Australia, especially the Kimberley and Pilbara)
- previous colonisation

- or infection with MRSA, particularly if recent or associated with the current episode of care
 - frequent stays, or a current prolonged stay, in a hospital with a high prevalence of MRSA, particularly if associated with antibiotic exposure or recent surgery
 - residence in an aged-care facility with a high prevalence of MRSA, particularly if the patient has had multiple course of antibiotics.
 - Current residence, or residence in the past 12 months, in a correctional facility
- If modifying empirical therapy based on the presence of risk factors consider local MRSA epidemiology and susceptibility patterns (particularly of community-associated MRSA).

Adapted with permission from Empirical regimens for sepsis or septic shock [published 2019 Apr. amended 2021 Sep]. In: Therapeutic Guidelines [digital]. Melbourne: Therapeutic Guidelines Limited, 2021 Mar. <<https://www.tg.org.au>>
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Recommend not to use

For uninfected ulcers
Systemic or local antibiotic therapy

Suggest not to use

For mild infections
Topical antimicrobial agent

For all infections
Hyperbaric or topical oxygen therapy if solely for treating infection

For infections associated with ulcers
Granulocyte colony stimulating factor treatment
Avoid routine use of topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy



Offloading

Australian guideline on offloading treatment for foot ulcers.

Pressure offloading management is critical for healing diabetes-related foot ulcers (DFU). Evidence-based guidelines have been developed over the years to weigh up the benefits, risks, quality of evidence and feasibility of different pressure offloading treatments to provide health professionals with best practice recommendations on how to provide optimal offloading treatment to people with DFU.

However, substantial new offloading evidence has been published over the last decade. Many international evidence-based diabetes-related disease (DFD) guidelines have taken this new evidence into account and recently been published, but their applicability to the Australian context is unclear.

These guidelines have been systematically adapted from suitable international guidelines to the Australian context to become the new Australian evidence-based guideline on offloading management for people with DFU.

By health professionals implementing these guidelines it should help:

- provide better DFU knowledge
- better treatments and healing outcomes for people living with DFU, communities, and our nation
- and in turn reduce the footprint of this condition on the lives of Australians living with diabetes today and into the future.

This toolkit provides a practical and condensed overview of the Australian offloading guideline designed to assist health professionals use the recommendation in daily practice.

To learn more about all each individual offloading recommendation, please refer to the Australian guideline on offloading treatments for foot ulcers.

Offloading recommendations

1a	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, use a non-removable knee-high offloading device rather than a removable offloading device to promote healing of the ulcer. (GRADE strength of recommendation: Strong; Quality of evidence: Moderate)
1b	When using a non-removable knee-high offloading device to heal a neuropathic plantar forefoot or midfoot ulcer in a person with diabetes, consider using either a total contact cast or non-removable knee-high walker, with the choice dependent on the local resources and technical skills available, and the person's preference and extent of foot deformity. (Weak; Low)
2	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, when non-removable knee-high offloading devices are contraindicated or not tolerated, consider using a removable knee-high offloading device (and explain the importance of using) during all weight-bearing activities rather than a removable ankle-high offloading device to reduce plantar pressure and promote healing of the ulcer. (Weak; Low)
3	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, when knee-high offloading devices are contraindicated or not tolerated, use a removable ankle-high offloading device (and explain the importance of using) during all weight-bearing activities rather than medical grade footwear to promote healing of the ulcer. (Strong; Very low)
4	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, when ankle-high offloading devices are contraindicated or not tolerated, use medical grade footwear rather than other footwear types or no footwear to promote healing of the ulcer. (Strong; Low)
5	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, consider using felted foam in combination with an offloading device or footwear rather than using the offloading device or footwear alone to further reduce plantar pressure and promote healing of the ulcer. (Weak; Very Low)
6a	If the best recommended offloading device option fails to heal a person with diabetes and a neuropathic plantar metatarsal head ulcer, consider using Achilles tendon lengthening or Gastrocnemius recession, metatarsal head resection(s), or joint arthroplasty to promote healing of the ulcer. (Weak; Low)
6b	If the best recommended offloading device option fails to heal a person with diabetes and a neuropathic plantar or apical ulcer on a non-rigid toe, consider using digital flexor tenotomy to promote healing of the ulcer. (Weak; Low)
7a	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischemia, consider using a non-removable knee-high offloading device to promote healing of the ulcer. (Weak; Low)
7b	In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischemia, or with either moderate infection or moderate ischaemia, consider using a removable knee-high offloading device to promote healing of the ulcer. (Weak; Low).

- | | |
|----|---|
| 7c | In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischaemia, or with either severe infection or severe ischemia, primarily address the infection and/or ischemia, and consider using a removable offloading intervention based on the patient's functioning, ambulatory status and activity level, to promote healing of the ulcer. (Weak; Low) |
| 8 | In a person with diabetes and a neuropathic plantar heel ulcer, consider using a knee-high offloading device or other offloading intervention that effectively reduces plantar pressure on the heel and is tolerated by the patient, to promote healing of the ulcer. (Weak; Low) |
| 9 | In a person with diabetes and a non-plantar foot ulcer, use a removable offloading device, medical grade footwear, felted foam, toe spacers or orthoses, depending on the type and location of the foot ulcer, rather than no offloading intervention to promote healing of the ulcer and to prevent further ulceration. (Strong; Very Low) |

Overall, there are now thirteen offloading treatment recommendations in the new 2021 guideline compared with two offloading treatment recommendations in the previous 2011 guideline. The increase in guideline recommendations are at least in part due to the substantial new offloading evidence published since the last guideline, including at least 11 RCTs and six meta-analyses. This new 2021 guideline provides specific evidence-based offloading treatment options for nearly all circumstances for people with DFU in Australia.

Using the Australian offloading guideline and pathway

The new Australian recommendations guide best practice offloading treatment in Australia and have been developed to suit the unique geography, diversity and needs of the Australian healthcare professionals, patients, and sectors.

To optimise the uptake of these new recommendations into national clinical practice, the guidelines provide a comprehensive range of implementation considerations for health professionals that include:

- facilitating people living with DFD to make an informed decision on which offloading treatment is best for their circumstances
- other considerations when prescribing offloading treatments, such as including pressure offloading insoles and contralateral shoe raises
- considerations on when and how to monitor the efficacy of offloading treatments for individuals.

All offloading recommendations have also been developed into a practical offloading pathway (over page) to optimise the implementation of recommendations by the multiple health professionals and disciplines caring for Australians with diabetes-related foot ulcers (DFU) in secondary and tertiary health care settings in Australia.

In addition to general implementation considerations for the Australian population, this guideline also provides specific implementation considerations for when treating people residing in geographically remote areas and Aboriginal and Torres Strait Islander Peoples, such as the impact of limited or infrequent access to DFU care, hot climates, dusty environments and cultural practices.

To learn more about each individual offloading recommendation, please refer to the Australian guideline on offloading treatments for foot ulcers.

Summary of offloading recommendations

In Australia, we recommend a step-down offloading treatment approach for people with plantar DFU based on their contraindications and tolerance.

We strongly recommend non-removable knee-high offloading devices as first line treatment, then removable knee-high offloading devices as second line, removable ankle-high offloading devices third, and medical grade footwear only as a last resort.

We also recommend considering using felted foam in combination with the chosen offloading device or footwear to further reduce plantar pressure.

For people with non-plantar DFU we recommend using a removable offloading device, felted foam, toe spacers or orthoses, or medical grade footwear depending on the type and location of the foot ulcer.

If offloading device options fail to heal a person with plantar DFU, depending on the location, we recommend considering various surgical offloading procedures.

Why offloading is critical:

The most common pathway to developing a DFU is via high plantar tissue stress (due to high pressure and/or high activity) on the foot of a person with a loss of protective sensation due to diabetes-related peripheral neuropathy (DPN).

Plantar tissue stress is the result of an accumulation of the repetitive cycles of plantar pressure and shear pressure during daily weight-bearing activity.

DPN not only causes a loss of protective sensation but can also result in higher plantar tissue stress due to detrimental changes in gait, soft tissue and foot deformities.

High plantar tissue stress if left untreated leads to subcutaneous tissue damage and eventually a DFU develops.

Reducing high plantar tissue stress that caused the DFU, or reducing high tissue stress in DFUs from other causes, is critical to healing people with DFU.

Optimal treatment for most effective DFU healing involves a multi-disciplinary team of different health professionals, in collaboration with the person affected by DFU, that collectively address the multiple factors contributing to the DFU aetiology by managing multiple aspects of the wound including infection, ischaemia and plantar tissue stress.

Pressure offloading aims to reduce high plantar tissue stress and has been found to be critical to achieve timely and complete DFU healing. To do this effectively, offloading should maximise the desirable effects (benefits) of minimising high plantar tissue stress, including reducing plantar pressure and weight-bearing activity; whilst also minimising any undesirable effects (risks), including adverse physical and psychosocial events and high costs.

Various offloading treatments have been used clinically, including offloading devices, footwear and corrective surgery. Yet, these different offloading treatments carry differing benefits and risks, quality of supporting evidence and feasibility of clinical uptake, making the clinical decision making for offloading treatments in people with DFU complex.

Offloading considerations for the Australian context

In Australia each year, DFU affects an estimated 50,000 people, resulting in around 30,000 hospitalisations, 5,000 amputations and nearly \$AU2 billion in health system costs. Aboriginal and Torres Strait Islander Peoples have up to a 38-fold risk of developing DFU and amputation. Thus, improved offloading treatment for Australians with DFU is critical to reducing a large cause of the national healthcare burden and to closing the gap in health inequality experienced by Aboriginal and Torres Strait Islander Peoples.

Geographically remote people

In addition to general implementation considerations, health professionals should also consider when determining the offloading requirements for people living in geographically remote locations the potential higher likelihood of adverse events due to:

- potential infrequent access to follow-up care
- hot climates
- dusty environments

In these circumstances, the balance of effects between the benefit and risks of the offloading treatment recommendation may change. It may mean the health professional and the person agree to choose a less effective offloading treatment so as to reduce the risks of adverse events.

For example, instead of using the first-line treatment of a non-removable knee-high offloading device, a removable knee-high offloading devices may be considered instead so it can be removed if needed for care and hygiene purposes.

Tips for using best practice offloading treatments in people with infrequent access to follow-up care

If agreeing to use a non-removable knee-high offloading device in a person with infrequent access to follow-up care, health professionals could consider using a removable knee-high walker made non-removable using a cohesive bandage (e.g. Coban™) wrap.

Whilst in theory non-removable, such a wrap is still potentially removable by the person using scissors. This might be needed in an emergency, such as for acute onset of a moderate-to-severe swelling of the foot or leg from infection or oedema. Evidence of removal of the wrap may also serve as a surrogate indicator to the health professional of device removal and thus lower adherence to use.

To learn more about each individual offloading recommendation and how they relate to the Australian context, please refer to the Australian guideline on offloading treatments for foot ulcers.

Aboriginal and Torres Strait Islander Peoples

Health professionals should always consider how to carefully explain and discuss care with Aboriginal and Torres Strait Islander Peoples. Ideally, we suggest that all considerations are discussed with the person in collaboration with their family, caregivers and support networks and a local Aboriginal and Torres Strait Islander Health Care Worker(s) to optimise everyone's understanding of:

- Personal circumstances, such as the need to care for family or participate in cultural practices.
- Benefits, risks and contraindications for the offloading treatment(s) being considered.
- Requirements of using such treatment(s), such as the length of time the device would need to be worn to heal the ulcer.
- How to make the treatment(s) as culturally appropriate as possible for the person, such as using culturally-appropriate information resources, using Aboriginal Medical Benefit Scheme entitlements for follow-up care, or incorporating artwork to personalise offloading treatment.

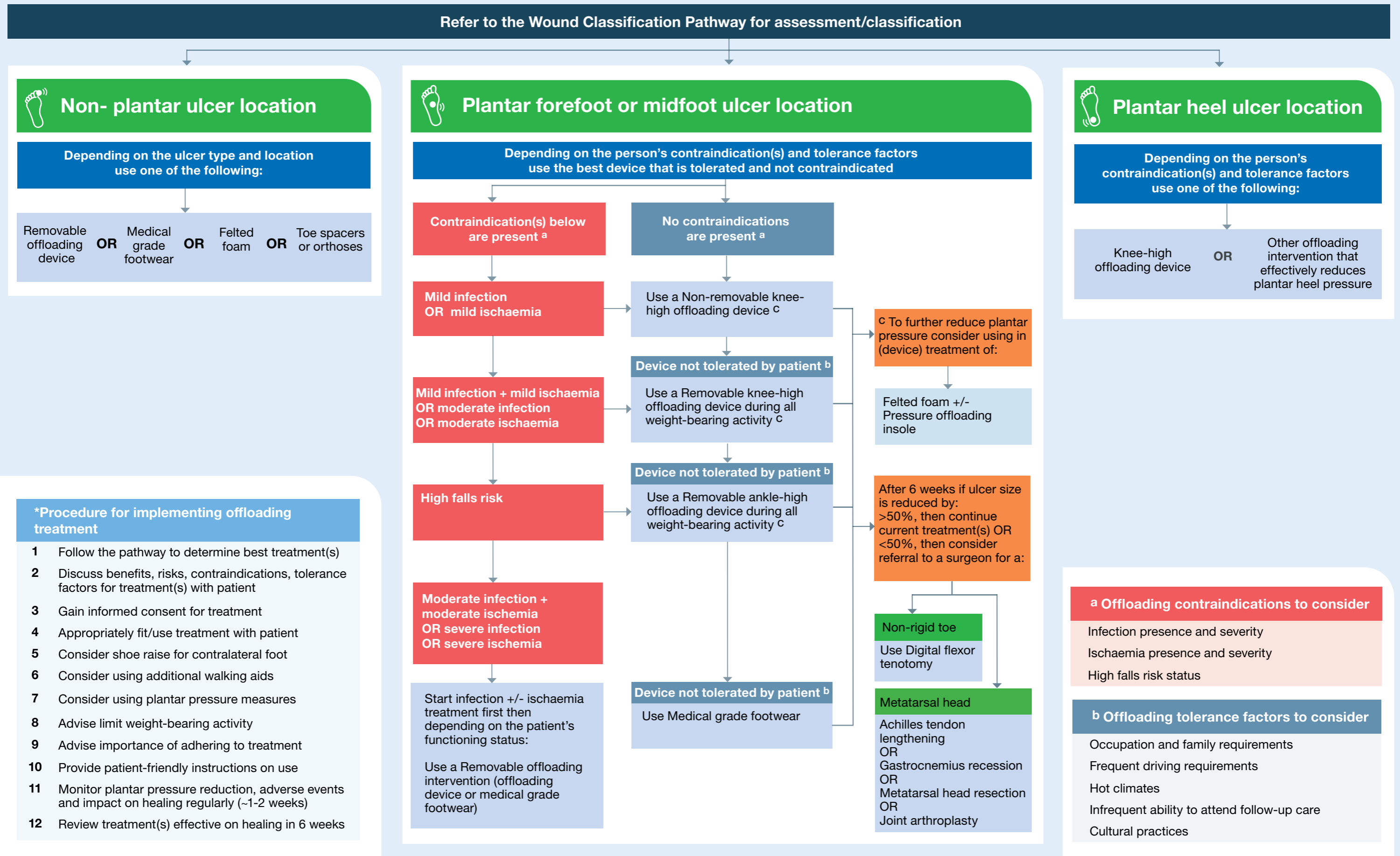
Providing culturally appropriate health care to Aboriginal and Torres Strait Islander Peoples helps to give a voice which encourages choice and informed consent.

In turn, this may help limit any psychological distress caused by DFU care, prevent future hospitalisation and disability and enable Aboriginal and Torres Strait Islander Peoples to have higher levels of social, emotional and physical wellbeing.

- Discuss with and understand the personal circumstances that may impact on offloading treatment, such as needing to participate in cultural practices where footwear may need to be removed.
- Discuss the benefits, risks, and requirements of the offloading treatment options with the person, in collaboration with their family and local Aboriginal and Torres Strait Islander Health Care Worker(s).
- Consider the aesthetic appearance of such devices for Aboriginal and Torres Strait Islander Peoples and whether the user would like their culture represented in the form of artwork or insignia to further personalise the device.



Offloading pathway for a person presenting with a classified diabetes-related foot ulcer(s)*^



a Offloading contraindications to consider

- Infection presence and severity
- Ischaemia presence and severity
- High falls risk status

b Offloading tolerance factors to consider

- Occupation and family requirements
- Frequent driving requirements
- Hot climates
- Infrequent ability to attend follow-up care
- Cultural practices

LEGEND ■ Ulcer location ■ Contraindication ■ Patient tolerance ■ Monitor and review progress ■ Offloading treatment(s) recommended ■ Best standard of care recommendation

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 offloading treatment of foot ulcers for full details about this pathway.



Wound healing interventions

Australian guideline on wound healing interventions to enhance healing of foot ulcers.

Diabetes-related foot disease causing diabetes-related foot ulceration (DFU) is one of the most devastating complications of diabetes. It precedes up to 75% of amputations in people with diabetes and accounts for a significant proportion of the global disability burden.

It is critical that interventions to enhance or facilitate healing of DFU are supported by strong evidence of benefit and cost-effectiveness, and all communities across Australia should have equitable access to these interventions.

Implementing this guideline should help:

- Guide health professionals on wound healing interventions to heal DFU
- Provide implementation considerations to deliver a good standard of DFU care
- Address the large burden and mitigate existing inequalities amongst Australians living with DFU.

This toolkit provides a practical and condensed overview of the Australian wound healing

interventions guideline designed to assist health professionals use the recommendations in daily practice.

All recommendations have also been developed into a practical wound healing interventions pathway (over page) to optimise the implementation of recommendations by the multiple health professionals and disciplines caring for Australians with DFU in secondary and tertiary health care settings in Australia.

To learn more about each individual recommendation, please refer to the Australian guideline on wound healing interventions to enhance healing of foot ulcers.

Wound healing interventions recommendations

1	Remove slough, necrotic tissue, and surrounding callus of a diabetes-related foot ulcer with sharp debridement in preference to other methods, taking relative contraindications such as pain or severe ischemia into account. (GRADE strength of recommendation: strong; quality of evidence: low)
2	Dressings should be selected principally on the basis of exudate control, comfort, and cost. (strong; low)
3	Do not use dressings/applications containing surface antimicrobial agents with the sole aim of accelerating the healing of an ulcer. (strong; low)
4	Consider the use of the sucrose-octasulfate impregnated dressing as an adjunctive treatment, in addition to best standard of care, in noninfected, neuro-ischaemic diabetic foot ulcers that are difficult to heal. (weak; moderate)
5	Consider the use of systemic hyperbaric oxygen therapy as an adjunctive treatment in non-healing ischaemic diabetes-related foot ulcers despite best standard of care. (weak; moderate)
6	We suggest not using topical oxygen therapy as a primary or adjunctive intervention in diabetic foot ulcers including those that are difficult to heal. (weak; low)
7	Consider the use of negative pressure wound therapy (NPWT) to reduce wound size, in addition to best standard of care, in patients with diabetes and a post-operative (surgical) wound on the foot. (weak; low)
8	We suggest not using negative pressure wound therapy in preference to best standard of care in nonsurgical diabetes-related foot ulcers. (weak; low)
9	Consider the use of placental derived products with informed consent as an adjunctive treatment, in addition to best standard of care, when the latter alone has failed to reduce the size of the wound. (weak; low)
10	We suggest not using growth factors, autologous platelet gels, bioengineered skin products, ozone, topical carbon dioxide, and nitric oxide in preference to best standard of care. (weak; low)
11	Consider the use of autologous combined leucocyte, platelet and fibrin as an adjunctive treatment, in addition to best standard of care, in non-infected diabetes-related foot ulcers that are difficult to heal only if this adjunctive treatment becomes approved for use in Australia. (weak; moderate)
12	We suggest not using agents reported to have an effect on wound healing through alteration of the physical environment including through the use of electricity, magnetism, ultrasound and shockwaves in preference to best standard of care. (weak; low)
13	We suggest not using interventions aimed at correcting the nutritional status (including supplementation of protein, vitamins and trace elements, pharmacotherapy with agents promoting angiogenesis) of patients with a diabetes-related foot ulcer, with the aim of improving healing, but nutritional status should be reviewed and adequate daily nutritional requirements should be met as part of best standard of care. (weak; low).

Implementing wound healing interventions considerations

All recommendations in this new 2021 Australian guideline should be implemented in conjunction with a good standard of DFU care.

The interventions recommended in this guideline in addition to good standard of care are likely to be more expensive (to both the individual and healthcare system), and cost-effectiveness data is generally lacking.

In selecting or considering a recommended intervention to promote DFU healing, the health professional should discuss with the person with DFU:

- the overall goals of care
- short-term outcomes desired for any wound dressing of exudate control, comfort and cost
- the desirable (improved wound healing)
- the undesirable effects (any adverse events, increased consultations needed and costs) of any suggested wound product recommended in the process of obtaining informed consent.

To deliver a good standard of DFU care:

Recommendations should be made on comprehensive DFU assessment

(refer to Wound classification guideline)

Appropriate debridement and wound dressings (refer to this guideline)

Antimicrobial management if infected (refer to infection guideline)

Revascularisation considerations if ischaemic (refer to Peripheral artery disease guideline)

Considerations for best offloading device (refer to Offloading guideline)

Overview of differences to previous guidelines

There are thirteen recommendations in the new Australian 2021 Wound healing guidelines compared with seven recommendations made in the previous 2011 Australian DFD Guidelines relating to wound healing interventions.

There are multiple new recommendations made in this new guideline that reflect the new high-quality evidence gained in this field over the last decade.

Of the thirteen recommendations:

- three relate to basic principles of wound care
- five recommend adjunct therapies for use in specific wound types in addition to best standard of care
- five therapies are recommended not for use.

The five adjunct therapies include the sucrose-octasulfate impregnated dressing, systemic hyperbaric oxygen therapy, negative pressure wound therapy, placental derived products, and the leucocyte platelet and fibrin dressing*.

Larval therapy and skin replacement therapies (cultured skin equivalents and skin grafting) were recommended in the 2011 NHMRC Guidelines, but due to differences in methodology were not considered for inclusion in this guideline.

(*when available in Australia)

Wound healing interventions considerations for the Australian context

Aboriginal and Torres Strait Islander Peoples are disproportionately affected by DFU, being up to 38 times more likely to have a major amputation compared to their non-Indigenous counterparts. It is critical that interventions to enhance or facilitate healing of DFU are supported by strong evidence of benefit and cost-effectiveness, and all communities across Australia should have equitable access to these interventions.

In rural and remote areas, there may be challenges for accessibility to skilled clinicians for sharp debridement, hyperbaric oxygen therapy (HBOT), and negative pressure wound therapy (NPWT). Where possible, health professionals considering these therapies should:

- develop required skillsets or competencies required
- and/or
- establish referral pathways for improved access to these therapies.

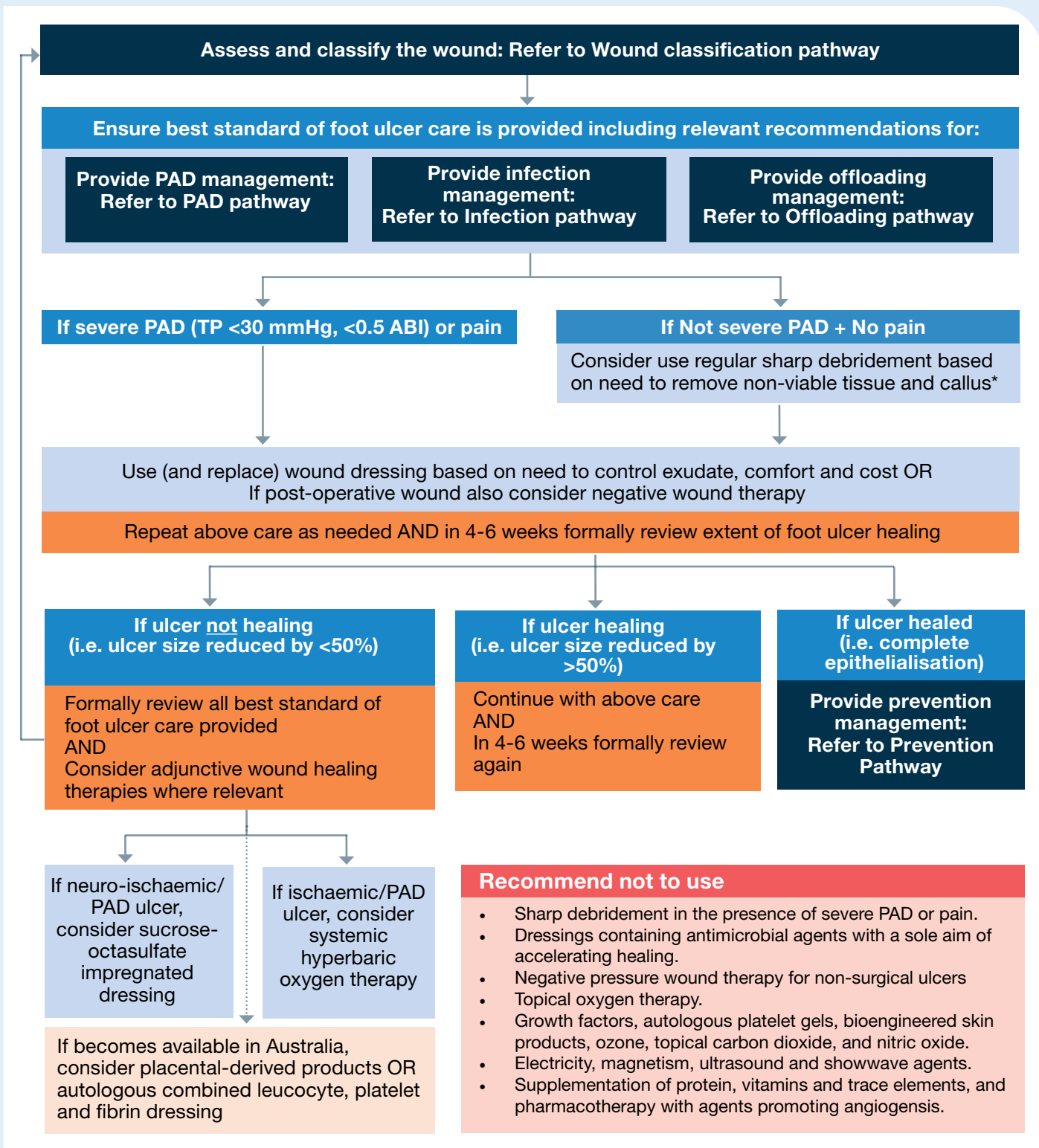
Aboriginal and Torres Strait Islander Peoples who reside in rural and remote Australia may have to travel away from their families to receive surgical care for DFU. Before initiating NPWT on a surgically treated DFU for a patient whose discharge destination is a rural and remote community, consider:

- availability of staff and equipment in the person's community upon discharge
- the potential desirable (potentially faster wound healing) outcomes
- the undesirable effects (higher costs or a longer admission)
- informed consent and patient-centered care.

People living in rural and remote regions of Australia may have reduced access to fresh food such as fruit and vegetables required for adequate daily nutritional intake. Inequitable access to fresh food may have implications for wound healing. Attempts should be made to rectify poor access to fresh food where possible.

Placental derived and blood-related products may be unacceptable to some Aboriginal and Torres Strait Islander Peoples due to traditional beliefs. Specific consent should be obtained prior to using these interventions.

Wound healing interventions pathway for any person presenting with a diabetes-related foot ulcer(s)



*Sharp debridement should only be provided by those that can demonstrate competency

ABBREVIATIONS **ABI:** Ankle brachial index **PAD:** Peripheral artery disease **TP:** Toe pressure

LEGEND

 Best standard of care recommendations	 Ulcer characteristics
 Wound healing therapy recommendations (in addition to best standard of foot ulcer care)	
 Monitor and review progress	 Wound healing therapies not recommended
 Adjunct wound healing therapy recommendations not yet available in Australia	

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 healing interventions to enhance healing of foot ulcers for full details about this pathway.

Glossary

ABI	Ankle-brachial index
CRP	C-reactive protein
DFD	Diabetes-related foot disease
DFU	Diabetes-related foot ulcer
DPN	Diabetes-related peripheral neuropathy
DSA	Digital subtraction angiography
ESR	Erythrocyte sedimentation ration
ESRD	End-stage renal disease
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBOT	Hyperbaric oxygen therapy
IDSA	Infectious Diseases Society of America
IWGDF	International Working Group on the Diabetic Foot
LEA	Lower extremity amputation
LOPS	Loss of protective sensation
MR	Magnetic resonance
MRSA	Methicillin resistant Staphylococcus aureus
NHMRC	National Health and Medical Research Council
NPWT	Negative pressure wound therapy
PAD	Peripheral artery disease
PN	Peripheral neuropathy
RCT	Randomised control trial
SINBAD	Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth classification system
TBI	Toe-brachial index
TP	Toe pressure
Wifl	Wound, Ischaemia, foot Infection classification system

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Bibliography

The information contained in this toolkit is sourced directly from the six guidelines in the 2021 Australian guidelines for diabetes-related foot disease. All references are located within each guideline with full references listed at the end of each guideline. This toolkit should be used in conjunction each guideline that can be located at diabetesfeetaustralia.org/new-guidelines/

At time of publication, the 2021 Australian guidelines for diabetes-related foot disease guidelines are also either under review or published with the Journal of Foot and Ankle Research.

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